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House of Representatives

The House met at 10 a.m. and was called to order by the Speaker pro tempore (Mr. MCCLINTOCK).

DESIGNATION OF SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,
June 20, 2012.

I hereby appoint the Honorable TOM MCCLINTOCK to act as Speaker pro tempore on this day.

JOHN A. BOEHNER,
Speaker of the House of Representatives.

REPORT ON H.R. 5972, TRANSPORTATION, HOUSING AND URBAN DEVELOPMENT, AND RELATED AGENCIES APPROPRIATIONS BILL, 2013

Mr. LATHAM, from the Committee on Appropriations, submitted a privileged report (Rept. No. 112–541) on the bill making appropriations for the Departments of Transportation, and Housing and Urban Development, and related agencies for the fiscal year ending September 30, 2013, and for other purposes, which was referred to the Union Calendar and ordered to be printed.

The SPEAKER pro tempore. Pursuant to clause 1, rule XXI, all points of order are reserved on the bill.

REPORT ON H.R. 5973, AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2013

Mr. LATHAM, from the Committee on Appropriations, submitted a privileged report (Rept. No. 112–542) on the bill making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2013, and for other purposes, which was referred to the Union Calendar and ordered to be printed.

The SPEAKER pro tempore. Pursuant to clause 1, rule XXI, all points of order are reserved on the bill.

MORNING-HOUR DEBATE

The SPEAKER pro tempore. Pursuant to the order of the House of January 17, 2012, the Chair will now recognize Members from lists submitted by the majority and minority leaders for morning-hour debate.

The Chair will alternate recognition between the parties, with each party limited to 1 hour and each Member other than the majority and minority leaders and the minority whip limited to 5 minutes each, but in no event shall debate continue beyond 11:50 a.m.

EQUALITY

The SPEAKER pro tempore. The Chair recognizes the gentleman from Oregon (Mr. BLUMENAUER) for 5 minutes.

Mr. BLUMENAUER. While there have been occasional steps backward in America's march towards equality for all citizens, progress and understanding have marched steadily onward. As a result, America is more diverse, and it is better for it; but we must continue to work hard to create a truly equal and just society.

Discriminating against an individual based on race, religion, or sexual identity is deplorable and unacceptable. Historically, the LGBT community has faced significant discrimination, but the country has come a long way in recent years in attitude. Most Americans are more accepting regardless of one's sexual orientation, but there remain too many areas where society still must translate the attitude of most Americans into rights and protections for all citizens.

LGBT students should be able to learn in a safe school environment, free of cruel bullying, psychological or physical abuse. The term ''bullying'' actually does not capture the behavior and the threat. Foster children should be adopted by loving families regardless of the parents' sexual orientations. Of course, most fundamentally, Americans should be afforded the right of marriage whether they are gay, lesbian, bisexual, or transsexual—the same as heterosexual couples.

I've been involved with these issues since I first chaired a hearing in the Oregon House of Representatives on antidiscrimination in 1973, right through today, in advocating the repeal of DOMA. I've been proud to work for equality throughout my career, but there remains much work to be done.

In the name of extending equal rights to all Americans, no matter who they love, at a minimum, we should take the following steps:

Most importantly, we should aggressively support marriage equality for all. The Respect for Marriage Act will repeal the Defense of Marriage Act and will guarantee that the Federal Government will recognize any marriage that is legal in the State in which it is performed;

The lowest hanging fruit is workplace discrimination. It is long past time to enact the Employment Non-Discrimination Act, ENDA, which would make it illegal to discriminate in the workplace based on actual or perceived sexual orientation or gender identity;

Educational institutions must be safe places for young people to learn and grow without the threat of bullying or the risk of being denied the chance to participate in extracurricular activities based on their identities. We

should pass the Safe Schools Improvement Act and the Tyler Clementi Higher Education Anti-Harassment Act of 2011;

We must stand up for real family values and support the Every Child Deserves a Family Act. All parents who wish to adopt a foster child deserve the chance to do so no matter their sexual identities;

Finally, I strongly support amending the Immigration and Nationality Act to grant same-sex partnerships the same rights and privileges as any other partnership.

One of the most important milestones in this struggle was the endorsement recently by President Obama and Vice President BIDEN of marriage equality for all Americans. With renewed momentum and with continued hard work, we will not only achieve marriage equality for our LGBT friends and families, but equality and fairness in all aspects of life.

Make no mistake, we are not striving just for tolerance; we are striving to make this country more equitable, just, and fair so that every man, woman, and child has the opportunity to pursue their dreams in a safe and accepting environment. Such freedom is the very cornerstone on which a livable community is established, where families are safe, healthy, and economically secure.

IN HONOR OF BRANDON ELIZARES

The SPEAKER pro tempore. The Chair recognizes the gentleman from Texas (Mr. REYES) for 5 minutes.

Mr. REYES. As a parent and a grandparent, I rise today with a heavy heart to take time to remember Brandon Elizares, a young man who left us 2½ weeks ago.

In our community, he will always be remembered for his smile, for his personality, and for his desire to serve as an inspiration to others. Brandon, like over 11 million people in this country, was gay, and like so many of his peers was being harassed and bullied until he took his own life on June 2 after being threatened with being buried alive and shot.

His last message echoed his infinite love for his family and his apologies for not being strong enough to continue taking the abuse that he had faced for over 2 years. His final words read, ''My name is Brandon Joseph Elizares, and I couldn't make it. I love you guys with all of my heart.''

High school should be an exciting time with an array of new experiences and challenges, but one thing it should not be is an environment in which young people worry about being bullied. Children in high school should be focused on their education, pure and simple. The sad reality, though, is that for many students their primary concerns don't lie in textbooks or in the upcoming exams but in the fear that they will not be accepted by their peers, that they will be physically abused, or, in the case of Brandon and in the cases of countless others like him, that they may consider taking their own lives to escape the terrible pain.

Brandon was a young man who exemplified our best in the El Paso community. He embodied what this Nation looks for in all its young people. He was a best friend, a loving son, an aspiring model and artist, an excellent student, and, to a teenage girl who had contemplated suicide herself due to bullying, Brandon was a superhero and an older brother.

Like so many El Pasoans, I feel a personal connection to Brandon, and his death reflects the unfortunate truth that many young people today in our community continue to suffer.

□ 1010

I stand here in the people's House to ask my colleagues to help me in ensuring that Brandon's death was not in vain. I ask my colleagues to join me in support of the Student Non-Discrimination Act, H.R. 998, and the Safe Schools Improvement Act, H.R. 1648, to protect LGBT students from discrimination and from bullying in the schools. I also ask that you stand with me in support of the ''It Gets Better Campaign,'' a project whose goal is to prevent suicide among youth by having adults and allies convey the message that these teens' lives will ultimately improve.

In our country today, unfortunately, the facts are clear. Fifty-six percent of students have personally felt some sort of bullying at school. Between the fourth and eighth grade in particular, 90 percent of students report being the victims of bullying. Nine out of ten LGBT youth reported being verbally harassed in school in the past year because of their sexual orientation. A victim of bullying is twice as likely to take his or her life compared to someone who has not been victimized.

Every day, thousands of children wake up fearing for their well-being as they go to school. If the Student Non-Discrimination Act and the Safe Schools Improvement Act were enacted today, we could provide students a sense of relief and some reassurance that their government is working to improve their lives by increasing awareness about their daily struggles. We owe that to Brandon and so many others who are suffering from bullying in our schools.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until noon today.

Accordingly (at 10 o'clock and 12 minutes a.m.), the House stood in recess.

□ 1200

AFTER RECESS

The recess having expired, the House was called to order by the Speaker at noon.

PRAYER

Reverend Richard Haynes, Salem Missionary Baptist Church, Lilburn, Georgia, offered the following prayer:

Our Father in heaven, we thank You for a brand-new day and for all of the opportunities and possibilities that comes with this day.

We thank You for another opportunity to be better. Thank You for another blessed opportunity to do better. We thank You for yet another chance to correct mistakes and make critical legislative adjustments for the betterment of this country and the world.

With a heart of gratitude for the many possibilities that this day brings, we declare with the Psalmist David that we will rejoice and be glad in it. May our rejoicings manifest themselves in good works that others may see, that You may be glorified.

In the name of Your darling Son, we pray.

Amen.

THE JOURNAL

The SPEAKER. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

PLEDGE OF ALLEGIANCE

The SPEAKER. Will the gentleman from Georgia (Mr. WOODALL) come forward and lead the House in the Pledge of Allegiance.

Mr. WOODALL led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

MESSAGE FROM THE SENATE

A message from the Senate by Ms. Curtis, one of its clerks, announced that the Senate has passed a bill of the following title in which the concurrence of the House is requested:

S. 3314. An act to specifically authorize certain funds for an intelligence or intelligence-related activity and for other purposes.

WELCOMING REVEREND RICHARD HAYNES

The SPEAKER. Without objection, the gentleman from Georgia (Mr. WOODALL) is recognized for 1 minute.

There was no objection.

Mr. WOODALL. Mr. Speaker, the House is fortunate today to have Reverend Dr. Richard Benjamin Haynes as

our guest chaplain. He's a life-long servant of the Lord, growing up as the son of a Baptist minister. He now pastors Salem Missionary Baptist Church in my home county of Gwinnett. He's an avid angler, a fisherman. But first and foremost, he's a fisher of men. In the 23-plus years that he's led Salem Missionary Baptist, his congregation has grown from 100 to over 4,500.

Beyond the pulpit, Reverend Haynes is active throughout our community. He is past chaplain for the Gwinnett County Sheriff's Department, past director of the Statewide Ministers Convention, and currently member of the Gwinnett County Board of Education Advisory Board, to name just a few.

I'm honored to have him in Washington, D.C., with me today. His wife, Beverly, is with us today, as is his daughter Sheena, and his two grandsons, Benjamin and VaShon.

Reverend, thank you for your prayer today and thank you for your ministry every day.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Ms. ROS-LEHTINEN). The Chair will entertain 15 further requests for 1-minute speeches on each side of the aisle.

JOB AVAILABILITY IS NOT IMPROVING

(Mr. WILSON of South Carolina asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. WILSON of South Carolina. Madam Speaker, the Bureau of Labor Statistics announced yesterday that the number of job openings is at its lowest point in 5 months. The number of available jobs dropped from 3.7 million in March to 3.4 million in April. This fact shows that the President's failed policies are destroying jobs across our Nation and undermining families.

Unemployment has been above 8 percent for 40 months, not including the millions who are underemployed or who have lost hope and are no longer looking for a job. And yet the President still believes our private sector is doing fine. In fact, sadly, now the President is offering work permits to illegal aliens to take jobs from hard-working Americans.

It is past the time for the President and his liberal colleagues in the other Chamber to pass the dozens of bipartisan job-creation bills which are stalled in the Senate graveyard.

In conclusion, God bless our troops, and we will never forget September the 11th in the global war on terrorism.

NATIONAL DAIRY MONTH

(Ms. HOCHUL asked and was given permission to address the House for 1 minute.)

Ms. HOCHUL. Did any of you wake up to a nice bowl of cereal or an instant breakfast drink, like I did? Did you give any thought to the effort that went into bringing that fresh, wholesome milk to your table? Well, I sure do.

Just this past week, I was visiting the Koener farm in Wyoming County, the largest dairy-producing county in New York State, which is the fourth largest producer in this great country. But I didn't go just to have their milk; I went to listen to their concerns. And I saw a mother, father, brother, sister getting up before any of us see the light of day to do their work, tremendously hard work; but there's a lot of pride in what they do.

So as we proudly salute the millions of families across this country, in particular the dairy-farming families during National Dairy Month, we need to do more for these stewards of our national food security. We can give out proclamations and pay lip service to the 51,000 families across this Nation who supply us with these products, or we can actually listen to them and do something to help.

First of all, they want a farm bill. They want certainty to know what the deal's going to be, not later, not later this year, but right now.

Secondly, they need labor. That's the number one issue I hear when I'm visiting the Nobles and the other family farmers, the Zubers, the Coynes. Let's give them what they need.

LIFE OF A CHAMPION—RICHARD SCHOENSTADT

(Mr. DOLD asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. DOLD. Madam Speaker, I join with many others in the greater Chicago area in recognizing the life and recent passing of a tremendously respected, selfless, and inspirational leader in our community—Richard Schoenstadt.

Richard, no doubt, made a difference in this world with his tireless dedication to strengthening the U.S.-Israel relationship. His sweeping passion and energy for pro-Israel advocacy set a very high bar, which both elevated and advanced the commitment of so many good people to pro-Israel causes.

Richard believed in engagement and activism, and he lived his life knowing there was only one way to do things—the right way. He served his community as an outstanding example of leadership and earned a reputation as a brilliant and committed mentor to many, many people.

Like so many who were lucky to know him, I feel I was given a special gift in Richard's friendship. My thoughts and prayers go out to his family—his wife, Cindy, his daughters, Carly and Kate, and the entire extended Schoenstadt family.

May his memory continue to inspire us all to action, and may we in this Congress now and forever remain dedicated to advancing the principles that Richard Schoenstadt so proudly stood and fought for throughout his life.

□ 1210

STUDENT LOAN RATES

(Mr. SIRES asked and was given permission to address the House for 1 minute.)

Mr. SIRES. Madam Speaker, access to affordable higher education is one of the reasons that our country is so great. As someone who lives in the gateway to America, I have seen firsthand the transformational power of education. However, access to higher education is now being threatened.

In less than 2 weeks, the interest rate for student loans is scheduled to double from 3.4 to 6.8 percent. This will make it extremely burdensome for students and families with limited financial resources to attend college. Just in the past 10 years, college tuition has increased by 28 percent. Middle class families are struggling to send their sons and daughters to school.

For many Americans, a college education is essential to future success. Over a lifetime, it is estimated that a college graduate makes an average of $2.27 million. In contrast, those with only a high school diploma are estimated to make $1.3 million.

The clock is ticking and we must act now. Congress should not block access to affordable education. Let us work together to keep student loan interest rates low.

WEST VIRGINIA DAY

(Mr. MCKINLEY asked and was given permission to address the House for 1 minute.)

Mr. MCKINLEY. Madam Speaker, the State of West Virginia is celebrating its 149th birthday today. Celebrations are being held as we speak throughout the State. I'm a proud seventh-generation West Virginian and honored to serve the State that I love.

Being a West Virginian comes with great honor, tradition, and pride. In concert with the restored State of Virginia, President Lincoln, on April 20, 1863, proclaimed that West Virginia would be admitted to the United States as a separate State. Sixty-one days later, on June 20, 1863, West Virginia became a member of the Union, the only State created during the War Between the States.

Every year, millions of people travel the country roads of our great State and view the beautiful scenic mountains, from the Shenandoah River to everything in between. Madam Speaker, I hope everyone enjoys this time-honored tradition of West Virginia Day and celebrates our wild and wonderful State.

Happy birthday, West Virginia.

30TH ANNIVERSARY OF MURDER OF VINCENT CHIN

(Ms. CHU asked and was given permission to address the House for 1 minute.)

Ms. CHU. Madam Speaker, 30 years ago, Vincent Chin, a young Chinese American engineer, was celebrating his impending wedding in Detroit, Michigan, when two unemployed autoworkers started shouting at him, saying, ''It is you Japanese who are taking away our jobs.'' They chased him down and bashed his head in with a baseball bat. Vincent's murderers were only punished with a $3,000 fine and got off without even spending a day in jail. In the meanwhile, instead of going to his wedding, Vincent's family went to his funeral.

This injustice led to the emergence of a national Asian Pacific American identity and movement. This week, as chair of the Congressional Asian Pacific Caucus, I will be introducing a resolution on the significance of the 30th anniversary of Vincent's death. His story remains an important reminder of why we must always combat the dangers of xenophobia and scapegoating.

AMNESTY

(Mr. SAM JOHNSON of Texas asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. SAM JOHNSON of Texas. Madam Speaker, most of us just returned from a week talking with our constituents back home. In the Third District of Texas, folks only had one thing on their mind: the President's disgraceful decision to grant amnesty to 1 million illegal immigrants. Americans across the country are outraged. Amnesty rewards people for breaking our laws and encourages others to do the same. Entry into the United States is not a right; it's a privilege.

Since taking office, the President has time and again taken reprehensible steps that weaken our border security and undermine the rule of law in America. By sidestepping Congress, the President is now single-handedly rewriting our immigration policies, violating the trust between the Congress and the President to uphold the laws of this land—just did it again today.

Enough is enough. This administration needs to stop putting politics ahead of the rights and privileges granted to him in the Constitution.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair would remind Members to refrain from engaging in personalities toward the President.

HONORING DEVIN BECK

(Mr. CICILLINE asked and was given permission to address the House for 1 minute.)

Mr. CICILLINE. Madam Speaker, I rise today to honor Devin Beck, a native of Tiverton, in my home State of Rhode Island.

Devin set a goal to raise $2,000 for Executives Without Borders, a nonprofit organization that works to engage business professionals in solving humanitarian challenges across the world.

So on January 11 of this year, Devin left St. Augustine, Florida, with the goal of bicycling to San Diego, California, a destination more than 2,000 miles away. On February 25, 46 days later, Devin arrived in San Diego, completing a journey that spanned 232 hours, 17 minutes, and 44 seconds on his bike.

In the end, Devin exceeded his goals and raised $6,000 for Executives Without Borders to benefit a program that is helping Haiti to build new recycling centers to recover from the devastating hurricane it suffered in 2010.

I congratulate this young man, Devin, as well as his parents, Donald and Kathleen, on his truly impressive accomplishments and wish him continued success.

NATURAL GAS

(Mr. THOMPSON of Pennsylvania asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. THOMPSON of Pennsylvania. Madam Speaker, on June 4, America's Natural Gas Alliance issued a report contesting the EPA's recent study on greenhouse gas emissions and natural gas development. Specifically, the study found that methane emissions from shale operations are 86 percent lower than EPA estimated. Furthermore, methane doesn't remain in the atmosphere for long relative to other gasses.

Unfortunately, some energy alternatives receiving government subsidies have worse emissions than what we thought. The new book, ''Green Illusions,'' by Ozzie Zehner, shows that building solar cells releases substantial quantities of emissions like sulfur hexafluoride, which lasts 267 times as long in the atmosphere, and have nearly doubled since 1998.

According to a May report from the International Energy Agency, U.S. carbon emissions are down more than any other country. In fact, since 2006, U.S. emissions have fallen 7.7 percent, with the increased use of shale gas as a key factor in the drop, according to the Agency's chief economist.

This leads to a conclusion that many might find paradoxical. If global warming is a problem we need to address, then we should welcome the increased production and use of natural gas as a prime energy source.

ACCESS TO EDUCATION

(Mr. BACA asked and was given permission to address the House for 1 minute.)

Mr. BACA. Madam Speaker, in these tough times, we should make every effort to increase access to higher education for all Americans. Making college more affordable doesn't just help students, it strengthens our economy.

Unfortunately, if Congress does not act soon, interest rates on student loans will double for over 7 million students in less than 2 weeks. July 1 is around the corner. It's time for a serious solution to help our Nation's children.

Instead of working towards a compromise, Republicans have put forward a plan to cut health services for women and children. Republicans just don't get it. Once again, they're too busy cutting taxes for millionaires and billionaires instead of working for our middle class. Republicans are showing their priorities are out of touch with hardworking Americans.

We need to act now on student loans. Let's help all of these students have access to education.

□ 1220

RECOGNIZING THE 25TH ANNIVERSARY OF THE NATIONAL AIR TRAFFIC CONTROLLERS ASSOCIATION

(Mrs. BIGGERT asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Mrs. BIGGERT. Madam Speaker, I rise today to salute the hardworking individuals who strive every day to protect the safety of air passengers. These are the men and women of the National Air Traffic Controllers Association, NATCA, who yesterday celebrated their 25th year as the guardians of the U.S. national airspace system.

On June 19, 1987, the Federal Labor Relations Authority certified NATCA as the exclusive bargaining representative for the Federal Aviation Administration air traffic controllers. NATCA now represents more than 20,000 air traffic controllers, engineers, and other aviation safety professionals. They have the safest record in history, guiding 70,000 flights per day and protecting over 700 million passengers per year.

Madam Speaker, I would ask all of my colleagues in the House today to join NATCA in celebrating a quarter century of hard work, keeping America's airspace system the safest in the world.

GREAT LAKES WATER QUALITY AGREEMENT

(Mr. HIGGINS asked and was given permission to address the House for 1 minute.)

Mr. HIGGINS. Madam Speaker, the Great Lakes are our most threatened national assets, yet they are the largest source of fresh water in the world, and account for $7 billion in economic activity annually. In my western New York community, the resurgence of our Inner and Outer Harbors along Lake Erie is an important reminder of the

relationship between the health of the Great Lakes and our region's economic future.

The State Department is finalizing a revision to the Great Lakes Water Quality Agreement with Canada. This important agreement expresses a joint commitment to protecting and restoring the Great Lakes ecosystem.

Madam Speaker, I recently joined my congressional colleagues in the Great Lakes region in asking the State Department for the status of this agreement and have offered to host a signing ceremony between the United States and Canada in Buffalo, New York. It is more important than ever before to affirm our commitment to protecting the health of the Great Lakes.

HONORING THE LIFE OF FIRST LIEUTENANT MATHEW FAZZARI

(Mrs. MCMORRIS RODGERS asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Mrs. MCMORRIS RODGERS. Madam Speaker, it's with a heavy heart today that I rise to honor the life of First Lieutenant Mathew Fazzari. He is a 25-year-old American hero.

He's a native of Walla Walla, Washington, and he graduated from Gonzaga University, was commissioned in the United States Army, was a member of the prestigious 82nd Airborne, and he gave his life in serving and defending our country.

He lost his life on June 6, 2012, when his helicopter was shot down by enemy attack in Afghanistan. He lost his life in the name of American freedom, and he lost his life to protect all of ours.

He leaves behind a community who admires him, a country who pays homage to him, and a family who's been forever changed by him. He was a son, a brother, a husband and a father. He says goodbye to a family that got the call they hoped they would never get.

Madam Speaker, we mourn his loss. We celebrate his life. A life of patriotism, courage, and valor. A life and a legacy that will endure forever.

May God bless Lieutenant Mathew Fazzari, his parents, Greg and Susan; his siblings, Luke, Shawn, and Danielle; his wife, Tovah, and their two young sons, Dominic and Samuel. May God bless his family and all the brave men and women who have answered America's call to freedom.

AMERICANS ARE SAYING ''PUT ME TO WORK''

(Mr. CARNAHAN asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. CARNAHAN. Madam Speaker, I stand here today frustrated but determined. Frustrated because I've heard from so many people in St. Louis, Missouri, that I represent, small business owners, veterans, students, and others. They're all saying the same thing: ''Put me to work.''

They want to help rebuild our economy. They want to help create new American jobs.

They're not saying, ''Kill me a sea lion.'' They're not saying, ''Allow corporations to pollute my air and water.'' They're not saying, ''Give more breaks for the well-off Americans and more burdens for seniors.'' They're saying, ''Put me to work.''

They are determined, and so am I. So I say to you, put Congress to work. Put us to work passing the student loan interest extension to protect students who are graduating into an unstable marketplace. Put us to work passing the Senate transportation bill that passed overwhelmingly with bipartisan support and would create thousands of jobs. Put us to work passing the STARTUP Act, to create new opportunities for American innovation.

Listen to our constituents. They want to go to work. They are cheering for our country to succeed and to work, and they expect and deserve their Congress to do the same.

THE PRIVATE SECTOR IS NOT DOING FINE

(Mrs. BLACK asked and was given permission to address the House for 1 minute.)

Mrs. BLACK. Madam Speaker, the President recently said that the private sector is doing just fine. But for millions of unemployed and underemployed Americans, and millions more struggling with higher food and energy prices, there is nothing fine about the state of the U.S. economy. That's why the House has passed more than a dozen bipartisan bills.

This week, the House will consider the Domestic Energy and Jobs Act. This package of domestic energy production bills, of which I am a cosponsor, will not only reduce energy costs for hardworking families and small businesses, but it will also get government out of the way so that American job creators can do what they do best, that is, grow the economy and put people back to work.

DOMESTIC ENERGY AND JOBS ACT

(Mr. HIMES asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. HIMES. Madam Speaker, today, this House takes up the cynically named Domestic Energy and Jobs Act, which is the latest Republican installment in their mad dash to allow polluters to dump garbage and poison into our air and water.

If I had more time I would point out that this bill would gut the Clean Air Act, which was signed into law in the early 1970s by a Republican President before that party abandoned the value that we should be stewards of our environment. I would talk about my daughter, who suffers from asthma. That asthma, and the asthma of millions of other young people, will get worse if this bill becomes law.

I would point out that the idea that this is about jobs is baloney. And I would cite the Bureau of Labor Statistics studies in 2010 that said that one-third of 1 percent of jobs and layoffs were because of government regulation.

Instead, I have a question. What happened to personal responsibility? What happened to the idea that we clean up our own mess?

Madam Speaker, why are we asking the entire American public to pay the cost of polluting our air and water? That, I don't understand.

DOMESTIC ENERGY AND JOBS ACT

(Ms. FOXX asked and was given permission to address the House for 1 minute.)

Ms. FOXX. Madam Speaker, summer is upon us. Traditionally, this is the season when Americans pack the family car to head out for a well-deserved vacation. Unfortunately, this year, many will not be able to do this because gas prices are too high due to the failed economic and energy policies of this administration and lack of action from the Senate.

House Republicans have crafted and passed many bipartisan bills to address this issue, but Senate intransigence has prevented them from moving forward to provide relief to the people we represent. Today, House Republicans will offer another solution, H.R. 4480, the Domestic Energy and Jobs Act. This legislation promotes job creation and addresses the high energy costs which are burdening so many families and small businesses across America.

Madam Speaker, the May jobs report and the high cost of energy demand immediate action. House Republicans are answering the calls from Americans with this act. I urge my colleagues to support this very important legislation.

CONGRESSIONAL OVERSIGHT OF THE UNITED STATES ATTORNEY GENERAL

(Ms. JACKSON LEE of Texas asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. JACKSON LEE of Texas. Madam Speaker, the Constitution is an enormously important document. The oversight of Congress is an enormously important responsibility. Lives lost in the course of various activities of our law enforcement are issues that we take with great concern.

As a member of the Judiciary Committee, it has been my responsibility over the years, from impeachments to Waco to issues beyond, to look deep into the facts, and I respect that. I'm appalled, however, when the chief law enforcement officer of the United States is called a liar. And I stand on this floor to reject any thought that a

United States Attorney that takes an oath of office would lie.

We can find a resolution to the facts of Fast and Furious, started under the Bush administration, that have been reinvestigated and reinvestigated. But we do not have to malign Attorney General Holder for doing his job. And I would ask this Congress to ultimately reject any contempt charge against the chief law enforcement officer, and to denounce lying.

□ 1230

OPTION ACT

(Mr. BROUN of Georgia asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. BROUN of Georgia. Madam Speaker, ObamaCare has not taken full effect yet, but it is already crippling our country and our economy: premiums are rising; businesses are shedding jobs; doctors and patients are constantly dealing with a third party making health care decisions—and that's the Federal Government.

Fortunately, the Supreme Court has some of these same concerns about ObamaCare; and, hopefully, they will strike down both the individual mandate and the entire law. However the Court rules, though, ObamaCare must go.

In the GOP Doctors Caucus, we know that the American health care system needs some serious surgery. We have brought forth many ideas to do just that. For example, my OPTION Act will revitalize American health care, not through government interference but by giving doctors and patients full control over their dollars and their decisions. When ObamaCare falls, my bill stands ready to provide the health care relief that Americans both want and need.

I hope my colleagues on both sides of the aisle will look to the OPTION Act as the example of what real reform looks like.

REJECT THE DOMESTIC ENERGY AND JOBS ACT

(Ms. HAHN asked and was given permission to address the House for 1 minute.)

Ms. HAHN. Madam Speaker, I grew up in Los Angeles in the fifties, which was when the smog was so bad that we actually had to stay inside the classroom during recess; and when you tried to inhale deeply, the pain in your chest was so severe from the pollution and the smog.

Thanks to government intervention, we have made huge strides, not only in Los Angeles but throughout this country, in cleaning our air for the health of our children. We've made progress, but we need to make a lot more. Unfortunately, to continue to combat this problem, Congress should take bold steps to invest in clean-energy technology, including in new electric vehicles and in the infrastructure to charge them.

But with H.R. 4480, my Republican friends are denying not only Los Angeles but all cities in this country the tools they need to continue to improve our air and improve our health. This bill would rob the EPA of the ability to effectively enforce clean air laws, and it would deepen our dependency on dirty fossil fuels.

15TH ANNUAL CONGRESSIONAL RENEWABLE ENERGY AND ENERGY EFFICIENCY EXPO AND FORUM

(Mr. BARTLETT asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. BARTLETT. Madam Speaker, tomorrow is the 15th Annual Congressional Renewable Energy and Energy Efficiency EXPO and Forum from 9:30 a.m. to 4:30 p.m. in the Cannon Caucus Room as well as in room 340 Cannon. It features more than 50 exhibitors, including six from Maryland; and it features 30 speakers, including Members of Congress, the executive branch, and the private sector.

Come and learn the present status and near-term potential of how the cross-section of renewable energy—that is biofuels-biomass, geothermal, solar, water, wind—and energy efficiency technologies are creating jobs and meeting 11.7 percent of domestic U.S. energy production and 12.7 percent of net U.S. electrical generation.

I encourage Members, staff and visitors to attend tomorrow's 15th Annual Congressional Renewable Energy and Energy Efficiency EXPO and Forum.

DISCLOSE ACT

(Mrs. DAVIS of California asked and was given permission to address the House for 1 minute.)

Mrs. DAVIS of California. Madam Speaker, Justice Brandeis said that sunlight is the best disinfectant. Sadly, in Citizens United, the Roberts' Court has turned its back on this wisdom, and it has given corporations the power to influence our government from the shadows.

To say that these are not dark days for our democracy is not an understatement. Millions upon millions of dollars are flowing into our political system through super PACs, but the identities of the donors who supply this money remain hidden.

Let's not fool ourselves. Let's not fool ourselves into thinking that the identities of these donors are a secret to the politicians whose campaigns are being helped by their money. To ignore the potential for unseemly influence here is truly naive. When one donor can decide the fate of a legislator's reelection, they clearly wield a great deal of power.

We should come together to pass the DISCLOSE Act, which allows the public to see who is making these megadonations, and together we can let sunlight back into our democracy.

CONGRESSIONAL ART COMPETITION

(Mr. COSTA asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. COSTA. Since 1982, the Congressional Art Competition has recognized the special power that the arts have had in our Nation's classrooms.

Today, I have the pleasure of recognizing my district's Art Competition winner, Sarah Fanucchi, who credits the arts for helping her overcome her learning challenges.

From an early age, Sarah struggled with reading and math, but she excelled with a sketchbook and a pencil in hand. Once her teachers at Bakersfield's South High tapped into that talent, Sarah's life changed. She became excited about school, and her grades improved. Sarah's mother, Carrie, said, ''Art was and, I suspect, always will be her refuge. It was her place to begin to shine, her place in school to belong.'' Carrie and Sarah are more than mother and daughter; they are best friends.

As I welcome her and her family to Washington this week, I applaud Sarah's artistic feat. More importantly, her perseverance through her challenges is what I find most impressive about this young lady. The art and life she has created is something any parent or teacher can and should be proud of as she continues to add value to our Nation's fabric.

PROVIDING FOR CONSIDERATION OF H.R. 4480, DOMESTIC ENERGY AND JOBS ACT

Mr. BISHOP of Utah. Madam Speaker, by direction of the Committee on Rules, I call up House Resolution 691 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

H. RES. 691

Resolved, That at any time after the adoption of this resolution the Speaker may, pursuant to clause 2(b) of rule XVIII, declare the House resolved into the Committee of the Whole House on the state of the Union for consideration of the bill (H.R. 4480) to provide for the development of a plan to increase oil and gas exploration, development, and production under oil and gas leases of Federal lands under the jurisdiction of the Secretary of Agriculture, the Secretary of Energy, the Secretary of the Interior, and the Secretary of Defense in response to a drawdown of petroleum reserves from the Strategic Petroleum Reserve. The first reading of the bill shall be dispensed with. All points of order against consideration of the bill are waived. General debate shall be confined to the bill and amendments specified in this resolution and shall not exceed two hours equally divided among and controlled by the chair and ranking minority member of the Committee on Energy and Commerce and the chair and ranking minority member

of the Committee on Natural Resources. After general debate the bill shall be considered for amendment under the five-minute rule. In lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce now printed in the bill, it shall be in order to consider as an original bill for the purpose of amendment under the five-minute rule an amendment in the nature of a substitute consisting of the text of Rules Committee Print 112-24. That amendment in the nature of a substitute shall be considered as read. All points of order against that amendment in the nature of a substitute are waived. No amendment to that amendment in the nature of a substitute shall be in order except those printed in the report of the Committee on Rules accompanying this resolution. Each such amendment may be offered only in the order printed in the report, may be offered only by a Member designated in the report, shall be considered as read, shall be debatable for the time specified in the report equally divided and controlled by the proponent and an opponent, shall not be subject to amendment, and shall not be subject to a demand for division of the question in the House or in the Committee of the Whole. All points of order against such amendments are waived. At the conclusion of consideration of the bill for amendment the Committee shall rise and report the bill to the House with such amendments as may have been adopted. Any Member may demand a separate vote in the House on any amendment adopted in the Committee of the Whole to the bill or to the amendment in the nature of a substitute made in order as original text. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions.

The SPEAKER pro tempore. The gentleman from Utah is recognized for 1 hour.

□ 1240

Mr. BISHOP of Utah. Madam Speaker, for the purposes of debate only, I yield the customary 30 minutes to the gentleman from Colorado (Mr. POLIS). Pending that, I yield myself such time as I may consume. During consideration of this resolution, all time yielded is for the purpose of debate only.

GENERAL LEAVE

Mr. BISHOP of Utah. I also ask that all Members may have 5 legislative days during which they may revise and extend their remarks.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Utah?

There was no objection.

Mr. BISHOP of Utah. This resolution provides for a structured rule for the consideration of H.R. 4480, the Strategic Energy Production Act of 2012, and it makes in order 27 individual amendments that are specified under the rule, two-thirds of which are Democrat amendments.

The rule provides for 2 hours of general debate equally divided and controlled by the chairman and ranking minority member of both the Committee on Energy and Commerce as well as the Committee on Natural Resources. So this structured rule is very fair, and it will provide for a balanced and open debate on the merits of the bill.

Madam Speaker, I'm actually pleased to stand before the House today in support of this rule as well as the underlying legislation, H.R. 4480. The lead sponsor of this legislation, the gentleman from Colorado (Mr. GARDNER), is to be commended for his hard work and leadership in putting this piece of legislation together. I also commend the chairmen of both the Energy and Commerce Committee and the Natural Resources Committee for their support and hard work, as well, on this particular act and on other important pieces of legislation aimed at making our Nation more energy independent.

Madam Speaker, this bill is yet another reminder that this administration is not doing enough to develop our own domestic energy resources, which are plentiful in many parts of our public lands. In my home State of Utah, for example, there are vast amounts of oil and oil shale reserves that remain untapped, largely due to special interest group politics that keeps these lands locked up, even as we go abroad and increase our dependence on foreign sources as well as increasing our trade deficit.

Energy is an absolute prerequisite to our economic engine and creates jobs. If this administration ever hopes to get unemployment down during its tenure, then helping to develop more domestic energy is the key.

This bill, H.R. 4480, stands for a very commonsense proposition. The proposition is that, whenever the President of the United States authorizes a release of oil from the Strategic Petroleum Reserve, the Secretary of Energy will be required to develop a plan to increase the percentage of Federal land oil production by a commensurate percentage to that released from the reserve. The reserve is a reserve. It is reserved for emergencies. Unfortunately, this administration is using our reserve to accommodate common daily life.

It is important and the purpose of this legislation is:

Number one, to develop our resources;

Number two, to make sure that we can streamline the process so that we do not delay the development of our resources;

Number three, to keep the reserve for real emergencies;

Number four, organize a plan to make sure that will be in effect; and

Number five, recognize clearly that energy is needed for job creation. Without that energy, we will not create the jobs that are necessary for this country to move forward.

This bill would actually limit the total amount of Federal lands to be leased, which is only 10 percent of the total of all public lands. Ten percent is very reasonable. The bill also excludes national parks, obviously, and congressionally designated wilderness areas from consideration of this bill.

It's a good bill. It's a commonsense bill. When passed, it will be a key part of our effective and comprehensive national energy strategy.

I urge adoption of the rule, which is a fair rule, and the underlying bill, which is a commonsense bill, and I reserve the balance of my time.

Mr. POLIS. Madam Speaker, I thank the gentleman for yielding me the customary 30 minutes, and I yield myself such time as I may consume.

Madam Speaker, I rise in opposition to the rule and the underlying bill, H.R. 4480, the so-called Domestic Energy and Jobs Act, what is really a death and destruction act, an act that will directly lead to the death of American citizens from various health-related causes—including cancer—and destruction. It is the destruction of not only our environment, but of our quality of life, including our quality of life in my home State of Colorado that is such an important part of driving our economy forward and creating jobs.

Here we are where several controversial, highly partisan bills have been packaged together. There are seven bills. While there is an attempt to dress this up as a jobs package, it's really a wish list for the oil industry that has no chance of becoming law. It's a huge giveaway to the oil industry at the expense of the health of American families, the health of our environment, and our enjoyment and recreational opportunities and economic opportunities on public lands.

Instead of allowing improvements to this drastic death and destruction bill, the House majority has blocked many amendments offered by Republicans and Democrats alike. Under this restrictive rule, commonsense amendments were blocked, including an amendment I offered that would have directed a study on the impacts of oil shale development on agricultural and municipal water usage. My colleague from California, Representative NAPOLITANO, offered a similar amendment in committee.

Those of us in the West, where farmers, ranchers, and community leaders consistently keep us abreast of water issues—and water is our most precious resource—know that we need some commonsense and objective data with regard to how energy production impacts resources, particularly our most precious resource: water.

What lies at the heart of this death and destruction bill today is simply a false premise. It's the false premise that somehow the United States is failing to make good on its natural energy resources.

The fact is, as a result of President Obama's all-of-the-above energy strategy, our Nation's dependence on foreign oil has fallen drastically, and crude oil production in the United States is at an 8-year high. President Obama has increased production of crude oil substantially over the Bush administration lows. The President's policies are demonstrating that we can have an approach to energy in the United States that boosts oil and gas

production and invests in the next generation of cleaner, job-creating, renewable energy technologies, such as wind, solar, and geothermal.

In contrast to the President's all-of-the-above approach, which will lead to reductions in gas prices and a sustainable energy future for our country, this death and destruction bill before us today is an oil-above-all approach. This death and destruction bill hands public lands that we all value over to the oil and gas industry and undermines the laws and rules that have made our air and water cleaner and safer over the past 40 years.

One of the scariest provisions in this package would gut important health-based standards provided for in the Clean Air Act established on a bipartisan basis in 1970. The Clean Air Act-based standards are especially important for protecting children, the elderly, and others who are susceptible to harmful air pollution.

Many nonpartisan public health and medical organizations have recognized that this bill would override clean air standards that have protected American people and families from harmful pollution in the past 40 years. That is why on this bill, which the majority purports deals with energy, we've heard from pediatricians, we've heard from doctors, we've heard from health care providers that this would lead to death, as well as the destruction of jobs, as well as the destruction of our environment and recreational opportunities.

Another controversial partisan provision in this bill would open up vast quantities of public lands to drilling. The bill sets an arbitrary requirement on the Department of the Interior to offer oil companies at least 25 percent of onshore areas that industry nominates each year. Let me say that again. The Department of the Interior wants to open up more lands to industry, even though oil and gas companies hold more than 25 million acres of public lands on shore where they're not producing oil and gas. In addition, these companies are sitting on 6,700 drilling permits that have been approved that they are not using. They need to explore lands where they already hold energy leases.

This is not a sensible energy policy. It's called an old-fashioned land grab and an old-fashioned water grab. They're coming after our land in the West, and they're coming after our water in the West. We're not going to take it sitting down.

Another extreme provision is that this bill would overturn the Federal Land Policy and Management Act to elevate energy production above other public land uses. My constituents in Colorado are tremendously concerned that somehow oil production would trump job-creating activities, including hunting, fishing, recreation, grazing, conservation, mainstays of jobs and the economy in my district that would be overridden in the name of oil, which would destroy jobs and destroy the health of Colorado families and families across the United States.

Another provision in this bill turns the review of applications to drill into nothing more than a rubber stamp. The bill says that if the Secretary of the Interior doesn't make a decision within 60 days, it's automatically approved. It will be automatically approved with no process.

At the same time, many of the proponents of this bill are attempting to gut the budget of many of the agencies that need to review these applications, effectively ensuring that no application can properly be dealt with and evaluated within 60 days, and therefore they would all be automatically approved regardless of the impact on people's health or economic opportunities and jobs.

□ 1250

Now there are so many troubling provisions in this bill. Another one—and this one would likely violate our Constitution, which we began this session of Congress by reciting very publicly in this body—it would limit a citizen's right to participate in the discussion of leasing and drilling by making all dissenters pay a $5,000 fee.

Now imagine you are a Coloradan, an Arizonan, a Pennsylvanian, a Texan who's concerned about drilling near your home or near your school or near your ranch. Now under this death and destruction bill, opening your mouth would cost you $5,000. Free speech would no longer be free, if this bill passes.

Madam Speaker, public lands are just that, public. We all own a share of them. We all benefit from them. They're not the private playground of oil and gas companies. They're owned by all Americans. And all Americans should have a say in how they're used, not just Americans who cough up $5,000.

Well, this bill would grant the oil and gas industry's wish list by opening up public lands and rolling back public health safeguards, hurting health and killing American families. But one thing this bill will not do is lower the price of gasoline. Economists agree: this bill has no impact on the price of gasoline.

There are actually now more drilling rigs in operation in the United States, thanks to President Obama's leadership today, than the rest of the world combined. In addition, the number of drilling rigs has doubled, doubled since 2009. President Obama's leadership has doubled the number of drilling rigs since 2009.

Now research going back more than three decades shows that there is very little correlation between the volume of domestic oil and the price of gasoline at the pump.

Go ahead and tell the American people that we want oil and gas companies to drill anywhere they like with no regard for public health. Is that the message that we want to send? This bill, this death and destruction bill, would not only lead to the deaths of Americans but would destroy jobs, destroy economic opportunities, and destroy recreational opportunities. It's nothing short of a Federal land grab and a Federal water grab.

Representing my constituents in Colorado, I encourage my colleagues to say, ''Heck, no,'' on both the bill as well as the rule.

I reserve the balance of my time.

Mr. BISHOP of Utah. I am pleased to yield 3 minutes to the gentleman from North Dakota (Mr. BERG), the gentleman whose home State has provided a program of death and destruction which has led to a 3 percent or less unemployment rate, through jobs in energy production.

Mr. BERG. I thank the gentleman for recognizing me today.

Madam Speaker, I rise in support of the underlying bill, the Domestic Energy and Jobs Act. In my home State of North Dakota, we're seeing unprecedented growth. As it was mentioned, at 3 percent, North Dakota has the lowest unemployment rate in the country. We have a nearly $2 billion budget surplus. We have stabilized our finances, and we've created certainty. And I couldn't be more proud of our State.

A large part of our economic success is due to a comprehensive energy policy and a commonsense regulatory environment which, in North Dakota, is known as EmPower North Dakota. In North Dakota, we know that all energy production is good energy production. Rather than picking winners and losers in energy, this EmPower act creates a stable, business-friendly climate. It does this by encouraging all energy production.

North Dakota embraces all forms of energy production and natural resources capabilities across our State. And North Dakota is really proof that ''all-of-the-above'' really does work, and there's no reason why we should not be taking this proven approach to developing energy and domestic energy production and applying it nationwide. That's really the goal of this legislation that's being considered here in the House today.

I am proud to offer my strong support for this legislation, and I encourage all of my colleagues to do the same by supporting this rule.

Mr. POLIS. Madam Speaker, I yield 3 minutes to the gentlewoman from Florida (Ms. CASTOR).

Ms. CASTOR of Florida. I thank the gentleman from Colorado for yielding the time.

Madam Speaker and colleagues, I rise to oppose the rule and the underlying bill for three primary reasons. First, the package is very poor public policy. Second, I offered a commonsense amendment, and the Republican majority blocked it from being debated, so it will not be heard today, unfortunately. And third, the House of Representatives shouldn't be wasting its time on a

package that's not going anywhere. Instead, we should be focused on job creation, especially passage of the transportation bill, through which we could create thousands and thousands of jobs across the country.

But first, as we marked up part of this package in the Energy and Commerce Committee, it became apparent that this package is chock-full of detrimental policy decisions for America. It creates new bureaucracies when it comes to energy policy and undermines the Nation's energy security. It rolls back policies that support the continued growth of safe and responsible energy production in the United States. And it improperly removes protections that we enjoy under the Clean Air Act that protect the health of American families all across this great Nation.

Second, if my colleagues recall, following the BP Deepwater Horizon blowout in the Gulf of Mexico, a major flaw in the law came to light: that the Department of Interior's maximum penalty for companies violating offshore drilling laws is limited to $40,000, and for major onshore drilling violations, it's only $5,000. So these amounts are not enough of a deterrent for bad behavior. That's why I offered an amendment to give the Secretary of the Interior the authority to increase civil fines against oil companies that violate the law while drilling. But unfortunately, my Republican colleagues have once again blocked sensible policy in order to protect Big Oil.

The Deepwater Horizon disaster was a major economic blow to my home State of Florida. If our laws do not establish appropriate deterrents, then you put our jobs at risk. Our tourism industry, small businesses, restaurants, fishermen, and the military rely on clean water and clean beaches. And our laws should protect American families and businesses, and not just Big Oil.

Finally, I strongly disagree with the Republican majority's decision to block the transportation bill and the thousands and thousands of jobs that are dependent on it. The Republican inaction on a bill that passed the United States Senate in a bipartisan way with over 70 votes is being blocked here on the floor of the House, and people should be up in arms. At a time when we've got to make greater progress when it comes to putting people back to work, that's the best path forward. I think the Republican inaction is causing great economic harm across the country, and that is what we should be debating today.

Mr. BISHOP of Utah. Madam Speaker, I yield 3 minutes to the gentleman from Louisiana, Dr. BOUSTANY, a State that truly understands what it means to have an all-of-the-above policy for energy production, and what energy means to job creation.

Mr. BOUSTANY. I thank the gentleman for yielding time to me.

Madam Speaker, the sad fact today is that this country does not have a coherent energy strategy, pure and simple.

Now I can tell you, I come from Louisiana, where we know firsthand, probably more than any other State, that good energy policy can march hand-in-hand with good economic policy and good environmental policy. We've lived that life. We know that the energy sector, American energy production, creates good-paying jobs. Many of these jobs go to people from families that have never had anyone attend college, and through these jobs, they have been able to pay for college for the next generation. These are good-paying jobs, better paying than most.

The first step in energy policy is, number one, don't punish your current energy production. Don't punish American energy production. And that's what we've seen from this administration. Four straight years of proposing high taxes, new taxes on independent small energy companies, small oil and gas companies. New taxes at a time when we ought to be developing our energy production makes no sense at all. Secondly, what's our transition strategy? We clearly have an abundance of oil and gas, new reserves, new technology.

□ 1300

We have led the world in this. We ought to be developing it. And we can achieve energy security for this country and create good-paying American jobs.

This administration proposed a moratorium on drilling in the Gulf of Mexico. And now, yes, they lifted the moratorium, but they still continue to slow-walk the permits. This bill would go forward and help us to streamline that process so we can get American energy production back up online in the Gulf of Mexico and to develop our energy security needs. We have the reserves. We have the opportunity.

The American energy production sector from upstream, midstream, downstream is accountable for 6 million jobs in this country; and we can grow more jobs. We can grow more jobs beyond that—good-paying jobs—if we do this—and meet our energy security needs.

The bottom line is this: I would ask my colleagues on the other side of the aisle to take a look at that plaque up there near the ceiling just above the Speaker's chair. Read the first sentence. It says: ''Let us develop the resources of our land,'' a quote from Daniel Webster. We should heed that advice. We should develop the resources of our land.

Let's develop our American energy production in the Gulf of Mexico and Alaska. Let's develop it in the shale plays. Let's create jobs. Let's create a secure energy future for this country, and let's move this country forward.

Mr. POLIS. If we defeat the previous question, I'll offer an amendment to this rule that will allow the House to consider the Stop the Rate Hike Act of 2012, legislation that would keep the student loan interest rate low and reduce the deficit. If Congress fails to act, more than 7 million students across this country will see their student loan interest rate double come July 1, just around the corner. It's outrageous that at this time of slow and painful economic recovery the majority continues to refuse to work on this issue in a bipartisan way.

To discuss this proposal, I yield 2 minutes to the gentleman from Connecticut (Mr. COURTNEY).

Mr. COURTNEY. Thank you, Mr. POLIS, for yielding and for, again, bringing this issue back to the floor, which, as my chart indicates, we're now down to 10 days.

When this chart was first created, it was 110 days, and it coincided with the delivery of 130,000 petition signatures from college campuses all across America, pleading with Congress to listen to President Obama's challenge on January 25 right from that podium that we should block the increase from going through.

My legislation, which was introduced at midnight the same night, had 152 cosponsors to lock in the lower rate. For 3 months, nothing happened. A bill was rushed to the floor by the majority without any consultation with the other side. It took money out of a fund to pay for cervical cancer screening and diabetes screening, a hyperpartisan measure which the President indicated he would veto even before the vote was taken.

The good news is Mr. BOEHNER has already moved away from that proposal. He sent a letter with Senator MCCONNELL to the Senate leadership offering new pay-fors and moving off the House bill. Again, that was rushed through with absolutely no consultation on any bipartisan basis.

There are 7 million college students who are waiting for an answer in the next 10 days to this issue. The rates will double from 3.4 percent to 6.8 percent. Senator REID has talked already about a proposal which is a pay-for that, again, there appears to be some willingness to move forward on. We should be focused on that issue right now, not this measure on the floor which is going nowhere. It's another bill which will never see the light of day in the Senate.

This issue, helping students pay for college at a time when student loan debt now exceeds $1 trillion, is the issue that America is watching and waiting. And editorially, from Florida all the way to the west coast, newspapers are demanding bipartisan compromise, not the kind of measure which was rammed through this House a month and a half ago.

The building blocks are there, but we have to focus on that, not the measure that's before us here today. And the Tierney bill is a perfect opportunity for us to do something which, again, has a balanced approach and which will protect students from the doubling of their student loan interest rates.

Mr. BISHOP of Utah. I am pleased to yield 3 minutes to a Member who is really a great and wonderful Member of this body, the gentlelady from Michigan (Mrs. MILLER).

Mrs. MILLER of Michigan. I certainly appreciate the gentleman for yielding time.

Madam Speaker, our economy is struggling, the American people need jobs, and too many families are struggling under the burden of ever-rising energy prices. It's certainly long past time for the Federal Government to act; and, today, this House will act.

This Nation, Madam Speaker, has been blessed with so many vast energy resources that if we actually advantaged ourselves, we could actually meet all of our Nation's energy needs. We could create countless good-paying jobs right here at home. We could provide needed funding for our Federal Treasury, expand our economy, and make our Nation more secure.

But, unfortunately, we don't do that. Instead, in fact, we are nearly the only Nation I think on the face of the planet, really, that does not take advantage of its own natural energy resources. Instead, we, unfortunately, have made the choice to rely on foreign sources of energy to meet many of our needs—many from unstable or unfriendly nations to whom we export literally hundreds of billions of dollars of our national wealth each and every year and we bypass the opportunity to create needed jobs right here at home. This absolutely needs to change.

While President Obama talks about an all-of-the-above energy strategy, his actions tell a different story, really. While exploration of oil and other energy resources is up overall, it's been reduced on lands under Federal control under this administration. And this administration's EPA has made the coal industry public enemy number one, even though it's the cheapest and most abundant source of electric generation that we have here in our Nation.

Today, this House will act on a true all-of-the-above energy strategy. This legislation will streamline and remove government red tape as a hurdle to energy production. It will require our Nation to put forward goals for production of all energy sources, including oil, natural gas, coal, renewables, of course, on Federal lands. And it will make the permitting process much easier, and it will open up new areas to exploration and development both onshore as well as offshore. This legislation will lower energy prices for hard-pressed consumers, it will create good-paying jobs here at home, and it will enhance our economic security and national security as well.

I certainly urge all of my colleagues to join me in supporting this critical legislation, and I support the rule as well.

Mr. POLIS. I yield 2 minutes to the gentlewoman from California (Mrs. CAPPS).

Mrs. CAPPS. I thank my colleague for yielding.

Madam Speaker, I rise to express my strong opposition to this rule and the underlying bill. We all know that high oil and gasoline prices take their toll on American consumers. Understandably, they want their elected officials to take action. But what the American people don't want is empty promises, and they don't want more political posturing designed to score cheap political points in an election year. And that's all this bill gives us.

H.R. 4480 blocks and delays EPA air-quality protections—protections that haven't even been proposed yet. It includes a radical proposal that damages the Clean Air Act goal that air should be clean enough to breathe safely. And it gives the Energy Department the job of developing a new drilling plan on Federal lands, even though this is not an area of expertise at all.

Madam Speaker, the idea behind this bill is just not thought out. It's not a solution to high oil and gasoline prices, nor will it create any immediate jobs. It is really nothing more than a transparent attempt to use this issue as an excuse for advancing an agenda in order to hurt our precious resources of lands and our own health.

And that's why I had sent to the Rules Committee a straightforward amendment that would have protected my State's coastline from new offshore drilling. My Republican colleague from California, Mr. BILBRAY, had a similar amendment on the same issue; but this Rules Committee is not allowing either amendment even to be debated, even to have its say on the House floor. A State where offshore drilling has been protected in State waters will now, because these amendments were not made in order, have to allow the Federal Government to work its will in contradiction to the State. And that's wrong. That's why Members from both sides should use their good sense and oppose this rule and oppose the underlying bill.

□ 1310

Mr. BISHOP of Utah. Madam Speaker, I am now pleased to yield 3 minutes to the distinguished gentleman from Texas, Chairman HALL, who has probably heard many of these arguments before.

Mr. HALL. Madam Speaker, I rise in support of H.R. 4480, the Domestic Energy and Jobs Act, a proactive piece of legislation that encourages and expands production of our vast domestic resources to help put Americans back to work.

I strongly believe that, other than prayer, energy is the most important word in the dictionary for our young people. It's the foundation upon which our Nation has prospered and key to our quality of life and standard of living.

America is blessed with a wealth of natural resources and energy reserves, leading Citigroup to predict that we could soon become the world's largest oil producer. The recent shale gas revolution has driven production to new heights and prices to new lows. It has created hundreds of thousands of new jobs and stimulated a resurgence of domestic manufacturing in this country. In 2010, unconventional natural gas production alone supported approximately 1 million American jobs.

Simultaneously, shale oil production has led to rapid and dramatic economic growth and job creation in places not typically known for energy production, such as North Dakota. Workers are flocking to the State to pursue the abundant opportunities in the Bakken shale. While the Nation suffers unemployment rates in excess of 8 percent, unemployment in North Dakota is the lowest in this country at just 3 percent.

The only thing preventing us from reaping the benefits of being a world leader in energy production is bureaucratic red tape. Permitting delays, declining production on Federal land, restricted access, and stifling regulations all stand in the way. H.R. 4480 would free us from these barriers put forth by the administration and, instead, set us on the right track to unleash the full energy potential of this Nation.

This bill addresses numerous issues the Science, Space, and Technology Committee has examined, including, for example, costly Tier 3 regulations that would increase the price of fuel at a time when families can least afford to pay more for their commute. Not only would this standard place a burden on household budgets, but the EPA ignored the law by failing to complete a study on the detrimental effects of RFS prior to beginning work on these standards. Quite simply, again the EPA failed to do its homework, instead barreling forward with regulations without a sufficient foundation.

Regulations like this one are far too often based on shaky science, devoid of adequate peer review, and rely on secret data EPA refuses to share with the public. The EPA ignores the scientific method in order to overstate the economic benefits of its rules in an attempt to justify their sizeable costs.

H.R. 4480 takes a timeout from EPA's activist regulatory agenda and seeks to put our country on track to pursue a genuine all-of-the-above energy strategy that would expand opportunities for production rather than stifle them.

I urge Members to support this rule as well as the underlying bill.

Mr. POLIS. Madam Speaker, this is a rare time when we are talking about energy, when we are hearing from the Academy of Pediatrics, the Heart Association, the American Lung Association, the Public Health Association, the National Association of City and County Health Officials, and a number of other signatories on this letter which says, very simply, that we should make sure that the EPA can determine whether our air is safe to breathe and not do it based on how much it costs to reduce air pollution.

JUNE 18, 2012.

DEAR REPRESENTATIVE: The undersigned public health and medical organizations

write to express our strong opposition to H.R. 4480, which includes dangerous provisions that would block and delay important public health safeguards under the Clean Air Act. Gutting the Clean Air Act will not address rising gas prices, but it will needlessly weaken the Clean Air Act's life-saving protections and delay much-needed air pollution safeguards.

Title II of H.R. 4480 indefinitely delays three overdue air quality safeguards, including standards for tailpipes emissions and gasoline sulfur content (Tier 3), air emissions standards for petroleum refineries and ground level ozone standards. Most egregiously, H.R. 4480 also repeals the health premise of the Clean Air Act.

In 1970, an overwhelming bipartisan majority in Congress agreed that to adequately protect public health, the U.S. Environmental Protection Agency (EPA) must set air quality standards to protect health with an adequate margin of safety. These standards are based on the best available health science. This system has worked for more than 40 years to let people know if the air is safe to breathe, and motivate action to improve air quality when it is not safe. EPA must retain this authority to establish health-based ambient air quality standards.

The Clean Air Act fully considers cost and feasibility in determining how to meet air quality standards. States and EPA consider these factors during the implementation process as strategies are implemented to meet air quality standards. Just as a doctor does not diagnose a patient based on the cost of treatment, EPA should not determine whether the air is safe to breathe based on how much it costs to reduce air pollution.

The Clean Air Act is one of the nation's premier public health laws. Since its establishment in 1970, the aggregate emissions of criteria air pollutants decreased 71%, while Gross Domestic Product increased 210%. Given the enormous contribution of the Clean Air Act to public health, we urge you to reject all efforts to weaken and delay it. Please vote NO on H.R. 4480.

Sincerely,

American Academy of Pediatrics.
American Heart Association.
American Lung Association.
American Public Health Association.
American Thoracic Society.
Asthma and Allergy Foundation of America.
Health Care Without Harm.
National Association of City and County Health Officials.
National Environmental Health Association.
Trust for America's Health.

Madam Speaker, I'm proud to yield 4 minutes to the gentleman from Massachusetts (Mr. MARKEY).

Mr. MARKEY. Madam Speaker, I thank the gentleman very much.

This bill represents the latest Republican attempt to give away our public lands to the wealthiest oil companies in the world. This bill is the culmination of the Republican oil-above-all agenda. Instead of approving this legislative love letter to Big Oil, the majority should be sending a thank-you note to President Obama for his actions to increase domestic energy production and decrease our dependence on foreign oil.

The truth is that oil production from Federal lands on shore today is higher than it was under President Bush. And across the United States, oil production from all public and private lands is unbelievably now at an 18-year high. Obama is drilling, baby; he's drilling.

The Obama administration's all-of-the-above strategy has also been successful in creating jobs. Since 2008, 14,000 new jobs have been created in oil and gas extraction. Thank you, President Obama. And 50,000 new jobs have also been created in wind and solar, but Republicans don't want a real all-of-the-above energy strategy.

At the Rules Committee, I offered an amendment, along with Mr. WELCH, that would have established a national renewable energy standard. That amendment would have created wind and solar all across our country as a standard. That amendment was germane to this bill and had no budgetary impact, but the Republican majority refused to even allow us to debate an amendment so that Members could have a chance to vote on an actual all-of-the-above package that wasn't just oil and gas.

And President Obama is about as good a President as you can have on that issue; but wind and solar and biomass and geothermal and all of these technologies of the future, they refused to even allow the Democrats to have a vote on that on the House floor this afternoon. They are not all of the above; they are oil above all. They don't want wind and solar because the oil industry doesn't want it, and the coal industry doesn't want it because it's real competition from the future.

The renewable electricity standard that I would have offered would have created 300,000 new jobs and saved consumers billions of dollars on their electricity bills.

In 2007, 32 Republicans joined 188 Democrats in overwhelming support of a similar renewable electricity standard. In 2009, the House again passed that policy on a bipartisan basis. It died in the Senate both times. Today, it dies here on the House floor because the Republicans don't want 32 Republicans to even have the right to vote for wind and solar and biomass and geothermal. They're afraid Republicans might vote for it, so there's a gag here, a gag order to the House floor saying no debate on the renewables because oil and coal don't want it debated. There will not be a vote on this.

The majority has voted more than 100 times in this Congress to help the oil industry, but they have not voted once in favor of clean energy in the year and a half that they have controlled the United States Congress.

Moreover, because they will not extend the production tax credit for wind, 40,000 jobs are going to be lost in the wind industry in the first 6 months of 2013. This is the Big Oil dream act. This is the dream act of the Republicans. This is something that should be opposed.

Mr. BISHOP of Utah. Ironically, I do agree with the gentleman from Massachusetts in one element of what he said, that this administration, President Obama, is drilling on permits that were granted by Bush and Clinton. The unfortunate side is that this administration is not permitting any new drilling permits for the future growth of this country.

With that, I'm pleased to yield 3 minutes to the gentlelady from Tennessee (Mrs. BLACKBURN) who has been working diligently for many years on this particular issue and has a clear understanding of it.

□ 1320

Mrs. BLACKBURN. I thank the gentleman from Utah for yielding the time.

I am so pleased, Madam Speaker, that we are pushing forward on some bills that are going to actually create the environment for jobs growth to take place. Of course we know that that is needed by the American people. We hear about it every single day.

We are at the longest streak that we have had since the Great Depression, the longest streak with unemployment being above 8 percent. If you look at underemployment, it's at 14.8 percent. Clearly, the American people are speaking out that they want action and they want to get back to work. The Domestic Energy and Jobs Act will do that, helping to create the environment for jobs growth to take place and helping to create the environment where we take actions to fuel this economy.

Our unemployment and underemployment numbers should be a wake-up call to the President, should be a wake-up call to the Senate. They can't continue to sit on their hands and play the blame game while 13 million Americans remain out of work.

As I said, this legislation will help create the jobs that are needed in our Nation's energy sector. What we want to see is more American-made energy, more American exploration. We want to see American innovation and end our dependence on foreign oil. Those are worthy goals, and these are steps in the right direction.

We also hear a lot about the price at the pump. I have many friends who are the mom in the minivan and are getting children back and forth, to and from activities. And at $3.50 a gallon as the new normal, if you will, gas having doubled, the price of gasoline as a transportation fuel having doubled since this President was sworn in, this is something that women talk to us about regularly. There are deep concerns about this.

The greatest potential for economic growth in this country can be found in this Nation's precious natural resources, in our energy resources. While the President is clearly preoccupied with telling Americans what we won't do on energy, what he will not take steps to do, the economy and jobs and what he isn't going to do there, House Republicans are laying out a pathway for what we can do.

By working hard, we can empower those innovators to harness our domestic energy capabilities using so many

of those new technologies that are out there, new innovations that have been brought forward by so many of the petroleum engineers and the innovators in this country.

The SPEAKER pro tempore. The time of the gentlewoman has expired.

Mr. BISHOP of Utah. I yield the gentlewoman 1 minute.

Mrs. BLACKBURN. I have to say this: with every new discovery of American energy and every new technology advancement, we are able to put more into the marketplace for our Nation's manufacturers, engineers, our leasing specialists, our rig operators, and much more.

I recently had the opportunity to be back in south Mississippi, where I grew up. I had the opportunity to talk with some of the men and women who are involved and working and innovating in the oil and gas industry every single day. What I heard from them was the degree of advancement and the number of opportunities that exist if the Federal Government will get out of the way and return our focus to creating the environment for energy exploration and jobs growth to take place in this great Nation.

Mr. POLIS. Madam Speaker, it's my honor to yield 1 minute to the gentleman from California (Mr. GARAMENDI).

Mr. GARAMENDI. Madam Speaker, the gentlelady was quite correct about worrying about the price of gasoline. And as you sit around talking about that, you ought to be concerned about the 24 million gallons of gasoline that's exported from the United States every day. You might also want to consider that the price of natural gas has plummeted by more than 60 percent during the Obama administration, providing us with an extraordinary opportunity for growth.

But what I'd really like to talk about is, this bill is not a Strategic Energy Production Act. It does not deal with the renewable energy. In fact, the wind energy industry in the United States is about to come to a screeching halt. Seventy-five thousand jobs are presently in this industry. We are already beginning to see the downsizing—17,000 are now being laid off because the production tax credit is not being extended. If we were to extend the production tax credit, we could probably find another 37,000 people working next year.

If we added to this my piece of legislation, H.R. 487, which requires that our tax dollars—in this case, the production tax credit—be spent on American-made equipment, we could see, perhaps, even more manufacturing in the United States.

Bottom line: the Strategic Energy Production Act is an act for the oil and coal industry. It is not for America. We need to change that. We need to look at all of the above, not just oil and coal.

Mr. BISHOP of Utah. I am pleased to yield 3 minutes to the gentleman from Arkansas (Mr. GRIFFIN).

Mr. GRIFFIN of Arkansas. Madam Speaker, I rise in strong support of H.R. 4480, the Domestic Energy and Jobs Act, a package of seven bills that, taken together, will create jobs and make America more energy independent.

There are a number of provisions, but among them the bill reforms and streamlines the energy permitting process by setting firm timelines for legal challenges and limiting the duration of injunctions. This provision is critical because it addresses all the red tape, the Washington red tape, and the constant wave of lawsuits by radical environmentalists that have prevented many American energy projects from ever getting off the ground. Some of them have been stalled for decades. Too often, activist Washington lawyers come between the American people and abundant affordable energy. With this bill, we are fighting back.

According to the U.S. Chamber of Commerce's Project No Project report, energy permitting reform could unleash investment to the tune of $3.4 trillion in economic benefits and over 2.6 million jobs created.

All you've got to do is look at the State of North Dakota for the benefits of producing American energy. Oil and gas production is booming, the State has a 3 percent unemployment rate—wouldn't we like to have that nationally? Good grief. And workers are sleeping in their cars, many of them, because the housing supply can't keep up with the demand.

In my home State of Arkansas, we've got our own success story. Production in the Fayetteville shale and the Brown Dense Formation has and will continue to create jobs and American energy, but we can't afford to let up. We have talked way too long about job creation and energy independence. We need less talk and more action.

I urge all my colleagues to support this important bill to create jobs and increase American energy independence.

Mr. POLIS. Madam Speaker, I would like to yield 1 minute to the gentlewoman from California (Ms. LEE).

Ms. LEE of California. Let me thank the gentleman for yielding and for your tremendous leadership on this issue. Of course I rise in strong opposition to the rule and also the bill.

This so-called Domestic Jobs and Energy Act is yet another example of how the Tea Party-led House is wasting the American people's time by passing legislation that will never become law.

This unconscionable wish list for Big Oil contains dangerous provisions that would irresponsibly expand drilling on public lands, roll back policies to provide for safe and responsible energy production in the United States, and it will endanger our public health by blocking important public health safeguards under the Clean Air Act. Gutting the Clean Air Act will not lower gas prices, but it will hurt the health of millions of Americans.

Madam Speaker, we need a real jobs agenda, not another massive giveaway to Big Oil. We must pass the American Jobs Act, invest in our infrastructure, increase job training efforts, and strengthen our safety net. We should support the economy and create jobs by investing in the American people.

The SPEAKER pro tempore. The time of the gentlewoman has expired.

Mr. POLIS. I yield the gentlewoman an additional 20 seconds.

Ms. LEE of California. In conclusion, this Congress must ensure that our Nation's safety net is a bridge that is strong enough to deliver us all—even the most vulnerable—over these troubled waters. This giveaway to Big Oil will not do that. We need to protect the public health of the American people.

Mr. BISHOP of Utah. I am pleased to yield 3 minutes to another member of the Resources Committee here who understands this issue very well, the gentleman from Colorado (Mr. COFFMAN).

Mr. COFFMAN of Colorado. Madam Speaker, this act removes the obstacles that are blocking our efforts to achieve greater American energy production and job creation by providing more certainty and clarity to the public lands leasing and permitting process.

In particular, my part of this legislation will ensure that Federal oil and natural gas lease sales occur on a consistent basis and provide the necessary lease certainty so production is made easier.

□ 1330

Currently, there are roughly 1,631 outstanding projects on Federal lands, including lands in Colorado, which have been delayed over 3 years. Federal regulatory delays to these projects prevent the creation of over 60,000 jobs.

We have endured several years of over 8 percent unemployment. Over 12 percent of our veterans who have served in Iraq and Afghanistan are still out of work. The fact that we are not fully benefiting from the employment and financial potential of our energy resources is simply wrong.

The President often boasts about his energy record, but this administration regularly delays and blocks leases. In fact, BLM only approved 11 oil and gas leases in Colorado in 2011 where, in 2006, there were 363 approvals.

We in Colorado understand the importance of harnessing our own resources and the value it provides our economy. The oil and gas industry in Colorado directly employs 50,000 people and supports over 190,000 jobs in our State. This industry is responsible for roughly 6 percent of total employment in Colorado. We have an opportunity with this legislation to create jobs by developing our own resources right here at home.

Opponents of domestic energy exploration claim that the industry already has thousands of acres but are not producing the wells. These critics point to recent Department of the Interior reports that this report represents the

reasons for nonproducing wells. More often than not, the factors that cause our production are delays instituted by the Interior Department itself by requiring redundant reviews of projects, one example being the newest Master Leasing Plans instituted by the Secretary.

Delays also occur because exploration companies do not have full information as to the capacity of production on the land until after the lease sale is finalized. Therefore, some leases prove to be noncommercial and go unused. Although industry has already paid the government thousands of dollars in fees for the opportunity to explore, many times they receive no economic benefit, and the risk is entirely on them.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. BISHOP of Utah. I yield the gentleman an additional minute.

Mr. COFFMAN of Colorado. Let me also be clear, because this fact is largely missed by the opponents of this legislation. Only lands that are already approved by BLM for exploration can be nominated by industry. This bill is not a green light for immediate production on all Federal acres. Rather, it grants access to a very small percentage of the total of Federal lands.

As a Coloradoan, I respect the need to preserve our wilderness areas, but I also understand the need to responsibly capitalize on our vast resources in order to get people back to work.

As a Marine Corps combat veteran who has served multiple tours in the Middle East, I fully understand the need to reduce our reliance on foreign oil, and this legislation will help do that.

For these reasons, I ask my colleagues to vote ''yes'' on certainty, ''yes'' on jobs, and ''yes'' on the final passage of the Domestic Energy and Jobs Act.

Mr. POLIS. Madam Speaker, I ask unanimous consent to insert the text of the amendment in the RECORD, along with extraneous material, immediately prior to the vote on the previous question.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Colorado?

There was no objection.

Mr. POLIS. And here we are. While we're debating this death and destruction, oil above all bill, the clock is ticking on student loan payments that will cost middle class families millions and millions of dollars.

I yield 3 minutes to the gentleman from Massachusetts (Mr. TIERNEY).

Mr. TIERNEY. I thank the gentleman for yielding.

At the end of this month, the student Federal loan interest rate is set to double from 3.4 percent to 6.8 percent. It's an urgent deadline for more than 7 million American students and more than 177,000 students across the Commonwealth of Massachusetts. It's an urgent deadline for students that I met with at Middlesex College all the way through to Endicott College in my district and elsewhere. These students are working many jobs. They're still carrying thousands of dollars in student debt, and they're deeply concerned about the doubling of the rate that will occur on July 1.

Madam Speaker, this is urgent deadline for House Democrats. We've been on top of this issue for many, many months. Our colleague, Mr. COURTNEY of Connecticut, introduced legislation establishing a permanent fix back in January. Our colleagues, Mr. MILLER of California and Mr. HINOJOSA of Texas, sent a letter to Education and the Workforce Committee Chairman Mr. KLINE in February asking that the question be taken before the committee to prevent the student loan interest hike.

It's unfortunate, Madam Speaker, that the majority in the House of Representatives does not appear to understand or share this urgency. There are 10 days left in June, and we're only scheduled to be in session for 5 of them. As of right now, taking action to stop the doubling of the student loan interest rates is still not on the House's legislative agenda between now and the end of the month. In fact, addressing the issue was not part of the majority leader's summer legislative agenda, and it was reported that Speaker BOEHNER privately called the issue a phony issue.

So let's make no mistake about it. This is nothing phony for the millions of students who will be impacted and will see their rates double in July.

Madam Speaker, since the House majority doesn't appear willing to move forward on this issue, we have to take this action today to defeat the previous question so the rule can be amended to allow for consideration of my bill, the Stop the Rate Hike Act of 2012. That bill continues the current need-based Stafford loan rate at 3.4 percent for 1 year and offsets the cost by closing a tax subsidy for the oil industry, just one tax subsidy, one that they weren't originally intended to benefit from at any rate. I think that's a fair and reasonable plan for eliminating an unjustified giveaway to a hugely profitable industry so millions of our constituents do not see an increase in their student loans.

I urge my colleagues to defeat the previous question so the House can consider that bill and stop the student loan interest rate hike.

Mr. BISHOP of Utah. I reserve the balance of my time.

Mr. POLIS. I would like to inquire of the other side if he has any remaining speakers.

Mr. BISHOP of Utah. No; I think I'm it.

Mr. POLIS. Very good. Then I'm prepared to close, and I will yield myself the balance of the time.

Now, this rule only provides for consideration of certain amendments. Why are the Republicans so concerned with letting the House work their will on such an important bill?

Now, a number of these measures have been brought forward by Representatives from Colorado. I want to be clear that these are policies that are not universally supported in Colorado and that many of us believe that the policies contained in this set of bills would destroy jobs as well as the quality of life and health of not only Colorado and the West, but the entire country.

In Colorado, we've created a balanced approach to energy policy that's worked. In some areas we lease, some areas we use for other purposes, some areas we protect. Many Colorado small business owners agree, our parks and public lands are critical not only to the economy and job growth, hiking, fishing, hunting, the outdoor industry, but also to our quality of life and our health.

This job-destroying Federal landgrab, Federal water grab bill would put tens of thousands of Coloradoans out of work and destroy the quality of life for our entire State. This bill puts the wish list of the oil and gas industry above all the other users of public lands, above the interest of hunters, above the interest of fishermen, above the interest of hikers, above the interest of tourism, above the interest of skiers, above the interest of conservationists. This bill is out of touch with the citizens of Colorado and will destroy jobs in Colorado and throughout the country.

Look, companies are able to drill. They've been drilling the last 40 years. President Obama's leadership has led to twice the number of drilling wells. Our energy production is at an 8-year peak from oil and gas, and we continue to increase our energy production on public lands, and there's a responsible way to do it.

But we need a balanced approach that doesn't throw out the safeguards and protections that protect the health of children and the health of families, to protect our jobs in the outdoor industry, that protect our jobs in the recreation industry and protect our quality of life across the Western United States, and laws that protect our water and laws that protect our air.

This bill, this series of omnibus death and destruction bills, simply fails that test. The American people deserve more than the death and destruction, oil above all omnibus package that's being offered here today. While millions of Americans are waiting in the unemployment lines, we need a bill that creates jobs rather than destroys jobs.

□ 1340

An increased concentration of toxic chemicals can harm the health of American citizens and Coloradans. Now there is great promise and opportunity in technology that will allow companies to drill with less of an impact on

human health and the environment. That's why we have a regulatory framework. It is to ensure that there is incentive to make sure that American families are safe.

This package of job-destroying bills that has been brought before us today would harm our sensitive lands and constitute a Federal land grab and Federal water grab, all without lowering the price at the pump and destroying tens of thousands of jobs in the process.

This death-and-destruction bill is simply not what this country needs to move forward. I urge my colleagues to oppose the rule and to oppose the bill. I urge a ''no'' vote on the rule and to defeat the previous question.

I yield back the balance of my time.

Mr. BISHOP of Utah. I yield myself the balance of my time.

In the 111th Congress, when the other side was in charge, H.R. 2454 was brought forth from the floor. It was called the American Clean Energy and Security Act. There were 224 amendments submitted, and one was made in order. In our bill today, 27 amendments are made in order, two-thirds of which are Democrat amendments. This is a very fair rule, and it will provide for an open and clear debate on the particular issue.

Let's face it, Madam Speaker. The United States has a lot of untapped areas on public lands that are involved not only in oil and oil shale but in natural gas and coal. We are an energy-rich country. We are an energy-producing country. It's about time we recognized that fact and developed the energy that we have for the betterment of our people and for job creation.

We need an all-of-the-above strategy that is not just a rhetorical exercise in an election year but an all-of-the-above strategy that, actually, really creates something without hidden delays disguised as procedural practices and processes.

This bill will create jobs. This bill will keep American dollars at home. This bill will provide economic growth instead of sending our money abroad. This is a good bill, and it is an incredibly fair rule. I urge its adoption.

The material previously referred to by Mr. POLIS is as follows:

AN AMENDMENT TO H. RES. 691 OFFERED BY MR. POLIS OF COLORADO

At the end of the resolution, add the following new sections:

Sec. 2. Immediately upon adoption of this resolution the Speaker shall, pursuant to clause 2(b) of rule XVIII, declare the House resolved into the Committee of the Whole House on the state of the Union for consideration of the bill (H.R. 4816) to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans, and for other purposes. The first reading of the bill shall be dispensed with. All points of order against consideration of the bill are waived. General debate shall be confined to the bill and shall not exceed one hour equally divided among and controlled by the chair and ranking minority member of the Committee on Education and the Workforce and the chair and ranking minority member of the Committee on Ways and Means. After general debate the bill shall be considered for amendment under the five-minute rule. All points of order against provisions in the bill are waived. At the conclusion of consideration of the bill for amendment the Committee shall rise and report the bill to the House with such amendments as may have been adopted. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. If the Committee of the Whole rises and reports that it has come to no resolution on the bill, then on the next legislative day the House shall, immediately after the third daily order of business under clause 1 of rule XIV, resolve into the Committee of the Whole for further consideration of the bill.

Sec. 3. Clause 1(c) of rule XIX shall not apply to the consideration of the bill specified in section 2 of this resolution.

(The information contained herein was provided by the Republican Minority on multiple occasions throughout the 110th and 111th Congresses.)

THE VOTE ON THE PREVIOUS QUESTION: WHAT IT REALLY MEANS

This vote, the vote on whether to order the previous question on a special rule, is not merely a procedural vote. A vote against ordering the previous question is a vote against the Republican majority agenda and a vote to allow the opposition, at least for the moment, to offer an alternative plan. It is a vote about what the House should be debating.

Mr. Clarence Cannon's Precedents of the House of Representatives (VI, 308–311), describes the vote on the previous question on the rule as ''a motion to direct or control the consideration of the subject before the House being made by the Member in charge.'' To defeat the previous question is to give the opposition a chance to decide the subject before the House. Cannon cites the Speaker's ruling of January 13, 1920, to the effect that ''the refusal of the House to sustain the demand for the previous question passes the control of the resolution to the opposition'' in order to offer an amendment. On March 15, 1909, a member of the majority party offered a rule resolution. The House defeated the previous question and a member of the opposition rose to a parliamentary inquiry, asking who was entitled to recognition. Speaker Joseph G. Cannon (R–Illinois) said: ''The previous question having been refused, the gentleman from New York, Mr. Fitzgerald, who had asked the gentleman to yield to him for an amendment, is entitled to the first recognition.''

Because the vote today may look bad for the Republican majority they will say ''the vote on the previous question is simply a vote on whether to proceed to an immediate vote on adopting the resolution . . . [and] has no substantive legislative or policy implications whatsoever.'' But that is not what they have always said. Listen to the Republican Leadership Manual on the Legislative Process in the United States House of Representatives, (6th edition, page 135). Here's how the Republicans describe the previous question vote in their own manual: ''Although it is generally not possible to amend the rule because the majority Member controlling the time will not yield for the purpose of offering an amendment, the same result may be achieved by voting down the previous question on the rule . . . When the motion for the previous question is defeated, control of the time passes to the Member who led the opposition to ordering the previous question. That Member, because he then controls the time, may offer an amendment to the rule, or yield for the purpose of amendment.''

In Deschler's Procedure in the U.S. House of Representatives, the subchapter titled ''Amending Special Rules'' states: ''a refusal to order the previous question on such a rule [a special rule reported from the Committee on Rules] opens the resolution to amendment and further debate.'' (Chapter 21, section 21.2) Section 21.3 continues: ''Upon rejection of the motion for the previous question on a resolution reported from the Committee on Rules, control shifts to the Member leading the opposition to the previous question, who may offer a proper amendment or motion and who controls the time for debate thereon.''

Clearly, the vote on the previous question on a rule does have substantive policy implications. It is one of the only available tools for those who oppose the Republican majority's agenda and allows those with alternative views the opportunity to offer an alternative plan.

Mr. BISHOP of Utah. With that, I yield back the balance of my time, and I move the previous question on the resolution.

The SPEAKER pro tempore. The question is on ordering the previous question.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

RECORDED VOTE

Mr. POLIS. Madam Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. Pursuant to clause 8 and clause 9 of rule XX, this 15-minute vote on ordering the previous question will be followed by 5-minute votes on adoption of the resolution, if ordered, and the motion to instruct conferees offered by Mr. WALZ of Minnesota.

The vote was taken by electronic device, and there were—ayes 242, noes 183, not voting 7, as follows:

[Roll No. 389]

AYES—242

Adams	Campbell	Fleming
Aderholt	Canseco	Flores
Akin	Cantor	Forbes
Alexander	Capito	Fortenberry
Amash	Carter	Foxx
Amodei	Cassidy	Franks (AZ)
Austria	Chabot	Frelinghuysen
Bachmann	Chaffetz	Gallegly
Barletta	Chandler	Gardner
Bartlett	Coble	Garrett
Barton (TX)	Coffman (CO)	Gerlach
Bass (NH)	Cole	Gibbs
Benishek	Conaway	Gibson
Berg	Cravaack	Gingrey (GA)
Biggert	Crawford	Gohmert
Bilbray	Crenshaw	Goodlatte
Bilirakis	Culberson	Gosar
Bishop (UT)	Davis (KY)	Gowdy
Black	Denham	Granger
Blackburn	Dent	Graves (GA)
Bonner	DesJarlais	Graves (MO)
Bono Mack	Diaz-Balart	Green, Gene
Boren	Dold	Griffin (AR)
Boustany	Dreier	Griffith (VA)
Brady (TX)	Duffy	Grimm
Brooks	Duncan (SC)	Guinta
Broun (GA)	Duncan (TN)	Guthrie
Buchanan	Ellmers	Hall
Bucshon	Emerson	Hanna
Buerkle	Farenthold	Harper
Burgess	Fincher	Harris
Burton (IN)	Fitzpatrick	Hartzler
Calvert	Flake	Hastings (WA)
Camp	Fleischmann	Hayworth

Heck
Hensarling
Herger
Herrera Beutler
Huelskamp
Huizenga (MI)
Hultgren
Hunter
Hurt
Issa
Jenkins
Johnson (IL)
Johnson (OH)
Johnson, Sam
Jones
Jordan
Kelly
King (IA)
King (NY)
Kingston
Kinzinger (IL)
Kline
Labrador
Lamborn
Lance
Landry
Lankford
Latham
LaTourette
Latta
LoBiondo
Long
Lucas
Luetkemeyer
Lummis
Lungren, Daniel E.
Mack
Manzullo
Marchant
Marino
Matheson
McCarthy (CA)
McCaul
McClintock
McCotter
McHenry
McIntyre
McKeon
McKinley
McMorris Rodgers
Meehan
Mica
Miller (MI)
Mulvaney
Murphy (PA)
Myrick
Neugebauer
Noem
Nugent
Nunes
Nunnelee
Olson
Palazzo
Paul
Paulsen
Pearce
Pence
Petri
Pitts
Platts
Poe (TX)
Pompeo
Posey
Price (GA)
Quayle
Rehberg
Reichert
Renacci
Ribble
Rigell
Rivera
Roby
Roe (TN)
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Rokita
Rooney
Ros-Lehtinen
Roskam
Ross (FL)
Royce
Runyan
Ryan (WI)
Scalise
Schilling
Schmidt
Schock
Schweikert
Scott (SC)
Scott, Austin
Sensenbrenner
Sessions
Shimkus
Shuler
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Southerland
Stearns
Stivers
Stutzman
Sullivan
Terry
Thompson (PA)
Thornberry
Tiberi
Tipton
Turner (NY)
Turner (OH)
Upton
Walberg
Walden
Walsh (IL)
Webster
West
Westmoreland
Whitfield
Wilson (SC)
Wittman
Wolf
Womack
Woodall
Yoder
Young (AK)
Young (FL)
Young (IN)

NOES—183

Ackerman
Altmire
Andrews
Baca
Baldwin
Barber
Barrow
Bass (CA)
Becerra
Berkley
Berman
Bishop (GA)
Bishop (NY)
Blumenauer
Bonamici
Boswell
Brady (PA)
Braley (IA)
Brown (FL)
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Castor (FL)
Chu
Cicilline
Clarke (MI)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Critz
Crowley
Cuellar
Cummings
Davis (CA)
Davis (IL)
DeFazio
DeGette
DeLauro
Deutch
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Edwards
Ellison
Engel
Eshoo
Farr
Fattah
Filner
Frank (MA)
Fudge
Garamendi
Gonzalez
Green, Al
Grijalva
Gutierrez
Hahn
Hanabusa
Hastings (FL)
Heinrich
Higgins
Himes
Hinchey
Hinojosa
Hirono
Hochul
Holden
Holt
Honda
Hoyer
Israel
Jackson Lee (TX)
Johnson (GA)
Johnson, E. B.
Kaptur
Keating
Kildee
Kind
Kissell
Kucinich
Langevin
Larsen (WA)
Larson (CT)
Lee (CA)
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Luján
Lynch
Maloney
Markey
Matsui
McCarthy (NY)
McCollum
McDermott
McGovern
McNerney
Meeks
Michaud
Miller (NC)
Miller, George
Moore
Moran
Murphy (CT)
Nadler
Napolitano
Neal
Olver
Owens
Pallone
Pascrell
Pastor (AZ)
Pelosi
Perlmutter
Peters
Peterson
Pingree (ME)
Polis
Price (NC)
Quigley
Rahall
Rangel
Reyes
Richardson
Richmond
Ross (AR)
Rothman (NJ)
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schrader
Schwartz
Scott (VA)
Scott, David
Serrano
Sewell
Sherman
Sires
Slaughter
Smith (WA)
Speier
Stark
Sutton
Thompson (CA)
Thompson (MS)
Tierney
Tonko
Towns
Tsongas
Van Hollen
Velázquez
Visclosky
Walz (MN)
Wasserman Schultz
Waters
Watt
Waxman
Welch
Wilson (FL)
Woolsey
Yarmuth

NOT VOTING—7

Bachus
Jackson (IL)
Lewis (CA)
Miller (FL)
Miller, Gary
Reed
Sánchez, Linda T.

□ 1408

Ms. WASSERMAN SCHULTZ, Ms. BROWN of Florida, Ms. SLAUGHTER, and Ms. VELÁZQUEZ changed their vote from ''aye'' to ''no.''

Mr. MCINTYRE and Mrs. MCMORRIS RODGERS changed their vote from ''no'' to ''aye.''

So the previous question was ordered.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore (Mr. YODER). The question is on the resolution.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. POLIS. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 245, nays 178, not voting 9, as follows:

[Roll No. 390]

YEAS—245

Adams
Aderholt
Akin
Alexander
Amash
Amodei
Austria
Bachmann
Barletta
Bartlett
Barton (TX)
Bass (NH)
Benishek
Berg
Biggert
Bilbray
Bilirakis
Bishop (UT)
Black
Blackburn
Bonner
Bono Mack
Boren
Boustany
Brady (TX)
Brooks
Broun (GA)
Buchanan
Bucshon
Buerkle
Burgess
Burton (IN)
Calvert
Camp
Campbell
Canseco
Cantor
Capito
Carter
Cassidy
Chabot
Chaffetz
Chandler
Coble
Coffman (CO)
Cole
Conaway
Cravaack
Crawford
Crenshaw
Culberson
Davis (KY)
Denham
Dent
DesJarlais
Diaz-Balart
Dold
Donnelly (IN)
Duffy
Duncan (SC)
Duncan (TN)
Ellmers
Emerson
Farenthold
Fincher
Fitzpatrick
Flake
Fleischmann
Fleming
Flores
Forbes
Fortenberry
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Gardner
Garrett
Gerlach
Gibbs
Gibson
Gingrey (GA)
Gohmert
Goodlatte
Gosar
Gowdy
Granger
Graves (GA)
Graves (MO)
Griffin (AR)
Griffith (VA)
Grimm
Guinta
Guthrie
Hall
Hanna
Harper
Harris
Hartzler
Hastings (WA)
Hayworth
Heck
Hensarling
Herger
Herrera Beutler
Hochul
Huelskamp
Huizenga (MI)
Hultgren
Hunter
Hurt
Issa
Jenkins
Johnson (IL)
Johnson (OH)
Johnson, Sam
Jones
Jordan
Kelly
King (IA)
King (NY)
Kingston
Kinzinger (IL)
Kissell
Kline
Labrador
Lamborn
Lance
Landry
Lankford
Latham
LaTourette
Latta
LoBiondo
Long
Lucas
Luetkemeyer
Lummis
Lungren, Daniel E.
Mack
Manzullo
Marchant
Marino
Matheson
McCarthy (CA)
McCaul
McClintock
McCotter
McHenry
McIntyre
McKeon
McKinley
McMorris Rodgers
Meehan
Mica
Miller (MI)
Mulvaney
Murphy (PA)
Myrick
Neugebauer
Noem
Nugent
Nunes
Nunnelee
Olson
Owens
Palazzo
Paul
Paulsen
Pearce
Pence
Petri
Pitts
Platts
Poe (TX)
Pompeo
Posey
Price (GA)
Quayle
Rehberg
Reichert
Renacci
Ribble
Rigell
Rivera
Roby
Roe (TN)
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Rokita
Rooney
Ros-Lehtinen
Roskam
Ross (AR)
Ross (FL)
Royce
Runyan
Ryan (WI)
Scalise
Schilling
Schmidt
Schock
Schweikert
Scott (SC)
Scott, Austin
Sensenbrenner
Sessions
Shimkus
Shuler
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Southerland
Stearns
Stivers
Stutzman
Sullivan
Terry
Thompson (PA)
Thornberry
Tiberi
Tipton
Turner (NY)
Turner (OH)
Upton
Walberg
Walden
Walsh (IL)
Webster
West
Westmoreland
Whitfield
Wilson (SC)
Wittman
Wolf
Womack
Woodall
Yoder
Young (AK)
Young (FL)
Young (IN)

NAYS—178

Ackerman
Altmire
Andrews
Baca
Baldwin
Barber
Barrow
Bass (CA)
Berkley
Berman
Bishop (GA)
Bishop (NY)
Blumenauer
Bonamici
Boswell
Brady (PA)
Braley (IA)
Brown (FL)
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Castor (FL)
Chu
Cicilline
Clarke (MI)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Critz
Crowley
Cuellar
Cummings
Davis (CA)
Davis (IL)
DeFazio
DeGette
DeLauro
Deutch
Dicks
Dingell
Doggett
Doyle
Edwards
Ellison
Engel
Eshoo
Farr
Fattah
Filner
Frank (MA)
Fudge
Garamendi
Gonzalez
Green, Al
Green, Gene
Grijalva
Gutierrez
Hahn
Hanabusa
Hastings (FL)
Heinrich
Higgins
Himes
Hinchey
Hinojosa
Hirono
Holden
Holt
Honda
Hoyer
Israel
Jackson Lee (TX)
Johnson (GA)
Johnson, E. B.
Kaptur
Keating
Kildee
Kind
Kucinich
Langevin
Larsen (WA)
Larson (CT)
Lee (CA)
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Luján
Lynch
Maloney
Markey
Matsui
McCarthy (NY)
McCollum
McDermott
McGovern
McNerney
Meeks
Michaud
Miller (NC)
Miller, George
Moore
Moran
Murphy (CT)
Nadler
Napolitano
Neal
Olver
Pallone
Pascrell
Pastor (AZ)
Pelosi
Perlmutter
Peters
Peterson
Pingree (ME)
Polis
Price (NC)
Quigley
Rahall
Rangel
Reyes
Richardson
Richmond
Rothman (NJ)
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schrader
Schwartz
Scott (VA)
Scott, David
Serrano
Sewell
Sherman
Sires
Slaughter
Smith (WA)
Speier
Stark
Sutton
Thompson (CA)
Thompson (MS)
Tierney
Tonko
Towns
Tsongas
Van Hollen
Velázquez
Visclosky
Walz (MN)
Wasserman Schultz
Waters

Watt	Welch	Woolsey
Waxman	Wilson (FL)	Yarmuth

NOT VOTING—9

Bachus	Lewis (CA)	Sánchez, Linda T.
Becerra	Miller (FL)	
Dreier	Miller, Gary	
Jackson (IL)	Reed	

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1415

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Mr. BECERRA. Mr. Speaker, on June 20, 2012, I was unavoidably detained and missed rollcall vote 390. If present, I would have voted "yea" on rollcall vote 390.

MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

The SPEAKER pro tempore. The unfinished business is the vote on the motion to instruct on H.R. 4348 offered by the gentleman from Minnesota (Mr. WALZ) on which the yeas and nays were ordered.

The Clerk will redesignate the motion.

The Clerk redesignated the motion.

The SPEAKER pro tempore. The question is on the motion to instruct.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 386, nays 34, answered ''present'' 1, not voting 11, as follows:

[Roll No. 391]

YEAS—386

Ackerman	Braley (IA)	Costello
Adams	Brooks	Courtney
Aderholt	Brown (FL)	Cravaack
Akin	Buchanan	Crawford
Alexander	Bucshon	Crenshaw
Altmire	Buerkle	Critz
Amodei	Burgess	Crowley
Andrews	Burton (IN)	Cuellar
Austria	Butterfield	Cummings
Baca	Calvert	Davis (CA)
Bachmann	Cantor	Davis (IL)
Baldwin	Capito	Davis (KY)
Barber	Capps	DeFazio
Barletta	Capuano	DeGette
Barrow	Cardoza	DeLauro
Bartlett	Carnahan	Denham
Barton (TX)	Carney	Dent
Bass (NH)	Carson (IN)	DesJarlais
Becerra	Cassidy	Deutch
Benishek	Castor (FL)	Diaz-Balart
Berg	Chabot	Dicks
Berkley	Chaffetz	Dingell
Berman	Chandler	Doggett
Biggert	Chu	Dold
Bilbray	Cicilline	Donnelly (IN)
Bilirakis	Clarke (MI)	Doyle
Bishop (GA)	Clarke (NY)	Duffy
Bishop (NY)	Clay	Duncan (SC)
Black	Cleaver	Duncan (TN)
Blackburn	Clyburn	Edwards
Blumenauer	Coble	Ellison
Bonamici	Coffman (CO)	Ellmers
Bonner	Cohen	Emerson
Bono Mack	Cole	Engel
Boren	Connolly (VA)	Eshoo
Boswell	Conyers	Farenthold
Boustany	Cooper	Farr
Brady (PA)	Costa	Fattah
Filner	Larson (CT)	Rivera
Fitzpatrick	Latham	Roby
Flake	LaTourette	Roe (TN)
Fleischmann	Latta	Rogers (AL)
Fleming	Lee (CA)	Rogers (KY)
Forbes	Levin	Rogers (MI)
Fortenberry	Lewis (GA)	Rohrabacher
Frank (MA)	Lipinski	Rokita
Franks (AZ)	LoBiondo	Ros-Lehtinen
Frelinghuysen	Loebsack	Roskam
Fudge	Lofgren, Zoe	Ross (AR)
Gallegly	Lowey	Ross (FL)
Garamendi	Lucas	Rothman (NJ)
Gardner	Luetkemeyer	Roybal-Allard
Gerlach	Luján	Royce
Gibbs	Lummis	Runyan
Gibson	Lungren, Daniel E.	Ruppersberger
Gonzalez	Lynch	Rush
Goodlatte	Mack	Ryan (OH)
Gosar	Maloney	Ryan (WI)
Gowdy	Manzullo	Sanchez, Loretta
Graves (GA)	Marchant	Sarbanes
Graves (MO)	Marino	Scalise
Green, Al	Markey	Schakowsky
Green, Gene	Matheson	Schiff
Griffin (AR)	Matsui	Schilling
Griffith (VA)	McCarthy (CA)	Schmidt
Grijalva	McCarthy (NY)	Schrader
Grimm	McCaul	Schwartz
Guinta	McCollum	Schweikert
Guthrie	McCotter	Scott (SC)
Gutierrez	McDermott	Scott (VA)
Hahn	McGovern	Scott, Austin
Hall	McHenry	Scott, David
Hanabusa	McIntyre	Sensenbrenner
Hanna	McKeon	Serrano
Harper	McKinley	Sewell
Harris	McMorris Rodgers	Sherman
Hartzler	McNerney	Shimkus
Hastings (FL)	Meehan	Shuler
Hastings (WA)	Meeks	Shuster
Hayworth	Mica	Simpson
Heck	Michaud	Sires
Heinrich	Miller (MI)	Slaughter
Hensarling	Miller (NC)	Smith (NE)
Herger	Miller, George	Smith (NJ)
Herrera Beutler	Moore	Smith (TX)
Higgins	Moran	Smith (WA)
Himes	Mulvaney	Southerland
Hinchey	Murphy (CT)	Speier
Hinojosa	Murphy (PA)	Stark
Hirono	Myrick	Stivers
Hochul	Nadler	Stutzman
Holden	Napolitano	Sullivan
Holt	Neal	Sutton
Honda	Noem	Terry
Hoyer	Nugent	Thompson (CA)
Huelskamp	Nunes	Thompson (MS)
Hultgren	Nunnelee	Tiberi
Hunter	Olson	Tierney
Hurt	Olver	Tipton
Israel	Owens	Tonko
Issa	Palazzo	Towns
Jackson Lee (TX)	Pallone	Tsongas
Jenkins	Pascrell	Turner (NY)
Johnson (GA)	Pastor (AZ)	Turner (OH)
Johnson (IL)	Paul	Upton
Johnson (OH)	Paulsen	Van Hollen
Johnson, E. B.	Pelosi	Velázquez
Johnson, Sam	Pence	Visclosky
Jones	Perlmutter	Walberg
Jordan	Peters	Walden
Kaptur	Peterson	Walz (MN)
Keating	Petri	Wasserman Schultz
Kelly	Pingree (ME)	Waters
Kildee	Pitts	Watt
Kind	Platts	Waxman
King (IA)	Polis	Welch
King (NY)	Price (GA)	West
Kingston	Price (NC)	Whitfield
Kinzinger (IL)	Quigley	Wilson (FL)
Kissell	Rahall	Wilson (SC)
Kline	Rangel	Wittman
Kucinich	Rehberg	Wolf
Labrador	Reichert	Womack
Lamborn	Renacci	Woodall
Lance	Reyes	Woolsey
Landry	Richardson	Yarmuth
Langevin	Richmond	Yoder
Lankford	Rigell	Young (FL)
Larsen (WA)		Young (IN)

NAYS—34

Amash	Campbell	Fincher
Bishop (UT)	Canseco	Flores
Brady (TX)	Carter	Foxx
Broun (GA)	Conaway	Garrett
Camp	Culberson	Gingrey (GA)
Gohmert	Poe (TX)	Thompson (PA)
Granger	Pompeo	Thornberry
Huizenga (MI)	Posey	Webster
Long	Quayle	Westmoreland
McClintock	Rooney	Young (AK)
Neugebauer	Sessions	
Pearce	Stearns	

ANSWERED ''PRESENT''—1

Ribble

NOT VOTING—11

Bachus	Lewis (CA)	Sánchez, Linda T.
Bass (CA)	Miller (FL)	
Dreier	Miller, Gary	Schock
Jackson (IL)	Reed	Walsh (IL)

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1422

Mr. GINGREY of Georgia changed his vote from ''yea'' to ''nay.''

So the motion to instruct was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

NOTICE OF INTENTION TO OFFER MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

Mr. HOYER. Mr. Speaker, pursuant to clause 7(c) of rule XXII, I hereby give notice of my intention to offer a motion to instruct conferees on H.R. 4348.

The form of the motion is as follows:

Mr. HOYER moves that the managers on the part of the House at the conference on the disagreeing votes of the two Houses on the Senate amendment to the bill H.R. 4348 be instructed to recede from disagreement to the amendment of the Senate.

NOTICE OF INTENTION TO OFFER MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

Mrs. BLACK. Mr. Speaker, pursuant to rule XXII, clause 7(c), I hereby announce my intention to offer a motion to instruct on H.R. 4348.

The form of the motion is as follows:

Mrs. BLACK moves that the managers on the part of the House at the conference on the disagreeing votes of the two Houses on the Senate amendment to the bill H.R. 4348 be instructed to reject section 31108 of the Senate amendment (relating to distracted driving grants), other than the matter proposed to be inserted as section 411(g) of title 23, United States Code (relating to a distracted driving study).

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. WESTMORELAND). Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on the motion to suspend the rules on which a recorded vote or the yeas and nays are

ordered, or on which the vote incurs objection under clause 6 of rule XX.

Any record vote on the postponed question will be taken later.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the bill (S. 3187) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the amendment is as follows:

Amendment:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Safety and Innovation Act''.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735(7) (21 U.S.C. 379g) is amended by striking ''expenses incurred in connection with'' and inserting ''expenses in connection with''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

Section 736 (21 U.S.C. 379h) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(B) in paragraph (1)(A)—

(i) in clause (i), by striking ''(c)(5)'' and inserting ''(c)(4)''; and

(ii) in clause (ii), by striking ''(c)(5)'' and inserting ''(c)(4)'';

(C) in the matter following clause (ii) in paragraph (2)(A)—

(i) by striking ''(c)(5)'' and inserting ''(c)(4)''; and

(ii) by striking ''payable on or before October 1 of each year'' and inserting ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section'';

(D) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(4)''; and

(II) by striking ''payable on or before October 1 of each year.'' and inserting ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.''; and

(ii) by amending subparagraph (B) to read as follows:

''(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

''(i) identified on the list compiled under section 505(j)(7) with a potency described in terms of per 100 mL;

''(ii) the same product as another product that—

''(I) was approved under an application filed under section 505(b) or 505(j); and

''(II) is not in the list of discontinued products compiled under section 505(j)(7);

''(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997); or

''(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.'';

(2) in subsection (b)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017'';

(ii) in subparagraph (A), by striking ''$392,783,000; and'' and inserting ''$693,099,000;''; and

(iii) by striking subparagraph (B) and inserting the following:

''(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

''(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).''; and

(B) by striking paragraphs (3) and (4) and inserting the following:

''(3) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

''(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

''(i) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

''(ii) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

''(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

''(i) $652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

''(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the methodology described in subsection (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

''(C) LIMITATION.—Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).'';

(3) by striking subsection (c) and inserting the following:

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

''(A) one;

''(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years, and

''(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

''(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

''(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

''(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

''(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

''(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. If such an adjustment is necessary,

the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

''(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

''(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.''; and

(4) in subsection (g)—

(A) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(B) in paragraph (2)—

(i) in subparagraph (A)(i), by striking ''shall be retained'' and inserting ''subject to subparagraph (C), shall be collected and available'';

(ii) in subparagraph (A)(ii), by striking ''shall only be collected and available'' and inserting ''shall be available''; and

(iii) by adding at the end the following new subparagraph:

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.'';

(C) in paragraph (3), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(D) in paragraph (4)—

(i) by striking ''fiscal years 2008 through 2010'' and inserting ''fiscal years 2013 through 2015'';

(ii) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(iii) by striking ''fiscal years 2008 through 2011'' and inserting ''fiscal years 2013 through 2016''; and

(iv) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B (21 U.S.C. 379h–2) is amended—

(1) by amending subsection (a) to read as follows:

''(a) PERFORMANCE REPORT.—

''(1) IN GENERAL.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning—

''(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

''(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

''(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

''(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

''(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

''(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

''(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

''(vi) the number of applications filed for review as fast track products per fiscal year for each review division;

''(vii) the number of applications filed for orphan-designated products per fiscal year for each review division; and

''(viii) the number of breakthrough designations for a fiscal year for each review division.

''(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.''.

(2) in subsection (b), by striking ''2008'' and inserting ''2013''; and

(3) in subsection (d), by striking ''2012'' each place it appears and inserting ''2017''.

SEC. 105. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 106 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) is repealed.

(2) CONFORMING AMENDMENT.—The Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) is amended in the table of contents in section 2, by striking the item relating to section 106.

(d) TECHNICAL CLARIFICATIONS.—

(1) Effective September 30, 2007—

(A) section 509 of the Prescription Drug User Fee Amendments Act of 2002 (Title V of Public Law 107–188) is repealed; and

(B) the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) is amended in the table of contents in section 1(b), by striking the item relating to section 509.

(2) Effective September 30, 2002—

(A) section 107 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) is repealed; and

(B) the table of contents in section 1(c) of such Act is amended by striking the item related to section 107.

(3) Effective September 30, 1997, section 105 of the Prescription Drug User Fee Act of 1992 (Public Law 102–571) is repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 107. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2007, but before October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2012.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the ''Medical Device User Fee Amendments of 2012''.

(b) FINDINGS.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

Section 737 (21 U.S.C. 379i) is amended—

(1) in paragraph (9), by striking ''incurred'' after ''expenses'';

(2) in paragraph (10), by striking ''October 2001'' and inserting ''October 2011''; and

(3) in paragraph (13), by striking ''is required to register'' and all that follows through the end of paragraph (13) and inserting the following: ''is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.''.

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(2) in paragraph (2)(A)—

(A) in the matter preceding clause (i)—

(i) by striking ''subsections (d) and (e)'' and inserting ''subsections (d), (e), and (f)'';

(ii) by striking ''October 1, 2002'' and inserting ''October 1, 2012''; and

(iii) by striking ''subsection (c)(1)'' and inserting ''subsection (c)''; and

(B) in clause (viii), by striking ''1.84'' and inserting ''2''; and

(3) in paragraph (3)—

(A) in subparagraph (A), by inserting ''and subsection (f)'' after ''subparagraph (B)''; and

(B) in subparagraph (C), by striking ''initial registration'' and all that follows through ''section 510.'' and inserting ''later of—

''(i) the initial or annual registration (as applicable) of the establishment under section 510; or

''(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.''.

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—

''(1) IN GENERAL.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

''(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

''Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application	$248,000	$252,960	$258,019	$263,180	$268,443
Establishment Registration	$2,575	$3,200	$3,750	$3,872	$3,872

''(3) TOTAL REVENUE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

''(A) $97,722,301 for fiscal year 2013.

''(B) $112,580,497 for fiscal year 2014.

''(C) $125,767,107 for fiscal year 2015.

''(D) $129,339,949 for fiscal year 2016.

''(E) $130,184,348 for fiscal year 2017.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) (21 U.S.C. 379j(c)) is amended—

(1) in the subsection heading, by inserting ''; ADJUSTMENTS'' after ''SETTING'';

(2) by striking paragraphs (1) and (2);

(3) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(4) by inserting before paragraph (4), as so redesignated, the following:

''(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

''(2) INFLATION ADJUSTMENTS.—

''(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2014 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

''(B) APPLICABLE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The applicable inflation adjustment for a fiscal year is—

''(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

''(I) the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.

''(C) BASE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—

''(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

''(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

''(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

''(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

''(I) is less than 1, such adjustment shall be considered to be equal to 1; or

''(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

''(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

''(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years 2014 through 2017, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be further adjusted, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).''.

(d) FEE WAIVER OR REDUCTION.—Section 738 (21 U.S.C. 379j) is amended by—

(1) redesignating subsections (f) through (k) as subsections (g) through (l), respectively; and

(2) by inserting after subsection (e) the following new subsection:

''(f) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

''(2) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

''(3) DURATION.—The authority provided by this subsection terminates October 1, 2017.''.

(e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C. 379j(h)(1)(A)), as redesignated by subsection (d)(1), is amended by striking ''$205,720,000'' and inserting ''$280,587,000''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 738(i) (21 U.S.C. 379j(i)), as redesignated by subsection (d)(1), is amended—

(1) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''shall be retained'' and inserting ''subject to subparagraph (C), shall be collected and available''; and

(ii) in clause (ii)—

(I) by striking ''collected and'' after ''shall only be''; and

(II) by striking ''fiscal year 2002'' and inserting ''fiscal year 2009''; and

(B) by adding at the end, the following:

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.'';

(3) by amending paragraph (3) to read as follows:

''(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c) and, for fiscal year 2017 only, as further adjusted under paragraph (4).''; and

(4) in paragraph (4)—

(A) by striking ''fiscal years 2008, 2009, and 2010'' and inserting ''fiscal years 2013, 2014, and 2015'';

(B) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(C) by striking ''June 30, 2011'' and inserting ''June 30, 2016'';

(D) by striking ''the amount of fees specified in aggregate in'' and inserting ''the cumulative amount appropriated pursuant to'';

(E) by striking ''aggregate amount in'' before ''excess shall be credited''; and

(F) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

(g) CONFORMING AMENDMENT.—Section 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by striking ''738(g)'' and inserting ''738(h)''.

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REAUTHORIZATION.—Section 738A(b) (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking ''2012'' and inserting ''2017''; and

(2) in paragraph (5), by striking ''2012'' and inserting ''2017''.

(b) PERFORMANCE REPORTS.—Section 738A(a) (21 U.S.C. 379j–1(a)) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) PERFORMANCE REPORT.—

''(A) IN GENERAL.—Beginning with fiscal year 2013, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

''(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.''; and

(2) in paragraph (2), by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

SEC. 205. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (in effect as of such day) that on or after October 1, 2007, but before October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 206. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 207. SUNSET CLAUSE.

(a) IN GENERAL.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2017. Section 738A (21 U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and reporting requirements) shall cease to be effective January 31, 2018.

(b) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 217 of the Food and Drug Administration Amendments Act of 2007 (Title II of Public Law 110–85) is repealed.

(2) CONFORMING AMENDMENT.—The Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) is amended in the table of contents in section 2, by striking the item relating to section 217.

(c) TECHNICAL CLARIFICATION.—Effective September 30, 2007—

(1) section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) is repealed; and

(2) the table of contents in section 1(b) of such Act is amended by striking the item related to section 107.

SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

''SEC. 714. STREAMLINED HIRING AUTHORITY.

''(a) IN GENERAL.—In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

''(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are activities under this Act related to the process for the review of device applications (as defined in section 737(8)).

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are with respect to the activities under subsection (b), the goals referred to in section 738A(a)(1).

''(d) INTERNAL CONTROLS.—The Secretary shall institute appropriate internal controls for appointments under this section.

''(e) SUNSET.—The authority to appoint employees under this section shall terminate on the date that is 3 years after the date of enactment of this section.''.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE.

(a) SHORT TITLE.—This title may be cited as the ''Generic Drug User Fee Amendments of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

''PART 7—FEES RELATING TO GENERIC DRUGS

''SEC. 744A. DEFINITIONS.

''For purposes of this part:

''(1) The term 'abbreviated new drug application'—

''(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

''(B) does not include an application for a positron emission tomography drug.

''(2) The term 'active pharmaceutical ingredient' means—

''(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

''(i) to be used as a component of a drug; and

''(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

''(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

''(3) The term 'adjustment factor' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

''(4) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(5)(A) The term 'facility'—

''(i) means a business or other entity—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

''(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

''(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(6) The term 'finished dosage form' means—

''(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

''(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

''(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

''(7) The term 'generic drug submission' means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

''(8) The term 'human generic drug activities' means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

''(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

''(B) The issuance of—

''(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

''(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

''(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

''(ii) document that no deficiencies need to be addressed.

''(D) Inspections related to generic drugs.

''(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

''(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

''(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

''(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

''(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.

''(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

''(G) Regulatory science activities related to generic drugs.

''(9) The term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

''(10) The term 'prior approval supplement' means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

''(11) The term 'resources allocated for human generic drug activities' means the expenses for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers and employees and to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

''(D) collecting fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

''(12) The term 'Type II active pharmaceutical ingredient drug master file' means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

"SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

''(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

''(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

''(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

''(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

''(2) DRUG MASTER FILE FEE.—

''(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

''(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

''(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

''(D) AVAILABILITY FOR REFERENCE.—

''(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

''(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

''(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

''(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

''(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

''(E) FEE DUE DATE.—

''(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

''(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

''(I) 30 calendar days after publication of the notice provided for in clause (i) or (ii) of subparagraph (C), as applicable; or

''(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section.

''(3) ABBREVIATED NEW DRUG APPLICATION AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

''(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application or a prior approval supplement to an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

''(B) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(C) FEE DUE DATE.—

''(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

''(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

''(I) the date on which the fee is due under clause (i);

''(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

''(III) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

''(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.

''(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval supplement that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

''(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, in the amount determined under subsection (d)(3), in addition to the fee required under subparagraph (A), if—

''(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

''(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

''(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

''(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

''(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

''(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission, shall be assessed an annual fee for each such facility.

''(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject to fees under both such clauses for that facility.

''(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(D) FEE DUE DATE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

''(I) not later than 45 days after the publication of the notice under subparagraph (B); or

''(II) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

''(I) the first business day on or after October 1 of each such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

''(5) DATE OF SUBMISSION.—For purposes of this Act, a generic drug submission or Type II pharmaceutical master file is deemed to be 'submitted' to the Food and Drug Administration—

''(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is

completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

''(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—

''(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of $299,000,000. Of that amount—

''(i) $50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

''(ii) $249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).

''(B) FISCAL YEARS 2014 THROUGH 2017.—For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $299,000,000, as adjusted pursuant to subsection (c).

''(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from the fees under paragraphs (2) through (4) of subsection (a) as follows:

''(A) Six percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

''(B) Twenty-four percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

''(C) Fifty-six percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

''(D) Fourteen percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

''(A) one;

''(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

''(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

''(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2018. Such fees may only be used in fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

''(d) ANNUAL FEE SETTING.—

''(1) FISCAL YEAR 2013.—For fiscal year 2013—

''(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

''(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

''(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

''(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

''(A) the sum of—

''(i) the total number of such active pharmaceutical ingredients in such submission; and

''(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

''(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

''(e) LIMIT.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

''(f) IDENTIFICATION OF FACILITIES.—

''(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall publish in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.

''(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (4) shall submit to the Secretary the information required under this subsection each year. Such information shall—

''(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

''(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.

''(3) CONTENTS OF NOTICE.—At a minimum, the submission required by paragraph (2) shall include for each such facility—

''(A) identification of a facility identified or intended to be identified in an approved or pending generic drug submission;

''(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

''(C) whether or not the facility is located within the United States and its territories and possessions;

''(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; and

''(E) whether the facility manufactures drugs that are not generic drugs.

''(4) CERTAIN SITES AND ORGANIZATIONS.—

''(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

''(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

''(i) a site in which a bioanalytical study is conducted;

''(ii) a clinical research organization;

''(iii) a contract analytical testing site; or

''(iv) a contract repackager site.

''(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

''(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

''(g) EFFECT OF FAILURE TO PAY FEES.—

''(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on a publicly available arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(2) DRUG MASTER FILE FEE.—

''(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

''(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by

a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

''(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

''(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

''(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

''(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

''(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

''(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

''(C) NONRECEIVAL FOR NONPAYMENT.—

''(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

''(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

''(h) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(i) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for human generic drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) subject to subparagraphs (C) and (D), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

''(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

''(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

''(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

''(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been 'substantially complete' on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.''.

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as added by section 302 of this Act, is amended by inserting after section 744B the following:

''SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected

under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the generic drug industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

''(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

''(D) publish the comments on the Food and Drug Administration's Internet Web site.

''(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

''(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 304. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act, as added by section 302 of this Act, shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 744C of the Federal Food, Drug, and Cosmetic Act, as added by section 303 of this Act, shall cease to be effective January 31, 2018.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this title, whichever is later, except that fees under section 302 shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after October 1, 2012, regardless of the date of enactment of this title.

SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744A(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.''.

SEC. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

Section 714, as added by section 208 of this Act, is amended—

(1) by amending subsection (b) to read as follows:

''(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are—

''(1) activities under this Act related to the process for the review of device applications (as defined in section 737(8)); and

''(2) activities under this Act related to human generic drug activities (as defined in section 744A).''; and

(2) by amending subsection (c) to read as follows:

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are—

''(1) with respect to the activities under subsection (b)(1), the goals referred to in section 738A(a)(1); and

''(2) with respect to the activities under subsection (b)(2), the goals referred to in section 744C(a).''.

SEC. 308. ADDITIONAL REPORTING REQUIREMENTS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.), as amended by section 208, is further amended by adding at the end the following:

''SEC. 715. REPORTING REQUIREMENTS.

''(a) GENERIC DRUGS.—Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 7 of subchapter C, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 7 of subchapter C, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

''(2) the average total time to decision by the Secretary for applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter;

''(3) the total number of applications under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications that were pending with the Secretary for more than 10 months on the date of enactment of the Food and Drug Administration Safety and Innovation Act; and

''(4) the number of applications described in paragraph (3) on which the Food and Drug Administration took final regulatory action in the previous fiscal year.''.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Biosimilar User Fee Act of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by inserting after part 7, as added by title III of this Act, the following:

''PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

''SEC. 744G. DEFINITIONS.

''For purposes of this part:

''(1) The term 'adjustment factor' applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

''(2) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(3) The term 'biosimilar biological product' means a product for which a biosimilar biological product application has been approved.

''(4)(A) Subject to subparagraph (B), the term 'biosimilar biological product application' means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

''(B) Such term does not include—

''(i) a supplement to such an application;

''(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

''(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

''(I) whole blood or a blood component for transfusion;

''(II) an allergenic extract product;

''(III) an in vitro diagnostic biological product; or

''(IV) a biological product for further manufacturing use only; or

''(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

''(5) The term 'biosimilar biological product development meeting' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

''(6) The term 'biosimilar biological product development program' means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

''(7)(A) The term 'biosimilar biological product establishment' means a foreign or domestic place of business—

''(i) that is at one general physical location consisting of one or more buildings, all of which are within 5 miles of each other; and

''(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

''(B) For purposes of subparagraph (A)(ii), the term 'manufactured' does not include packaging.

''(8) The term 'biosimilar initial advisory meeting'—

''(A) means a meeting, if requested, that is limited to—

''(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and

''(ii) if so, general advice on the expected content of the development program; and

''(B) does not include any meeting that involves substantive review of summary data or full study reports.

''(9) The term 'costs of resources allocated for the process for the review of biosimilar biological product applications' means the expenses in connection with the process for the review of biosimilar biological product applications for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers employees and committees and to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

''(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

''(10) The term 'final dosage form' means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

''(11) The term 'financial hold'—

''(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

''(B) does not mean that any of the bases for a 'clinical hold' under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

''(12) The term 'person' includes an affiliate of such person.

''(13) The term 'process for the review of biosimilar biological product applications' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

''(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

''(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

''(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

''(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

''(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

''(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

''(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

''(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

''(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

''(14) The term 'supplement' means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

''SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

''(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

''(ii) MEETING REQUEST.—The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

''(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as 'investigational new drug application') describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

''(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

''(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

''(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

''(I) Not later than 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

''(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

''(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as 'annual biosimilar biological product development fee').

''(ii) DUE DATE.—The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

''(I) the first business day on or after October 1 of each such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

''(iii) EXCEPTION.—The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

''(I) submitted a marketing application for the biological product that was accepted for filing; or

''(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

''(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

''(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

''(ii) if an investigational new drug application concerning the product has been submitted, withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

''(D) REACTIVATION FEE.—

''(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological

product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as 'reactivation fee') by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

''(II) Upon the date of submission (after the date on which such participation was discontinued) of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

''(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

''(E) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

''(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

''(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

''(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

''(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

''(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

''(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

''(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

''(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO REFUNDS.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

''(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

''(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION AND SUPPLEMENT FEE.—

''(A) IN GENERAL.—Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

''(i) A fee for a biosimilar biological product application that is equal to—

''(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval; minus

''(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

''(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

''(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

''(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

''(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

''(B) REDUCTION IN FEES.—Notwithstanding section 404 of the Biosimilars User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

''(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

''(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

''(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

''(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (c).

''(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

''(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

''(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

''(i) the first business day on or after October 1 of such fiscal year; or

''(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

''(D) APPLICATION TO ESTABLISHMENT.—

''(i) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

''(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

''(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

''(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

''(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

''(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

''(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (b)(1)(F).

''(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

''(i) the first business day on or after October 1 of each such year; or

''(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

''(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

''(b) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application

described in section 736(a)(1)(A)(i) for that fiscal year.

''(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug establishment for that fiscal year.

''(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

''(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

''(c) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

''(1) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(A) application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

''(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

''(2) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

''(3) SMALL BUSINESS DEFINED.—In this subsection, the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

''(d) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

''(e) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

''(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.''.

SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 8 of subchapter C of chapter VII, as added by section 402, is further amended by inserting after section 744H the following:

''SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 401(b) of the Biosimilar User Fee Act of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

''(b) FISCAL REPORT.—Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) STUDY.—

''(1) IN GENERAL.—The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

''(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

''(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

''(e) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.''.

SEC. 404. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act, as added by section 402 of this Act, shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act, as added by section 403 of this Act, shall cease to be effective January 31, 2018.

SEC. 405. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by this title shall take effect on the later of—

(1) October 1, 2012; or

(2) the date of the enactment of this title.

(b) EXCEPTION.—Fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as added by this title, shall be assessed for all biosimilar biological product applications received on or after October 1, 2012, regardless of the date of the enactment of this title.

SEC. 406. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2007, but before October 1, 2012, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 407. CONFORMING AMENDMENT.

Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amended by striking ''or (k)''.

SEC. 408. ADDITIONAL REPORTING REQUIREMENTS.

Section 715, as added by section 308 of this Act, is amended by adding at the end the following:

''(b) BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under part 8 of subchapter C, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

''(A) the number of applications for approval filed under section 351(k) of the Public Health Service Act; and

''(B) the percentage of applications described in subparagraph (A) that were approved by the Secretary.

''(2) ADDITIONAL INFORMATION.—As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under part 2 are not used to review an application under section 351(k) of the Public Health Service Act.''.

TITLE V—PEDIATRIC DRUGS AND DEVICES

SEC. 501. PERMANENCE.

(a) PEDIATRIC STUDIES OF DRUGS.—Section 505A (21 U.S.C. 355a) is amended by striking subsection (q) (relating to a sunset).

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C. 355c) is amended—

(1) by striking subsection (m); and

(2) by redesignating subsection (n) as subsection (m).

SEC. 502. WRITTEN REQUESTS.

(a) IN GENERAL.—

(1) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Subsection (h) of section 505A (21 U.S.C. 355a) is amended to read as follows:

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are the subject of a written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under section 505B.''.

(2) PUBLIC HEALTH SERVICE ACT.—Section 351(m)(1) of the Public Health Service Act (42 U.S.C. 262(m)(1)) is amended by striking ''(f), (i), (j), (k), (l), (p), and (q)'' and inserting ''(f), (h), (i), (j), (k), (l), (n), and (p)''.

(b) NEONATES.—Subparagraph (A) of section 505A(d)(1) is amended by adding at the end the following: ''If a request under this subparagraph does not request studies in neonates, such request shall include a statement describing the rationale for not requesting studies in neonates.''.

SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COMMITTEE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall issue internal standard operating procedures that provide for the review by the internal review committee established under section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d) of any significant modifications to initial pediatric study plans, agreed initial pediatric study plans, and written requests under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c). Such internal standard operating procedures shall be made publicly available on the Internet Web site of the Food and Drug Administration.

SEC. 504. ACCESS TO DATA.

Not later than 3 years after the date of enactment of this Act, the Secretary shall make available to the public, including through posting on the Internet Web site of the Food and Drug Administration, the medical, statistical, and clinical pharmacology reviews of, and corresponding written requests issued to an applicant, sponsor, or holder for, pediatric studies submitted between January 4, 2002, and September 27, 2007, under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) for which 6 months of market exclusivity was granted and that resulted in a labeling change. The Secretary shall make public the information described in the preceding sentence in a manner consistent with how the Secretary releases information under section 505A(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(k)).

SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC STUDIES.

(a) EXTENSION OF DEADLINE FOR DEFERRED STUDIES.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)(3)—

(A) by redesignating subparagraph (B) as subparagraph (C);

(B) by inserting after subparagraph (A) the following:

''(B) DEFERRAL EXTENSION.—

''(i) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral approved under subparagraph (A) for submission of some or all assessments required under paragraph (1) if—

''(I) the Secretary determines that the conditions described in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

''(II) the applicant submits a new timeline under subparagraph (A)(ii)(IV) and any significant updates to the information required under subparagraph (A)(ii).

''(ii) TIMING AND INFORMATION.—If the deferral extension under this subparagraph is requested by the applicant, the applicant shall submit the deferral extension request containing the information described in this subparagraph not less than 90 days prior to the date that the deferral would expire. The Secretary shall respond to such request not later than 45 days after the receipt of such letter. If the Secretary grants such an extension, the specified date shall be the extended date. The sponsor of the required assessment under paragraph (1) shall not be issued a letter described in subsection (d) unless the specified or extended date of submission for such required studies has passed or if the request for an extension is pending. For a deferral that has expired prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act or that will expire prior to 270 days after the date of enactment of such Act, a deferral extension shall be requested by an applicant not later than 180 days after the date of enactment of such Act. The Secretary shall respond to any such request as soon as practicable, but not later than 1 year after the date of enactment of such Act. Nothing in this clause shall prevent the Secretary from updating the status of a study or studies publicly if components of such study or studies are late or delayed.''; and

(C) in subparagraph (C), as so redesignated—

(i) in clause (i), by adding at the end the following:

''(III) Projected completion date for pediatric studies.

''(IV) The reason or reasons why a deferral or deferral extension continues to be necessary.''; and

(ii) by amending clause (ii) to read as follows:

''(ii) PUBLIC AVAILABILITY.—Not later than 90 days after the submission to the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the public in an easily accessible manner, including through the Internet Web site of the Food and Drug Administration—

''(I) such information;

''(II) the name of the applicant for the product subject to the assessment;

''(III) the date on which the product was approved; and

''(IV) the date of each deferral or deferral extension under this paragraph for the product.''; and

(2) in subsection (f)—

(A) in the subsection heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,'';

(B) in paragraph (1), by inserting '', deferral extension,'' after ''deferral''; and

(C) in paragraph (4)—

(i) in the paragraph heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,''; and

(ii) by inserting '', deferral extensions,'' after ''deferrals''.

(b) TRACKING OF EXTENSIONS; ANNUAL INFORMATION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D)) is amended to read as follows:

''(D) aggregated on an annual basis—

''(i) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for each such deferral or deferral extension;

''(ii) the timeline for completion of the assessments; and

''(iii) the number of assessments completed and pending;''.

(c) ACTION ON FAILURE TO COMPLETE STUDIES.—

(1) ISSUANCE OF LETTER.—Subsection (d) of section 505B (21 U.S.C. 355c) is amended to read as follows:

''(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit a required assessment described in subsection (a)(2), fails to meet the applicable requirements in subsection (a)(3), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b), the following shall apply:

''(1) Beginning 270 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue a non-compliance letter to such person informing them of such failure to submit or meet the requirements of the applicable subsection.

Such letter shall require the person to respond in writing within 45 calendar days of issuance of such letter. Such response may include the person's request for a deferral extension if applicable. Such letter and the person's written response to such letter shall be made publicly available on the Internet Web site of the Food and Drug Administration 60 calendar days after issuance, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply.

''(2) The drug or biological product that is the subject of an assessment described in subsection (a)(2), applicable requirements in subsection (a)(3), or request for approval of a pediatric formulation, may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303), but such failure shall not be the basis for a proceeding—

''(A) to withdraw approval for a drug under section 505(e); or

''(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.''.

(2) TRACKING OF LETTERS ISSUED.—Subparagraph (D) of section 505B(f)(6) (21 U.S.C. 355c(f)(6)), as amended by subsection (b), is further amended—

(A) in clause (ii), by striking ''; and'' and inserting a semicolon;

(B) in clause (iii), by adding ''and'' at the end; and

(C) by adding at the end the following:

''(iv) the number of postmarket non-compliance letters issued pursuant to subsection (d), and the recipients of such letters;''.

SEC. 506. PEDIATRIC STUDY PLANS.

(a) IN GENERAL.—Subsection (e) of section 505B (21 U.S.C. 355c) is amended to read as follows:

''(e) PEDIATRIC STUDY PLANS.—

''(1) IN GENERAL.—An applicant subject to subsection (a) shall submit to the Secretary an initial pediatric study plan prior to the submission of the assessments described under subsection (a)(2).

''(2) TIMING; CONTENT; MEETING.—

''(A) TIMING.—An applicant shall submit the initial pediatric plan under paragraph (1)—

''(i) before the date on which the applicant submits the assessments under subsection (a)(2); and

''(ii) not later than—

''(I) 60 calendar days after the date of the end-of-Phase 2 meeting (as such term is used in section 312.47 of title 21, Code of Federal Regulations, or successor regulations); or

''(II) such other time as may be agreed upon between the Secretary and the applicant.

Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric plan earlier than the date otherwise applicable under this subparagraph.

''(B) CONTENT OF INITIAL PLAN.—The initial pediatric study plan shall include—

''(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach);

''(ii) any request for a deferral, partial waiver, or waiver under this section, if applicable, along with any supporting information; and

''(iii) other information specified in the regulations promulgated under paragraph (7).

''(C) MEETING.—The Secretary—

''(i) shall meet with the applicant to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A);

''(ii) may determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting is necessary; and

''(iii) if the Secretary determines that no meeting is necessary, shall so notify the applicant and provide written comments of the Secretary as soon as practicable, but not later than 90 calendar days after the receipt of the initial pediatric study plan.

''(3) AGREED INITIAL PEDIATRIC STUDY PLAN.—Not later than 90 calendar days following the meeting under paragraph (2)(C)(i) or the receipt of a written response from the Secretary under paragraph (2)(C)(iii), the applicant shall document agreement on the initial pediatric study plan in a submission to the Secretary marked 'Agreed Initial Pediatric Study Plan', and the Secretary shall confirm such agreement to the applicant in writing not later than 30 calendar days of receipt of such agreed initial pediatric study plan.

''(4) DEFERRAL AND WAIVER.—If the agreed initial pediatric study plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under paragraph (3) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

''(5) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed initial pediatric study plan may be amended at any time. The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed initial pediatric study plan.

''(6) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric study plan, agreed initial pediatric plan, and any significant amendments to such plans.

''(7) REQUIRED RULEMAKING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall promulgate proposed regulations and issue guidance to implement the provisions of this subsection.''.

(b) CONFORMING AMENDMENTS.—Section 505B (21 U.S.C. 355c) is amended—

(1) by amending subclause (II) of subsection (a)(3)(A)(ii) to read as follows:

''(II) a pediatric study plan as described in subsection (e);''; and

(2) in subsection (f)—

(A) in the subsection heading, by striking ''PEDIATRIC PLANS,'' and inserting ''PEDIATRIC STUDY PLANS,'';

(B) in paragraph (1), by striking ''all pediatric plans'' and inserting ''initial pediatric study plans, agreed initial pediatric study plans,''; and

(C) in paragraph (4)—

(i) in the paragraph heading, by striking ''PEDIATRIC PLANS,'' and inserting ''PEDIATRIC STUDY PLANS,''; and

(ii) by striking ''pediatric plans'' and inserting ''initial pediatric study plans, agreed initial pediatric study plans,''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section shall take effect 180 calendar days after the date of enactment of this Act, irrespective of whether the Secretary has promulgated final regulations to carry out such amendments.

(2) RULE OF CONSTRUCTION.—Paragraph (1) shall not be construed to affect the deadline for promulgation of proposed regulations under section 505B(e)(7) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.

SEC. 507. REAUTHORIZATIONS.

(a) PEDIATRIC ADVISORY COMMITTEE.—Section 14(d) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''to carry out the advisory committee's responsibilities under sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c, and 360j(m))''.

(b) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.—Section 15(a)(3) of the Best Pharmaceuticals for Children Act (Public Law 107–109), as amended by section 502(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), is amended by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''for the duration of the operation of the Oncologic Drugs Advisory Committee''.

(c) HUMANITARIAN DEVICE EXEMPTION EXTENSION.—Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking ''2012'' and inserting ''2017''.

(d) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN PHSA.—Section 409I(e)(1) of the Public Health Service Act (42 U.S.C. 284m(e)(1)) is amended by striking ''to carry out this section'' and all that follows through the end of paragraph (1) and inserting ''to carry out this section, $25,000,000 for each of fiscal years 2013 through 2017.''.

SEC. 508. REPORT.

(a) IN GENERAL.—Not later than four years after the date of enactment of this Act and every five years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the Internet Web site of the Food and Drug Administration, a report on the implementation of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

(b) CONTENTS.—Each report under subsection (a) shall include—

(1) an assessment of the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act in improving information about pediatric uses for approved drugs and biological products, including the number and type of labeling changes made since the date of enactment of this Act and the importance of such uses in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section 505B, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted;

(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under subsection (d) of such section 505B;

(3) an assessment of the timeliness and effectiveness of pediatric study planning since the date of enactment of this Act, including the number of initial pediatric study plans not submitted in accordance with the requirements of subsection (e) of such section 505B and any resulting rulemaking;

(4) the number of written requests issued, accepted, and declined under such section 505A since the date of enactment of this Act, and a listing of any important gaps in pediatric information as a result of such declined requests;

(5) a description and current status of referrals made under subsection (n) of such section 505A;

(6) an assessment of the effectiveness of studying biological products in pediatric populations

under such sections 505A and 505B and section 409I of the Public Health Service Act (42 U.S.C. 284m);

(7)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe); and

(B) the results of such efforts;

(8)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs under such sections 505A and 505B and under section 409I of the Public Health Service Act; and

(B) any recommendations for modifications to such programs that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation;

(9) any recommendations for modification to such programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products;

(10) an assessment of the successes of and limitations to studying drugs for rare diseases under such sections 505A and 505B; and

(11) an assessment of the Secretary's efforts to address the suggestions and options described in any prior report issued by the Comptroller General, Institute of Medicine, or the Secretary, and any subsequent reports, including recommendations therein, regarding the topics addressed in the reports under this section, including with respect to—

(A) improving public access to information from pediatric studies conducted under such sections 505A and 505B; and

(B) improving the timeliness of pediatric studies and pediatric study planning under such sections 505A and 505B.

(c) STAKEHOLDER COMMENT.—At least 180 days prior to the submission of each report under subsection (a), the Secretary shall consult with representatives of patient groups (including pediatric patient groups), consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products.

SEC. 509. TECHNICAL AMENDMENTS.

(a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A (21 U.S.C. 355a) is amended—

(1) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(2) in subsection (l)—

(A) in paragraph (1)—

(i) in the paragraph heading, by striking ''YEAR ONE'' and inserting ''FIRST 18-MONTH PERIOD''; and

(ii) by striking ''one-year'' and inserting ''18-month'';

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''YEARS'' and inserting ''PERIODS''; and

(ii) by striking ''one-year period'' and inserting ''18-month period'';

(C) by redesignating paragraph (3) as paragraph (4); and

(D) by inserting after paragraph (2) the following:

''(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.'';

(3) in subsection (n)—

(A) in the subsection heading, by striking ''COMPLETED'' and inserting ''SUBMITTED''; and

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''have not been completed'' and inserting ''have not been submitted by the date specified in the written request issued or if the applicant or holder does not agree to the request'';

(ii) in subparagraph (A)—

(I) in the first sentence, by inserting '', or for which a period of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act has not ended'' after ''expired''; and

(II) by striking ''Prior to'' and all that follows through the period at the end; and

(iii) in subparagraph (B), by striking ''no listed patents or has 1 or more listed patents that have expired,'' and inserting ''no unexpired listed patents and for which no unexpired periods of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act apply,''; and

(4) in subsection (o)(2), by amending subparagraph (B) to read as follows:

''(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use.''.

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the matter before subparagraph (A), by inserting ''for a drug'' after ''(or supplement to an application)''; and

(B) in paragraph (4)(C)—

(i) in the first sentence, by inserting ''partial'' before ''waiver is granted''; and

(ii) in the second sentence, by striking ''either a full or'' and inserting ''such a'';

(2) in subsection (b)(1), in the matter preceding subparagraph (A), by striking ''After providing notice'' and all that follows through ''studies), the'' and inserting ''The'';

(3) in subsection (g)—

(A) in paragraph (1)(A), by inserting ''that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review'' after ''after the date of the submission of the application or supplement''; and

(B) in paragraph (2), by striking ''the label of such product'' and inserting ''the labeling of such product'';

(4) in subsection (h)(1)—

(A) by inserting ''an application (or supplement to an application) that contains'' after ''date of submission of'';

(B) by inserting ''if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review,'' after ''under this section,''; and

(5) in subsection (i)—

(A) in paragraph (1)—

(i) in the paragraph heading, by striking ''YEAR ONE'' and inserting ''FIRST 18-MONTH PERIOD''; and

(ii) by striking ''one-year'' and inserting ''18-month'';

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''YEARS'' and inserting ''PERIODS''; and

(ii) by striking ''one-year period'' and inserting ''18-month period'';

(C) by redesignating paragraph (3) as paragraph (4); and

(D) by inserting after paragraph (2) the following:

''(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.''.

(c) INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—Section 505C (21 U.S.C. 355d) is amended—

*(1) in the section heading, by inserting ''**DEFERRAL EXTENSIONS,**'' after ''**DEFERRALS,**''; and*

(2) by inserting ''neonatology,'' after ''pediatric ethics,''.

(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by inserting ''or section 351(m) of this Act,'' after ''Cosmetic Act,'';

(B) in subparagraph (A)(i), by inserting ''or section 351(k) of this Act'' after ''Cosmetic Act''; and

(C) by amending subparagraph (B) to read as follows:

''(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and''; and

(2) in paragraph (2)—

(A) in the paragraph heading, by striking ''FOR DRUGS LACKING EXCLUSIVITY'';

(B) by striking ''under section 505 of the Federal Food, Drug, and Cosmetic Act''; and

(C) by striking ''505A of such Act'' and inserting ''505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act''.

(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC ADVISORY COMMITTEE.—Section 15(a) of the Best Pharmaceuticals for Children Act (Public Law 107–109), as amended by section 502(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), is amended in paragraph (1)(D), by striking ''section 505B(f)'' and inserting ''section 505C''.

(f) FOUNDATION OF NATIONAL INSTITUTES OF HEALTH.—Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act''.

(g) APPLICATION; TRANSITION RULE.—

(1) APPLICATION.—Notwithstanding any provision of section 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provision applies beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007 or the date of the enactment of the Pediatric Research Equity Act of 2007, any amendment made by this Act to such a provision applies beginning on the date of the enactment of this Act.

(2) TRANSITIONAL RULE FOR ADVERSE EVENT REPORTING.—With respect to a drug for which a labeling change described under section 505A(l)(1) or 505B(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved or made, respectively, during the one-year period that ends on the day before the date of enactment of this Act, the Secretary shall apply section 505A(l) and section 505B(i), as applicable, to such drug, as such sections were in effect on such day.

SEC. 510. PEDIATRIC RARE DISEASES.

(a) PUBLIC MEETING.—Not later than 18 months after the date of enactment of this Act, the Secretary shall hold at least one public

meeting to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases.

(b) REPORT.—Not later than 180 days after the date of the public meeting under subsection (a), the Secretary shall issue a report that includes a strategic plan for encouraging and accelerating the development of new therapies for treating pediatric rare diseases.

SEC. 511. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.

Section 6 of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a) is amended—

(1) in subsection (c)—

(A) in paragraph (1), by striking ''and'' at the end;

(B) by redesignating paragraph (2) as paragraph (4); and

(C) by inserting after paragraph (1) the following:

''(2) subject to subsection (d), one or more additional individuals with necessary expertise in a pediatric subpopulation that is, as determined through consideration of the reports and recommendations issued by the Institute of Medicine and the Comptroller General of the United States, less likely to be studied as a part of a written request issued under section 505A of the Federal Food, Drug, and Cosmetic Act or an assessment under section 505B of such Act;

''(3) one or more additional individuals with expertise in pediatric epidemiology; and''; and

(2) by adding at the end the following:

''(d) NEONATOLOGY EXPERTISE.—For the 5-year period beginning on the date of enactment of this subsection, at least one of the individuals described in subsection (c)(2) shall have expertise in neonatology.''.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

SEC. 601. INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended—

(1) in paragraph (2)(B)(ii), by inserting ''safety or effectiveness'' before ''data obtained''; and

(2) in paragraph (4), by adding at the end the following:

''(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

''(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

''(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

''(iii) an additional or different investigation may be necessary to support clearance or approval of the device.''.

SEC. 602. CLARIFICATION OF LEAST BURDENSOME STANDARD.

(a) PREMARKET APPROVAL.—Section 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) by redesignating clause (iii) as clause (v); and

(2) by inserting after clause (ii) the following:

''(iii) For purposes of clause (ii), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

''(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.''.

(b) PREMARKET NOTIFICATION UNDER SECTION 510(k).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is amended—

(1) by striking ''(D) Whenever'' and inserting ''(D)(i) Whenever''; and

(2) by adding at the end the following:

''(ii) For purposes of clause (i), the term 'necessary' means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

''(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.''.

SEC. 603. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.

Chapter V is amended by inserting after section 517 (21 U.S.C. 360g) the following:

''SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.

''(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

''(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

''(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such substantive summary to the person who is seeking to submit, or who has submitted, such report or application.

''(b) REVIEW OF SIGNIFICANT DECISIONS.—

''(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the individual who made the significant decision.

''(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

''(3) TIMEFRAME.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

''(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.''.

SEC. 604. DEVICE MODIFICATIONS REQUIRING PREMARKET NOTIFICATION PRIOR TO MARKETING.

Section 510(n) (21 U.S.C. 360(n)) is amended by—

(1) striking ''(n) The Secretary'' and inserting ''(n)(1) The Secretary''; and

(2) by adding at the end the following:

''(2)(A) Not later than 18 months after the date of enactment of this paragraph, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: 'could significantly affect the safety or effectiveness of the device', 'a significant change or modification in design, material, chemical composition, energy source, or manufacturing process', and 'major change or modification in the intended use of the device'. The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

''(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled 'Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device', dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue—

''(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

''(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

''(C) The Food and Drug Administration guidance entitled 'Deciding When to Submit a 510(k) for a Change to an Existing Device', dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.''.

SEC. 605. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

Chapter V is amended by inserting after section 518 (21 U.S.C. 360h) the following:

''SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

''(a) IN GENERAL.—The Secretary shall—

''(1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

''(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

''(3) develop detailed criteria for assessing whether a person performing a device recall has performed an effective correction or action plan for the recall; and

''(4) document the basis for each termination by the Food and Drug Administration of a device recall.

''(b) ASSESSMENT CONTENT.—The program established under subsection (a)(1) shall, at a minimum, identify—

''(1) trends in the number and types of device recalls;

''(2) devices that are most frequently the subject of a recall; and

''(3) underlying causes of device recalls.

''(c) TERMINATION OF RECALLS.—The Secretary shall document the basis for the termination by the Food and Drug Administration of a device recall.

''(d) DEFINITION.—In this section, the term 'recall' means—

''(1) the removal from the market of a device pursuant to an order of the Secretary under subsection (b) or (e) of section 518; or

''(2) the correction or removal from the market of a device at the initiative of the manufacturer or importer of the device that is required to be reported to the Secretary under section 519(g).''.

SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

''(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

''(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

''(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

''(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.''.

SEC. 607. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) IN GENERAL.—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended—

(1) by inserting ''(i)'' after ''(2)(A)'';

(2) in subparagraph (A)(i), as so designated by paragraph (1), by striking ''under the criteria set forth'' and all that follows through the end of subparagraph (A) and inserting a period;

(3) by adding at the end of subparagraph (A) the following:

''(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

''(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

''(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low-moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

''(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.''; and

(4) in subparagraph (B), by striking ''Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary'' and inserting ''The Secretary''.

(b) CONFORMING AMENDMENTS.—Section 513(f) (21 U.S.C. 360c(f)) is amended in paragraph (1)—

(1) in subparagraph (A), by striking '', or'' at the end and inserting a semicolon;

(2) in subparagraph (B), by striking the period and inserting ''; or''; and

(3) by inserting after subparagraph (B) the following:

''(C) the device is classified pursuant to a request submitted under paragraph (2).''.

SEC. 608. RECLASSIFICATION PROCEDURES.

(a) CLASSIFICATION CHANGES.—

(1) IN GENERAL.—Section 513(e)(1) (21 U.S.C. 360c(e)(1)) is amended to read as follows:

''(e)(1)(A)(i) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code. The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including—

''(I) the public health benefit of the use of the device, and the nature and, if known, incidence of the risk of the device;

''(II) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device; and

''(III) in the case of reclassification from class III to class II, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are sufficient to provide a reasonable assurance of safety and effectiveness for such device.

''(ii) An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

''(B) Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(e)(2) (21 U.S.C. 360c(e)(2)) is amended by striking ''regulation promulgated'' and inserting ''an order issued''.

(B) Section 514(a)(1) (21 U.S.C. 360d(a)(1)) is amended by striking ''under a regulation under section 513(e) but such regulation'' and inserting ''under an administrative order under section 513(e) (or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation)''.

(C) Section 517(a)(1) (21 U.S.C. 360g(a)(1)) is amended by striking ''or changing the classification of a device to class I'' and inserting '', an administrative order changing the classification of a device to class I,''.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this subsection shall have no effect on a regulation promulgated with respect to the classification of a device under section 513(e) of the Federal Food, Drug, and Cosmetic Act prior to the date of enactment of this Act.

(B) APPLICABILITY OF OTHER PROVISIONS.—In the case of a device reclassified under section 513(e) of the Federal Food, Drug, and Cosmetic Act by regulation prior to the date of enactment of this Act, section 517(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 517(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(b) DEVICES MARKETED BEFORE MAY 28, 1976.—

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ''regulation promulgated under subsection (b)'' and inserting ''an order issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)'';

(B) in subsection (b)—

(i) in paragraph (1)—

(I) in the heading, by striking ''Regulation'' and inserting ''Order''; and

(II) in the matter following subparagraph (B)—

(aa) by striking ''by regulation, promulgated in accordance with this subsection'' and inserting ''by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code''; and

(bb) by adding at the end the following: ''Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.'';

(ii) in paragraph (2)—

(I) by striking subparagraph (B); and

(II) in subparagraph (A)—

(aa) by striking ''(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—'' and inserting ''(2) A proposed order required under paragraph (1) shall contain—'';

(bb) by redesignating clauses (i) through (iv) as subparagraphs (A) through (D), respectively;

(cc) in subparagraph (A), as so redesignated, by striking ''regulation'' and inserting ''order''; and

(dd) in subparagraph (C), as so redesignated, by striking ''regulation'' and inserting ''order'';

(iii) in paragraph (3)—

(I) by striking ''proposed regulation'' each place such term appears and inserting ''proposed order'';

(II) by striking ''paragraph (2) and after'' and inserting ''paragraph (2),'';

(III) by inserting ''and a meeting of a device classification panel described in section 513(b),'' after ''such proposed regulation and findings,'';

(IV) by striking ''(A) promulgate such regulation'' and inserting ''(A) issue an administrative order under paragraph (1)'';

(V) by striking ''paragraph (2)(A)(ii)'' and inserting ''paragraph (2)(B)''; and

(VI) by striking ''promulgation of the regulation'' and inserting ''issuance of the administrative order''; and

(iv) by striking paragraph (4); and

(C) in subsection (i)—

(i) in paragraph (2)—

(I) in the matter preceding subparagraph (A)—

(aa) by striking ''December 1, 1995'' and inserting ''the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act''; and

(bb) by striking ''publish a regulation in the Federal Register'' and inserting ''issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in

section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code,'';

(II) in subparagraph (B), by striking ''final regulation has been promulgated under section 515(b)'' and inserting ''administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)'';

(III) in the matter following subparagraph (B), by striking ''regulation requires'' and inserting ''administrative order issued under this paragraph requires''; and

(IV) by striking the third and fourth sentences; and

(ii) in paragraph (3)—

(I) by striking ''regulation requiring'' each place such term appears and inserting ''order requiring''; and

(II) by striking ''promulgation of a section 515(b) regulation'' and inserting ''issuance of an administrative order under subsection (b)''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Section 501(f) (21 U.S.C. 351(f)) is amended—

(A) in subparagraph (1)(A)—

(i) in subclause (i), by striking ''a regulation promulgated'' and inserting ''an order issued''; and

(ii) in subclause (ii), by striking ''promulgation of such regulation'' and inserting ''issuance of such order'';

(B) in subparagraph (2)(B)—

(i) by striking ''a regulation promulgated'' and inserting ''an order issued''; and

(ii) by striking ''promulgation of such regulation'' and inserting ''issuance of such order''; and

(C) by adding at the end the following:

''(3) In the case of a device with respect to which a regulation was promulgated under section 515(b) prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act, a reference in this subsection to an order issued under section 515(b) shall be deemed to include such regulation.''.

(3) APPROVAL BY REGULATION PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—The amendments made by this subsection shall have no effect on a regulation that was promulgated prior to the date of enactment of this Act requiring that a device have an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for premarket approval.

(c) REPORTING.—The Secretary of Health and Human Services shall annually post on the Internet Web site of the Food and Drug Administration—

(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1));

(2) the number and type of class II and class III devices reclassified as class I or class II in the previous calendar year under such section 513(e)(1); and

(3) the number and type of devices reclassified in the previous calendar year under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e).

SEC. 609. HARMONIZATION OF DEVICE PREMARKET REVIEW, INSPECTION, AND LABELING SYMBOLS.

Paragraph (4) of section 803(c) (21 U.S.C. 383(c)) is amended to read as follows:

''(4) With respect to devices, the Secretary may, when appropriate, enter into arrangements with nations regarding methods and approaches to harmonizing regulatory requirements for activities, including inspections and common international labeling symbols.''.

SEC. 610. PARTICIPATION IN INTERNATIONAL FORA.

Paragraph (3) of section 803(c) (21 U.S.C. 383(c)) is amended—

(1) by striking ''(3)'' and inserting ''(3)(A)''; and

(2) by adding at the end the following:

''(B) In carrying out subparagraph (A), the Secretary may participate in appropriate fora, including the International Medical Device Regulators Forum, and may—

''(i) provide guidance to such fora on strategies, policies, directions, membership, and other activities of a forum as appropriate;

''(ii) to the extent appropriate, solicit, review, and consider comments from industry, academia, health care professionals, and patient groups regarding the activities of such fora; and

''(iii) to the extent appropriate, inform the public of the Secretary's activities within such fora, and share with the public any documentation relating to a forum's strategies, policies, and other activities of such fora.''.

SEC. 611. REAUTHORIZATION OF THIRD-PARTY REVIEW.

(a) PERIODIC REACCREDITATION.—Section 523(b)(2) (21 U.S.C. 360m(b)(2)) is amended by adding at the end of the following:

''(E) PERIODIC REACCREDITATION.—

''(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

''(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

''(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which such persons are reaccredited.''.

(b) DURATION OF AUTHORITY.—Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

SEC. 612. REAUTHORIZATION OF THIRD-PARTY INSPECTION.

Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) by striking clause (i) and inserting the following:

''(i) The device with respect to which the exemption is granted—

''(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

''(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.''; and

(ii) by striking clause (ii) and inserting the following:

''(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for such device. In this paragraph, the term 'annual distribution number' means the number of such devices reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States. The Secretary shall determine the annual distribution number when the Secretary grants such exemption.''; and

(B) by amending subparagraph (C) to read as follows:

''(C) A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (A)(ii) with respect to a device if additional information arises, and the Secretary may modify such annual distribution number.'';

(2) in paragraph (7), by striking ''regarding a device'' and inserting ''regarding a device described in paragraph (6)(A)(i)(I)''; and

(3) in paragraph (8), by striking ''of all devices described in paragraph (6)'' and inserting ''of all devices described in paragraph (6)(A)(i)(I)''.

(b) APPLICABILITY TO EXISTING DEVICES.—A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the date of enactment of this Act may seek a determination under subclause (I) or (II) of section 520(m)(6)(A)(i) (as amended by subsection (a)). If the Secretary of Health and Human Services determines that such subclause (I) or (II) applies with respect to a device, clauses (ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), (D), and (E) of paragraph (6) of such section 520(m) shall apply to such device, and the Secretary shall determine the annual distribution number for purposes of clause (ii) of such subparagraph (A) when making the determination under this subsection.

SEC. 614. UNIQUE DEVICE IDENTIFIER.

Section 519(f) (21 U.S.C. 360i(f)) is amended—

(1) by striking ''The Secretary shall promulgate'' and inserting ''Not later than December 31, 2012, the Secretary shall issue proposed''; and

(2) by adding at the end the following: ''The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.''.

SEC. 615. SENTINEL.

Section 519 (21 U.S.C. 360i) is amended by adding at the end the following:

''(h) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(1) IN GENERAL.—

''(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

''(B) EXCEPTION.—Subclause (II) of clause (i) of section 505(k)(3)(C) shall not apply to devices.

''(C) CLARIFICATION.—With respect to devices, the private sector health-related electronic data provided under section 505(k)(3)(C)(i)(III)(bb) may include medical device utilization data, health insurance claims data, and procedure and device registries.

''(2) DATA.—In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, including claims data, patient survey data, and any other data deemed appropriate by the Secretary.

''(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system as described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program,

through a public hearing, advisory committee meeting, maintenance of a public docket, or other similar public measures.

''(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification, mitigation, and analysis for devices.''.

SEC. 616. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360l) is amended—

(1) in subsection (a)(1)(A), in the matter preceding clause (i), by inserting '', at the time of approval or clearance of a device or at any time thereafter,'' after ''by order''; and

(2) in subsection (b)(1), by inserting ''The manufacturer shall commence surveillance under this section not later than 15 months after the day on which the Secretary issues an order under this section.'' after the second sentence.

SEC. 617. CUSTOM DEVICES.

Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:

''(b) CUSTOM DEVICES.—

''(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

''(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

''(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

''(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

''(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

''(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

''(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

''(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

''(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

''(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

''(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

''(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

''(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

''(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).''.

SEC. 618. HEALTH INFORMATION TECHNOLOGY.

(a) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, and in consultation with the National Coordinator for Health Information Technology and the Chairman of the Federal Communications Commission, shall post on the Internet Web sites of the Food and Drug Administration, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology, a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.

(b) WORKING GROUP.—

(1) IN GENERAL.—In carrying out subsection (a), the Secretary may convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations required for the report under subsection (a).

(2) REPRESENTATIVES.—If the Secretary convenes the working group under paragraph (1), the Secretary, in consultation with the Commissioner of Food and Drugs, the National Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall determine the number of representatives participating in the working group, and shall, to the extent practicable, ensure that the working group is geographically diverse and includes representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary.

SEC. 619. GOOD GUIDANCE PRACTICES RELATING TO DEVICES.

Subparagraph (C) of section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended—

(1) by striking ''(C) For guidance documents'' and inserting ''(C)(i) For guidance documents''; and

(2) by adding at the end the following:

''(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, such notice shall be treated as a guidance document for purposes of this subparagraph.''.

SEC. 620. PEDIATRIC DEVICE CONSORTIA.

(a) IN GENERAL.—Section 305(e) of Pediatric Medical Device Safety and Improvement Act (Public Law 110–85; 42 U.S.C. 282 note)) is amended by striking ''$6,000,000 for each of fiscal years 2008 through 2012'' and inserting ''$5,250,000 for each of fiscal years 2013 through 2017''.

(b) FINAL RULE RELATING TO TRACKING OF PEDIATRIC USES OF DEVICES.—The Secretary of Health and Human Services shall issue—

(1) a proposed rule implementing section 515A(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(a)(2)) not later than December 31, 2012; and

(2) a final rule implementing such section not later than December 31, 2013.

TITLE VII—DRUG SUPPLY CHAIN

SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISHMENTS.

Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking ''On or before'' and all that follows through the period at the end and inserting the following: ''During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.; and

(B) by adding at the end the following:

''(3) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.''; and

(2) in subsection (c), by striking ''with the Secretary his name, place of business, and such establishment'' and inserting ''with the Secretary—

''(1) with respect to drugs, the information described under subsection (b)(1); and

''(2) with respect to devices, the information described under subsection (b)(2).''.

SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.

(a) ENFORCEMENT OF REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking ''in any State''.

(b) REGISTRATION OF FOREIGN DRUG ESTABLISHMENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

(1) in paragraph (1)—

(A) by amending the matter preceding subparagraph (A) to read as follows: ''Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—'';

(B) by amending subparagraph (A) to read as follows:

''(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

''(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name of each importer of such drug in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug to the United States for purposes of importation; and

''(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and''; and

(C) by amending subparagraph (B) to read as follows:

''(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.''; and

(2) by adding at the end the following:

''(4) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs. The requirement to include a unique facility identifier in a registration under paragraph (1) with respect to drugs shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.''.

SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMATION WITH PRODUCT LISTING.

Section 510(j) (21 U.S.C. 360(j)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (C), by striking ''; and'' and inserting a semicolon;

(B) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of such excipient, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.''; and

(2) by adding at the end the following:

''(4) The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems specified under subsections (b)(3) and (i)(4) with respect to drugs. Such requirement shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.''.

SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended—

(1) by striking ''(p) Registrations and listings'' and inserting the following:

''(p) ELECTRONIC REGISTRATION AND LISTING.—

''(1) IN GENERAL.—Registrations and listings''; and

(2) by adding at the end the following:

''(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

''(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

''(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

''(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).''.

SEC. 705. RISK-BASED INSPECTION FREQUENCY.

Section 510(h) (21 U.S.C. 360(h)) is amended to read as follows:

''(h) INSPECTIONS.—

''(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

''(2) BIENNIAL INSPECTIONS FOR DEVICES.—Every establishment described in paragraph (1), in any State, that is engaged in the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

''(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as 'drug establishments') in accordance with a risk-based schedule established by the Secretary.

''(4) RISK FACTORS.—In establishing the risk-based scheduled under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

''(A) The compliance history of the establishment.

''(B) The record, history, and nature of recalls linked to the establishment.

''(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

''(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.

''(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.

''(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

''(6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Beginning in 2014, not later than February 1 of each year, the Secretary shall make available on the Internet Web site of the Food and Drug Administration a report regarding—

''(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year; and

''(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous fiscal year;

''(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug, a finished drug product, or an excipient of a drug, the number of each such type of establishment; and

''(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).''.

SEC. 706. RECORDS FOR INSPECTION.

Section 704(a) (21 U.S.C. 374(a)) is amended by adding at the end the following:

''(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records requested.

''(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

''(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.''.

SEC. 707. PROHIBITION AGAINST DELAYING, DENYING, LIMITING, OR REFUSING INSPECTION.

(a) IN GENERAL.—Section 501 (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is a drug and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.''.

(b) GUIDANCE.—Not later than 1 year after the date of enactment of this section, the Secretary of Health and Human Services shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

SEC. 708. DESTRUCTION OF ADULTERATED, MISBRANDED, OR COUNTERFEIT DRUGS OFFERED FOR IMPORT.

(a) IN GENERAL.—The sixth sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting before the period at the end the following: '', except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1)) and was not brought into compliance as described under subsection (b).''.

(b) NOTICE.—Subsection (a) of section 801 (21 U.S.C. 381), as amended by subsection (a), is further amended by inserting after the sixth sentence the following: ''The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug under the sixth sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee.''.

(c) APPLICABILITY.—The amendment made by subsection (a) shall apply beginning on the effective date of the regulations promulgated pursuant to the amendment made by subsection (b).

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall adopt final regulations implementing the amendments made this section.

(2) PROCEDURE.—In promulgating a regulation implementing the amendments made by this section, the Secretary of Health and Human Services shall—

(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the effective date of the regulation.

(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall promulgate regulations implementing the amendments made by this section only as described in paragraph (2).

SEC. 709. ADMINISTRATIVE DETENTION.

(a) IN GENERAL.—Section 304(g) (21 U.S.C. 335a(g)) is amended—

(1) in paragraph (1), by inserting '', drug,'' after ''device'', each place it appears;

(2) in paragraph (2)(A), by inserting '', drug,'' after ''(B), a device''; and

(3) in paragraph (2)(B), by inserting ''or drug'' after ''device'' each place it appears.

(b) REGULATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations in accordance with section 304(i) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2) of this subsection, to implement administrative detention authority with respect to drugs, as authorized by the amendments made by subsection (a). Before promulgating such regulations, the Secretary shall consult with stakeholders, including manufacturers of drugs.

(2) IN GENERAL.—Section 304 (21 U.S.C. 334) is amended by adding at the end the following:

''(i) PROCEDURES FOR PROMULGATING REGULATIONS.—

''(1) IN GENERAL.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the regulation's effective date.

''(2) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (1).''.

(c) EFFECTIVE DATE.—The amendments made by subsection (a) shall not take effect until the Secretary has issued a final regulation under subsection (b).

SEC. 710. EXCHANGE OF INFORMATION.

Section 708 (21 U.S.C. 379) is amended—

(1) by striking ''CONFIDENTIAL INFORMATION'' and all that follows through ''The Secretary may provide'' and inserting the following:

''SEC. 708. CONFIDENTIAL INFORMATION.

''(a) CONTRACTORS.—The Secretary may provide''; and

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENTS.—

''(1) IN GENERAL.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), or any other provision of law, any information relating to drugs obtained from a foreign government agency, if—

''(A) the information concerns the inspection of a facility, is part of an investigation, alerts the United States to the potential need for an investigation, or concerns a drug that has a reasonable probability of causing serious adverse health consequences or death to humans or animals;

''(B) the information is provided or made available to the United States Government voluntarily on the condition that it not be released to the public; and

''(C) the information is covered by, and subject to, a written agreement between the Secretary and the foreign government.

''(2) TIME LIMITATIONS.—The written agreement described in paragraph (1)(C) shall specify the time period for which paragraph (1) shall apply to the voluntarily disclosed information. Paragraph (1) shall not apply with respect to such information after the date specified in such agreement, but all other applicable legal protections, including the provisions of section 552 of title 5, United States Code, and section 319L(e)(1) of the Public Health Service Act, as applicable, shall continue to apply to such information. If no date is specified in the written agreement, paragraph (1) shall not apply with respect to such information for a period of more than 36 months.

''(3) DISCLOSURES NOT AFFECTED.—Nothing in this section authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

''(4) RELATION TO OTHER LAW.—For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in subsection (b)(3)(B) of such section 552.

''(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements to provide information referenced in section 301(j) to foreign governments subject to the following criteria:

''(1) CERTIFICATION.—The Secretary may enter into a written agreement to provide information under this subsection to a foreign government only if the Secretary has certified such government as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner of Food and Drugs.

''(2) WRITTEN AGREEMENT.—The written agreement to provide information to the foreign government under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

''(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(j) in only the following circumstances:

''(A) Information concerning the inspection of a facility may be provided to a foreign government if—

''(i) the Secretary reasonably believes, or the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

''(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

''(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.''.

SEC. 711. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following flush text:

''For purposes of paragraph (a)(2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.''.

SEC. 712. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

''SEC. 809. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

''(a) INSPECTION.—The Secretary—

''(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 510(i) in order to facilitate risk-based inspections in accordance with the schedule established in section 510(h)(3);

''(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conduction inspections that meet the applicable requirements of this Act; and

''(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this Act.

''(b) RESULTS OF INSPECTION.—The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

''(1) evidence of compliance with section 501(a)(2)(B) or section 801(r); and

''(2) for any other purposes as determined appropriate by the Secretary.''.

SEC. 713. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (o), by striking ''drug or''; and

(2) by adding at the end the following:

''(r)(1) The Secretary may require, pursuant to the regulations promulgated under paragraph (4)(A), as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

''(2) The information described under paragraph (1) may include—

''(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

''(B) facility information, such as proof of registration and the unique facility identifier;

''(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

''(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

''(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

''(A) through representation by a foreign government, if an inspection is conducted by a foreign government using standards and practices as determined appropriate by the Secretary;

''(B) through representation by a foreign government or an agency of a foreign government recognized under section 809; or

''(C) other appropriate documentation or evidence as described by the Secretary.

''(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 505(i).

''(B) In promulgating the regulations under subparagraph (A), the Secretary—

''(i) may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections; and

''(ii) shall—

''(I) issue a notice of proposed rulemaking that includes the proposed regulation;

''(II) provide a period of not less than 60 days for comments on the proposed regulation; and

''(III) publish the final regulation not less than 30 days before the effective date of the regulation.

''(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).''.

SEC. 714. REGISTRATION OF COMMERCIAL IMPORTERS.

(a) PROHIBITIONS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(aaa) The failure to register in accordance with section 801(s).''.

(b) REGISTRATION.—Section 801 (21 U.S.C. 381), as amended by section 713 of this Act, is further amended by adding at the end the following:

''(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

''(1) REGISTRATION.—The Secretary shall require a commercial importer of drugs—

''(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

''(B) subject to paragraph (4), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

''(2) REGULATIONS.—

''(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this Act and the Public Health Service Act.

''(B) PROCEDURE.—In promulgating a regulation under subparagraph (A), the Secretary shall—

''(i) issue a notice of proposed rulemaking that includes the proposed regulation;

''(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

''(iii) publish the final regulation not less than 30 days before the regulation's effective date.

''(C) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this subsection, the Secretary shall only promulgate regulations as described in subparagraph (B).

''(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

''(4) UNIQUE FACILITY IDENTIFIER.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

''(5) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.''.

(c) MISBRANDING.—Section 502(o) (21 U.S.C. 352) is amended by inserting ''if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s),'' after ''not duly registered under section 510,''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate the regulations required to carry out section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(2) PROCEDURES FOR PROMULGATING REGULATIONS.—

(A) IN GENERAL.—In promulgating a regulation under paragraph (1), the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the regulation's effective date.

(B) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), the Secretary shall promulgate regulations only as described in subparagraph (A).

(3) EFFECTIVE DATE.—In establishing the effective date of the regulations under paragraph (1), the Secretary of Health and Human Services shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.

SEC. 715. NOTIFICATION.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 714 of this Act, is further amended by adding at the end the following:

''(bbb) The failure to notify the Secretary in violation of section 568.''.

(b) NOTIFICATION.—Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. NOTIFICATION.

''(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—

''(1) that the use of such drug in the United States may result in serious injury or death;

''(2) of a significant loss or known theft of such drug intended for use in the United States; or

''(3) that—

''(A) such drug has been or is being counterfeited; and

''(B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce in the United States; or

''(ii) such drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

''(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in such manner and by such means as the Secretary may specify by regulation or guidance.

''(c) SAVINGS CLAUSE.—Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this Act or the Public Health Service Act.

''(d) DEFINITION.—In this section, the term 'regulated person' means—

''(1) a person who is required to register under section 510 or 801(s);

''(2) a wholesale distributor of a drug product; or

''(3) any other person that distributes drugs except a person that distributes drugs exclusively for retail sale.''.

SEC. 716. PROTECTION AGAINST INTENTIONAL ADULTERATION.

Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.''.

SEC. 717. PENALTIES FOR COUNTERFEITING DRUGS.

(a) COUNTERFEIT DRUG PENALTY ENHANCEMENT.—

(1) OFFENSE.—Section 2320(a) of title 18, United States Code, is amended—

(A) by striking ''or'' at the end of paragraph (2);

(B) by inserting ''or'' at the end of paragraph (3);

(C) by inserting after paragraph (3) the following:

''(4) traffics in a counterfeit drug,''; and

(D) by striking ''through (3)'' and inserting ''through (4)''.

(2) PENALTIES.—Section 2320(b)(3) of title 18, United States Code, is amended—

(A) in the heading, by inserting ''AND COUNTERFEIT DRUGS'' after ''SERVICES''; and

(B) by inserting ''or counterfeit drug'' after ''service''.

(3) DEFINITION.—Section 2320(f) of title 18, United States Code, is amended—

(A) by striking ''and'' at the end of paragraph (4);

(B) by striking the period at the end of paragraph (5) and inserting ''; and''; and

(C) by adding at the end the following:

''(6) the term 'counterfeit drug' means a drug, as defined by section 201 of the Federal Food, Drug, and Cosmetic Act, that uses a counterfeit mark on or in connection with the drug.''.

(4) PRIORITY GIVEN TO CERTAIN INVESTIGATIONS AND PROSECUTIONS.—The Attorney General shall give increased priority to efforts to investigate and prosecute offenses under section 2320 of title 18, United States Code, that involve counterfeit drugs.

(b) SENTENCING COMMISSION DIRECTIVE.—

(1) DIRECTIVE TO SENTENCING COMMISSION.—Pursuant to its authority under section 994(p) of title 28, United States Code, and in accordance with this subsection, the United States Sentencing Commission shall review and amend, if appropriate, its guidelines and its policy statements applicable to persons convicted of an offense described in section 2320(a)(4) of title 18, United States Code, as amended by subsection (a), in order to reflect the intent of Congress that such penalties be increased in comparison to those currently provided by the guidelines and policy statements.

(2) REQUIREMENTS.—In carrying out this subsection, the Commission shall—

(A) ensure that the sentencing guidelines and policy statements reflect the intent of Congress that the guidelines and policy statements reflect the serious nature of the offenses described in paragraph (1) and the need for an effective deterrent and appropriate punishment to prevent such offenses;

(B) consider the extent to which the guidelines may or may not appropriately account for the potential and actual harm to the public resulting from the offense;

(C) assure reasonable consistency with other relevant directives and with other sentencing guidelines;

(D) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

(E) make any necessary conforming changes to the sentencing guidelines; and

(F) assure that the guidelines adequately meet the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code.

SEC. 718. EXTRATERRITORIAL JURISDICTION.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act

in furtherance of the violation was committed in the United States.''.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505D the following:

''SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the 7-year period described in section 527, as applicable, shall be extended by 5 years.

''(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

''(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

''(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

''(2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

''(3) a product that does not meet the definition of a qualified infectious disease product under subsection (g) based upon its approved uses.

''(d) DESIGNATION.—

''(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 505(b) for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

''(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

''(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section, including developing the list of qualifying pathogens described in subsection (f).

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

''(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection, if such drugs meet the definition of a qualified infectious disease product described in subsection (g).

''(f) QUALIFYING PATHOGEN.—

''(1) DEFINITION.—In this section, the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

''(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

''(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

''(C) multi-drug resistant tuberculosis; and

''(D) Clostridium difficile.

''(2) LIST OF QUALIFYING PATHOGENS.—

''(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

''(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section, the Secretary shall—

''(i) consider—

''(I) the impact on the public health due to drug-resistant organisms in humans;

''(II) the rate of growth of drug-resistant organisms in humans;

''(III) the increase in resistance rates in humans; and

''(IV) the morbidity and mortality in humans; and

''(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

''(C) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

''(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(2) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) APPLICATION.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act.

SEC. 802. PRIORITY REVIEW.

(a) AMENDMENT.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 524 the following:

''SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''If the Secretary designates a drug under section 505E(d) as a qualified infectious disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 505(b).''.

(b) APPLICATION.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 803. FAST TRACK PRODUCT.

Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended by section 901(b) of this Act, is amended by inserting '', or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d)'' before the period at the end of the first sentence.

SEC. 804. CLINICAL TRIALS.

(a) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising such guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

(2) ISSUES FOR REVIEW.—At a minimum, the review under paragraph (1) shall address the appropriate animal models of infection, in vitro techniques, valid microbiological surrogate markers, the use of noninferiority versus superiority trials, trial enrollment, data requirements, and appropriate delta values for noninferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise effect the guidance documents of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes may be necessary to be conducted with the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 505E of such Act.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) of such drug for the use described in paragraph (1).

(c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801 of this Act.

SEC. 805. REASSESSMENT OF QUALIFIED INFECTIOUS DISEASE PRODUCT INCENTIVES IN 5 YEARS.

(a) IN GENERAL.—Not later than 5 years after the date of enactment of this Act, the Secretary of Health and Human Services shall, in consultation with the Food and Drug Administration, the Centers for Disease Control and Prevention, and other appropriate agencies, submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that contains the following:

(1)(A) The number of initial designations of drugs as qualified infectious disease products

under section 505E of the Federal Food, Drug, and Cosmetic Act.

(B) The number of qualified infectious disease products approved under such section 505E.

(C) Whether such products address the need for antibacterial and antifungal drugs to treat serious and life-threatening infections.

(D) A list of qualified infectious disease products with information on the types of exclusivity granted for each product, consistent with the information published under section 505(j)(7)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)(iii)).

(E) The progress made regarding the review and revision of the clinical trial guidance documents required under section 804 and the impact such review and revision has had on the review and approval of qualified infectious disease products.

(F) The Federal contribution, if any, to funding of the clinical trials for each qualified infectious disease product for each phase.

(2) Recommendations—

(A) based on the information under paragraph (1) and any other relevant data, on any changes that should be made to the list of pathogens that are defined as qualifying pathogens under section 505E(f)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 801 of this Act; and

(B) on whether any additional program (such as the development of public-private collaborations to advance antibacterial drug innovation) or changes to the incentives under this subtitle may be needed to promote the development of antibacterial drugs.

(3) An examination of—

(A) the adoption of programs to measure the use of antibacterial drugs in health care settings; and

(B) the implementation and effectiveness of antimicrobial stewardship protocols across all health care settings.

(4) Any recommendations for ways to encourage further development and establishment of stewardship programs.

(5) A description of the regulatory challenges and impediments to clinical development, approval, and licensure of qualified infectious disease products, and the steps the Secretary has taken and will take to address such challenges and ensure regulatory certainty and predictability with respect to qualified infectious disease products.

(b) DEFINITION.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801 of this Act.

SEC. 806. GUIDANCE ON PATHOGEN-FOCUSED ANTIBACTERIAL DRUG DEVELOPMENT.

(a) DRAFT GUIDANCE.—Not later than June 30, 2013, in order to facilitate the development of antibacterial drugs for serious or life-threatening bacterial infections, particularly in areas of unmet need, the Secretary of Health and Human Services shall publish draft guidance that—

(1) specifies how preclinical and clinical data can be utilized to inform an efficient and streamlined pathogen-focused antibacterial drug development program that meets the approval standards of the Food and Drug Administration; and

(2) provides advice on approaches for the development of antibacterial drugs that target a more limited spectrum of pathogens.

(b) FINAL GUIDANCE.—Not later than December 31, 2014, after notice and opportunity for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall publish final guidance consistent with this section.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the ''FDA'') serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.—Section 506 (21 U.S.C. 356) is amended to read as follows:

''SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

''(a) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

''(b) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—

''(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval'.

''(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

''(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

''(A) That the sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

''(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

''(A) the sponsor fails to conduct any required postapproval study of the drug with due diligence;

''(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

''(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data

submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

''(A) provides a schedule for submission of information necessary to make the application complete; and

''(B) pays any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

''(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

''(e) CONSTRUCTION.—

''(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).''.

(c) GUIDANCE; AMENDED REGULATIONS.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall—

(A) issue final guidance; and

(B) amend the regulations governing accelerated approval in parts 314 and 601 of title 21, Code of Federal Regulations, as necessary to conform such regulations with the amendment made by subsection (b).

(3) CONSIDERATION.—In developing the guidance under paragraphs (1) and (2)(A) and the amendments under paragraph (2)(B), the Secretary shall consider how to incorporate novel approaches to the review of surrogate endpoints based on pathophysiologic and pharmacologic evidence in such guidance, especially in instances where the low prevalence of a disease renders the existence or collection of other types of data unlikely or impractical.

(4) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.

(5) NO EFFECT OF INACTION ON REQUESTS.—The issuance (or nonissuance) of guidance or conforming regulations implementing the amendment made by subsection (b) shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).

(d) INDEPENDENT REVIEW.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Any such evaluation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

SEC. 902. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 901 of this Act, is further amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(2) by redesignating subsection (d) as subsection (f);

(3) by inserting before subsection (b), as so redesignated, the following:

''(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—

''(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

''(i) holding meetings with the sponsor and the review team throughout the development of the drug;

''(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

''(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

''(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.''; and

(4) in subsection (f)(1), as so redesignated, by striking ''applicable to accelerated approval'' and inserting ''applicable to breakthrough therapies, accelerated approval, and''.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(B) AMENDED REGULATIONS.—

(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by this section only as described in clause (ii).

(2) REQUIREMENTS.—Guidance issued under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) CONFORMING AMENDMENTS.—Section 506B(e) (21 U.S.C. 356b) is amended by striking ''section 506(b)(2)(A)'' each place such term appears and inserting ''section 506(c)(2)(A)''.

SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 715 of this Act,

is further amended by adding at the end the following:

"SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

''(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

''(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

''(2) CONSULTATION WITH EXTERNAL EXPERTS.—

''(A) IN GENERAL.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.

''(B) EXTERNAL EXPERTS.—For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

''(b) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

''(1) rare diseases;

''(2) the severity of rare diseases;

''(3) the unmet medical need associated with rare diseases;

''(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

''(5) an assessment of the benefits and risks of therapies to treat rare diseases;

''(6) the general design of clinical trials for rare disease populations and subpopulations; and

''(7) the demographics and the clinical description of patient populations.

''(c) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

''(d) PROTECTION OF CONFIDENTIAL INFORMATION AND TRADE SECRETS.—

''(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

''(2) CONSENT REQUIRED FOR DISCLOSURE.—The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18, United States Code) or the disclosure is otherwise authorized by law.

''(e) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

''(f) NO RIGHT OR OBLIGATION.—

''(1) NO RIGHT TO CONSULTATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

''(2) NO ALTERING OF GOALS.—Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

''(3) NO CHANGE TO NUMBER OF REVIEW CYCLES.—Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.

''(g) NO DELAY IN PRODUCT REVIEW.—

''(1) IN GENERAL.—Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 505(i), a new drug application under section 505(b), or a biologics license application under section 351 of the Public Health Service Act, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

''(A) such consultation will—

''(i) facilitate the Secretary's ability to complete the Secretary's review; and

''(ii) address outstanding deficiencies in the application; or

''(B) the sponsor authorized such consultation.

''(2) LIMITATION.—The requirements of this subsection shall apply only in instances where the consultation is undertaken solely under the authority of this section. The requirements of this subsection shall not apply to any consultation initiated under any other authority.''.

SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIPTION DRUG CONTAINER LABELS BY VISUALLY IMPAIRED AND BLIND CONSUMERS.

(a) ESTABLISHMENT OF WORKING GROUP.—

(1) IN GENERAL.—The Architectural and Transportation Barriers Compliance Board (referred to in this section as the ''Access Board'') shall convene a stakeholder working group (referred to in this section as the ''working group'') to develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired.

(2) MEMBERS.—The working group shall be comprised of representatives of national organizations representing blind and visually impaired individuals, national organizations representing the elderly, and industry groups representing stakeholders, including retail, mail-order, and independent community pharmacies, who would be impacted by such best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

(3) BEST PRACTICES.—

(A) IN GENERAL.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

(B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be made publicly available, including through the Internet Web sites of the working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities.

(C) LIMITATIONS.—The best practices developed under subparagraph (A) shall not be construed as accessibility guidelines or standards of the Access Board, and shall not confer any rights or impose any obligations on working group participants or other persons. Nothing in this section shall be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other Federal or State law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

(4) CONSIDERATIONS.—In developing and issuing the best practices under paragraph (3)(A), the working group shall consider—

(A) the use of—

(i) Braille;

(ii) auditory means, such as—

(I) ''talking bottles'' that provide audible container label information;

(II) digital voice recorders attached to the prescription drug container; and

(III) radio frequency identification tags;

(iii) enhanced visual means, such as—

(I) large font labels or large font ''duplicate'' labels that are affixed or matched to a prescription drug container;

(II) high-contrast printing; and

(III) sans-serf font; and

(iv) other relevant alternatives as determined by the working group;

(B) whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices; and

(C) such other factors as the working group determines to be appropriate.

(5) INFORMATION CAMPAIGN.—Upon completion of development of the best practices under subsection (a)(3), the National Council on Disability, in consultation with the working group, shall conduct an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about such best practices.

(6) FACA WAIVER.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group.

(b) GAO STUDY.—

(1) IN GENERAL.—Beginning 18 months after the completion of the development of best practices under subsection (a)(3)(A), the Comptroller General of the United States shall conduct a review of the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription drug container labels for blind and visually impaired individuals continue.

(2) REPORT.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted under paragraph (1). Such report shall include recommendations about how best to reduce the barriers experienced by blind and visually impaired individuals to independently accessing information on prescription drug container labels.

(c) DEFINITIONS.—In this section—

(1) the term ''pharmacy'' includes a pharmacy that receives prescriptions and dispenses prescription drugs through an Internet Web site or by mail;

(2) the term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(3) the term ''prescription drug container label'' means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispensed to the consumer.

SEC. 905. RISK-BENEFIT FRAMEWORK.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of

benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for premarket approval of a drug.''.

SEC. 906. GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.

(a) QUALIFIED TESTING DEFINITION.—Section 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A)(ii)) is amended by striking ''after the date such drug is designated under section 526 of such Act and''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) AUTHORIZATION OF APPROPRIATIONS.—For grants and contracts under subsection (a), there is authorized to be appropriated $30,000,000 for each of fiscal years 2013 through 2017.''.

SEC. 907. REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS IN CLINICAL TRIALS AND DATA ANALYSIS IN APPLICATIONS FOR DRUGS, BIOLOGICS, AND DEVICES.

(a) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall publish on the Internet Web site of the Food and Drug Administration a report, consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act, addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the Food and Drug Administration, and shall provide such publication to Congress.

(2) CONTENTS OF REPORT.—The report described in paragraph (1) shall contain the following:

(A) A description of existing tools to ensure that data to support demographic analyses are submitted in applications for drugs, biological products, and devices, and that these analyses are conducted by applicants consistent with applicable Food and Drug Administration requirements and Guidance for Industry. The report shall address how the Food and Drug Administration makes available information about differences in safety and effectiveness of medical products according to demographic subgroups, such as sex, age, racial, and ethnic subgroups, to health care providers, researchers, and patients.

(B) An analysis of the extent to which demographic data subset analyses on sex, age, race, and ethnicity is presented in applications for new drug applications for new molecular entities under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262), and in premarket approval applications under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) for products approved or licensed by the Food and Drug Administration, consistent with applicable requirements and Guidance for Industry, and consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act.

(C) An analysis of the extent to which demographic subgroups, including sex, age, racial, and ethnic subgroups, are represented in clinical studies to support applications for approved or licensed new molecular entities, biological products, and devices.

(D) An analysis of the extent to which a summary of product safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity is readily available to the public in a timely manner by means of the product labeling or the Food and Drug Administration's Internet Web site.

(b) ACTION PLAN.—

(1) IN GENERAL.—Not later than 1 year after the publication of the report described in subsection (a), the Secretary, acting through the Commissioner, shall publish an action plan on the Internet Web site of the Food and Drug Administration, and provide such publication to Congress.

(2) CONTENT OF ACTION PLAN.—The plan described in paragraph (1) shall include—

(A) recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling;

(B) recommendations, as appropriate, on the inclusion of such data, or the lack of availability of such data in labeling;

(C) recommendations, as appropriate, to otherwise improve the public availability of such data to patients, health care providers, and researchers; and

(D) a determination with respect to each recommendation identified in subparagraphs (A) through (C) that distinguishes between product types referenced in subsection (a)(2)(B) insofar as the applicability of each such recommendation to each type of product.

(c) DEFINITIONS.—In this section:

(1) The term ''Commissioner'' means the Commissioner of Food and Drugs.

(2) The term ''device'' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(3) The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(4) The term ''biological product'' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 908. RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM.

Subchapter B of chapter V (21 U.S.C. 360aa et seq.) is amended by adding at the end the following:

''SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

''(2) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a rare pediatric disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the rare pediatric disease product application.

''(3) RARE PEDIATRIC DISEASE.—The term 'rare pediatric disease' means a disease that meets each of the following criteria:

''(A) The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

''(B) The disease is a rare disease or condition, within the meaning of section 526.

''(4) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term 'rare pediatric disease product application' means a human drug application, as defined in section 735(1), that—

''(A) is for a drug or biological product—

''(i) that is for the prevention or treatment of a rare pediatric disease; and

''(ii) that contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of this Act or section 351(a) or 351(k) of the Public Health Service Act;

''(B) is submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act;

''(C) the Secretary deems eligible for priority review;

''(D) that relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;

''(E) that does not seek approval for an adult indication in the original rare pediatric disease product application; and

''(F) is approved after the date of the enactment of the Prescription Drug User Fee Amendments of 2012.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a rare pediatric disease product application upon approval by the Secretary of such rare pediatric disease product application.

''(2) TRANSFERABILITY.—

''(A) IN GENERAL.—The sponsor of a rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

''(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.

''(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012.

''(4) NOTIFICATION.—

''(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

''(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

''(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary, based on the difference between—

''(A) the average cost incurred by the Food and Drug Administration in the review of a human drug application subject to priority review in the previous fiscal year; and

''(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2012, the amount of the priority review user fee for that fiscal year.

''(4) PAYMENT.—

''(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(4)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

''(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

''(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriations Acts.

''(d) DESIGNATION PROCESS.—

''(1) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate—

''(A) the new drug as a drug for a rare pediatric disease; and

''(B) the application for the new drug as a rare pediatric disease product application.

''(2) REQUEST FOR DESIGNATION.—The request for a designation under paragraph (1) shall be made at the same time a request for designation of orphan disease status under section 526 or fast-track designation under section 506 is made. Requesting designation under this subsection is not a prerequisite to receiving a priority review voucher under this section.

''(3) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under paragraph (1), the Secretary shall determine whether—

''(A) the disease or condition that is the subject of such request is a rare pediatric disease; and

''(B) the application for the new drug is a rare pediatric disease product application.

''(e) MARKETING OF RARE PEDIATRIC DISEASE PRODUCTS.—

''(1) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the rare pediatric disease product for which such voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act.

''(2) POSTAPPROVAL PRODUCTION REPORT.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare pediatric disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

''(A) The estimated population in the United States suffering from the rare pediatric disease.

''(B) The estimated demand in the United States for such rare pediatric disease product.

''(C) The actual amount of such rare pediatric disease product distributed in the United States.

''(f) NOTICE AND REPORT.—

''(1) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet Web site of the Food and Drug Administration not later than 30 days after the occurrence of each of the following:

''(A) The Secretary issues a priority review voucher under this section.

''(B) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher under this section.

''(2) NOTIFICATION.—If, after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, a sponsor of an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug uses a priority review voucher under this section for such application, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a document—

''(A) notifying such Committees of the use of such voucher; and

''(B) identifying the drug for which such priority review voucher is used.

''(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act.

''(h) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of drugs for tropical diseases and rare pediatric diseases.

''(i) GAO STUDY AND REPORT.—

''(1) STUDY.—

''(A) IN GENERAL.—Beginning on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, the Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under this section in the development of human drug products that treat or prevent such diseases.

''(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

''(i) The indications for which each rare disease product for which a priority review voucher was awarded was approved under section 505 or section 351 of the Public Health Service Act.

''(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval of such a rare disease product.

''(iii) The value of the priority review voucher if transferred.

''(iv) Identification of each drug for which a priority review voucher was used.

''(v) The length of the period of time between the date on which a priority review voucher was awarded and the date on which it was used.

''(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report containing the results of the study under paragraph (1).''.

TITLE X—DRUG SHORTAGES

SEC. 1001. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS.

(a) IN GENERAL.—Section 506C (21 U.S.C. 356c) is amended to read as follows:

''SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining; or

''(C) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery; and

''(2) that is not a radio pharmaceutical drug product or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States, and the reasons for such discontinuance or interruption.

''(b) TIMING.—A notice required under subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the discontinuation or interruption of the manufacture of the drugs described in subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, as described in section 506E.

''(d) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(e) COORDINATION WITH ATTORNEY GENERAL.—Not later than 30 days after the receipt of a notification described in subsection (a), the Secretary shall—

''(1) determine whether the notification pertains to a controlled substance subject to a production quota under section 306 of the Controlled Substances Act; and

''(2) if necessary, as determined by the Secretary—

''(A) notify the Attorney General that the Secretary has received such a notification;

''(B) request that the Attorney General increase the aggregate and individual production quotas under section 306 of the Controlled Substances Act applicable to such controlled substance and any ingredient therein to a level the Secretary deems necessary to address a shortage of a controlled substance based on the best available market data; and

''(C) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (C) available to the public on the Internet Web site of the Food and Drug Administration.

''(f) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

''(1) the Secretary shall issue a letter to such person informing such person of such failure;

''(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

''(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the

Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the Internet Web site of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

''(g) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may—

''(1) expedite the review of a supplement to a new drug application submitted under section 505(b), an abbreviated new drug application submitted under section 505(j), or a supplement to such an application submitted under section 505(j) that could help mitigate or prevent such shortage; or

''(2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage.

''(h) DEFINITIONS.—For purposes of this section—

''(1) the term 'drug'—

''(A) means a drug (as defined in section 201(g)) that is intended for human use and that is subject to section 503(b)(1); and

''(B) does not include biological products (as defined in section 351 of the Public Health Service Act), unless otherwise provided by the Secretary in the regulations promulgated under subsection (i);

''(2) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug; and

''(3) the term 'meaningful disruption'—

''(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product; and

''(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

''(i) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt a final regulation implementing this section.

''(2) CONTENTS.—Such regulation shall define, for purposes of this section, the terms 'life-supporting', 'life-sustaining', and 'intended for use in the prevention or treatment of a debilitating disease or condition'.

''(3) INCLUSION OF BIOLOGICAL PRODUCTS.—

''(A) IN GENERAL.—The Secretary may by regulation apply this section to biological products (as defined in section 351 of the Public Health Service Act), including plasma products derived from human plasma protein and their recombinant analogs, if the Secretary determines such inclusion would benefit the public health. Such regulation shall take into account any supply reporting programs and shall aim to reduce duplicative notification.

''(B) RULE FOR VACCINES.—If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary shall—

''(i) consider whether the notification requirement under subsection (a) may be satisfied by submitting a notification to the Centers for Disease Control and Prevention under the vaccine shortage notification program of such Centers; and

''(ii) explain the determination made by the Secretary under clause (i) in the regulation.

''(4) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the regulation's effective date.

''(5) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (4).''.

(b) EFFECT OF NOTIFICATION.—The submission of a notification to the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') for purposes of complying with the requirement in section 506C(a) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) shall not be construed—

(1) as an admission that any product that is the subject of such notification violates any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.

SEC. 1002. ANNUAL REPORTING ON DRUG SHORTAGES.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506C, as amended by section 1001 of this Act, the following:

''SEC. 506C–1. ANNUAL REPORTING ON DRUG SHORTAGES.

''(a) ANNUAL REPORTS TO CONGRESS.—Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on drug shortages that—

''(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 506C(a) during such calendar year;

''(2) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

''(3)(A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (7);

''(B) in the list under subparagraph (A), includes—

''(i) the number of applications and supplements for which the Secretary expedited review under section 506C(g)(1) during such calendar year; and

''(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 506C(g)(2) during such calendar year;

''(4) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

''(5) identifies the number of and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

''(6) lists the names of manufacturers that were issued letters under section 506C(f); and

''(7) specifies the number of drug shortages occurring during such calendar year, as identified by the Secretary.

''(b) TREND ANALYSIS.—The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

''(c) DEFINITION.—In this section, the term 'drug shortage' or 'shortage' has the meaning given such term in section 506C.''.

SEC. 1003. COORDINATION; TASK FORCE AND STRATEGIC PLAN.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506C–1, as added by section 1002 of this Act, the following:

''SEC. 506D. COORDINATION; TASK FORCE AND STRATEGIC PLAN.

''(a) TASK FORCE AND STRATEGIC PLAN.—

''(1) IN GENERAL.—

''(A) TASK FORCE.—As soon as practicable after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

''(B) STRATEGIC PLAN.—The strategic plan described in subparagraph (A) shall include—

''(i) plans for enhanced interagency and intra-agency coordination, communication, and decisionmaking;

''(ii) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

''(iii) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;

''(iv) plans for considering the impact of drug shortages on research and clinical trials; and

''(v) an examination of whether to establish a 'qualified manufacturing partner program', as described in subparagraph (C).

''(C) DESCRIPTION OF PROGRAM.—In conducting the examination of a 'qualified manufacturing partner program' under subparagraph (B)(v), the Secretary—

''(i) shall take into account that—

''(I) a 'qualified manufacturer', for purposes of such program, would need to have the capability and capacity to supply products determined or anticipated to be in shortage; and

''(II) in examining the capability and capacity to supply products in shortage, the 'qualified manufacturer' could have a site that manufactures a drug listed under section 506E or have the capacity to produce drugs in response to a shortage within a rapid timeframe; and

''(ii) shall examine whether incentives are necessary to encourage the participation of 'qualified manufacturers' in such a program.

''(D) CONSULTATION.—In carrying out this paragraph, the task force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall engage external stakeholders and experts as appropriate.

''(2) TIMING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the task force shall—

''(A) publish the strategic plan described in paragraph (1); and

''(B) submit such plan to Congress.

''(b) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under section 506C(a), there is communication with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

''(c) ACTION.—If the Secretary determines, after the communication described in subsection (b), that an enforcement action or a warning

letter could reasonably cause or exacerbate a shortage of a drug described under section 506C(a), then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

''(d) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a mechanism by which health care providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

''(e) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the Secretary under this section shall—

''(1) be subject to judicial review; or

''(2) be construed to establish a defense to an enforcement action by the Secretary.

''(f) SUNSET.—Subsections (a), (b), (c), and (e) shall cease to be effective on the date that is 5 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act.''.

SEC. 1004. DRUG SHORTAGE LIST.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506D, as added by section 1003 of this Act, the following:

''SEC. 506E. DRUG SHORTAGE LIST.

''(a) ESTABLISHMENT.—The Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States.

''(b) CONTENTS.—For each drug on such list, the Secretary shall include the following information:

''(1) The name of the drug in shortage, including the National Drug Code number for such drug.

''(2) The name of each manufacturer of such drug.

''(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

''(A) Requirements related to complying with good manufacturing practices.

''(B) Regulatory delay.

''(C) Shortage of an active ingredient.

''(D) Shortage of an inactive ingredient component.

''(E) Discontinuation of the manufacture of the drug.

''(F) Delay in shipping of the drug.

''(G) Demand increase for the drug.

''(4) The estimated duration of the shortage as determined by the Secretary.

''(c) PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

''(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

''(3) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available under paragraph (1) or section 506C(c) if the Secretary determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients).''.

SEC. 1005. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

''(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

''(A) complete review of such request; and

''(B)(i) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or

''(ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (B)(ii) available to the public on the Internet Web site of the Food and Drug Administration.

''(2) A request is described in this paragraph if—

''(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 506E of the Federal Food, Drug, and Cosmetic Act;

''(B) the request is submitted by the manufacturer of the controlled substance; and

''(C) the controlled substance is in schedule II.''.

SEC. 1006. ATTORNEY GENERAL REPORT ON DRUG SHORTAGES.

Not later than 6 months after the date of the enactment of this Act, and annually thereafter, the Attorney General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages that—

(1) identifies the number of requests received under section 306(h) of the Controlled Substances Act (as added by section 1005 of this Act), the average review time for such requests, the number of requests granted and denied under such section, and, for each of the requests denied under such section, the basis for such denial;

(2) describes the coordination between the Drug Enforcement Administration and Food and Drug Administration on efforts to prevent or alleviate drug shortages; and

(3) identifies drugs containing a controlled substance subject to section 306 of the Controlled Substances Act when such a drug is determined by the Secretary to be in shortage.

SEC. 1007. HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506E, as added by section 1004 of this Act, the following:

''SEC. 506F. HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE.

''(a) DEFINITIONS.—In this section:

''(1) DRUG.—The term 'drug' excludes any controlled substance (as such term is defined in section 102 of the Controlled Substances Act).

''(2) HEALTH SYSTEM.—The term 'health system' means a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

''(3) REPACKAGE.—For the purposes of this section only, the term 'repackage', with respect to a drug, means to divide the volume of a drug into smaller amounts in order to—

''(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list under section 506E; and

''(B) facilitate access to the drug by hospitals within the same health system.

''(b) EXCLUSION FROM REGISTRATION.—Notwithstanding any other provision of this Act, a hospital shall not be considered an establishment for which registration is required under section 510 solely because it repackages a drug and transfers it to another hospital within the same health system in accordance with the conditions in subsection (c)—

''(1) during any period in which the drug is listed on the drug shortage list under section 506E; or

''(2) during the 60-day period following any period described in paragraph (1).

''(c) CONDITIONS.—Subsection (b) shall only apply to a hospital, with respect to the repackaging of a drug for transfer to another hospital within the same health system, if the following conditions are met:

''(1) DRUG FOR INTRASYSTEM USE ONLY.—In no case may a drug that has been repackaged in accordance with this section be sold or otherwise distributed by the health system or a hospital within the system to an entity or individual that is not a hospital within such health system.

''(2) COMPLIANCE WITH STATE RULES.—Repackaging of a drug under this section shall be done in compliance with applicable State requirements of each State in which the drug is repackaged and received.

''(d) TERMINATION.—This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage.''.

SEC. 1008. STUDY ON DRUG SHORTAGES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study to examine the cause of drug shortages and formulate recommendations on how to prevent or alleviate such shortages.

(b) CONSIDERATION.—In conducting the study under this section, the Comptroller General shall consider the following questions:

(1) What are the dominant characteristics of drugs that have gone into a drug shortage over the preceding 3 years?

(2) Are there systemic high-risk factors (such as drug pricing structure, including Federal reimbursements, or the number of manufacturers producing a drug product) that have led to the concentration of drug shortages in certain drug products that have made such products vulnerable to drug shortages?

(3) Is there a reason why drug shortages have occurred primarily in the sterile injectable market and in certain therapeutic areas?

(4)(A) How have regulations, guidance documents, regulatory practices, policies, and other actions of Federal departments and agencies (including the effectiveness of interagency and intra-agency coordination, communication, strategic planning, and decisionmaking), including those used to enforce statutory requirements, affected drug shortages?

(B) Do any such regulations, guidances, policies, or practices cause, exacerbate, prevent, or mitigate drug shortages?

(C) How can regulations, guidances, policies, or practices be modified, streamlined, expanded, or discontinued in order to reduce or prevent such drug shortages?

(D) What effect would the changes described in subparagraph (C) have on the public health?

(5) How does hoarding affect drug shortages?

(6) How would incentives alleviate or prevent drug shortages?

(7) To what extent are health care providers, including hospitals and physicians responding to drug shortages, able to adjust care effectively to compensate for such shortages, and what impediments exist that hinder provider ability to adjust to such shortages?

(8)(A) Have drug shortages led market participants to stockpile affected drugs or sell such drugs at inflated prices?

(B) What has been the impact of any such activities described in subparagraph (A) on Federal revenue, and are there any economic factors that have exacerbated or created a market for such activities?

(C) Is there a need for any additional reporting or enforcement actions to address such activities?

(9)(A) How have the activities under section 506D of the Federal Food, Drug, and Cosmetic Act (as added by section 1003 of this Act) improved the efforts of the Food and Drug Administration to mitigate and prevent drug shortages?

(B) Is there a need to continue the task force and strategic plan under such section 506D, or are there any other recommendations to increase communication and coordination inside the Food and Drug Administration, between the Food and Drug Administration and other agencies, and between the Food and Drug Administration and stakeholders?

(c) CONSULTATION WITH STAKEHOLDERS.—In conducting the study under this section, the Comptroller General shall consult with relevant stakeholders, including physicians, pharmacists, hospitals, patients, drug manufacturers, and other health providers.

(d) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the results of the study under this section.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

(a) IN GENERAL.—Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ''2012'' and inserting ''2017''.

(b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting ''clinical'' after ''any''.

SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subsection (f) of section 566 (21 U.S.C. 360bbb–5) is amended to read as follows:

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $6,000,000 for each of fiscal years 2013 through 2017.''.

Subtitle B—Medical Gas Product Regulation

SEC. 1111. REGULATION OF MEDICAL GASES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter G—Medical Gases

''SEC. 575. DEFINITIONS.

''In this subchapter:

''(1) The term 'designated medical gas' means any of the following:

''(A) Oxygen that meets the standards set forth in an official compendium.

''(B) Nitrogen that meets the standards set forth in an official compendium.

''(C) Nitrous oxide that meets the standards set forth in an official compendium.

''(D) Carbon dioxide that meets the standards set forth in an official compendium.

''(E) Helium that meets the standards set forth in an official compendium.

''(F) Carbon monoxide that meets the standards set forth in an official compendium.

''(G) Medical air that meets the standards set forth in an official compendium.

''(H) Any other medical gas deemed appropriate by the Secretary, after taking into account any investigational new drug application or investigational new animal drug application for the same medical gas submitted in accordance with regulations applicable to such applications in title 21 of the Code of Federal Regulations, unless any period of exclusivity under section 505(c)(3)(E)(ii) or section 505(j)(5)(F)(ii), or the extension of any such period under section 505A, applicable to such medical gas has not expired.

''(2) The term 'medical gas' means a drug that—

''(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

''(B) is administered as a gas.

''SEC. 576. REGULATION OF MEDICAL GASES.

''(a) CERTIFICATION OF DESIGNATED MEDICAL GASES.—

''(1) SUBMISSION.—Beginning 180 days after the date of enactment of this section, any person may file with the Secretary a request for certification of a medical gas as a designated medical gas. Any such request shall contain the following information:

''(A) A description of the medical gas.

''(B) The name and address of the sponsor.

''(C) The name and address of the facility or facilities where the medical gas is or will be manufactured.

''(D) Any other information deemed appropriate by the Secretary to determine whether the medical gas is a designated medical gas.

''(2) GRANT OF CERTIFICATION.—The certification requested under paragraph (1) is deemed to be granted unless, within 60 days of the filing of such request, the Secretary finds that—

''(A) the medical gas subject to the certification is not a designated medical gas;

''(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or

''(C) denying the request is necessary to protect the public health.

''(3) EFFECT OF CERTIFICATION.—

''(A) IN GENERAL.—

''(i) APPROVED USES.—A designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512, subject to all applicable post-approval requirements, for the following indications for use:

''(I) In the case of oxygen, the treatment or prevention of hypoxemia or hypoxia.

''(II) In the case of nitrogen, use in hypoxic challenge testing.

''(III) In the case of nitrous oxide, analgesia.

''(IV) In the case of carbon dioxide, use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

''(V) In the case of helium, the treatment of upper airway obstruction or increased airway resistance.

''(VI) In the case of medical air, to reduce the risk of hyperoxia.

''(VII) In the case of carbon monoxide, use in lung diffusion testing.

''(VIII) Any other indication for use for a designated medical gas or combination of designated medical gases deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 505(c)(3)(E), clause (iii) or (iv) of section 505(j)(5)(F), or section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas or combination of gases has not expired.

''(ii) LABELING.—The requirements of sections 503(b)(4) and 502(f) are deemed to have been met for a designated medical gas if the labeling on final use container for such medical gas bears—

''(I) the information required by section 503(b)(4);

''(II) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and

''(III) appropriate directions and warnings concerning storage and handling.

''(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

''(i) NO EXCLUSIVITY FOR A CERTIFIED MEDICAL GAS.—No designated medical gas deemed under subparagraph (A)(i) to have in effect an approved application is eligible for any period of exclusivity under section 505(c), 505(j), or 527, or the extension of any such period under section 505A, on the basis of such deemed approval.

''(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under section 505(c), 505(j), or section 527, or the extension of any such period under section 505A, with respect to an application for a drug product shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in subsection (a)(3)(A)(i)(VIII) and section 575(1)(H).

''(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

''(A) WITHDRAWAL, SUSPENSION OF APPROVAL.—Nothing in this subchapter limits the Secretary's authority to withdraw or suspend approval of a drug product, including a designated medical gas deemed under this section to have in effect an approved application under section 505 or section 512 of this Act.

''(B) REVOCATION OF CERTIFICATION.—The Secretary may revoke the grant of a certification under paragraph (2) if the Secretary determines that the request for certification contains any material omission or falsification.

''(b) PRESCRIPTION REQUIREMENT.—

''(1) IN GENERAL.—A designated medical gas shall be subject to the requirements of section 503(b)(1) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such medical gas from the requirements of section 503(b)(1), the gas is approved for use without a prescription pursuant to an application under section 505 or 512, or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

''(2) OXYGEN.—

''(A) NO PRESCRIPTION REQUIRED FOR CERTAIN USES.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

''(i) For use in the event of depressurization or other environmental oxygen deficiency.

''(ii) For oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

''(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements of section 503(b)(4) shall be deemed to have been met if its labeling bears a warning that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

''SEC. 577. INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.

''A designated medical gas, alone or in combination with another designated gas or gases (as medically appropriate) deemed under section 576 to have in effect an approved application shall not be assessed fees under section 736(a) on the basis of such deemed approval.''.

SEC. 1112. CHANGES TO REGULATIONS.

(a) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public, shall—

(1) determine whether any changes to the Federal drug regulations are necessary for medical gases; and

(2) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding any such changes.

(b) REGULATIONS.—If the Secretary determines under subsection (a) that changes to the Federal drug regulations are necessary for medical gases, the Secretary shall issue final regulations revising the Federal drug regulations with respect to medical gases not later than 48 months after the date of the enactment of this Act.

(c) DEFINITIONS.—In this section:

(1) The term ''Federal drug regulations'' means regulations in title 21 of the Code of Federal Regulations pertaining to drugs.

(2) The term ''medical gas'' has the meaning given to such term in section 575 of the Federal Food, Drug, and Cosmetic Act, as added by section 1111 of this Act.

(3) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

SEC. 1113. RULES OF CONSTRUCTION.

Nothing in this subtitle and the amendments made by this subtitle applies with respect to—

(1) a drug that is approved prior to May 1, 2012, pursuant to an application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b);

(2) any gas listed in subparagraphs (A) through (G) of section 575(1) of the Federal Food, Drug, and Cosmetic Act, as added by section 1111 of this Act, or any combination of any such gases, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(A)(i) of such Act; and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512; or

(3) any designated medical gas added pursuant to subparagraph (H) of section 575(1) of such Act for an indication that—

(A) is not included in, or is different from, those originally added pursuant to subparagraph (H) of section 575(1) and section 576(a)(3)(A)(i)(VIII); and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

Subtitle C—Miscellaneous Provisions

SEC. 1121. GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

SEC. 1122. COMBATING PRESCRIPTION DRUG ABUSE.

(a) IN GENERAL.—To combat the significant rise in prescription drug abuse and the consequences of such abuse, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in coordination with other Federal agencies, as appropriate, shall review current Federal initiatives and identify gaps and opportunities with respect to—

(1) ensuring the safe use of prescription drugs with the potential for abuse; and

(2) the treatment of prescription drug dependance.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall post on the Department of Health and Human Service's Internet Web site a report on the findings of the review under subsection (a). Such report shall include findings and recommendations on—

(1) how best to leverage and build upon existing Federal and federally funded data sources, such as prescription drug monitoring program data and the sentinel initiative of the Food and Drug Administration under section 505(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool;

(2) how best to develop and disseminate widely best practices models and suggested standard requirements to States for achieving greater interoperability and effectiveness of prescription drug monitoring programs, especially with respect to provider participation, producing standardized data on adverse events, patient safety, and patient outcomes; and

(3) how best to develop provider, pharmacist, and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON ABUSE-DETERRENT PRODUCTS.—Not later than 6 months after the date of enactment of this Act, the Secretary shall promulgate guidance on the development of abuse-deterrent drug products.

SEC. 1123. OPTIMIZING GLOBAL CLINICAL TRIALS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 903 of this Act, is further amended by adding at the end the following:

''SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.

''(a) IN GENERAL.—The Secretary shall—

''(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world; and

''(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—

''(A) enhance medical product development;

''(B) facilitate the use of foreign data; and

''(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or nonclinical studies.

''(b) MEDICAL PRODUCT.—In this section, the term 'medical product' means a drug, as defined in subsection (g) of section 201, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

''(c) SAVINGS CLAUSE.—Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this Act.

''SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.

''(a) IN GENERAL.—In determining whether to approve, license, or clear a drug or device pursuant to an application submitted under this chapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug or device in the United States.

''(b) NOTICE TO SPONSOR.—If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug or device pursuant to an application submitted under this chapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.''.

SEC. 1124. ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH INNOVATION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement commitment letter transmitted by the Secretary to Congress on April 20, 2012, and shall—

(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisions throughout regulatory decisionmaking of the Food and Drug Administration with respect to medical products;

(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources toward such regulatory science priorities;

(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, licensure, or clearance of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies and methodologies in a safe and effective manner;

(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner; and

(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

(B) adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

(c) PERFORMANCE REPORTS.—The annual performance reports submitted to Congress under sections 736B(a) (as amended by section 104 of this Act), 738A(a) (as amended by section 204 of this Act), 744C(a) (as added by section 303 of this Act), and 744I(a) (as added by section 403 of this Act) of the Federal Food, Drug, and Cosmetic Act for each of fiscal years 2014 and 2016, shall include a report from the Secretary on the progress made with respect to—

(1) advancing the regulatory science priorities identified under paragraph (2) of subsection (b) and resolving the gaps identified under paragraph (3) of such subsection, including reporting on specific metrics identified under paragraph (4) of such subsection;

(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement transmitted by the Secretary to Congress on April 20, 2012.

(d) MEDICAL PRODUCT.—In this section, the term ''medical product'' means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

SEC. 1125. INFORMATION TECHNOLOGY.

(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) report to Congress on—

(A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or

purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

(C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

(D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

(2) develop—

(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and

(B) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

(b) GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a)(1)(A) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1)(A);

(2) the effectiveness of the comprehensive information technology strategic plan described in subsection (a)(1)(A), including the results-oriented goals and performance measures; and

(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.

SEC. 1126. NANOTECHNOLOGY.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or other statutes administered by the Food and Drug Administration, to address issues relevant to the regulation of those products, including the potential toxicology of such nanomaterials, the potential benefit of new therapies derived from nanotechnology, the effects of such nanomaterials on biological systems, and the interaction of such nanomaterials with biological systems.

(b) ACTIVITIES.—In conducting activities related to nanotechnology, the Secretary may—

(1) assess scientific literature and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to the Food and Drug Administration;

(2) in cooperation with other Federal agencies, develop and organize information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

(3) promote Food and Drug Administration programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

(4) promote and participate in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

(5) collect, synthesize, interpret, and disseminate scientific information and data related to the interactions of nanomaterials with biological systems;

(6) build scientific expertise on nanomaterials within the Food and Drug Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

(7) ensure ongoing training, as well as dissemination of new information within the centers of the Food and Drug Administration, and more broadly across the Food and Drug Administration, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

(8) encourage the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials; and

(9) carry out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

SEC. 1127. ONLINE PHARMACY REPORT TO CONGRESS.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes any problems posed by pharmacy Internet Web sites that violate Federal or State law, including—

(1) the methods by which Internet Web sites are used to sell prescription drugs in violation of Federal or State law or established industry standards;

(2) the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet Web sites;

(3) efforts by the Federal Government and State and local governments to investigate and prosecute the owners or operators of pharmacy Internet Web sites, to address the threats such Web sites pose, and to protect patients;

(4) the level of success that Federal, State, and local governments have experienced in investigating and prosecuting such cases;

(5) whether the law, as in effect on the date of the report, provides sufficient authorities to Federal, State, and local governments to investigate and prosecute the owners and operators of pharmacy Internet Web sites that violate Federal or State law or established industry standards;

(6) additional authorities that could assist Federal, State, and local governments in investigating and prosecuting the owners and operators of pharmacy Internet Web sites that violate Federal or State law or established industry standards;

(7) laws, policies, and activities that would educate consumers about how to distinguish pharmacy Internet Web sites that comply with Federal and State laws and established industry standards from those pharmacy Internet Web sites that do not comply with such laws and standards; and

(8) activities that private sector actors are taking to address the prevalence of illegitimate pharmacy Internet Web sites, and any policies to encourage further activities.

SEC. 1128. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

(1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;

(2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;

(3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;

(4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;

(5) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(6) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration; and

(7) barriers small businesses encounter in the drug and medical device approval process.

SEC. 1129. PROTECTIONS FOR THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Section 221(a) of the Public Health Service Act (42 U.S.C. 213a(a)) is amended by adding at the end the following:

''(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.''.

(b) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 213a(b)) is amended by adding at the end the following: ''For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.''.

SEC. 1130. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the- Counter Human Use; Delay of Compliance Dates'' (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use'' (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

SEC. 1131. STRATEGIC INTEGRATED MANAGEMENT PLAN.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Such strategic management plan shall—

(1) identify strategic institutional goals, priorities, and mechanisms to improve efficiency, for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health;

(2) describe the actions the Secretary will take to recruit, retain, train, and continue to develop the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to fulfill the public health mission of the Food and Drug Administration; and

(3) identify results-oriented, outcome-based measures that the Secretary will use to measure the progress of achieving the strategic goals, priorities, and mechanisms identified under paragraph (1) and the effectiveness of the actions

identified under paragraph (2), including metrics to ensure that managers and reviewers of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including new requirements under parts 2, 3, 7, and 8 of subchapter C of title VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.).

SEC. 1132. ASSESSMENT AND MODIFICATION OF REMS.

(a) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—Section 505–1(g) (21 U.S.C. 355–1(g)) is amended—

(1) in paragraph (1), by striking '', and propose a modification to,'';

(2) in paragraph (2)—

(A) in the matter before subparagraph (A)—

(i) by striking '', subject to paragraph (5),''; and

(ii) by striking '', and may propose a modification to,'';

(B) in subparagraph (C), by striking ''new safety or effectiveness information indicates that'' and all that follows and inserting the following: ''an assessment is needed to evaluate whether the approved strategy should be modified to—

''(i) ensure the benefits of the drug outweigh the risks of the drug; or

''(ii) minimize the burden on the health care delivery system of complying with the strategy.''; and

(C) by striking subparagraph (D);

(3) in paragraph (3), by striking ''for a drug shall include—'' and all that follows and inserting the following ''for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.''; and

(4) by amending paragraph (4) to read as follows:

''(4) MODIFICATION.—

''(A) ON INITIATIVE OF RESPONSIBLE PERSON.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, modification, or removal of any goal or element of the strategy.

''(B) ON INITIATIVE OF SECRETARY.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

''(i) ensure the benefits of the drug outweigh the risks of the drug; or

''(ii) minimize the burden on the health care delivery system of complying with the strategy.''.

(b) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS AND MODIFICATIONS OF APPROVED STRATEGIES.—Section 505–1(h) (21 U.S.C. 355–1(h)) is amended—

(1) in the subsection heading by inserting ''AND MODIFICATIONS'' after ''REVIEW OF ASSESSMENTS'';

(2) in paragraph (1)—

(A) by inserting ''and proposed modification to'' after ''under subsection (a) and each assessment of''; and

(B) by inserting '', and, if necessary, promptly initiate discussions with the responsible person about such proposed strategy, assessment, or modification'' after ''subsection (g)'';

(3) by striking paragraph (2);

(4) by redesignating paragraphs (3) through (9) as paragraphs (2) through (8), respectively;

(5) in paragraph (2), as redesignated by paragraph (4)—

(A) by amending subparagraph (A) to read as follows:

''(A) IN GENERAL.—

''(i) TIMEFRAME.—Unless the dispute resolution process described under paragraph (3) or (4) applies, and, except as provided in clause (ii) or clause (iii) below, the Secretary, in consultation with the offices described in subsection (c)(2), shall review and act on the proposed risk evaluation and mitigation strategy for a drug or any proposed modification to any required strategy within 180 days of receipt of the proposed strategy or modification.

''(ii) MINOR MODIFICATIONS.—The Secretary shall review and act on a proposed minor modification, as defined by the Secretary in guidance, within 60 days of receipt of such modification.

''(iii) REMS MODIFICATION DUE TO SAFETY LABEL CHANGES.—Not later than 60 days after the Secretary receives a proposed modification to an approved risk evaluation and mitigation strategy to conform the strategy to approved safety label changes, including safety labeling changes initiated by the sponsor in accordance with FDA regulatory requirements, or to a safety label change that the Secretary has directed the holder of the application to make pursuant to section 505(o)(4), the Secretary shall review and act on such proposed modification to the approved strategy.

''(iv) GUIDANCE.—The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.''; and

(B) by amending subparagraph (C) to read as follows:

''(C) PUBLIC AVAILABILITY.—Upon acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary shall make publicly available an action letter describing the actions taken by the Secretary under such subparagraph (A).'';

(6) in paragraph (4), as redesignated by paragraph (4)—

(A) in subparagraph (A)(i)—

(i) by striking ''Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the'' and inserting ''The''; and

(ii) by inserting '', after the sponsor is required to make a submission under subsection (a)(2) or (g),'' before ''request in writing''; and

(B) in subparagraph (I)—

(i) by striking clauses (i) and (ii); and

(ii) by striking ''if the Secretary—'' and inserting ''if the Secretary has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under subparagraphs (B), (F), and (G), respectively.'';

(7) in paragraph (5), as redesignated by paragraph (4)—

(A) in subparagraph (A), by striking ''any of subparagraphs (B) through (D)'' and inserting ''subparagraph (B) or (C)''; and

(B) in subparagraph (C), by striking ''paragraph (4) or (5)'' and inserting ''paragraph (3) or (4)''; and

(8) in paragraph (8), as redesignated by paragraph (4), by striking ''paragraphs (7) and (8)'' and inserting ''paragraphs (6) and (7).''.

(c) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance that, for purposes of section 505–1(h)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h)(2)(A)), describes the types of modifications to approved risk evaluation and mitigation strategies that shall be considered to be minor modifications of such strategies.

SEC. 1133. EXTENSION OF PERIOD FOR FIRST APPLICANT TO OBTAIN TENTATIVE APPROVAL WITHOUT FORFEITING 180-DAY-EXCLUSIVITY PERIOD.

(a) EXTENSION.—

(1) IN GENERAL.—If a first applicant files an application during the 30-month period ending on the date of enactment of this Act and such application initially contains a certification described in paragraph (2)(A)(vii)(IV) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), or if a first applicant files an application and the application is amended during such period to first contain such a certification, the phrase ''30 months'' in paragraph (5)(D)(i)(IV) of such section shall, with respect to such application, be read as meaning—

(A) during the period beginning on the date of enactment of this Act, and ending on September 30, 2015, ''40 months''; and

(B) during the period beginning on October 1, 2015, and ending on September 30, 2016, ''36 months''.

(2) CONFORMING AMENDMENT.—In the case of an application to which an extended period under paragraph (1) applies, the reference to the 30-month period under section 505(q)(1)(G) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1)(G)) shall be read to be the applicable period under paragraph (1).

(b) PERIOD FOR OBTAINING TENTATIVE APPROVAL OF CERTAIN APPLICATIONS.—If an application is filed on or before the date of enactment of this Act and such application is amended during the period beginning on the day after the date of enactment of this Act and ending on September 30, 2017, to first contain a certification described in paragraph (2)(A)(vii)(IV) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), the date of the filing of such amendment (rather than the date of the filing of such application) shall be treated as the beginning of the 30-month period described in paragraph (5)(D)(i)(IV) of such section 505(j).

(c) DEFINITIONS.—For the purposes of this section, the terms ''application'' and ''first applicant'' mean application and first applicant, as such terms are used in section 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)).

SEC. 1134. DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.

(a) IN GENERAL.—Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

''(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.''.

(b) APPLICATION.—The amendment made by subsection (a) shall apply to any petition that is submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), on or after the date of enactment of this Act.

SEC. 1135. FINAL AGENCY ACTION RELATING TO PETITIONS AND CIVIL ACTIONS.

Section 505(q) (21 U.S.C. 355(q)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by striking ''subsection (b)(2) or (j)'' and inserting ''subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act''; and

(B) in subparagraph (F), by striking ''180 days'' and inserting ''150 days'';

(2) in paragraph (2)(A)—

(A) in the subparagraph heading, by striking ''180'' and inserting ''150''; and

(B) in clause (i), by striking ''180-day'' and inserting ''150-day'';

(3) in paragraph (4)—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving such clauses, as so redesignated, 2 ems to the right;

(B) by striking ''This subsection does not apply to—'' and inserting the following:

''(A) This subsection does not apply to—''; and

(C) by adding at the end the following:

''(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.''; and

(4) in paragraph (5), by striking ''subsection (b)(2) or (j)'' inserting ''subsection (b)(2) or (j) of the Act or 351(k) of the Public Health Service Act''.

SEC. 1136. ELECTRONIC SUBMISSION OF APPLICATIONS.

Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is amended by inserting after section 745 the following:

''SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

''(a) DRUGS AND BIOLOGICS.—

''(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

''(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

''(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561.

''(b) DEVICES.—

''(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, presubmissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such presubmissions or submissions, shall include an electronic copy of such presubmissions or submissions.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide standards for the electronic copy required under such paragraph; and

''(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.''.

SEC. 1137. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 1123 of this Act, is further amended by adding at the end the following:

''SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION.

''(a) IN GENERAL.—The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

''(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

''(2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

''(b) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such laws, regulations, or policies would apply to consultation with individuals and organizations prior to the date of enactment of this section.

''(c) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

''(d) NO RIGHT OR OBLIGATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.

''(e) FINANCIAL INTEREST.—In this section, the term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.''.

SEC. 1138. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL SUBGROUPS.

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black-box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by health care professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEB SITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet Web site of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate Internet Web site, and seek public comment on the communication plan.

SEC. 1139. SCHEDULING OF HYDROCODONE.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, if practicable, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall hold a public meeting to solicit advice and recommendations to assist in conducting a scientific and medical evaluation in connection with a scheduling recommendation to the Drug Enforcement Administration regarding drug products containing hydrocodone, combined with other analgesics or as an antitussive.

(b) STAKEHOLDER INPUT.—In conducting the evaluation under subsection (a), the Secretary shall solicit input from a variety of stakeholders including patients, health care providers, harm prevention experts, the National Institute on Drug Abuse, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration regarding the health benefits and risks, including the potential for abuse and the impact of up-scheduling of these products.

(c) TRANSCRIPT.—The transcript of any public meeting conducted pursuant to this section shall be published on the Internet Web site of the Food and Drug Administration.

SEC. 1140. STUDY ON DRUG LABELING BY ELECTRONIC MEANS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the benefits and efficiencies of electronic patient labeling of prescription drugs, as a complete or partial substitute for patient labeling in paper form. The study shall address the implementation costs to the different levels of the distribution system, logistical barriers to utilizing a system of electronic patient labeling, and any anticipated public health impact of movement to electronic labeling.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall submit to Congress a report on the results of the study under subsection (a).

SEC. 1141. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(a) IN GENERAL.—The Secretary of Health and Human Services may facilitate, and, as appropriate, may consult with the Attorney General to facilitate, the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription drug information across State lines by States receiving grant funds under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748); and

(2) the Controlled Substance Monitoring Program established under section 399O of the Public Health Service Act (42 U.S.C. 280g–3).

(b) REQUIREMENTS.—The Secretary of Health and Human Services shall consider the following in facilitating the development of recommendations on interoperability of prescription drug monitoring programs under subsection (a)—

(1) open standards that are freely available, without cost and without restriction, in order to promote broad implementation;

(2) the use of exchange intermediaries, or hubs, as necessary to facilitate interstate interoperability by accommodating State-to-hub, hub-to-hub, and direct State-to-State communication;

(3) the support of transmissions that are fully secured as required, using industry standard methods of encryption, to ensure that protected health information and personally identifiable information are not compromised at any point during such transmission;

(4) access control methodologies to share protected information solely in accordance with State laws and regulations; and

(5) consider model interoperability standards developed by the Alliance of States with Prescription Monitoring Programs.

(c) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription drug monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs.

(2) CONTENTS.—The report required under paragraph (1) shall include—

(A) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability;

(B) a discussion of how State prescription drug monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases;

(C) any recommendations for addressing challenges that impact interoperability of State prescription drug monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs; and

(D) an assessment of the extent to which providers use prescription drug management programs in delivering care and preventing prescription drug abuse.

SEC. 1142. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Section 712 (21 U.S.C. 379d–1) is amended—

(1) by striking subsections (b) and (c) and inserting the following subsections:

''(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

''(1) IN GENERAL.—The Secretary shall—

''(A) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

''(B) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities;

''(C) at least every 180 days, request referrals for potential members of advisory committees from a variety of stakeholders, including—

''(i) product developers, patient groups, and disease advocacy organizations; and

''(ii) relevant—

''(I) professional societies;

''(II) medical societies;

''(III) academic organizations; and

''(IV) governmental organizations; and

''(D) in carrying out subparagraphs (A) and (B), take into account the levels of activity (including the numbers of annual meetings) and the numbers of vacancies of the advisory committees.

''(2) RECRUITMENT ACTIVITIES.—The recruitment activities under paragraph (1) may include—

''(A) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

''(B) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

''(C) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person whom the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

''(3) EXPERTISE.—In carrying out this subsection, the Secretary shall seek to ensure that the Secretary has access to the most current expert advice.

''(c) DISCLOSURE OF DETERMINATIONS AND CERTIFICATIONS.—Notwithstanding section 107(a)(2) of the Ethics in Government Act of 1978, the following shall apply:

''(1) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but (except as provided in paragraph (2)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, or a written certification as referred to in section 208(b)(3) of such title, applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Web site of the Food and Drug Administration—

''(A) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination or certification applies; and

''(B) the reasons of the Secretary for such determination or certification, including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.

''(2) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, or a written certification as referred to in section 208(b)(3) of such title applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 552a of title 5, United States Code) on the Internet Web site of the Food and Drug Administration, the information described in subparagraphs (A) and (B) of paragraph (1) as soon as practicable after the Secretary makes such determination or certification, but in no case later than the date of such meeting.'';

(2) in subsection (d), by striking ''subsection (c)(3)'' and inserting ''subsection (c)'';

(3) by amending subsection (e) to read as follows:

''(e) ANNUAL REPORT.—

''(1) IN GENERAL.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives, a report that describes—

''(A) with respect to the fiscal year that ended on September 30 of the previous year, the number of persons nominated for participation at meetings for each advisory committee, the number of persons so nominated, and willing to serve, the number of vacancies on each advisory committee, and the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

''(B) with respect to such year, the number of persons contacted for services as members for each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

''(C) with respect to such year, the number of members attending meetings for each advisory committee; and

''(D) with respect to such year, the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom such disclosures did not apply who served on such committee.

''(2) PUBLIC AVAILABILITY.—Not later than 30 days after submitting any report under paragraph (1) to the committees specified in such paragraph, the Secretary shall make each such report available to the public.'';

(4) in subsection (f), by striking ''shall review guidance'' and all that follows through the end of the subsection and inserting the following: ''shall—

''(1) review guidance of the Food and Drug Administration with respect to advisory committees regarding disclosure of conflicts of interest and the application of section 208 of title 18, United States Code; and

''(2) update such guidance as necessary to ensure that the Food and Drug Administration receives appropriate access to needed scientific expertise, with due consideration of the requirements of such section 208.''; and

(5) by adding at the end the following:

''(g) GUIDANCE ON REPORTED DISCLOSED FINANCIAL INTEREST OR INVOLVEMENT.—The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are disclosed under subsection (c) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18, United States Code for the purposes of participating in a particular matter.''.

(b) APPLICABILITY.—The amendments made by subsection (a) apply beginning on October 1, 2012.

SEC. 1143. NOTIFICATION OF FDA INTENT TO REGULATE LABORATORY-DEVELOPED TESTS.

(a) IN GENERAL.—The Food and Drug Administration may not issue any draft or final guidance on the regulation of laboratory-developed tests under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) without, at least 60 days prior to such issuance—

(1) notifying the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the Administration's intent to take such action; and

(2) including in such notification the anticipated details of such action.

(b) SUNSET.—Subsection (a) shall cease to have force or effect on the date that is 5 years after the date of enactment of this Act.

Subtitle D—Synthetic Drugs

SEC. 1151. SHORT TITLE.

This subtitle may be cited as the ''Synthetic Drug Abuse Prevention Act of 2012''.

SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In paragraph (1):

''(A) The term 'cannabimimetic agents' means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

''(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

''(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

''(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

''(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

''(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

''(B) Such term includes—

''(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

''(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

''(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

''(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

''(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

''(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

''(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

''(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

''(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

''(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

''(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

''(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

''(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

''(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

''(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).''.

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

''(18) 4-methylmethcathinone (Mephedrone).

''(19) 3,4-methylenedioxypyrovalerone (MDPV).

''(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).

''(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).

''(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).

''(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).

''(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).

''(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).

''(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).

''(27) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).

''(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).''.

SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY EXPANSION.

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C. 811(h)(2)) is amended—

(1) by striking ''one year'' and inserting ''2 years''; and

(2) by striking ''six months'' and inserting ''1 year''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. UPTON) and the gentleman from California (Mr. WAXMAN) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. UPTON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous material in the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. UPTON. Mr. Speaker, I yield myself 2 minutes.

Mr. Speaker, I want to thank Mr. WAXMAN, Chairman HARKIN, Senator ENZI, and Members on both sides of the aisle in both the House and the Senate who played a role in this process. S. 3187 is a reflection of the hard work put in by both Members and staff, and of everyone's willingness to put partisanship aside to look at the issues together. Because of that outstanding dedication, we have a bill today that will make a real difference in the lives of so many patients and provide much-needed support for innovators across our great country.

At the outset of this Congress, I set a goal of enacting this bill by the end of June—and here we are, well before the clock expires for this month—in order to provide certainty for American patients and innovators. I never lost confidence that we could deliver the bipartisan reforms we needed, and I am so proud that we will accomplish that goal.

Mr. Speaker, this is a jobs bill, and it's a medical innovation bill. And as we put this package together, our goal was to improve the predictability, consistency, transparency, and efficiency of FDA regulation. These reforms will help get new treatments to patients more quickly. They will help us not only keep jobs in Michigan and all across the country, but also to create new ones. In order to get it right, we turned to patients, innovators, and job creators who provided firsthand experience of how the current system is broken. And we included many of their suggestions in the bill.

This bill includes significant accountability and reform measures designed to hold the FDA responsible for its performance. The measure includes independent assessments of FDA's drug and device review process. It also includes requiring quarterly reporting from the device center so we don't have to wait a year to find out FDA's progress. The bill is about patients, and that's why so many patient advocates have spoken out in support of these reforms. Whether it is steps that we took to support treatments for rare diseases or mitigate drug shortages or speed up the approval of devices that will improve a patient's quality of life, these are steps that will make a real and significant difference.

□ 1430

They're going to keep the U.S. at the forefront of medical innovation where we belong.

This bill is just the first step. This bill provides the resources and the game plans so that FDA can improve its performance.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. UPTON. I yield myself an additional minute.

It is now up to the FDA to execute that game plan. And I give my commitment today that our committee will continue to monitor and hold the FDA accountable for its performance. So, together, the Members of the House and the Senate have produced a bill that is a win for American patients, innovation, and job creation.

Before I conclude, I would like to recognize Warren Burke and Megan Renfrew from the Legislative Counsel's Office for their tireless work. The role of Legislative Counsel often goes unnoticed. I also want to appreciate our staff, starting with our staff director, Gary Andres, for pushing this legislation over the finish line; Clay Alspach, on the majority staff; Rachel Sher, on the minority staff; and in particular, Ryan Long, the chief counsel for the Health Subcommittee.

This bill, when it becomes law, patients will benefit from faster, newer, and better treatments, and American workers will keep us on the cutting edge of medical innovation.

I reserve the balance of my time.

Mr. WAXMAN. Mr. Speaker, I yield myself 3 minutes.

Today, the House considers a bill that represents a significant bipartisan and bicameral achievement.

On May 30 of this year, the House passed its user fee legislation by a dramatic vote of 387–5. That bill was a strong one, but through our collaborative process with the Senate, we have made it even better.

It has been a pleasure to work not only with Mr. UPTON, Mr. PITTS, Mr. PALLONE, and Mr. DINGELL, among many involved House colleagues, but also with our Senate colleagues, Senators HARKIN and ENZI.

When we began this process, there were divergent views on the various issues contained in this bill. But we worked together and found ways to bridge our differences in a fashion that protects patients and fosters innovation.

This legislation contains many provisions that are critical to the functioning of major parts of the FDA. We reauthorize the FDA's drug and medical device user fee programs which will provide resources to enable the efficient review of applications and give patients rapid access to new therapies. We're also reauthorizing two pediatric programs which foster the development and safe use of prescription drugs in children.

This year, we're establishing two new programs to help the FDA speed up their review of new generics and biosimilars. These provisions illustrate our bipartisan commitment to ensuring a vibrant generic marketplace. All

of us will see the benefits when more low-cost generics are on the market.

One of the most important improvements to the House-passed bill is in the area of antibiotics. We accepted the Senate language that directs incentives for the development of antibiotics toward serious and life-threatening infections.

This bill also includes provisions to modernize FDA's authorities with respect to the drug supply chain. Today, 80 percent of active ingredients and bulk chemicals used in U.S. drugs come from abroad and 40 percent of finished drugs are manufactured abroad. FDA has been trying to keep pace with this increasingly globalized drug supply change using an outdated statute. This legislation will give the FDA critical new tools to police this dramatically different marketplace.

We have also worked to address the area of drug shortages, which is a complex and multifaceted problem, but this legislation takes some sensible first steps.

I want to thank my colleagues on both sides of the aisle and their staffs for the hard work they've put into making this a strong bipartisan bill. I particularly want to thank Mr. PALLONE and Mr. DINGELL's staff members, Tiffany Guarascio and Kim Trzeciak, as well as Mr. UPTON and Mr. PITT'S staff, Ryan Long and Clay Alspach.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. WAXMAN. I yield myself an additional 30 seconds.

Warren Burke and Megan Renfrew have done tremendous work on this bill. I'd like to express my appreciation for their efforts. I want to thank my own staff: Karen Nelson, Rachel Sher, Eric Flamm, and Arun Patel.

The American public will benefit from the provisions of this bill. The FDA will have the resources to remain the gold standard for the future. This is an important bill, a good one. I urge its support.

I reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the chairman emeritus of the Energy and Commerce Committee, the gentleman from Texas (Mr. BARTON).

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks.)

Mr. BARTON of Texas. I thank the distinguished chairman.

Mr. Speaker, I rise in strong support of this bill. When the American public asks, ''Why can't Congress just work together?'' we should hold this bill up as Exhibit A that it is possible.

As the ranking member just pointed out, this is a bipartisan, bicameral preconference agreement for a very complicated bill. We reauthorize the Food and Drug Administration user fee program for 5 years. We also reauthorize the medical device user fee program for 5 years, and, I believe for the first time, do one for generic and biosimilars. This is a complicated, complex piece of legislation, but it has been worked out in a bipartisan agreement.

I have had some concerns about the extent and the cost of the user fees. I will continue to monitor that, Mr. Speaker. But this is a good piece of legislation. The chairman and ranking member and the subcommittee chairman and ranking member and all the others who have worked on this should be commended. This is an excellent bill, and I hope that the Congress will unanimously support it and the Senate will agree when we send it to the other body.

Mr. WAXMAN. Mr. Speaker, at this time, I'd like to yield 3 minutes to the gentleman from New Jersey (Mr. PALLONE), the ranking member of the Health Subcommittee, the subcommittee that was responsible for this legislation in its first instance.

I ask unanimous consent that Mr. PALLONE be permitted to manage the rest of the time on our side of the aisle.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. PALLONE. Thank you, Chairman WAXMAN.

I want to say I'm very proud to support the bill before us, which would reauthorize and revitalize a number of different programs at the FDA.

This bill really represents a great compromise between the House and the Senate and strikes the right balance by including strong provisions that will be good for both innovation and patient safety.

When we passed the House version of this bill, I spoke highly of a great cordial process, and I'm happy to be able to echo those sentiments again here today. This process should be a model for congressional bipartisan cooperation in the future. Not only did we all work so well together, staffs were able to rectify the differences among the two Chambers' versions of the bill in a matter of 2 weeks. That's commendable. It's a clear indication that Congress is certainly capable of greatness if we just allow ourselves to set politics aside and simply legislate.

I want to thank Chairman UPTON and Ranking Member WAXMAN for your leadership. And to all the staff who worked around the clock—and of course particularly Tiffany Guarascio, who is my staff person—they were all dedicated to achieving a comprehensive and consensus product, and they've done just that.

The bill before us today provides the FDA with more than $6 billion over 5 years to pay for the timely and efficient reviews of medical products. Together, these agreements will ensure that Americans have access to safe and effective new medicines and medical devices. It will reduce the drug costs for consumers by speeding the approval of lower cost generic drugs with the establishment of a new user fee program for generic drugs and for lower cost versions of biotech drugs as well.

It also includes promising provisions that address the safety of the supply chain, help to foster the development and safe use of prescription drugs for children, increase efforts to address drug shortages, change conflict of interest rules so that the FDA has access to the best expertise on their advisory panels, and other provisions which are important to the pubic health of our Nation.

This bill is good for the FDA; it's good for industry; it's good for patients alike. I'm confident we will pass this critical bill overwhelmingly today and that the Senate will act early next week so we can send it to the President for his signature as soon as possible.

I urge all Members to support this bill, and I reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the distinguished chairman of the Health Subcommittee, the gentleman from Pennsylvania (Mr. PITTS).

Mr. PITTS. Mr. Speaker, I stand to strongly support this legislation.

This bipartisan agreement represents over 18 months of work from the Energy and Commerce Health Subcommittee, and I'm especially proud and appreciative of the hard work of Ryan Long and Clay Alspach for their diligent and tireless efforts in helping to make this bill possible.

The FDA Safety and Innovation Act is critical to saving lives, improving regulatory operations, and sustaining a vital and dynamic American industry.

□ 1440

American companies are the leading developers of new medical devices and drugs to save and sustain life. To ensure that products are both safe and effective, we've tasked the Food and Drug Administration with reviewing products before they make their way into the market, and this is a critical responsibility.

The device and drug industries are dynamic and innovative. Companies spend hundreds of millions of dollars and years of research and work to develop products. The review stage is a critical time for any company. Inconsistent reviews mean that the true cost of developing new products is hidden, making it difficult to properly prepare.

When our Health Subcommittee began considering this legislation last year, we heard from a number of individuals about the increasing difficulty of working through the review process. American patients were waiting almost 4 years longer for new devices that had already been approved in Europe. And despite the slower U.S. review process, the safety outcomes were comparable.

The FDA Safety and Innovation Act contains important reforms to the Medical Device User Fee Act and will hold the FDA accountable and keep reviews on schedule. There are many reforms in this bill.

Finally, we include language to help patients and doctors and hospitals deal with drug shortages. Mr. Speaker, I'm

proud of the work we've done. I'm proud that we have such a bipartisan effort.

I'd like to especially thank Ranking Member FRANK PALLONE and his staff for patiently working with us, for Mr. DINGELL, Mr. WAXMAN. We've accomplished much with this legislation, and it will help save lives, create jobs—two goals that we can all agree on. Thanks to our chairman, Mr. UPTON.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to our chairman emeritus, the gentleman from Michigan (Mr. DINGELL), who worked so hard on this bill, particularly with regard to the safety provisions.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Mr. Speaker, this is a good bill. I urge my colleagues to support it. I rise in strong support of it, and I urge my colleagues to join.

This legislation enjoys broad bipartisan support on both sides of the Capitol and from industry and patient groups. We should also be proud of the work we have done to get it here today.

I would observe that it has been done because the Members worked together in the finest traditions of this body. And I'm also proud of the work that my colleagues on the committee and the staff have done on this matter. I was pleased to work with them to include strong upstream drug supply chain provisions, something that's been a long priority of mine.

I'm also pleased that, for the first time, commercial importers will be required to register, so we'll know who's bringing what in and whether it's safe or not. There will also be parity between inspections of domestic and foreign drug facilities, something which is a major problem because foreign facilities and foreign manufacturers now import much into this country, much of which is unsafe and improperly inspected.

FDA will be able to maintain a practice in which they will detain and destruct counterfeit drugs and those which are unsafe or intentionally or otherwise adulterated, and they will be able to impose increased penalties on those who adulterate these drugs and pharmaceuticals.

These provisions, which mirror safety provisions in my drug safety bill, will equip FDA with the authorities it needs to better oversee our increasingly globalized drug supply chain and will give American families comfort that the pharmaceuticals that they are taking are safe, and help to deter and to respond to any future heparin-like incidents which killed some 80 Americans and hurt thousands more.

While I am disappointed we were unable to come forward with a consensus on a national track-and-trace standard, it's my hope that we will continue to work on this in coming days. And I want to commend my colleagues, Mr. MATHESON and Mr. BILBRAY, for the fine work they have done on this matter.

I've also been working on this issue for many years, and we've come closer than ever before to finding a consensus. Given additional time, I think we could have resolved this issue; but because of time pressures, we were not able to.

I also want to thank my friends, Mr. UPTON, Mr. HARKIN, Ranking Members WAXMAN and ENZI, and their staff for the hard work they did to send this critical bill to the President before July 4. I also want to thank Kimberly Trzeciak of my staff for her diligence on the supply chain provisions and other matters.

I urge my colleagues to support this bill. It will be something of which we will be proud. It will confer much safety on the American people in areas of very substantial danger; and it will see to it that, to a modest degree at least, the industry-supported provisions, including those which involved the collection of fees, will begin to work for the benefit of the American people.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the gentleman from Texas (Mr. BURGESS), the distinguished vice chair of the Health Subcommittee.

Mr. BURGESS. I thank the chairman for yielding and the Speaker for the recognition.

Today, we are considering the Food and Drug Administration's Safety Innovation Act, and I urge my colleagues to support it. This bill reauthorizes Food and Drug Administration's user fee programs. The bill will allow industry to continue to partner in providing our physicians the tools they need to prevent and alleviate human suffering.

The legislation retains significant reforms that were made in our House bill and enhances other provisions, such as those on drug shortages. The bill will ensure that the Food and Drug Administration has the scientific and medical expertise they need when reviewing products utilizing emerging science, or for those populations with very rare diseases.

This bill will spur innovation for antibiotics, will help those with rare diseases, and be particularly helpful to the community of physicians that takes care of our pediatric cancer patients.

The Food and Drug Administration is now required to notify Congress before issuing guidance regarding the regulation of laboratory-developed tests. I still believe we should strengthen and improve CLIA's oversight of laboratory-developed tests, instead of even contemplating any type of duplicative regulation.

The bill avoids provisions added by the other Chamber that I thought crossed the line into the practice of medicine by Congress and actually threatened patient treatment. It will address numerous other issues to enhance the work of the FDA, while correcting missteps of the Agency in such areas as public input, good guidance practices, and the manufacture of custom devices.

The process to this vote from the very beginning was respectful and resulted from hundreds of hours of negotiations. Chairman UPTON, thank you, and Chairman PITTS, Ranking Members WAXMAN and PALLONE. I specifically want to thank Ryan Long and Clay Alspach on the staff of the majority who sacrificed much to get this product to the floor today.

This vote is really about patients who will be served by the passage of this bill, and I urge its expeditious passage.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Colorado (Ms. DEGETTE), who worked very hard on the drug shortage provisions of the legislation.

Ms. DEGETTE. Mr. Speaker, I'm delighted to support this bipartisan legislation which addresses critical problems affecting the safety of drugs and medical devices in this country. There are several highlights I'd like to talk about, like Dr. GINGREY's incentives for antibiotic development, or the supply chain legislation that Mr. DINGELL has worked on tirelessly for years.

But there's one issue that I've been working on on a bipartisan basis throughout this Congress that I want to discuss briefly. Drug shortages have rattled our hospitals, our doctors, and our families. Figures recently released by the University of Utah show there were 56 more newly reported drug shortages in the U.S. last year than in 2010 when there were 211.

So, again, let me say 211 drugs in shortage. How can this be happening, and what can we do about it?

Representative TOM ROONEY from Florida and I introduced the bipartisan Preserving Access to Life-Saving Medications Act, which eventually had 85 cosponsors. The bill creates an early warning system between the FDA, drug companies, and providers so a community can respond to a drug shortage quickly and efficiently. It won't solve the root problems of the drug shortage crisis, but it will help providers and doctors and hospitals identify those crises and help with the patient.

This February, for example, under a voluntary program, the FDA stepped in to allow for temporary emergency importation of the cancer drug, Doxil, which was in shortage. And at the same time, the FDA prioritized the review of a new manufacturer of the same drug when the cancer drug went into shortage.

So what our bill will do is make this program mandatory. What we think it will do is it will help patients across the spectrum get the drugs they need. It will help the hospitals and the providers identify potential shortages, and it will help the manufacturers better make sure that they get the drugs to the patients that need them.

I'm thrilled that this is contained, and I want to thank the chairman.

□ 1450

Mr. UPTON. Mr. Speaker, I yield 1 minute to the distinguished gentleman from Florida (Mr. STEARNS).

Mr. STEARNS. My colleagues, this reauthorization of the FDA's user fees will provide stability for the FDA's new product review as companies submit new and innovative drugs, medical devices, and biologics for approval.

I am especially proud that my bill, the Faster Access to Specialized Treatments, H.R. 4132, FAST, was included in the FDA Reform Act. FAST modernizes the FDA's accelerated approval pathway to reflect scientific developments that have occurred over the past 20 years. This will allow for new drugs for people suffering from rare diseases. There are 30 million Americans suffering from one of over 7,000 rare diseases, but only 250 currently have any treatment. FAST will save lives.

I am pleased also that the bill includes the EXPERRT Act, H.R. 4156. This will help the FDA consult with medical experts when evaluating drugs designed for rare diseases, such as cystic fibrosis. As the cofounder of the Cystic Fibrosis Caucus, I am glad we are finally providing this tool to the FDA.

I obviously support the passage of this bill.

Mr. Speaker, the Food and Drug Administration Safety and Innovation Act (S. 3187) is based on user fee negotiations between FDA and the prescription drug, generic drug, biologic, and medical device industry. This reauthorization of the FDA user fees will provide stability with FDA's new product review as companies submit new and innovative devices and drugs for approval.

This bill is the result of hard work and negotiations between industry and FDA, and the hard work between Republicans and Democrats, and between the House and the Senate. This bill is a true bipartisan, bicameral bill that will serve the American people well.

In codifying the User Fee Agreement, this committee has included additional provisions designed to address some of the defects of the regulatory structure and overreach by the FDA. Under my Chairmanship of the Oversight and Investigation Subcommittee, we held a hearing into FDA's regulatory efforts in the medical device space. During our hearing, many of the witnesses talked about the reluctance of FDA to approve devices and how FDA continually moved the goalposts for approval. I am glad that Title VI of this bill includes a significant number of reform provisions designed to bring certainty to the medical device field.

In addition to reforming approaches to medical devices through Title VI, the FDA's approach to rare diseases must also be modernized.

I want to take this opportunity to thank Dr. Emil Kakkis, Julia Jenkins, Harry Sporidis, Tim Perrin, Steve Stranne, everyone at the EveryLife Foundation for Rare Diseases, Pat Furlong, Nick Manetto, everyone at the Parent Project Muscular Dystrophy, and the other 150 rare disease groups that supported FAST and ULTRA. In 2011, I met with Dr. Kakkis who introduced me to two parents who had children with rare diseases and limited options as most rare diseases do not have treatments. One parent talked about his frustration at not having any treatments, except for a drug trial happening in Europe, not the United States. We talked about how we need FDA to properly address the issue of drug approval for the rare disease community, which led to examining the Accelerated Approval pathway and trying to modernize it. We developed the Unlocking Lifesaving Treatments for Rare-Diseases Act (ULTRA, H.R. 3737), which I introduced with my friend and colleague, Rep. ED TOWNS, to nudge the FDA into using Accelerated Approval for rare diseases.

However, after further review of the law, FDA's history of usage of Accelerated Approval and the feedback we received from stakeholders, we realized that amending the law was not sufficient. Instead, we worked with all the stakeholders to rewrite the entirety of the Accelerated Approval statute. In March, Representative TOWNS and I introduced the Faster Access to Specialized Treatments Act (FAST, H.R. 4132). FAST updates and modernizes Section 506 of the Food, Drug & Cosmetic Act, and updates the Accelerated Approval statute to reflect two decades worth of medical sciences that has occurred since Accelerated Approval was first created. FAST will help FDA implement broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases by using modern scientific tools.

The use of surrogate endpoints may result in fewer, smaller or shorter clinical trials without compromising FDA's existing high standards for safety or efficacy. Surrogate and clinical endpoints only need to be reasonable predictors of clinical benefit to support accelerated approval. They do not need to be validated or proven first. The changes made to current law permitting the Secretary to require validation of surrogates following accelerated approval is not intended to change FDA's long history of granting accelerated approval based on unvalidated, but predictive, surrogate endpoints.

Additionally, FAST includes explicit language for FDA to think about the challenges of rare diseases when developing their guidance and gives the rare disease community an opportunity to publically comment on FDA's draft guidance. FAST ensures that the voices of the 30 million Americans with a rare disease will be heard by FDA. There are about 7,000 rare diseases and only about 250 have any treatment. FAST will save lives, and give a voice to the voiceless; and I am glad it is in the final bill.

Lastly, the committee included the Expanding and Promoting Expertise in Review of Rare Treatments, (EXPERRT Act, H.R. 4156), a bill my fellow Co-Chairs of the Cystic Fibrosis Caucus and I introduced. EXPERRT will have the FDA consult with experts in rare diseases. This will ensure that FDA has access to the knowledge needed when dealing with drug approvals for diseases where FDA may lack subject matter expertise. As one of the Co-Founders of the Cystic Fibrosis Caucus, I am glad that we are giving this tool to the FDA. I also want to thank Stephanie Krenrich and the Cystic Fibrosis Foundation for all their hard work in developing EXPERRT.

I would like to submit these letters from the EveryLife Foundation for Rare Diseases and the Parent Project Muscular Dystrophy into the RECORD.

S. 3187 is a good bill that will help new drugs and new medicines get into the market and be available to patients. I support passage of the FDA Safety and Innovation Act.

PARENT PROJECT
MUSCULAR DYSTROPHY,
Hackensack, NJ, June 20, 2012.

Hon. CLIFF STEARNS,
U.S. Congress, Washington, DC.
Rayburn House Office Building,

DEAR REPRESENTATIVE STEARNS: On behalf of all patients and families living with Duchenne muscular dystrophy—the most common form of muscular dystrophy and the most common lethal genetic condition diagnosed in childhood—Parent Project Muscular Dystrophy (PPMD) would like to express its deep gratitude for your efforts to include provisions of deep interest to the rare disease community in S. 3187, the Food and Drug Administration Safety and Innovation Act. The final user fee reconciliation package between the House of Representatives and Senate includes a number of measures that will accelerate the Food and Drug Administration (FDA) process of reviewing potential therapies for serious life-threatening conditions like Duchenne, will ensure that the patient voice has a seat at the table when key decisions are made, and will incent industry to develop treatments for pediatric rare diseases.

As you know, Duchenne muscular dystrophy exemplifies the challenges faced by many patients and families afflicted by rare diseases. It is a fatal condition with most patients not living past their late 20s, and the only approved therapies are steroids, which cause significant complications long-term. With nearly 20 potential therapies in various stages of clinical trials, our community is hopeful that better times are ahead, and we recognize that a more efficient FDA attuned to the needs of the rare disease patient population is critical to our success. Again, we are most appreciative of your efforts to ensure that the above mentioned provisions were included in the final legislation. On behalf of Duchenne and the broader rare disease community, thank you for your leadership and support.

Sincerely,

PAT FURLONG,
Founding President and CEO.

EVERYLIFE FOUNDATION
FOR RARE DISEASES,
Novato, CA, June 19, 2012.

Hon. CLIFF STEARNS,
House of Representatives, Rayburn House Office Building, Washington, DC.
Hon. EDOLPHUS TOWNS,
House of Representatives, Rayburn House Office Building, Washington, DC.

DEAR REPRESENTATIVES STEARNS AND TOWNS: On behalf of the EveryLife Foundation for Rare Diseases and our 180 patient organization partners, thank you for championing the FAST Act which is included in The Food and Drug Administration Safety and Innovation Act, S. 3187. This essential legislation will improve access to the Accelerated Approval pathway for rare diseases and spur the development of lifesaving treatments.

Currently, there are fewer than 400 approved treatments for 7,000 rare diseases affecting more than 30 million Americans. Without a treatment, diagnosis of a rare disease can be a death sentence for these patients, many of whom are young children. The science exists for many of these diseases to be treated, and the inclusion of this legislation will provide a more predictable development and regulatory pathway to unlock the investment potential for rare disease treatments.

The language from the FAST Act will fix a ''catch–22'' that prevents very rare diseases

from accessing the Accelerated Approval pathway. We applaud you both for your tremendous leadership in ensuring that this essential provision be included in the FDA user fee legislation. This provision provides FDA the ability to utilize all the tools available to them to help bring new drugs to market to treat rare and ultra-rare diseases while maintaining the FDA's strong safety and efficacy standards. Access to the Accelerated Approval pathway will significantly decrease the time and cost to develop a treatment and has been extremely successful in getting treatments approved for cancer and AIDS patients. Additionally, this provision has an added benefit of promoting private investment in new biotechnology companies and job growth in the United States.

We thank you for your strong commitment to accelerating the delivery of safe and effective therapies to patients in need. We also would like to thank the more than 200 patient organizations including Parent Project Muscular Dystrophy, and the thousands of patient advocates who worked to support this legislation. Passage of this legislation is testament of perseverance of the rare disease community and the commitment of the Congress to promote the development of life-saving treatments.

Sincerely,

EMIL KAKKIS,
President.

Mr. PALLONE. Mr. Speaker, I yield 1½ minutes to the gentlewoman from California (Mrs. CAPPS).

Mrs. CAPPS. I thank my colleague for yielding.

Mr. Speaker, I rise today in strong support of the FDA Safety and Innovation Act. This bipartisan effort will improve the health and safety of the American people; and at the same time, it will support good jobs and innovation in the health care industry. I am especially pleased that this bill includes two provisions which I authored:

The first is modeled on my SAFE Devices Act, which will improve the postmarket surveillance of medical devices and the implementation of the unique device identifier program. This essential provision will allow us to identify potential device problems early, thereby protecting patients and identifying issues when they are easier and less costly to address;

The second provision I authored comes from my bipartisan HEART for Women Act, which the House has passed two times. It requires the FDA to report on the availability of new drug and device safety and efficacy data by sex, age, and racial and ethnic subgroups. Drugs and devices can have dissimilar effects among various populations, and this provision will help reduce substantial disparities in health care, especially for women and minorities.

So I thank the chairmen and ranking members for their leadership on the FDA Safety and Innovation Act and for their support of these two provisions. I urge my colleagues to support this bipartisan bill.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the distinguished gentlewoman from North Carolina, the vice chair of the Energy and Commerce Committee, Mrs. MYRICK.

Mrs. MYRICK. Thank you, Mr. Chairman.

The bill before us contains critical improvements to the current law. Among them is the creation of a priority review voucher program for companies that develop treatments for rare pediatric diseases. I am pleased with this and other advances.

Yet the long-term success or failure of crucial drug and device approvals doesn't just depend on approving new funds and guidelines for the FDA. It also depends on instilling a culture at the FDA that seeks out practical solutions to the diseases that our constituents face. The FDA must recognize that patients, especially those with fatal illnesses, deserve to have potential treatments made available.

Whenever possible, the FDA should use all the tools it has available to appropriately warn doctors and patients of risks associated with a treatment without removing patient access. Patients facing fatal diagnoses, whether it's metastatic cancer, ALS or others, should be given the benefit of the doubt unless treatments are very risky. This should be a guiding principle of the FDA and not simply a consideration.

I urge the support of the bill.

Mr. PALLONE. Mr. Speaker, I yield 1 minute to the gentleman from New York (Mr. ENGEL).

Mr. ENGEL. I thank my friend for yielding to me.

I rise in strong support of S. 3187, the Food and Drug Administration Safety and Innovation Act of 2012.

This is one of these rare occasions these days when Congress is working in a bipartisan manner to get good things done. This bipartisan, bicameral agreement is something of which we can all be proud; and it is a prime example, again, of the good legislative work that can be done by this body when compromises are accepted.

In particular, I would like to thank the chairmen and ranking members of the full Energy and Commerce Committee and of the Health Subcommittee for their hard work to finalize this bill in such a timely manner. I would also like to thank them for including the reauthorization of the Critical Path Public-Private Partnerships in this legislation, something for which I pushed for a long time so that needed improvements in regulatory science can continue.

I believe this bill will help meet the needs of the FDA industry and, most importantly, of the patients. I look forward to its passage.

Mr. UPTON. I yield 1 minute to the distinguished gentleman from Pennsylvania, Dr. MURPHY.

Mr. MURPHY of Pennsylvania. Mr. Speaker, what good are life-saving drugs if you can't afford them?

That's why real reform of the Nation's health care system begins with promoting quality and affordability. I am excited this legislation is moving forward because the FDA will finally have a system for bringing more life-saving generic drugs to market.

Today's bill authorizes the first generic drug user-fee program in order to expedite the approval of generics, which are only a fraction of the cost of brand-name drugs. Generic medications can save a patient $1,000 a year on medication alone, but it may well yield billions in savings across our Nation when affordable generic drugs are used to treat acute and chronic illness. Right now, consumers are spending millions, if not billions, more in out-of-pocket costs because the FDA doesn't have the resources to tackle 2,800 generic applications awaiting review.

There will be fewer strokes, heart attacks, and cases of cardiovascular disease when this bill moves forward into law, and we will be assured the medicines our families take are of the highest quality. Under this bill, regulators will no longer be able to look past China's history of tainted drugs, like the 2007 heparin scare that killed 200 people.

I would like to thank Congressmen DINGELL and WAXMAN and Chairman UPTON for moving forward with this bipartisan bill. I urge its adoption.

Mr. PALLONE. Mr. Speaker, I inquire of how much time remains on both sides.

The SPEAKER pro tempore. The gentleman from New Jersey has 6½ minutes remaining, and the gentleman from Michigan has 9 minutes remaining.

Mr. PALLONE. I now yield 1½ minutes to the gentleman from North Carolina (Mr. BUTTERFIELD).

Mr. BUTTERFIELD. Let me thank you, Mr. PALLONE, for yielding the time, and I thank you so very much for your leadership on the Health Subcommittee. You do extraordinary work on our committee.

Mr. Speaker, I rise today in support of S. 3187, the amended version of the Food and Drug Administration Safety and Innovation Act. I strongly support this bill, and I am particularly pleased that the intent of H.R. 3059, the Creating Hope Act, sponsored by my good friend from Texas (Mr. MCCAUL) and myself, was included in the final bill.

I am thrilled to highlight section 908, the Rare Pediatric Disease Priority Review Voucher Incentive program. The program will incentivize pharmaceutical companies to develop new drugs for children with rare pediatric diseases, such as childhood cancers and sickle cell disease, by expanding the cost-neutral priority review voucher program. Expanding the voucher program will allow pharmaceutical companies to expedite the FDA review of more profitable drugs in return for developing treatments for rare pediatric diseases. I think that is a good trade-off.

I would like to thank Mr. MCCAUL, Mr. WAXMAN, Mrs. MYRICK, and all of those who have worked on this bill with us. I want to thank our Senate colleagues, Messrs. CASEY and BROWN, for working diligently with me and our

colleagues to see to its inclusion. Finally, I want to recognize Nancy Goodman, with Kids Versus Cancer, who continues to be a tireless advocate for this issue.

Mr. UPTON. Mr. Speaker, I yield 1 minute to a member of the committee, the distinguished gentleman from California (Mr. BILBRAY).

Mr. BILBRAY. Mr. Speaker, I stand in support of this bill.

I want to thank Chairman UPTON and the leadership on both sides of the aisle for getting together and doing what's right for the American people.

In this time that we talk about economic strife, we've got to remember that the FDA can be a friend or an enemy of not only our health but also of our jobs and our economic opportunities. In California alone, Mr. Speaker, we have over 267 people working in the pharmaceutical industry.

□ 1500

We have over 42,000 just working in San Diego County.

This bill will not only help to protect jobs, but this bill is a bipartisan bill to save lives. What better message can we send to the American people than Washington is listening to the fact that they want bipartisan support and bipartisan efforts and bipartisan successes on things that matter?

This bill is something that matters. We're talking about preserving the economic opportunities of our fellow citizens, and we're talking about saving the lives of our family members and our neighbors.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from Massachusetts (Mr. MARKEY).

Mr. MARKEY. I would like to thank Chairman UPTON and Chairman PITTS and Ranking Member WAXMAN and Ranking Member PALLONE and their staffs for their work in bringing the FDA Safety and Innovation Act to the floor today.

Passing this bill will allow the FDA to continue its critical mission of bringing safe and effective drugs and medical devices to the patients who need them. Reviewing drug and device applications has become increasingly challenging. Medical breakthroughs of today often target rare diseases or genetic subsets of those diseases. FDA reviewers must now assess a growing pipeline of very specialized treatments.

I'm pleased that this bill includes language I helped author to improve collaboration between FDA and external experts in rare diseases like cystic fibrosis and sickle cell disease.

The bill before us today also includes an important provision I helped author to ensure that the millions of Americans who are blind or visually impaired have safe and independent access to the information on prescription drug labels. No one should have to sacrifice their privacy or independence to access the vital information on these bottles, and I'm glad we're taking steps to address that here today.

Finally, this bill helps increase the availability of pediatric medical devices and ensures that medications are tested and labeled appropriately for children. I was proud to work on these provisions with my colleagues, Congresswoman ESHOO and Congressman ROGERS.

I would have liked to have seen additional measures included in this bill to ensure the safety of medical devices based on defective models that have already been approved by the FDA, that unfortunately continue to be sold and jeopardize patients' health all across this country. I am going to continue to work on this critical issue. I believe it's a problem that we must solve. Once the FDA approves a device and then it turns out that there's a defect, there should be no excuse for allowing new companies to build their devices based upon the old approved defective model that the FDA had approved. Tens of thousands of Americans are put in jeopardy, and I would like to work to solve that problem.

Nonetheless, this is an excellent piece of legislation, and I hope that the House gives it its overwhelming approval.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the distinguished gentleman from Georgia, Dr. GINGREY, a member of the committee.

Mr. GINGREY of Georgia. Mr. Speaker, I thank the gentleman for yielding.

The FDA Safety and Innovation Act of 2012 may not be a great bill, but it is a darn good bill. And as a physician and a member of the Energy and Commerce Committee, I strongly support it.

As my colleagues have said on both sides, this is a bicameral, bipartisan piece of legislation, and yes, we can get our work done. I want to particularly thank Chairman UPTON, Ranking Member WAXMAN, Health Subcommittee Chairman PITTS, Ranking Member PALLONE, and all of the Members that have worked so hard on this really vast, huge bill that covers a lot of things, not the least of which, of course, is to provide 65 percent of the funding for the FDA so they can, indeed, hire the best and brightest scientists so they get their work done in a timely manner, get new drugs to the market, medical devices, and bottom line, keep the health care system in this country the best in the world for our constituents and our patients.

Mr. Speaker, I want to mention one particular aspect of the bill that I was very much involved in, and that's this issue of antibiotic shortage. The bill as it stood alone was called the GAIN Act, and I had a tremendous amount of help on both sides of the aisle. On the Democratic side, there was Congresswoman ESHOO, Congresswoman DEGETTE, and Congressman GENE GREEN. On my side of the aisle, there was MIKE ROGERS of Michigan, Mr. SHIMKUS, and Mr. WHITFIELD. What we do with that portion of the bill is to provide an opportunity for the manufacturers of antibiotics to have an additional 5 years of exclusivity so they can bring these innovative fifth- and sixth-generation antibiotics to the market and still have an opportunity to recoup the investment and the expense of doing so.

I want to just say to my colleagues on both sides of the aisle, it's a proud day, I think, for all of us, for Chairman Emeritus DINGELL, the former chairman on our side of the aisle, Mr. BARTON, and everybody involved in this bill. I thank all of you. Let's all unanimously support this bill.

Mr. PALLONE. Mr. Speaker, I have no additional speakers, so I will reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from New Jersey (Mr. LANCE), a member of the committee.

Mr. LANCE. Thank you, Mr. Chairman.

Mr. Speaker, such legislation will ensure that patients get improved access to innovative, lifesaving therapies and medical devices while protecting and creating U.S. jobs. The bill is critically important to New Jersey, where we have a high concentration of medical device, pharmaceutical, and life science employees.

I'm pleased that the conference report contains provisions important to streamline and modernize FDA regulations while promoting patient safety. Just as important, today's measure is fiscally responsible, reducing the deficit by $311 billion over the next 10 years according to the CBO.

I thank Chairman UPTON, Chairman PITTS, Ranking Member WAXMAN, Ranking Member PALLONE, and members of the Energy and Commerce Committee for working together in a bipartisan capacity on a final bill that protects patients and brings much needed certainty to the medical and biopharmaceutical industries. This is the way Congress should work.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Kentucky (Mr. GUTHRIE).

Mr. GUTHRIE. Mr. Speaker, I appreciate the gentleman for yielding.

I rise today in support of the legislation to reauthorize the Prescription Drug and Medical Device User Fee Act and authorize new user fee programs for generic drugs and biosimilars. The legislation also includes important reforms to grant patients improved access to new therapies and promotes innovation and job creation.

Jobs and the economy are top issues for most Americans, and this bill focuses on that. As a manufacturer, I've heard many stories from many device manufacturers across the country about problems they face with the FDA and how those struggles are making it harder for them to manufacture in America.

This bill includes important changes, including one that I championed, to reform the FDA's guidance process that will inject certainty into the process and create more American jobs.

This bill is an example of working in a bipartisan way to achieve a quality product that creates jobs. I thank the chairman and the ranking member for their work. And, Mr. Speaker, I urge my colleagues to support this bill.

The SPEAKER pro tempore (Mr. DANIEL E. LUNGREN of California). The gentleman from New Jersey has 3 minutes remaining, and the gentleman from Michigan has 4 minutes remaining.

Mr. PALLONE. Mr. Speaker, I yield 30 seconds to the gentleman from Virginia (Mr. MORAN).

Mr. MORAN. Mr. Speaker, I don't oppose the bill, but I do have concerns about one element of this bill, and that is the provision that affects whistleblowers in the Public Health Service.

The law that would apply to these employees is that of the military, the Defense Department, which, frankly, is weaker than that which applies to protecting whistleblowers who are in the civil service, civilian whistleblowers.

I do think protection of whistleblowers needs to be a priority. In this case, I would hope that we could work in subsequent legislation to protect the rights of whistleblowers who are essential to our being able to do our job, as well as those people in the executive branch. I just wanted to make note of that point.

□ 1510

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from New Hampshire (Mr. BASS), a member of the committee.

Mr. BASS of New Hampshire. I thank the distinguished chairman of the committee for recognizing me for 1 minute.

Mr. Speaker, I rise in strong support of the Food and Drug Administration Safety and Innovation Act.

The user fee process at the FDA is a vital element in maintaining operations at the FDA to bring valuable drugs and devices through the approval pathway and to market. I am optimistic that, with the enhanced financial incentives and resources available to the FDA included in the user fee agreements, we will see shorter approval times and more products available to patients.

Throughout this process, there has been a commitment to addressing the unique issues associated with the rare disease community and bringing it to the forefront of this debate. And I am proud to have had my bill, the Humanitarian Device Reform Act, included as a provision in this device regulatory section. This language will make it easier for medical device manufacturers to create devices specifically for the treatment of individuals, both children and adults, who are afflicted with very rare diseases.

With this increased focus on providing incentives to manufacturers to invest in the development of these devices and drugs, it can be an attainable goal for an individual and family affected by rare diseases to not only improve the quality of life but possibly even find a cure.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Minnesota (Mr. PAULSEN).

Mr. PAULSEN. Mr. Speaker, I want to applaud, first of all, the chairman, the subcommittee chairman, and the ranking members for their leadership in bringing this bipartisan package to the floor.

Mr. Speaker, nearly every week, I get a chance to tour a medical device company in my district. And almost every week, I hear a similar story from these companies that talk about how the FDA has become so burdensome and bureaucratic and inefficient that they move the goalpost in the process of the device approval process. As a result, some of these companies are closing their doors. Some of these companies are investing overseas and moving jobs, as opposed to keeping them in their home State of Minnesota or here in the United States.

Unfortunately, it seems that Washington tends to thrive on these types of bureaucracies and inefficiencies. And I think the package that is before us today is designed to help correct that. The FDA review process needs to be rigorous, but it also needs to be relevant. You have heard that message time and time again: We have to find ways to streamline and modernize the FDA so that the United States can remain the leader in global medical innovation.

This package absolutely moves us closer to meeting all of those goals. These reforms will make the device approval process much more transparent, much more consistent, and much more predictable. And specifically, I'm happy that my provisions to streamline the third-party review process were included as well.

I want to thank the chairman and Members for their bipartisan support, and I urge the support of my colleagues.

Mr. UPTON. Mr. Speaker, may I ask how much time remains on each side?

The SPEAKER pro tempore. The gentleman from Michigan has 2 minutes remaining, and the gentleman from New Jersey has 2½ minutes remaining.

Mr. UPTON. Mr. Speaker, I have no further requests for time. So if the gentleman wants to close, then I will close.

The SPEAKER pro tempore. The gentleman from New Jersey is recognized for 2½ minutes.

Mr. PALLONE. Thank you, Mr. Speaker. I won't use all the time.

I just want to stress, again, that the process of getting this bill passed and moved both here and in the Senate has been just a great model, if you will, for what we can do when we want to get together and work together on a bipartisan, bicameral basis. So I can't say enough about everyone who was involved on both sides of the aisle and staff for making this happen today.

I also want to reiterate some of the things that some of my colleagues have said about how important this is. Because it's on a suspension, some people may say, Well, how important is it? It is extremely important. And some of those sentiments have been echoed by those who talk about the drug and medical device industry, which is really so important to this country.

We pride ourselves on innovation. As some of you know, many of these companies are in my district. And we pride ourselves on the fact that Thomas Edison had his lab at Menlo Park, in my district, and that we are an innovative area in New Jersey, and New Jersey as a whole. But innovation can't continue to happen in this industry unless we continue to have an FDA process that runs smoothly and effectively.

The fact of the matter is that this legislation is designed to make sure that that continues to happen, that the money is available so we can have an efficient process that continues to make the United States the innovator in the area of pharmaceuticals and medical devices.

I'm very proud to have been part of this today. I urge everyone to support the bill. I thank my colleagues.

I yield back the balance of my time.

The SPEAKER pro tempore. The gentleman from Michigan is recognized for 2 minutes.

Mr. UPTON. Thank you, Mr. Speaker.

Mr. Speaker, I just want to say that with all of the positive comments here, this bill was not a piece of cake. There was a lot of hard work on both sides of the aisle, particularly by the staff on both sides of the aisle. Again, I want to cite Clay and Ryan on our staff.

But let's face it: All of us particularly involved on the health side of the issues, as we meet with different folks afflicted with different diseases, we want to find a cure. And it would be great to find that cure here in America because we have outstanding pharmaceutical industries that have the talent and the staff to work with the different departments, whether it be the NIH, the CDC, certainly the FDA.

So we really did set out last summer to embark on a good listening session to find out what it is that we needed to do not only to find the cures and the prescriptions but the right process for them to be approved so that those companies that are willing to make that investment would stay here in America and not go overseas. Because we really do want it made in America. We have the best folks here. And that's what this bill does.

The hard work in so many of the hearings that JOE PITTS led with Mr. PALLONE, the work, the amendments, the subcommittee, the full committee, that whole process to get it done before it really expired later on this year is so important not only to the workers but, more importantly, to the patients.

So dealing with the drug shortages and working with Mr. MCCAUL and the different rare diseases, all of those different elements, we were able to weave

into what I think is a mighty fine, strong bill. And to then, of course, work with our counterparts in the Senate, whom we often bash here, but they actually stayed with us, and we were able to work in a very strong bipartisan way to get our two bills refined and done in order to bring up on the House floor this afternoon.

I want to compliment everyone—and certainly Mr. WAXMAN, who is back on the floor—our leadership, the team that we had on both sides of the aisle and, again, our hardworking staff that really worked so hard to get this done, which impacts millions of lives.

I urge my colleagues to support this bill, and I yield back the balance of my time.

Mr. RAHALL. Mr. Speaker, I support the passage of the Food and Drug Administration Reform Act, which reauthorizes vital programs that will ensure the FDA continues to study and approve life-saving drugs and medical devices and work to prevent drug shortages of much needed medications.

I am concerned, however, that the Congress is not doing more to fight prescription drug abuse. Members of the House were not permitted to offer amendments to address prescription drug addiction when this measure came before us last month, even though the FDA has a vital role in regulating the addictive qualities of drugs that are manufactured and ensuring sufficient education and awareness for health care providers and the general public.

This conference report is a bittersweet pill to swallow. While it includes a provision that will ban the sale of dangerous synthetic drugs, which I support and the House of Representatives passed late last year, the FDA's programs could have been strengthened significantly to address substance abuse and its impact on our Nation's economic and security needs.

If one reads any newspaper in southern West Virginia, you will undoubtedly find downright scary stories of families, children and seniors devastated by prescription drug abuse, and the crime that it engenders. As many of my colleagues know, fighting back against this unending wave of abuse will take the action of all—local, state and federal governments. I have introduced legislation, as have a number of my colleagues who serve in the Prescription Drug Abuse Caucus, which would arm our law enforcement, physicians, and local communities in this fight—making it harder for pills to get into the wrong hands and be misused, and ensuring that all prescriptions are properly monitored.

Though this bill mentions the need to combat abuse of prescription drugs, it is not nearly strong enough, nor should we consider it sufficient, in addressing what has become a crisis in too many Appalachian communities. Our families and communities need more than recommendations—they need action, and they simply cannot wait any longer for help.

I urge House leadership to work with members of this body who are committed to fighting back against this plague and saving our communities to consider legislation that will stop this scourge.

Mr. DENT. Mr. Speaker, I rise in support of the Food and Drug Administration Safety and Innovation Act and particularly the provisions related to synthetic drugs.

I introduced H.R. 1254, the Synthetic Drug Control Act, after the issue of synthetic or designer drugs was first brought to my attention by a constituent whose son had been abusing legal substitutes for marijuana.

H.R. 1254 passed the House by a strong, bipartisan vote of 317 to 98 this past December.

After months of hard work, I am glad to see that similar language has been included in the House Amendment to the Senate-passed FDA reform bill. I would like to thank Chairmen UPTON and SMITH for their diligent efforts in advancing this legislation.

This legislation will finally add a long list of dangerous drugs to Schedule I of the Controlled Substances Act.

It covers synthetic cannabinoids, which affect the brain in a manner similar to marijuana but can actually be even more harmful, as well as many of the chemicals used in so-called ''bath salts,'' which have properties similar to cocaine, methamphetamine, LSD, and other hard street drugs.

It will also double the amount of time that DEA may temporarily ban a new substance while working to prove that the drug in question should be banned permanently.

As we speak, the proliferators of these deadly chemicals are working on new formulas to circumvent Federal law.

This additional time will enhance DEA's ability to combat new and emerging substances.

This legislation is especially timely given the recent reports of inhuman and psychotic acts committed by individuals high on bath salts.

Last month, we all heard the horrifying story of a Miami man who stripped naked, assaulted another individual, and chewed his face off before being shot dead by the police.

Last year, a man in my district was arrested after injecting himself with bath salts and firing a gun out of his window in a university neighborhood. He later attributed his actions to a drug-induced state of paranoia.

Poison control centers nationwide have reported exponential increases in calls related to synthetic drugs, and far too many deaths have resulted both from overdoses and the Psychotic behavior that the drugs induce.

For the inclusion of this important public safety language and for the many ways this legislation will spur economic growth and medical innovation, I urge all of my colleagues to vote in favor of the underlying bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, S. 3187, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

□ 1520

MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

Mr. MCKINLEY. Mr. Speaker, I have a motion at the desk.

The SPEAKER pro tempore. The Clerk will report the motion.

The Clerk read as follows:

Mr. MCKINLEY moves that the managers on the part of the House at the conference on the disagreeing votes of the two houses on the Senate amendment to the bill H.R. 4348 be instructed to insist on the provisions contained in title V of the House bill (relating to coal combustion residuals).

The SPEAKER pro tempore. Pursuant to clause 7 of rule XXII, the gentleman from West Virginia (Mr. MCKINLEY) and the gentleman from California (Mr. WAXMAN) each will control 30 minutes.

The Chair recognizes the gentleman from West Virginia.

Mr. MCKINLEY. Mr. Speaker, I yield myself 7 minutes.

Concrete is a fundamental element of roads, bridges, and infrastructure projects, and an important element of concrete is coal ash. This is now the fourth time the House has affirmed and reaffirmed its support for the beneficial use of recycling coal ash.

Currently, the conference committee on H.R. 4348 is deep in productive negotiations, and strong bipartisan compromises have occurred relative to the coal ash provision. My intent today is to urge the conferees to continue these bipartisan negotiations and retain this important, cost-saving provision in the final bill.

We're not here to rehash the same ideologically motivated arguments that we have heard from the extremists. Simply put, we are here to help put people back to work, to give American businesses certainty, and to protect the health and environment of our families and friends.

For those who say coal ash is irrelevant to roads and bridges, they couldn't be further from the truth. Concrete suppliers have been incorporating coal ash into concrete mixtures since the construction of the Hoover Dam over 80 years ago. Without coal ash, the cost of construction projects would increase by $100 billion, according to the American Road and Transportation Builders Association, thereby reducing the amount of moneys available for roads and bridges and infrastructure in America.

Keep in mind, less construction results in fewer jobs. By retaining this bipartisan section of the highway bill, Congress will be also protecting the 316,000 jobs that are at stake in the recycling of fly ash—jobs involving concrete block, brick, drywall, ceramic tile, bowling balls, and even in the cosmetics industry. For those who have been asking where the jobs bills are, this is a jobs bill.

Among the supporters of this language are the Chamber of Commerce, the National Association of Manufacturers, the International Brotherhood of Electrical Workers, the United Mine Workers, the United Transportation Union, the American Road and Transportation Builders Association, the International Brotherhood of Boilermakers, and the AFL–CIO's building and construction trades.

Consider these quotes, Mr. Speaker:

''Removing coal ash from the supply chain could increase the price of concrete by an average of 10 percent,'' according to the National Association of Homebuilders.

According to the National Association of Manufacturers:

''Coal ash contributes $6-$11 billion annually to the U.S. economy through revenues from sales for beneficial use, avoided cost of disposal, and savings from use as sustainable building materials.''

Mr. Speaker, currently 60 million tons of coal ash is recycled annually. According to EPA's own data, coal ash replaces between 15 and 30 percent of the Portland cement used in concrete. The EPA has noted that the use of coal ash in concrete has resulted in saving as much as 25 million tons of greenhouse gas emissions annually and as much as 54 million barrels of oil. The EPA has indicated the annual financial benefits of using coal ash as a substitute for Portland cement contributes nearly $5 billion in energy savings, $41 billion in water savings, $240 million in emission reductions, and nearly $18 billion in nongreenhouse gas-related air pollution. The EPA itself states that coal ash leads to ''better road performance.''

Two studies, one in 1993 and another in 2000, both under the Clinton administration's EPA, found that coal ash did not warrant the regulations being pushed by the Obama administration. In 2005, the EPA, the Federal Highway Administration, and the Department of Energy collaborated with the private sector to craft guidance on the appropriate uses and benefits of coal ash in highway construction.

Mr. Speaker, I reserve the balance of my time.

Mr. WAXMAN. Mr. Speaker, I yield myself 5 minutes.

Reauthorizing the surface transportation programs is important for communities across the country. It will help revitalize our transportation infrastructure and will create jobs. The Transportation Conference Committee must work together to finalize a conference report as soon as possible to get people back to work.

The Senate worked in a bipartisan manner to develop a strong bill that will create jobs and help the economy. They focused on the core issues, ignoring the temptation to attach side issues to this important legislation. Unfortunately, the transportation bill is now being jeopardized by extraneous and antienvironmental provisions being pushed by Republicans in the House.

Instead of working to come to agreement on important transportation policy provisions, House Republicans are holding the bill hostage for a legislative earmark for the Keystone XL tar sands pipeline, provisions that steamroll environmental review of projects, and the McKinley coal ash bill that eliminates existing authority to protect human health and the environment from the risks posed by unsafe disposal of coal ash.

This motion to instruct is the latest effort to push these positions. It would instruct the transportation conferees to insist on the McKinley coal ash bill in the transportation bill.

But the McKinley coal ash proposal is extraneous. If we do nothing on the transportation bill to address coal ash disposal, then coal ash will continue to be available for use in concrete for transportation projects just as it is today. Current Federal regulations do not restrict the use of coal ash in concrete. And counter to what you may hear today, EPA has not proposed to regulate such beneficial reuses.

Although some may suggest that recycling of coal ash will decrease because of stigma, experience has shown that when waste materials are regulated, as EPA has proposed to do for coal ash, the rates of recycling and reuse increase. This has happened with other regulated wastes, and it has happened with coal ash in Wisconsin, which has a robust regulatory scheme. There's a very simple reason for this: Disposal in unsafe pits is inexpensive but environmentally dangerous. When reasonable environmental safeguards are put in place, the cost of disposal will increase. That makes alternatives like using coal ash in concrete more attractive.

The coal ash legislation that this motion seeks to include will not ensure the safe disposal of coal ash. It will not prevent coal ash impoundments from catastrophically failing. It will not protect against significant environmental and economic damage. And it will not prevent contamination of public drinking water systems.

The McKinley coal ash bill will not stop another spill like we saw in Kingston, air pollution like we have seen in Gambrills, Maryland, or water pollution like we have seen nationwide.

□ 1530

What this coal ash proposal will do is stop the transportation conference from succeeding. This motion to instruct attempts to lock the House conferees into a position that the Senate will only reject, and it will doom the transportation conference committee to failure.

We can retreat to intractable positions on extraneous issues, making a transportation bill difficult, if not impossible, to pass, particularly in the time frame that we have set out for us; or, we can work together in the time we have to produce a transportation bill that will be signed by the President and will keep our economy on the mend.

A vote for this motion is a vote against completing the transportation conference. I urge all Members to say ''yes'' to transportation and vote ''no'' on this position motion.

I reserve the balance of my time.

Mr. MCKINLEY. Mr. Speaker, I yield 3 minutes to my colleague from Illinois (Mr. SHIMKUS).

(Mr. SHIMKUS asked and was given permission to revise and extend his remarks.)

Mr. SHIMKUS. Mr. Speaker, it is great to be down here.

This is why this provision of this bill is really pertinent to the highway bill. Here it is: Flex concrete, fly ash, lighter, more durable.

I have two documents I brought to the floor. The second one reads in the acknowledgments:

This document was prepared by the U.S. EPA in cooperation with the following agencies and associations: Department of Energy, Federal Highway Administration, American Coal Ash Association, and the Utility Solid Waste Activities Group.

What is interesting about these two books, one published in June 2003, the other one published in 2005, is they go through all of the great uses of fly ash in construction, and I would like to read just a few of those.

Here's one: ''Fly ash improves workability for pavement of concrete.''

Remember, a DOT book, EPA approved, DOE approved.

The next one has: ''Fly ash concrete is used in severe exposure applications such as the decks and piers of Tampa Bay's Sunshine Skyway Bridge.''

Nice photo here, beautiful bridge. So this is not new. This is reaffirming what the construction industry has been doing for decades. And actually in this other pamphlet, I'll talk about even greater use.

Here's another one: ''Fly ash concrete finishing.''

Again, this is a Federal Highway Administration book, Department of Energy book, sponsored by the U.S. EPA, all saying good things about fly ash in road construction.

''Full-depth reclamation of a bituminous road.''

Another one: ''Flowable fill used in a utility trench application,'' all dealing with fly ash.

''Fly Ash in Structural Fills and Embankments''; a nice photo of them using that in the construction sector.

Also, ''Soil Stabilization to Improve Soil Strength,'' all using fly ash applications.

We have a highway bill, and that's why this provision is very, very important; because if the EPA has its way and they label fly ash as toxic, guess what, no more flex concrete, no more building of buildings that have fly ash applications.

This is one of my favorite ones: ''Use of Ash in Construction Through the Ages. In ancient times, the Romans added volcanic ash to concrete to strengthen structures such as the Roman Pantheon and the Coliseum—both of which still stand today.

''The first major use of coal fly ash in concrete in the United States occurred in 1942 to repair a tunnel spillway at the Hoover Dam.

''One of the most impressive concrete structures in the country, the Hungry Horse Dam near Glacier National Park in Montana, was constructed from 1948

to 1952, with concrete containing''—you guessed it—''fly ash.''

We're in Washington, D.C.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. MCKINLEY. I yield the gentleman an additional 30 seconds.

Mr. SHIMKUS. One of the great things we see here, ''In Washington, D.C., both the metropolitan area subway system (Metro) and the new Ronald Reagan Building and International Trade Center were built with''—you guessed it—fly ash and concrete.

''Other significant structures utilizing coal fly ash in concrete include the 'Big Dig' in Boston and the decks and piers of Tampa Bay's Sunshine Skyway Bridge.''

That's why this is applicable to the highway bill. I commend my colleague.

Mr. WAXMAN. Mr. Speaker, at this time I'd like to yield 5 minutes to the gentleman from Illinois (Mr. RUSH), the ranking member of the Energy Subcommittee.

Mr. RUSH. Mr. Speaker, I want to thank the ranking member on the Energy and Commerce Committee and let him know how much I appreciate not only his leadership on other issues, but particularly his leadership on this issue here.

Mr. Speaker, I stand here astounded, amazed, and bemused at the remarks of the past speaker. You know, he wants the American people to be convinced that fly ash is as healthy to them as it can be and that they should, in fact, maybe go out and go to their local drugstore and ask for a bottle of fly ash so they can sprinkle it over their dinner meal as they would maybe a salad dressing. I don't think that the American people would be pleased with that.

Mr. Speaker, I stand in strong opposition to this motion to instruct. At a time when we are facing historic levels of joblessness in communities around the country, in the African American communities and other minority communities, Republicans are playing chicken with the transportation bill, which is intended to provide American jobs and repair our aging infrastructure. It is not to further the contamination of the water supplies, the air supplies in our most vulnerable communities, so why don't we stop the charade. Why don't we stop the asthmatic assault on the most vulnerable segments, the most vulnerable communities in our Nation.

This motion to instruct contains a deadly and dangerous provision that would only allow more poison, more disease, and more death from one of our Nation's biggest waste products—the deadly, cancerous coal ash that's under discussion today.

Coal ash, I want to remind you, is a waste leftover after thousands of tons of coal are burned at coal-fired power plants, and it is laden from top to bottom with toxins such as mercury, arsenic, cadmium, chromium, and lead. These are pollutants that cause cancer, that cause organ disease, breathing problems, neurological damage, developmental problems, and even the final problem, which is death.

Mr. Speaker, title V of H.R. 4348 gives companies an unprecedented ability to pollute under the Resource Conservation and Recovery Act, even though the EPA, the Environmental Protection Agency, found some coal ash ponds pose a 1-in-50 risk of cancer related to residents drinking arsenic-contaminated water, a risk that is 2,000 times the EPA's regulatory goal.

Dangerous coal ash disposal affects thousands of U.S. communities, but research informs us that income and race remain strong predictors of the amount of pollution that Americans face. The majority of coal ash is disposed in grossly inadequate dumpsites, which are primarily located in low-income communities, disproportionately impacting those who are least equipped to respond to water contamination and the onslaught of toxic dust in the air.

□ 1540

Mr. Speaker, low-income citizens are more likely to rely on groundwater supplies and less likely to have access to medical insurance and health care.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. WAXMAN. I yield the gentleman an additional minute.

Mr. RUSH. Mr. Speaker, title V of H.R. 4348 fails to protect communities and their drinking water from toxic coal ash or from another messy spill like the disaster that occurred in Kingston, Tennessee, in 2008.

Mr. Speaker, let me conclude by saying that my State alone produces 4.4 million tons of coal ash annually, and at least 19 coal ash dumpsites have contaminated local water supplies. Additionally, each and every day a steam-fired steamship, the SS *Badger*, dumps 4 tons of coal ash into Lake Michigan, my beloved city of Chicago's primary water supply system.

I urge all of my colleagues to vote against the motion to instruct.

Mr. MCKINLEY. Mr. Speaker, I yield 2 minutes to my colleague from Pennsylvania (Mr. HOLDEN).

Mr. HOLDEN. I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of the gentleman from West Virginia's motion to instruct conferees to resolve the coal ash provision in the highway bill.

There are more co-generation plants in my congressional district than any congressional district in the country. For more than 100 years, coal refuse piles created eyesores throughout northeastern Pennsylvania. These culm banks are now baseball fields and shopping centers.

Coal ash is not hazardous. EPA determined that fact in regulatory determinations in 1993 and in 2000. The fact that EPA continues to leave a hazardous waste designation for coal ash on the table—even though these three decades of science and facts point the other way—is directly contributing to the loss of current and future recycling.

This designation would harm companies in the still emerging coal combustion byproduct markets that make everyday products like concrete, shingles, and wall board. It will also hinder State departments of transportation that use CCB in job-creating highway and infrastructure projects and overwhelm State budgets and employee resources by more than doubling the volume of waste subject to hazardous waste controls, and translate into increased energy rates for millions of American consumers.

As a member of the Transportation and Infrastructure Committee, I see no better way to create jobs than to pass the highway bill. During the last highway bill, Pennsylvania received over $10 billion, which created over 400,000 jobs. The coal ash provision in the highway bill only strengthens job creation. Simply put, highway spending strengthens the fabric of our Nation's infrastructure while creating jobs for millions of Americans.

I urge passage of the gentleman's motion to instruct.

Mr. WAXMAN. Mr. Speaker, at this time I yield 5 minutes to the gentleman from Virginia (Mr. MORAN).

Mr. MORAN. I thank the very distinguished gentleman, the ranking member on Energy and Commerce.

Mr. Speaker, I rise in opposition to this motion to instruct conferees to include the Coal Residuals and Reuse Management Act into any final conference agreement on the surface transportation authorization bill.

The bill my colleague seeks to include in the surface transportation bill is bad policy. It has nothing to do with transportation, and it would place communities living downstream from coal ash ponds in real danger.

When properly recycled, coal ash and other residuals from burning coal do have economic value—that's not the issue here, but managed improperly, they can be extremely hazardous. Coal ash shouldn't be dumped in unregulated ponds to contaminate water and spill into nearby streams and rivers.

In 2008, as Mr. RUSH pointed to, the Kingston fossil plant in Tennessee failed to properly maintain its coal ash impoundment pond. The pond collapsed, and it dumped 1.1 billion gallons of coal ash slurry into the Clinch River and inundated several houses with up to six feet of ash and mud. And then when they independently tested the Clinch River after the Tennessee Valley Authority impoundment collapse, it showed high levels of arsenic, copper, barium, cadmium, chromium, lead, mercury, nickel, and thallium all related to that spill. The spill contaminated the water, it killed the fish, and it destroyed property. The cleanup pricetag is still being assessed, but it's estimated to cost between $700 million and $1 billion. The motion my colleague from West Virginia is proposing

would prevent EPA from setting standards for this type of coal ash dump, allowing these problems to continue unchecked.

We need to preserve the Environmental Protection Agency's authority to advance regulations that discourage improper disposal of coal ash and to encourage recycling. Every year, coal-fired power plants and industrial boilers in the United States generate about 67 million tons of coal ash and slag and about 19 million tons of coal sludge.

While fly ash, bottom ash, flue gas desulfurization mineral, and boiler slag all have a number of beneficial reuses in concrete, road, wallboard, and roofing, they also contain heavy metals—including lead, arsenic, cadmium, and mercury, as well as radioactive elements. These hazardous components dictate that we must be careful in the handling use, reuse, and disposal of the material.

Contrary to much of the publicity surrounding the coal ash issue, EPA is not trying to ban the beneficial reuse of coal ash. In fact, EPA proposed two separate possible regulatory regimes to encourage recycling and reduce improper coal ash disposal. EPA wants to ensure that coal ash reuse is preserved while guaranteeing that any disposal is done safely and effectively.

EPA's proposed rules received extensive public involvement, including thousands of public comments and eight public hearings around the country. The Coal Residuals and Reuse Management Act is designed to deprive EPA of the ability to use the best available science in its decisions, and it would negate those thousands of public comments that were received after the rule's proposal. It would also give a free pass to power companies to pollute at taxpayer expense.

Coal ash is a national, interstate issue and should be subject to Federal regulation.

As Congress stated when passing the Resource Conservation and Recovery Act:

> The problems of waste disposal have become a matter national in scope and in concern and necessitate Federal action. Disposal of solid waste and hazardous waste in or on the land without careful planning and management can present a danger to human health and the environment.

That was true in 1976, and 30 years later it's still true. In the years since, we have found that proper regulation of waste disposal encourages rather than discourages recycling. Implementing environmental and safety controls makes recycling far more attractive and far more likely to occur. Thirty years of data on solid and hazardous waste disposal and recycling have borne this out. Let's not revisit the Wild West past of hazardous waste disposal.

We need to stand up for the same principles Congress stated in the Resource Conservation and Recovery Act over 30 years ago. That's why I strongly urge my colleagues to oppose the McKinley motion. Prevent more Kingston ash impoundment disasters; they will be replicated, and it will be our fault. We need to allow EPA to regulate responsibly and to allow the beneficial use of coal ash.

Mr. MCKINLEY. Mr. Speaker, I might suggest, with all due respect, I think that those who are opposing this amendment, Mr. Speaker, I would encourage them to read the bill.

Mr. Speaker, I yield 2 minutes to my friend and colleague from wild, wonderful West Virginia (Mrs. CAPITO).

Mrs. CAPITO. I want to thank my colleague from West Virginia (Mr. MCKINLEY) for his solid work on this issue.

I want to say to my colleague from California, who said that this issue is going to hold the transportation conference bill hostage, it's absolutely not a fair statement. I'm on the transportation conference committee. We're working day and night, in a bicameral, bipartisan way, to reach a compromise on a jobs bill, and this coal ash provision is very important.

□ 1550

Many Americans are unfamiliar with this, but 40 percent is used as raw material to build our highways and our bridges.

I was just visiting the Sutton Dam in Braxton County in West Virginia. My colleague talks about the Hoover Dam. We celebrated its 50-year birthday of its construction. It's built with coal ash, and it's just as effective today as it was 50 years ago. It is an essential and safe material to be used in our infrastructure.

According to the American Road and Transportation Builders Association, if we don't use coal ash in bridge and road construction, the cost would increase over $100 billion over 20 years. We simply can't afford this.

Let's be smart about this. We can find the way, and we've known the way, as the Sutton Dam and the Hoover Dam have shown us. I think we can find a way to safely reduce the costs of construction in our roads and bridges by using coal ash.

We have unemployment of over 8 percent for 30 consecutive months. We need a transportation bill. We need a smart transportation bill that's going to put America back to work and rebuild our infrastructure.

Mr. MCKINLEY's legislation, and this motion, takes the right approach by giving the States the authority to deal with this. I hope my fellow conferees will work to ensure that this important provision remains in the bill, that we pass the gentleman's motion to instruct. This will not be an obstruction to us passing the transportation bill, and I look forward to passing that bill on the floor in a bipartisan way.

Mr. WAXMAN. Mr. Speaker, I'm pleased at this time to yield 5 minutes to the gentleman from Massachusetts (Mr. MARKEY).

Mr. MARKEY. I thank the gentleman.

Today marks the summer solstice, the longest day of the year. Instead of spending the daylight hours passing a clean transportation bill that will help shore up real jobs for Americans, the Congress will be spending the day repealing public health protections and giving away nearly all of our public lands to oil and gas companies in the culmination of the Republican majority's Oil Above All agenda. It is really a ''Midsummer's Nightmare'' for the American people.

But before we get to voting on the Republican oil package, we get to debate whether another Republican bill, whose sole premise is to prevent EPA from following the scientific evidence, should be included in the Transportation bill.

This bill says that no matter what EPA learns about the sludge that comes out of coal-fired power plants, no matter how high the concentrations of poisonous arsenic, mercury or chromium, no matter what EPA learns about how these materials find their way into our drinking water, EPA is forbidden to classify or regulate it as hazardous waste. EPA is forbidden to require that this toxic material be disposed of carefully.

This bill turns a blind eye to evidence of known hazards and takes us back to the Dark Ages, to a time before science was valued and before advanced knowledge transformed society. It takes us back to an era when mercury and arsenic, major components of coal ash, were used to cure toothaches and clear up your complexion. It takes us back to an era where children were sent deep into the bowels of the Earth to rip coal from the mines and die early deaths.

Apparently, House Republicans not only wish to embrace the principal energy source of the 19th century; they also wish to return us to the 19th-century principles about public health and the environment regarding arsenic and mercury and their danger to the citizens of our country.

Now, there are good uses for coal ash, beneficial uses. It can be used to construct highways and shingles. That's good. It can be mixed into concrete and grout. That's good.

But what we don't want is for the industry to be able to use it to construct a golf course, like what they did in Battlefield, Virginia, because it can directly contaminate the groundwater. It can pollute and cause injury and cancers in the neighbors of that golf course.

We also don't want it to be disposed of in pits that aren't sealed to handle this special waste, like what happened in Tennessee when a TVA disposal pit collapsed, engulfing an entire small town in toxic sludge. We should have regulations to protect against that ever happening in our country again.

This is exactly what this bill, the Republican bill, will do. It will blast us back into the past and allow coal ash to be disposed of without proper construction or monitoring.

At the end of this month, transit and highway funding will expire, hundreds of thousands of jobs are at stake, and our transportation infrastructure will be in peril. Even Senate Republicans have recognized the dangers inherent in allowing this to occur and have joined with Senate Democrats to craft a bipartisan bill so we can put people back to work using coal ash in the highways of our country.

But in spite of this, the House Republicans are insisting that unrelated and unnecessary toxic provisions dangerous to the health and well-being of Americans be attached to this bill in order to protect Big Oil and Big Coal.

Instead of allowing the coal industry and Republicans to transport our country's environmental and public health standards back to the era of Charles Dickens, we should be holding them to higher expectations for the 21st century, for the public health and well-being of our people.

I urge a ''no'' vote on this preposterous Republican initiative.

Mr. MCKINLEY. Mr. Speaker, I yield 3 minutes to my colleague from Ohio (Mr. RENACCI).

Mr. RENACCI. Mr. Speaker, I rise today in strong support of this motion to instruct the Surface Transportation bill conferees. The EPA's proposed rule to classify coal ash as a hazardous material is yet another example of this administration's continual attack on coal and the affordable domestic energy it generates.

The production and use of coal ash has grown into a multi-billion dollar industry supporting thousands of jobs in my home State of Ohio. Coal ash is used in more than 75 percent of the concrete primarily because of its cost effectiveness. Eliminating it would force concrete producers to use expensive alternatives, driving up the cost of building roads and bridges in America by more than $5 billion a year. That means construction costs won't go as far at a time when our infrastructure is in dire need of repair.

In addition, classifying coal ash as a hazardous material will prove extremely costly for coal-fired power plants. Some energy companies may analyze the costs and find it simply too expensive to continue operating. Others may attempt to pass the new costs on to consumers in the form of higher utility costs. Either way, the outcome would be devastating for a State like Ohio that derives 80 percent of its electric power from coal. With our economy still struggling, that is the last thing Ohio businesses, construction companies, and families need right now.

Despite decades of research and studies concluding there is no reason to consider coal ash hazardous, many of which the EPA itself carried out, the Agency now appears willing to jeopardize thousands of jobs with this inaccurate ruling. It is critical that efforts are taken to prevent the implementation of this regulation. Instead, allow each State to set up their own coal ash recycling programs following existing EPA health and environmental regulations. This approach will protect jobs and our economy in my home State and across America.

I applaud Representative MCKINLEY for his continued leadership on this issue, and I urge the conferees to keep the bipartisan House language in the final version of the Surface Transportation bill.

□ 1600

Mr. WAXMAN. Mr. Speaker, I now have the pleasure to yield 1 minute to the gentleman from Illinois (Mr. QUIGLEY).

Mr. QUIGLEY. Mr. Speaker, today the House will vote on yet another environmental ruinous bill. This motion would instruct surface transportation conferees to retain the language of H.R. 2273, which prohibits the EPA from regulating coal ash.

Coal ash is the toxic combination of mercury, boron, aluminum, thallium, sodium, and arsenic that is produced by burning coal. Shockingly, people living near unlined coal ash ponds have a risk of cancer that is 2,000 times greater than EPA's acceptable level.

This motion would disallow the EPA from doing its job. Allowing the EPA to enforce safeguards against coal ash pollution would help to avoid disasters like the 2008 spill in Tennessee, where a dam holding more than 1 billion gallons of toxic coal ash failed. That spill destroyed 300 acres and dozens of homes, devastated wildlife, poisoned two rivers—and apparently taught us nothing.

I urge my colleagues to oppose this latest attempt to bar the EPA from saving lives and preserving the environment.

Mr. MCKINLEY. Mr. Speaker, I yield 3 minutes of my remaining time to the gentleman from Pennsylvania, Congressman DOYLE.

Mr. DOYLE. Mr. Speaker, I rise in support of the gentleman's motion to instruct.

Coal ash is a serious issue for this country and especially for Pennsylvania. Nearly all of my constituents get their power from coal, and with that power generation comes its by-product—coal ash. It's an unavoidable part of our power generation in southwestern Pennsylvania.

Though the Commonwealth of Pennsylvania has some of the toughest coal ash disposal standards in the country, I've been convinced that coal ash needs to be federally regulated under the Resource Conservation and Recovery Act. However, this motion to instruct does not fully encompass my position on the issue.

Although this motion to instruct calls on conferees to insist upon the House language on coal ash, that is not the whole story. In fact, I support the coal ash language that the bipartisan group of Senators is working on. I've seen much of the work they've been doing, and I can tell you that I believe it to be an improvement on what we're doing here in the House. The question is: Will the conferees agree to a bill at all and will it include coal ash?

My vote in favor of this motion is meant to urge my colleagues to finish the process so that we can resolve the coal ash issue in a way that's good for the environment, our constituents, and the purposes of recycling these materials.

I want to make it clear that I do not believe that any coal ash or Keystone provisions should be used to hold up the transportation bill conference. Above all else, it is essential that this Congress does its job and completes the highway bill conference before the current program expires on June 30. I continue to support the Federal regulation of coal ash as a nonhazardous waste, and I encourage my colleagues to work quickly towards a bipartisan, bicameral resolution on this issue.

Mr. WAXMAN. Mr. Speaker, I yield 3 minutes to the gentleman from Rhode Island (Mr. LANGEVIN).

(Mr. LANGEVIN asked and was given permission to revise and extend his remarks.)

Mr. LANGEVIN. I thank the gentleman for yielding.

Mr. Speaker, another summer building season is well under way without a long-term transportation bill; and we are, quite frankly, down to the wire on the current funding authorization, which expires next Sunday. Yet here we are debating the addition of even more non-transportation-related measures.

Congressman MCKINLEY's motion to instruct on coal ash is another example of delay. The transportation conferees ought to be urgently completing their work on a long-term authorization, not being saddled with extraneous requirements which pose a threat to public health. With thousands of jobs on hold until Congress acts, this delay is unconscionable.

Our State Departments of Transportation gave us early warning that if Congress did not act on a long-term transportation bill by March 31 the summer building season would be compromised. The Senate recognized this concern, and it sent to the House bipartisan legislation known as MAP–21, which is a bill that passed the Senate with the strong bipartisan support of 74 Senators. Then, as we saw the March 31 deadline come and go, House leadership refused to take up the bipartisan Senate bill, knowing full well that carrying an extension through the summer building season would cost jobs. And it has.

Nowhere is our Nation's fragile recovery more apparent than in my home State of Rhode Island, which currently has an unemployment rate of 11 percent. According to RIDOT, millions of dollars in projects have already been delayed, including a $6.4 million project to carry I-95 over Ten Rod Road in Exeter; a $1.5 million project to provide traffic improvements on I-295

ramps along the borders of Cranston and Johnston; a $3.5 million project to resurface State Street to Broad Street and Main Street to route 1A in Westerly, Rhode Island. These projects not only improve the infrastructure upon which our businesses and residents rely, but they mean real jobs, desperately needed jobs, for Rhode Islanders.

MAP–21 will help rebuild America's economy so it is on a stronger, more sustainable foundation. It will provide the financing for critical highway and transit projects and support almost 2 million jobs, 9,000 of them in my home State of Rhode Island.

The 90-day extension, Mr. Speaker, is almost up. It was reluctantly passed back in March with the promise of a long-term measure to follow, a bill which has yet to materialize. We must let the conferees finish their work, and we must let the EPA continue to do its job of protecting the public from the risks of coal ash, which include cancer, neurological disorders, birth defects, and asthma.

I urge my colleagues to vote against this industry-driven motion and to vote for moving forward on the path to rebuilding our roads, our communities, and our economy by bringing the American people a long-term transportation bill.

Mr. MCKINLEY. Mr. Speaker, I yield 2 minutes to my colleague from Texas (Mr. OLSON).

Mr. OLSON. I rise in support of my good friend Mr. MCKINLEY in his efforts to include the Coal Residuals Reuse and Management Act in the final transportation authorization bill.

EPA's goal of issuing new Federal rules to regulate coal combustion residuals would have far-reaching and negative impacts on our economy. These EPA rules would severely hamper American energy production, thereby risking our Nation's ability to meet the electricity generation we need to grow our economy and to get our country back on track working again.

President Obama wants to eliminate coal as a source of energy for America. This should come as no surprise to those who listened to President Obama's comments when he was a candidate for office. He spoke from his heart in San Francisco in 2008.

Here is a summary of what he said:

Let me sort of describe my overall policy. What I've said is that we would put a cap-and-trade system in place that is as aggressive, if not more aggressive, than anybody else's out there.

He later said:

So, if somebody wants to build a coal-powered plant, they can. It's just that it will bankrupt them because they're going to be charged a huge sum for all that greenhouse gas that's being emitted.

We need common sense at the EPA, and we need a President who understands that an all-of-the-above strategy includes American coal. That is why I am supporting Mr. MCKINLEY's Coal Residuals Reuse and Management Act in the final transportation authorization bill, and I urge my colleagues to vote for Mr. MCKINLEY's motion to instruct conferees.

Mr. MARKEY. I reserve the balance of my time.

Mr. MCKINLEY. Mr. Speaker, I yield the next 2 minutes of my time to my colleague from West Virginia (Mr. RAHALL).

Mr. RAHALL. I thank the gentleman from West Virginia for yielding, my good friend, and I commend him for his dogged determination on this issue and for his patience and persistence. I certainly rise in support of this motion to instruct.

This gentleman from West Virginia was, after all, the Democratic floor manager of the House bill which got us into conference with the Senate. It accepted the amendment offered by Mr. MCKINLEY, which passed by a voice vote on April 18.

□ 1610

This amendment, known as the ''coal ash provision,'' is an important provision; and I, like many others, do not want to see it derail the entire transportation bill in its entirety. But I think if this body were to follow the instructions of the House, both in this motion and in the previous motion adopted by Mr. WALZ of Minnesota, which instructed conferees to report back by June 22, then I believe we would have a transportation bill that this Nation would benefit from and our American workers would benefit.

Since 1980, the EPA has struggled to figure out whether coal ash should be regulated under the Resource Conservation and Recovery Act and, if so, in what fashion. As of this date, 32 years later, no EPA regulation is in place.

The Agency had its shot, and now it's time to move on. The provision by the House is aimed at the States bolstering their programs governing the regulation of coal ash and includes enforcement actions if they fail to do so.

Given the nexus between the use of coal ash and the manufacturing of cement and that product's use in our transportation system, it is an appropriate matter to be considered within the scope of the conference of the transportation bill.

Contrary to some remarks we've heard on the floor today, these motions to instruct do not delay the work of conferees. Being a conferee myself, I know that the conference continues to meet with proposals going back and forth.

We're currently playing ping-pong on a lot of these proposals, but that's good. It means that we're talking, and it means the process is going forward. I'm very optimistic and hopeful that we can reach agreement sooner rather than later so that America's economy can continue to recover and American workers can go back to work with certainty.

Mr. MARKEY. Mr. Speaker, I inquire of the Chair how much time is remaining on both sides.

The SPEAKER pro tempore (Mr. WOMACK). The gentleman from Massachusetts has 5½ minutes remaining, and the gentleman from West Virginia has 9 minutes remaining.

Mr. MARKEY. Mr. Speaker, I then continue to reserve the balance of my time.

Mr. MCKINLEY. Mr. Speaker, I yield 2 minutes to the gentleman from Kentucky (Mr. WHITFIELD).

Mr. WHITFIELD. I rise today to support Mr. MCKINLEY's motion to instruct conferees to the highway transportation bill to stop the EPA from regulating coal ash as a hazardous material.

Since the formation of the EPA, the EPA has looked periodically at coal ash. Most recently, they did it in 1993 and 2000 under the Clinton administration and came to the conclusion that coal ash does not warrant being regulated as a hazardous waste.

The only difference between today and then is that this administration is determined to put the coal business out of business, yet America gets about 48 percent of its electricity from coal. We cannot expect to meet the demands of this Nation's electricity needs over the next 20 years without coal.

If the EPA is successful in treating coal ash as a hazardous waste, which is quite radical, we know that independent analyses have shown that the costs associated with road and bridge building in America will increase by more than $100 billion over a 20-year period. And in America today, to stimulate our economy, to get our goods to market, we need to improve the infrastructure of this country.

At this time in our Nation's history, with the economic problems that we have, to try to increase the cost for construction to meet the vital needs of this country is really unconscionable, particularly when there's been no causal relationship found between coal ash and health problems.

Mr. WAXMAN. I continue to reserve the balance of my time.

Mr. MCKINLEY. Mr. Speaker, I yield 2 minutes of the remaining time to the gentleman from Pennsylvania (Mr. CRITZ).

Mr. CRITZ. I thank the gentleman from West Virginia for yielding.

Mr. Speaker, I rise today in support of the McKinley motion to instruct conferees, asking that the bipartisan-supported coal combustion residuals program language from H.R. 4348 be retained in the final transportation reauthorization bill.

Coal ash is of critical importance, as it is contained in the composition of the concrete used in our roads, bridges, and other infrastructure. The use of coal ash in transportation has allowed our country to maintain lower costs for infrastructure building.

Studies have shown that coal ash costs 20 to 50 percent less than other products on the market today. During a time when our roads are deficient and we need solutions that are cost efficient, coal ash serves as a reliable resource. We need to invest in materials

that will allow us the highest return on investment and stretch our highway dollars for needed improvements.

In addition to the cost savings that this will provide, including this language is also critical to support our environment and nearly 300,000 jobs that rely on coal ash use across the Nation.

In western Pennsylvania, I've witnessed the importance of coal ash to many communities in my district and surrounding areas. We have seen a transformation from orange skies and orange streams to an area whose beauty has been restored thanks to the safe use of coal ash for landfill, transportation use, and other purposes.

For these reasons, I strongly urge my colleagues to include in the final conference report the McKinley language so critical to our Nation's economic and infrastructure needs.

Mr. WAXMAN. Mr. Speaker, I yield myself 3 minutes.

The way I understand the argument on the other side is that, if the EPA regulates coal ash and calls it hazardous, that stigma will lead construction companies to avoid it as a building material.

If I could address the gentleman from West Virginia, Mr. MCKINLEY. Is that an accurate statement, that you're fearful of the designation and the stigma of that designation as hazardous?

I yield to the gentleman from West Virginia.

Mr. MCKINLEY. You say is there going to be a stigma?

Mr. WAXMAN. Is your fear that, if the EPA regulates coal ash and it's called hazardous, that that designation will be a stigma and will lead to the nonuse of coal ash by construction companies as a building material?

Mr. MCKINLEY. Mr. WAXMAN, I believe there is a stigma associated with that pending decision, yes.

Mr. WAXMAN. That is your fear?

Mr. MCKINLEY. There is a stigma associated with the misinformation that's been disseminated. That's correct.

Mr. WAXMAN. My colleagues, the thing that is so confusing to me is that coal ash is often used as a substitute for Portland cement in concrete to lower the costs; it reduces the waste, reduces the greenhouse gas emissions, and we don't need to pass legislation to have that happen.

But I want to point out that Portland cement is designated as hazardous. It's a hazardous chemical under the OSHA Hazard Communications rule. It's a hazardous substance under the Superfund amendments. It's a hazardous substance under Federal Hazardous Substances Act, and it's a hazardous material under the Canadian Hazardous Products Act. But Portland cement continues to be used extensively in concrete and transportation projects.

The EPA is not seeking to call coal ash ''hazardous.'' They want to call it a ''special waste.'' But even if they called it hazardous, why would it not be used the way Portland cement is now used, even though that substance is designated as hazardous in all these other statutes?

Mr. MCKINLEY. Will the gentleman yield?

Mr. WAXMAN. I yield to the gentleman from West Virginia.

Mr. MCKINLEY. What we're trying to do is allow more time for the conference committee to work rather than to debate the pros and cons of the environmental aspects of it. We want the committee to continue to work, to reach a compromise. And I've been told there's been great progress being made on that, but don't stop at this 11th hour. They're close to making it happen. We want to stand beside them and make sure they finish their work on these negotiations.

□ 1620

Mr. WAXMAN. Reclaiming my time, I yield myself 1 additional minute.

The reason I ask for more time is, as I understand the McKinley bill, which was adopted by the House, it would prohibit EPA from regulating coal ash because it would be designated possibly as hazardous. And the argument has been that that would be a problem when it is to be used as a substance for concrete and building materials. But I don't believe that to be the case.

Now I think that the committee, with the Senate and the House, ought to complete its business. But I don't think your amendment is needed under any circumstances. That is why I urge Members to vote against this instruction because it is trying to interject in that highway bill something that's really not part of the highway bill and something that, on its own, should not be adopted in the form of the McKinley bill.

I reserve the balance of my time.

Mr. MCKINLEY. Mr. Speaker, how much time do I have remaining?

The SPEAKER pro tempore. The gentleman from West Virginia has 5½ minutes remaining. The gentleman from California has 1½ minutes.

Mr. MCKINLEY. Mr. Speaker, I yield 2 minutes of my time to my fellow engineering colleague from the State of Texas (Mr. BARTON).

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks.)

Mr. BARTON of Texas. I thank the gentleman for yielding.

I wasn't planning on speaking on this bill. But I was listening in my office to the debate between the proponents and opponents of the bill and felt moved to come over and try to answer some of the questions that the opponents have asked of the bill.

EPA is supposed to be a fair referee. They're supposed to say: If it's a strike, it's a strike; if it's a ball, it's a ball; if he's out, he's out; if he's safe, he's safe. But the Obama EPA is not a fair referee. It's not a fair umpire. The Obama EPA has a preconceived—what I consider to be a radical environmental agenda, and they appear heck-bent to impose it on the American people, whether there is a scientific rationale or not.

As Mr. OLSON of Texas just pointed out, the President, as a candidate, said that he basically wanted to try to make it impossible to build any more coal-fired power plants in America. When he became President, he appointed a regional administrator down in Texas, Dr. Armendariz, who said that he wanted to try to put hydraulic fracturing out of business and brought a case against Range Resources in Texas that was thrown out on its face because of the lack of evidence that there was any environmental damage caused by hydraulic fracturing, in this specific case in Parker County.

You had the civil servant at the EPA early in the Obama administration, when they were considering their endangerment finding, which they had to impose in order to say they could regulate greenhouse gases, they had a career civil servant who sent a detailed, I think 50- or 60-page analysis of the proposed endangerment finding and basically said it was hogwash. And he got back emails from within the White House and the higher rankings at political subdivisions of the EPA that said, Don't tell us the facts. We've already made up our minds.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. MCKINLEY. I yield the gentleman an additional 1 minute.

Mr. BARTON of Texas. This same Dr. Armendariz made a comment not too many years ago that he wanted to crucify industry. He has since resigned because of those comments.

Those of us who support the McKinley motion to instruct do so because we don't think the current EPA is fair. Sometimes we have to tell the EPA what to do because they seem to be incapable of applying basic scientific methods, scientific principles. They want to impose a radical environmental agenda, apparently. And some of us don't think that's right, and we don't think it's good for the American people and the American economy.

So I strongly support what my good friend from West Virginia is doing because it at least makes it possible for a source that, for years and years and decades, has been used without any problem at all to continue to be used. And I think that's a good thing. So I rise in support. I thank the gentleman for the time, and I hope the House will adopt his motion to instruct conferees.

Mr. WAXMAN. Mr. Speaker, my colleagues, the gentleman from Texas told us that he was so moved to come here to correct the record. But he told us three things that are absolutely inaccurate:

The President has never said he doesn't want to build new power plants in this country. It is not true. The gentleman from Texas who worked for the EPA never said that this administration, or that he personally, was against hydraulic fracturing. It's just not true.

And the analysis of the endangerment finding by the Bush administration was signed off on not by just a career civil servant, but by the head of the EPA, appointed by President Bush.

So when you get these wrong statements in your head, you can dream up a reason to be paranoid about EPA. EPA wants to protect the public health and safety in regulating coal ash, but in doing so, they will not prevent coal ash from being used for other building purposes.

I urge that we defeat this motion to instruct, and I yield back the balance of my time.

Mr. MCKINLEY. Mr. Speaker, it's fairly obvious that a lot of the folks that have been speaking on the other side of this issue have not read the bill and don't understand what's included in the provision. But perhaps reading the bill, reading the amendment would have given them greater insight as to the role of the EPA. Because by virtue of this amendment, we are giving them great insight, great involvement in the proper disposal of the amount of fly ash that's not recycled.

So, Mr. Speaker, it really just comes down to an issue being very clear. Our opponents are just opposed to the coal industry. They're opposed to the men and women working in our coal industry. They're opposed to the 700-plus coal-fired electric utilities. They're opposed to keeping utility costs low. There is a war on coal, Mr. Speaker. And it's time that we stand up for the coal workers, the men and women working in the coalfields all across the United States, and for the men and women and the consumers that use electricity at low cost.

Now let's go to what the Departments of Interior and Transportation have said: The Department of Interior said that they concur that if fly ash is designated as hazardous waste, as is being considered, fully or in a hybrid classification, it would no longer be used in concrete. It also said, ''Fly ash costs approximately 20 to 50 percent less than the cost of cement.'' The Department of Transportation: ''Fly ash is a valuable byproduct used in highway construction. It is a vital component of concrete and a number of other infrastructure uses.''

Mr. Speaker, I ask all of my colleagues to join me today in supporting this motion to instruct conferees to continue discussing this bipartisan negotiation on this part of the highway bill and to ask their Senators to do the same. Let's maximize the use of all the money that we have available to build more roads, rebuild more bridges, do more infrastructure, but most importantly, put America back to work.

So I encourage my colleagues to vote for this motion to instruct, and I yield back the balance of my time.

The SPEAKER pro tempore. Without objection, the previous question is ordered on the motion to instruct.

There was no objection.

The SPEAKER pro tempore. The question is on the motion to instruct.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. MCKINLEY. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

GENERAL LEAVE

Mr. MCKINLEY. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous materials on my motion to instruct conferees on H.R. 4348.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from West Virginia?

There was no objection.

□ 1630

DOMESTIC ENERGY AND JOBS ACT

GENERAL LEAVE

Mr. UPTON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks on the legislation and to insert extraneous material on H.R. 4480.

The SPEAKER pro tempore (Mr. GARDNER). Is there objection to the request of the gentleman from Michigan?

There was no objection.

The SPEAKER pro tempore. Pursuant to House Resolution 691 and rule XVIII, the Chair declares the House in the Committee of the Whole House on the state of the Union for the consideration of the bill, H.R. 4480.

The Chair appoints the gentleman from Arkansas (Mr. WOMACK) to preside over the Committee of the Whole.

□ 1631

IN THE COMMITTEE OF THE WHOLE

Accordingly, the House resolved itself into the Committee of the Whole House on the state of the Union for the consideration of the bill (H.R. 4480) to provide for the development of a plan to increase oil and gas exploration, development, and production under oil and gas leases of Federal lands under the jurisdiction of the Secretary of Agriculture, the Secretary of Energy, the Secretary of the Interior, and the Secretary of Defense in response to a drawdown of petroleum reserves from the Strategic Petroleum Reserve, with Mr. WOMACK in the chair.

The Clerk read the title of the bill.

The CHAIR. Pursuant to the rule, the bill is considered read the first time.

General debate shall be confined to the bill and shall not exceed 2 hours equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce and the chair and ranking minority member of the Committee on Natural Resources.

The gentleman from Michigan (Mr. UPTON), the gentleman from California (Mr. WAXMAN), the gentleman from Washington (Mr. HASTINGS), and the gentleman from Massachusetts (Mr. MARKEY) each will control 30 minutes.

The Chair recognizes the gentleman from Michigan (Mr. UPTON).

Mr. UPTON. I yield myself such time as I may consume.

Mr. Chairman, the price of gas and the unemployment rate both remain way too high, and American families are struggling as a result. That's why I support H.R. 4480, the Domestic Energy and Jobs Act, and I urge my colleagues to do the same. This bill is truly a win-win for steps that it takes to expand supplies of domestic affordable energy that will create many jobs in the process.

It's no secret that I don't see eye-to-eye with President Obama on energy policy, but perhaps the most inexplicable energy policy move the administration has made was the June 2011 decision to withdraw 30 million barrels of oil from the Strategic Petroleum Reserve with no plan to replace it. It is hard to understand why the President would take oil from the Nation's emergency stockpile while at the same time keeping off limits the far greater amounts beneath federally controlled lands and offshore areas. It's like a couple pawning their wedding rings for cash while ignoring a major gold discovery in their own backyard.

The amount of untapped oil in areas kept out of reach by this administration is estimated to exceed the entire Strategic Petroleum Reserve dozens of times over. And these estimates are not mere speculation. Indeed, the recent increases in oil production on State and privately owned lands demonstrate the tremendous energy development on Federal lands. But that potential will only be realized if the administration's roadblocks are removed.

Title I of this bill does that. It requires that the next time the President withdraws oil from the Strategic Petroleum Reserve, he must also commit to more oil leasing on Federal lands in offshore areas. The result will be greater supplies of domestic oil and lower prices, not to mention thousands of new energy industry jobs.

Gaining access to untapped oil reserves is part of the equation; but before that oil can reach consumers at the pump, it has to be refined into gasoline and diesel fuel. Title II of this bill will help American refiners so they can keep fueling our economy and fueling the country, because what refiners really need is a little common sense, a little regulatory certainty. It would be an understatement to say that this administration's regulators have not been friendly to domestic oil production, and the truth is they have been no better to the refiners who produce the fuels that we use. In fact, EPA is moving ahead with a number of new regs affecting refineries and other facilities—regs that are likely to drive up the price at the pump and jeopardize refining sector jobs.

Title II requires that we learn about the consequences before imposing additional red tape. It sets up an interagency committee that will analyze the cumulative effects of several upcoming EPA regs on fuel prices as well as jobs. It also defers the finalization of three measures until after the analysis is completed.

The good news is that a future of chronically high gas prices is not inevitable. These policies that I have discussed and numerous other provisions in the legislation will in fact move us toward more secure, more affordable American energy and the jobs that go with it. The Nation can increase domestic energy supplies, lower future prices at the pump, and create many more jobs. This legislation takes the steps to usher in this brighter future. I urge my colleagues to join with me in supporting it, and I reserve the balance of my time.

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, DC, June 8, 2012.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: Thank you for the opportunity to review the text of H.R. 4480, the Strategic Energy Production Act of 2012, as ordered reported by the Committee on Energy and Commerce for provisions of the bill that fall within the jurisdiction of this Committee.

Knowing of your interest in expending this legislation and in maintaining the continued consultation between our Committees on these matters, I agree to discharge H.R. 4480 from further consideration by the Committee on Agriculture. I do so with the understanding that it does not in any way prejudice the Committee with respect to the appointment of conferees or its jurisdictional prerogatives on this bill or similar legislation in the future.

I would appreciate your response to this letter, confirming our mutual understanding with respect to H.R. 4480, and would ask that a copy of our exchange of letters on this matter be inserted into the Congressional Record during consideration on the House floor.

Thank you for your courtesy and I look forward to continued cooperation between our respective committees.

Sincerely,

FRANK D. LUCAS,
Chairman.

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
WASHINGTON, DC JUNE 8, 2012.

Hon. FRANK D. LUCAS,
Chairman, Committee on Agriculture, Longworth House Office Building, Washington, DC.

DEAR CHAIRMAN LUCAS: Thank you for your letter regarding H.R. 4480, the ''Strategic Energy Production Act of 2012.'' As you noted, there are provisions of the bill that fall within the Rule X jurisdiction of the Committee on Agriculture.

I appreciate your willingness to forgo action on H.R. 4480, and I agree that your decision should not prejudice the Committee on Agriculture with respect to the appointment of conferees or its jurisdictional prerogatives on this or similar legislation.

I will include a copy of your letter and this response in the Congressional Record during consideration of H.R. 4480 on the House floor.

Sincerely,

FRED UPTON,
Chairman.

U.S. HOUSE OF REPRESENTATIVES,
Washington, DC, June 19, 2012.
COMMITTEE ON ARMED SERVICES,

Hon. Fred Upton,
Chairman, Committee on Energy and Commerce, U.S. House of Representatives, 2125 Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN UPTON: I am writing to you concerning the bill H.R. 4480, the Strategic Energy Production Act of 2012, as amended. This legislation includes a provision that deals with military readiness and training activities, which fall within the Rule X jurisdiction of the Committee on Armed Services.

Our committee recognizes the importance of H.R. 4480, and the need for the legislation to move expeditiously. Therefore, while we have a valid claim to jurisdiction over this legislation, the Committee on Armed Services will waive further consideration of H.R. 4480. I do so with the understanding that by waiving consideration of the bill, the Committee on Armed Services does not waive any future jurisdictional claim over the subject matters contained in the bill which fall within its Rule X jurisdiction. I request that you urge the Speaker to name members of this committee to any conference committee which is named to consider this provision.

Please place this letter and your committee's response into the Congressional Record during consideration of the Measure on the House floor. Thank you for the cooperative spirit in which you have worked regarding this matter and others between our respective committees.

Sincerely,

HOWARD P. ''BUCK'' MCKEON,
Chairman.

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, June 20, 2012.

Hon. HOWARD P. ''BUCK'' MCKEON,
Chairman, Committee on Armed Services, Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN MCKEON: Thank you for your letter regarding H.R. 4480, the ''Strategic Energy Production Act of 2012.'' As you noted, there are provisions of the bill that fall within the Rule X jurisdiction of the Committee on Armed Services.

I appreciate your willingness to forgo action on H.R. 4480, and I agree that your decision should not prejudice the Committee on Armed Services with respect to the appointment of conferees or its jurisdictional prerogatives on this or similar legislation.

I will include a copy of your letter and this response in the Congressional Record during consideration of H.R. 4480 on the House floor.

Sincerely,

FRED UPTON,
Chairman.

Mr. WAXMAN. Mr. Speaker, I yield myself 4 minutes.

Throughout this Congress, House Republicans have made an all-out assault on our Nation's most basic public health and environmental protections. And they have blocked any effort to address climate change, move towards clean energy, or promote energy efficiency.

On Monday, Congressman MARKEY and I released a report that documents this all-out assault. It confirms that this is the most anti-environment House in the history of Congress. Over the last 18 months, the House has voted 247 times to undermine protection of the environment. That's almost one out of every five votes taken in the House.

The oil and gas industry has benefited more than any other sector from these anti-environment votes. Since the beginning of 2011, the House has voted 109 times for policies that would advance the interests of the oil and gas industry at the expense of the environment, public health, and the taxpayer. The result is a grave and growing peril to our environment, to public health, and to our economy. The massive wildfires, floods, droughts, and heat waves that have been afflicting our country are a harbinger of what is to come.

Americans know this. As the Washington Post reported this morning, the vast majority of Americans believe our environment is deteriorating, and they know that unchecked pollution from oil refineries and other industrial sources is making the problem worse. Yet what are we doing today? Today's bill is one more massive giveaway, and it is one more assault on the environment.

This bill contains two proposals reported by the Energy and Commerce Committee. One would block standards for oil companies to clean up their pollution. The other seeks to bypass existing leasing programs in order to pry open every possible acre of Federal land for oil drilling.

This legislation has been promoted as a solution to high gasoline prices. But this bill is a Trojan horse. This bill would not lower prices by one penny. This bill doesn't protect consumers. It hurts them. The bill will keep dirty gasoline on the market, allow oil refineries to spew toxic emissions, and forestall action to address climate change.

Tucked inside this legislation is the Latta amendment. The language of this amendment cuts the heart out of the Clean Air Act, radically changing the way air quality standards are set. Rather than basing smog standards on what is healthy for our children to breathe, this bill would require standards to be based on what industry says it will cost to reduce pollution. This radical proposal will undermine decades of progress on cleaning up the air. The bill will also cost jobs. The regulations blocked by this bill would create tens of thousands of jobs installing pollution controls and modernizing oil refineries.

□ 1640

In addition, this bill would make it harder for the President to tap the Strategic Petroleum Reserve during emergencies by layering on new bureaucratic requirements to force drilling across a vast expanse of public land.

This bill may be good for the oil companies, it may be good for the special

interests, but it is a disaster for the American people. The Republican energy policy isn't an all-of-the-above policy; it's oil above all.

I reserve the balance of my time.

Mr. UPTON. Mr. Chairman, I yield 2 minutes to the gentleman from Kentucky (Mr. WHITFIELD).

Mr. WHITFIELD. I rise today to support the Domestic Energy and Jobs Act for a number of reasons. First of all, it would encourage more production of energy in the United States. Two, it would lower energy costs. Three, it would create additional jobs for the American people. And, four, just as important, it would keep America more competitive in the global marketplace.

We live in a global economy, and our ability to have cheap, affordable, and abundant energy is absolutely necessary if we are going to compete with countries around the world. So that's what this legislation is designed to do.

All of us have a responsibility to the environment, but we genuinely believe after hearing after hearing after hearing after hearing, people who create jobs come in and talk about the additional costs they're incurring because of this overly aggressive EPA, headed up by Administrator Lisa Jackson.

I would also say that one portion of this bill is a very commonsense approach. While it would not immediately lower gasoline prices, it does ask the President to establish an interagency task force to examine the impact on jobs, prices, and competitiveness of three regulations that the EPA has initiated. They haven't finalized it, they haven't decided they are going to finalize it, but they have started the first steps. And so we ask this Agency to look at what is the impact on fuel prices with these regulations if they are adopted and to report back to Congress and to not finalize any of these rules until at least 6 months after they report back to Congress. It seems to me a commonsense approach. We have a responsibility to the American people to have some idea about the impact of these regulations on the economy.

Mr. WAXMAN. Mr. Chairman, I yield 5 minutes to the ranking member of the Energy Subcommittee, the gentleman from Illinois (Mr. RUSH), and I would like to ask unanimous consent that he be permitted to control the rest of the time for our side of the aisle on the general debate.

The CHAIR. The gentleman from Illinois will control the time.

Mr. RUSH. Mr. Chairman, since the beginning of the 112th Congress, we have held over 30 Energy and Power Subcommittee and joint subcommittee hearings. We have held over a dozen subcommittee and full committee markups, and including H.R. 4480, which we will vote on today, we have had 10 bills that originated from the Energy and Power Subcommittee that have been voted on by the full House.

Yet, Mr. Chairman, from all of that time and all that effort, the Energy and Power Subcommittee has produced exactly one substantive bill. Let me repeat: only one substantive, significant bill, the Pipeline Safety Reauthorization Act, the only one that has actually become law.

Mr. Chairman, instead of focusing our efforts on trying to create the clean energy jobs of the 21st century, the majority party has spent the past 18 months lobbing partisan attacks against the EPA and the Clean Air Act in order to appease Big Oil and some of the more extreme constituencies that the Republican Party represents.

Mr. Chairman, most Americans would like to see us utilizing our time working in a bipartisan manner to address critical issues, such as access to jobs, clean air, and clean water, less dependence on foreign oil, enhanced energy-efficiency measures, and an increased reliance on the cleaner and renewable energy sources of the future.

Instead, here we are again debating yet another bill that would continue the concerted effort by the majority party to weaken the authority of the EPA and to delegitimize the Agency's regulations as job killers.

Mr. Chairman, with just a little over 20 days remaining before the August recess, we should be focusing our limited time on legislation that will create jobs and move America forward toward a smarter energy future that is less vulnerable to the whims of the world oil market. However, nothing in this bill accomplishes that.

The most offensive provision of this bill, the Gasoline Regulations Act, would fundamentally change a cornerstone of public health law, the Clean Air Act, and I ask my colleagues: Why, to what end?

This bill will not create any jobs but, rather, would block EPA rules to make the fuel we put into our cars cleaner. This bill would also block rules that would cut toxic air pollution from refineries.

This bill blocks the EPA from requiring new refineries from cutting carbon pollution that causes climate change, and it even blocks the agency from revising the national air quality standard for ozone to reflect the best-available science and medical evidence about how much ozone is safe to breathe without serious health effects.

Mr. Chairman, one truth remains, and that truth is that H.R. 4480 isn't really about jobs, isn't really about lowering gasoline prices. It is about an excuse to push a profoundly anti-environmental agenda and provide oil companies with more items from their election year wish list.

Oppose this bill because it would strike at the heart of the Clean Air Act and would not provide any tangible benefits to the American people. I urge all of my colleagues to oppose it as well.

I reserve the balance of my time.

Mr. UPTON. Mr. Chairman, I yield 2 minutes to the gentleman from Kansas (Mr. POMPEO), and I would ask that at the conclusion of his 2 minutes that the balance of my time be controlled by the gentleman from Colorado (Mr. GARDNER).

The CHAIR. The gentleman from Colorado will control the time.

The Chair recognizes the gentleman from Kansas.

Mr. POMPEO. Mr. Chairman, H.R. 4480, the Domestic Energy and Jobs Act, the legislation we'll vote on before too long, has three very simple missions. The first is to lower and create affordable energy for folks all across America. The second is to create the jobs that go with it. And, finally, it's to begin to put American energy policy back on a commonsense, simple standard that allows affordable energy to be produced here in America by Americans for Americans.

You know, we've seen in these discussions, these debates, that there are two opposing views on how to do this. The first is the view of the folks on the other side who think if we just had one more rule, one more set of regulations, another subsidy, another handout from the taxpayers, we here in Washington, D.C. could find that next great affordable energy source. We've seen how that's worked. We've got gasoline at $3.50 a gallon. We've got utilities all across the country asking for rate increases.

There's another view. There's another way to go about it. It's to let the market respond to price signals. It's to get the Federal Government out of the way, to reduce regulations across the board while making sure that we've still got safe drinking water and clean air. Both of these objectives can be accomplished.

This legislation simply streamlines and simplifies the leasing and permitting processes on Federal lands to make sure that consumers have access to affordable American energy. We have tremendous opportunities right here in America. Right in Kansas' Fourth Congressional District, in Harper and Kingman and Stafford and Edwards and Barber and Pratt, all over south central Kansas, an enormous new opportunity, creating real, affordable energy produced by Americans with American jobs.

□ 1650

We also, through this legislation, say if we're going to tap this important American resource, the SPR, the Strategic Petroleum Reserve, we're going to make sure and replenish it—again, with American affordable energy.

This is one of the most consumer-friendly, ratepayer-friendly, taxpayer pieces of energy legislation to reach the House floor in a long time, and I would urge all my colleagues to support this legislation.

Mr. RUSH. Mr. Speaker, I yield 4 minutes to my friend, the gentlewoman from my home State of Illinois (Ms. SCHAKOWSKY).

Ms. SCHAKOWSKY. I thank the gentleman for yielding, and I appreciate his leadership on the Energy Subcommittee.

As a member of the full Energy and Commerce Committee, frankly, I'm ashamed that this House is actually considering legislation that puts public health decisions in the hands of the oil industry.

Title II of H.R. 4480 eliminates a core principle of the Clean Air Act with respect to smog. For over 40 years, the Environmental Protection Agency has set health-based air quality standards using scientific and medical evidence to identify the maximum safe levels of air pollution for human beings to breathe. Title II would do away with that precedent by requiring that the cost to industry be the primary consideration in determining healthy emission standards. Yes, if this legislation passes, health-based decisions will play second fiddle to dollar considerations for the first time.

Over the years, our air has become cleaner and safer because industry has had to comply with more stringent standards. Lead is no longer poisoning our children from the pump. There are fewer kids with asthma due to gas pollutants. And oil companies, rather than suffering, are now making record profits. We don't have to pass the hat for the oil companies. The five largest made $137 billion in profit last year and $33.5 billion in the first quarter of 2012. Our health decisions should be made by health experts, not our worst polluters.

H.R. 4480 continues the policy of the 112th Congress: if the oil industry asks, the oil industry gets, no matter the impact on American families.

Title II sets up a new interagency bureaucracy to conduct an impossible study of the alleged economic impact of several EPA rules to reduce pollution from refineries and fuels—which haven't even been proposed—using data that doesn't exist. In the meantime, this title blocks the EPA from finalizing several air quality protections that the oil industry would prefer go away.

Title II does nothing to protect the consumer from price spikes at the pump or to reduce our country's dependence on oil. Instead, it is a giveaway to the oil industry under the false pretense of lowering gasoline prices.

The oil industry doesn't want to reduce the amount of toxic air pollution spewing from its refineries. The oil industry doesn't want to produce cleaner burning gasoline. The oil industry would rather not construct new refineries that are more efficient and less damaging to the world's climate. Oil industry executives would prefer to pocket all their billions in annual profits rather than invest any of it in modern, less polluting technology.

I offered an amendment yesterday that would have simply said that the unnecessary and impossible study required under title II would be paid for by the one industry that most stands to gain from its implementation, Big Oil. My amendment was not made in order.

The American people deserve better than this. They deserve clean air and clean water. They deserve more than a few months of a transportation bill. They deserve a jobs package that will put millions to work, including teachers and construction workers and firefighters and police officers. They deserve affordable student loan rates. Instead, the Republicans of this House have elected to carve out additional privileges for Big Oil.

Mr. GARDNER. I yield 1 minute to the gentlelady from Kansas (Ms. JENKINS).

Ms. JENKINS. I thank the gentleman for yielding.

Mr. Speaker, as a member of the House Energy Action Committee and a Representative from an energy State, I come to the floor today to support an all-of-the-above energy bill and an all-of-the-above jobs bill.

I know firsthand the tremendous economic growth and job creation that comes from unlocking American-made energy. My State of Kansas is undergoing an energy boom. Farmers are making money, tractor dealerships are selling new tractors, and families are paying off loans. Even church contributions have benefited.

Sadly, this American success story has been attacked by the current administration's repeated rejection of policies that would increase domestic energy production and create thousands of high-paying American jobs.

This important legislation strengthens our energy security, it removes the bureaucratic red tape hindering American energy production, and it creates American jobs.

Simply, we cannot afford to delay action that would create thousands of jobs. I urge passage of this legislation.

Mr. RUSH. Mr. Speaker, I yield 4 minutes to the gentleman from Pennsylvania (Mr. DOYLE), a fine member of the subcommittee and a distinguished member of the full committee.

Mr. DOYLE. Mr. Speaker, I rise in opposition to this bill before us.

Today we're debating a bill that Republicans tell us will embrace an all-of-the-above energy strategy. The way this bill purports to do this is by opening large swaths of land to oil and gas drilling, halting regulations, and gutting the Clean Air Act. It's clear that this is not a true effort to develop an all-of-the-above strategy, but instead is a narrow-minded approach to oil and gas development at any cost.

Republicans continue to criticize President Obama and congressional Democrats for opposing efforts to increase U.S. domestic oil production, but the facts disprove this notion. The President hasn't agreed with every proposal to expand oil and gas drilling in the United States and its territorial waters, but he has taken action to open up substantial new public lands and coastal waters to oil and gas development.

Today, roughly 75 percent of U.S. oil reserves on public lands and under our coastal waters have been leased out to oil drillers. In fact, domestic oil production is at an 8-year high, and the production of natural gas plant liquids—liquefied petroleum gases that are used for fuel—is currently at an all-time high of more than 2 million barrels per day. All told, the U.S. Energy Information Agency estimates that U.S. petroleum production in 2012 will average more than 8 million barrels per day.

The number of oil rigs in the United States has quadrupled under President Obama. At the same time, petroleum consumption in the United States has dropped by more than 2 million barrels per day since its all-time peak in 2006. Now, since domestic oil production is up and petroleum consumption is down, U.S. oil imports are at a 17-year low. In fact, the United States is importing 10 percent less oil than it was 8 years ago.

Now, one might reasonably conclude that since the United States is producing more oil and consuming less, oil and gas prices would be going down, but that's not happening. Oil and gas prices are going up. Well, how can that be? Oil prices—and consequently gas prices—are rising because, while oil consumption may be lower in the United States, global demand for oil is, in fact, rising.

Rest assured, this bill does nothing to address the real problem of high gas prices, and it does nothing to develop a real all-of-the-above energy strategy for the United States. This bill is going nowhere in the Senate, and it's a true disappointment as this Congress' effort to address high gas prices and an expanded energy portfolio.

I urge my colleagues to reject this bill.

Mr. GARDNER. Mr. Speaker, I yield 2 minutes to the gentleman from Louisiana (Mr. SCALISE).

Mr. SCALISE. I thank the gentleman from Colorado for his leadership and for bringing this legislation to put a good energy policy in place in this country, which we do not have today under President Obama.

If you look at components of the bill, it talks about the Strategic Petroleum Reserve. The President has used the Strategic Petroleum Reserve as his bailout fund, basically, for his failed policies.

□ 1700

He's raided it. Last year he raided 30 million barrels from SPR and still, to this day, hasn't replaced that oil. But on top of that, the President took those dollars, billions of dollars, and spent them on unrelated government spending. So that's what the President's been doing with SPR—using it as his personal piggy bank and bailout fund for his failed policies.

The President and others like to talk about an all-of-the-above strategy. They love to talk about energy production never being higher. One thing they fail to mention is that energy production on Federal lands, where the Federal Government actually has control,

is down. In fact, President Obama's own administration, the Energy Information Agency, confirmed again recently that production this year on Federal lands is down 30 percent just in the Gulf of Mexico from last year. So they talk about production being higher. It's higher on private lands where they have no control.

And by the way, through EPA and Department of the Interior and other Federal agencies they're trying to regulate and shut that down right now, too. So while they're bragging about it, they're trying to shut it down.

Just today, in New Orleans they had a lease sale; first lease sale we've had in more than 2 years. And in fact, it shows that there's tremendous interest in exploring for American energy. The only problem is there is no more plan in place.

Normally, you always have a 5-year plan in this country. By law, the President's supposed to have a 5-year plan. After today, there's nothing on the books for any more future lease sales. And, in fact, the proposal that the President has been sitting on shuts off 85 percent of the areas that were getting ready to be opened up for exploration. And what does that lead to? It leads to a greater dependency on Middle Eastern oil, on these foreign countries that don't like us.

The President has shipped tens of thousands of energy jobs out of this country. We've tracked rigs that have left the states and gone to places like Egypt and Ghana and Brazil. Those jobs ought to be here. We ought to be creating those jobs here and seeking energy independence, and this bill is a great start. I urge its support.

Mr. RUSH. Mr. Chairman, I yield 2 minutes to the gentleman from Oregon (Mr. BLUMENAUER).

Mr. BLUMENAUER. I appreciate the gentleman's courtesy.

This bill, sadly, is a missed opportunity. It would have been an opportunity to deal with an all-of-the-above and a jobs bill, but it simply is not.

We're in a situation where domestic oil production is strong. And what we are looking at, currently they're talking about giving out, encouraging more land to be locked up for the future, rather than using the 25 million acres currently authorized for drilling that are not being used by oil companies today. They would allow people to sit on land, paying only $1.50, $2 an acre for up to 10 years.

Now, I think it's wise for us to be able to move forward to encourage energy production. There would be an opportunity here to deal more aggressively with incenting sustainable energy, clean energy, energy that will be with us for decades to come, rather than depleting existing resources and tying up leases in the future.

This is an excuse to undermine existing environmental protections. Why, in heaven's name, would we seek to undermine tailpipe emission regulations that are already supported by the auto industry? It makes no sense at all.

It is not wise to have language that orders the EPA to consider the cost of a clean energy rule, rather than the impact on public health, turning on its head longstanding priorities.

I suppose you could diagnose lung cancer, but say, well, it's pretty expensive, so let's not say that it's lung cancer. Let's call it a cough.

Mr. Chairman, it's important for EPA to make the decisions to protect public health rather than company profits, which are exploding in time.

This is a missed opportunity. I suggest its rejection.

Mr. GARDNER. Mr. Chairman, I would like to inquire as to how much time my side has remaining.

The CHAIR. The gentleman from Colorado has 19½ minutes remaining. The gentleman from Illinois has 12 minutes remaining.

Mr. GARDNER. Mr. Chairman, I yield 1½ minutes to the gentleman from Texas (Mr. CANSECO).

Mr. CANSECO. Mr. Chairman, I thank the gentleman from Colorado for yielding time.

High energy prices are having a negative impact on our economy and on our family budgets. But don't take my word for it. This is what my constituents have told me firsthand.

There's David from Castroville, Texas, who wrote:

> As a self-employed carpenter, gas prices for a large truck cut into my profits. It is madness that the USA is not oil and gas independent. Energy independence is essential for our economy to grow and protect our freedom.

Another constituent, Ray, stated:

> I'm a retired engineer and planned to travel with my wife this summer but had to curtail these plans because of the high cost of gasoline. This has cut deeply into my retirement pay and I'm spending more time at home because of gasoline prices.

Mr. Chairman, this isn't rhetoric from Washington insiders, but input from working-class Americans who are struggling to make ends meet. I urge my colleagues to support the Domestic Energy and Jobs Act in order to increase energy production, eliminate red tape, and create jobs.

Mr. RUSH. Mr. Speaker, I yield 3 minutes to the gentleman from California (Mr. GARAMENDI).

Mr. GARAMENDI. I thank the gentleman for his courtesy.

Facts are really kind of difficult if you have to deal with them. The gentleman just spoke about a sad case of an individual that wasn't able to go on a trip because of the high price of gasoline. He may want to tell that individual that the oil industry, on average, over the last several months, has exported over 24 million gallons of gasoline a day, 24 million gallons of gasoline a day, exported from the United States. Maybe that has something to do with the high prices.

But a few other facts. As of March of 2011, onshore, the Department of the Interior offered, between 2009 and 2011, 6 million acres of land for leasing. The oil industry only took 4 million acres. As of that time, March 2011, 38 million acres of land were under lease. 25 million acres of land were inactive. A full 65 percent of the available leased land already in the hands of the oil industry was inactive, not explored, not being produced. 65 percent unused, inactive.

Offshore, 37 million acres were under lease. 2.4 million acres were active. 70 percent not being used.

So why are we here opening more land? There's a reason for it. There is a reason why the oil industry wants to do this. If they are able to acquire a lease, they put it on their books as an asset, thereby giving the appearance that they have a lot of assets available to them, when, in fact, they have no intention to, in the near term, probably the next decade or so, actually explore and produce. It is a financial game. It is not a game of producing oil.

Now, if we really wanted to do something, we would immediately put in place a production tax credit for the wind turbine industry, which is languishing now because we are refusing, Republicans, in this case, refusing to put forth a renewal of the production tax so that the wind industry can actually continue to produce energy for our Nation.

So what does it mean?

There are some 70,000 jobs in the wind industry today. Some 17,000 more would immediately go into place if the production tax credit were in this bill and became law.

What does it mean?

If we were to enact my bill, H.R. 487, those wind turbines would be manufactured in the United States, and thousands more jobs.

The CHAIR. The time of the gentleman has expired.

Mr. RUSH. I yield another 30 seconds to the gentleman.

Mr. GARAMENDI. The bottom line of this: this is simply a play by the oil industry to gather more assets on their balance sheet, at the expense of the environment and, just as important, at the expense of a real, all of the above energy policy.

It's a sad day that we're here debating an energy bill that really doesn't do anything at all to help us meet the energy needs of this Nation. There's nothing in this about renewables. It's unfortunate.

□ 1710

Mr. GARDNER. I yield 1½ minutes to the gentleman from Ohio (Mr. LATTA).

Mr. LATTA. I appreciate the gentleman for yielding.

Mr. Chairman, I rise today in support of H.R. 4480, the Domestic Energy and Jobs Act.

This bill comes at a critical time as consumers, farmers, and small businesses are facing high fuel prices and as the President is restricting Federal leases from oil production while at the same time considering releasing oil from the United States' Strategic Petroleum Reserve.

I represent an area of the State of Ohio that has the largest number of agriculture producers, manufacturing jobs, and small businesses. When you look at these numbers, we'd have a very high, disproportionate hit for my constituents because of high oil prices.

As this bill requires, all regulations should be subject to a thorough analysis of cost, benefits, and potential hurdles to implementation. The Gasoline Regulations Act of 2012, which is part of this bill, will delay regulations that could significantly increase fuel prices on consumers, farmers, and small businesses while these regulations are under review. It will also provide some much-needed regulatory relief to refiners, who are struggling to stay in business due to the high cost of fuel.

Reducing the costs of refining fuel is a great first step, but the key to reducing fuel prices is to bring more supply into the market. The only time that oil should be released from the Strategic Petroleum Reserve is to counter a severe supply interruption. I support legislation that will allow the increased access to responsible domestic oil production, and for these reasons, I support the bill.

Mr. RUSH. Mr. Chairman, I reserve the balance of my time.

Mr. GARDNER. I would like to yield 2 minutes to the majority whip, the gentleman from California (Mr. MCCARTHY).

Mr. MCCARTHY of California. I want to thank freshman CORY GARDNER for bringing this legislation to the floor.

Mr. Chairman, I want to for one moment imagine. I want to imagine a country, an America that doesn't have 40 months of 8 percent unemployment. I want to imagine an America with 3 percent unemployment. Could you imagine a country that had a trade deficit that was shrunk? Could you imagine a government that, instead of saying it wants to raise taxes, actually cut them? Imagine that, in a housing crisis, you're not sitting with foreclosures, but you actually need more houses to be built and that people are flying into the country because the jobs are there and it is the place to be. I want to imagine, when you go down to even work at McDonald's, you're making $15 an hour.

A lot of people in this country turn on the news and think that's farfetched. They think that's impossible to dream or to even imagine. But do you know what? That's taking place in parts of this country. That's exactly what's happening in North Dakota. And why is it happening in North Dakota? It's because they created a State energy policy that is unshackled.

There is a team here, Mr. Chairman, that is called the HEAT Team, the House Energy Action Team. We went across the country and saw all walks of life—from California, to driving an electric car in Colorado, to going into the fields of North Dakota, which is where I went. Do you know what? I drove past the windmills. I looked at new technology which is able to extract in a much more pinpointed method and environmentally friendly way so that we can get those resources. What has it done? It has transformed the State with regard to job creation. More importantly, it has transformed our Nation because, yes, we are importing less today than in 1994, but that's only on private lands, not on public lands.

The CHAIR. The time of the gentleman has expired.

Mr. GARDNER. I yield the gentleman an additional 30 seconds.

Mr. MCCARTHY of California. So today, on this floor, we are debating something that can change America. No longer will you sit back at home and think, one day, I could only imagine unemployment low, revenues high, and everybody who wants a job can have one.

This bill today is about jobs. It's about jobs that not only create a new America but that change our foreign policy. It creates a new America in which we invest today, and it makes us energy independent.

Mr. Chairman, I ask all to vote ''aye,'' and I thank the gentleman for bringing it to the floor.

Mr. RUSH. Mr. Chairman, I continue to reserve the balance of my time.

Mr. GARDNER. I would like to yield 1 minute to the majority leader, the gentleman from Virginia (Mr. CANTOR).

Mr. CANTOR. I thank the gentleman.

I rise in support of this legislation before us, which will boost domestic energy production, spur job creation, and grow the economy.

The Domestic Energy and Jobs Act opens up more of our domestic energy resources, brings greater certainty to leasing on public lands, and does take steps to cut red tape that is increasing the cost of fuel and blocking energy development. Increasing energy production on our Nation's public lands and in its waters can create millions of jobs, boost the economy, lower energy costs, and make America more secure.

It wasn't too long ago that an energy-secure America seemed like an unreachable goal. Today, energy security is on the horizon because of innovations that have helped increase our domestic energy supply and that have created thousands of good-paying jobs along the way. I saw these innovative technologies firsthand a few weeks ago when I was out on a deep-sea rig off the coast of Louisiana. With this legislation, we give our Nation's energy producers the certainty they need to invest in the innovations that are essential to American-made energy and American-made jobs.

The oil and gas industry is the lifeblood of so many communities across our Nation, but this President's policies have stifled the development of many of our Nation's energy resources. Red tape and restrictions coming from the Obama administration are keeping America's abundant energy resources under lock and key, away from our job-creating private sector.

As a result of some of these policies, small businesses are feeling the squeeze of high energy costs; families planning their summer vacations are facing historically high gas prices; and new jobs are being sidelined. People are wondering, when will things get better? They're looking for leadership out of Washington. Frankly, this administration has not delivered.

Since the President took office, production on public lands has decreased. While I welcome the administration's announcement that it is moving forward with a long delayed lease sale in the central Gulf of Mexico, it is simply unacceptable that this is the first lease sale the administration has held in the central gulf since 2010. Our Nation's energy producers have been ready and waiting to put their capital on the line to develop our Nation's resources.

Delaying decisions critical to energy development creates uncertainty and slows job creation. In fact, the Obama administration has canceled more lease sales than it has actually held, so I think the big question is, why aren't we doing more? Why aren't we developing more of our Nation's Outer Continental Shelf, such as that off the coast of Virginia, where there is broad bipartisan consensus in my State supporting such development?

After years of watching the President fail to embrace a pro-growth energy policy, the American people do deserve more. The future of our country depends on a true, all-of-the-above energy strategy that promotes domestic energy production, job creation, and economic growth.

By adding certainty to the regulatory process, we can promote domestic energy development in an environmentally sensitive way. We can promote economic growth and get Americans back to work. These seven bills, as part of the HEAT Team package, will help bring down high energy costs, which are hurting families and crippling small businesses, so that we can then spur the creation of thousands of jobs.

I want to salute and thank the House Energy Action Team: the bill's chief sponsor, Congressman CORY GARDNER; Congressman ED WHITFIELD; Congressmen SCOTT TIPTON and MIKE COFFMAN; and Congressmen DOUG LAMBORN and BILL JOHNSON for putting forward these measures that will harness our domestic energy resources.

Finally, I would like to thank our whip, KEVIN MCCARTHY, for his leadership and for bringing all of us together, as well as thank Chairman FRED UPTON and Chairman DOC HASTINGS for their leadership on these measures that are essential to our Nation's competitiveness and job creation.

□ 1720

Mr. RUSH. Mr. Chairman, I yield 4 minutes to one of the most remarkable leaders that this Congress has ever

seen, the gentleman from Maryland (Mr. HOYER).

Mr. HOYER. I thank my friend, and I would have come up here just for that introduction. I thank him so much.

I am pleased to follow my friend, the distinguished majority leader, Mr. CANTOR. I'm going to have some remarks. But before I get to those remarks, I want to give you some statistics that I know you'll find very interesting. I want you to take them to heart.

The Energy Information Administration reports that oil production from Federal lands and waters was higher the first 3 years of the Obama administration than the last 3 years of President Bush's administration.

In addition, oil imports are at the lowest they have been since 1997. In 2011, U.S. crude oil production reached its highest level in 8 years, increasing by an estimated 110,000 barrels per day over 2010 levels to 5.59 million barrels per day. We now produce more than 50 percent of the crude oil we use domestically.

The U.S., by the way, has 1,971 rigs in operation. The rest of the world has 1,471.

The U.S. natural gas production is record breaking. In 2011, 28.5 million cubic feet. In 1973, which was the previous record, it was 24 million cubic feet. But hear this: In 2005, during the Bush administration, it was 5 million less.

Net imports as a share of total consumption has declined from 2005, where it was 60 percent in the Bush administration, to 2011, where it is 47 percent.

The administration has announced that the 2012–2017 5-year leasing plan will open up more than 75 percent of our potential offshore oil and gas resources. The U.S. production for Federal lands on shore is similar to and has surpassed the Bush administration. In 2005, it was 649 million barrels; in 2010, it was 739 million barrels, otherwise known as almost 100 million more barrels.

Ladies and gentlemen, we understand that we need to produce and use energy in America. Mr. Chairman, we should be working, however, together to find real solutions to meet our pressing challenges. We ought to pass a long-term highway bill to create thousands of construction jobs. We ought to address the looming deadline when student loan interest rates are set to go up on July 1. We ought to get to work on taxes so we can keep low rates in place for middle class families. And we ought to get serious about comprehensive deficit reduction before we find ourselves on the edge of a fiscal cliff this year.

Instead, Mr. Chairman, once again, we have a solution looking for a problem. Our Republican friends have called up two bills on the floor this week that make this very clear.

While gas prices have thankfully retreated, the first bill would enact an extreme drill-only energy strategy that won't lower gasoline prices. That bill is notable for what it doesn't do: invest in diverse energy sources that create jobs, reduce our oil dependence, and enhance energy security; nor does it make our Nation a global leader in energy technology.

The CHAIR. The time of the gentleman has expired.

Mr. RUSH. I yield the gentleman an additional 1 minute.

Mr. HOYER. Mr. Chairman, I thank the gentleman for yielding.

The second bill, which we considered yesterday, would impose a radical policy on our border areas that would undermine security coordination and bring polluting industries to some of our most pristine parks and historic sites, even though our border enforcement officials have said such legislation is unnecessary. That's what we worked on yesterday. Not jobs, not student loans, not transportation, but a piece of legislation that they said wasn't necessary.

These are not what Congress ought to be focusing on this week or next week. Let's turn our attention to our most pressing issues—student loans, construction jobs, keeping middle class taxes low, and reducing deficits—instead of wasting the American people's time on partisan bills that won't solve any of our real problems.

Mr. Chairman, I'm hopeful that either in the next 24 hours or in the next 9 days we will, in fact, pass a jobs bill that will create jobs, and everybody knows that that's the highway bill.

The CHAIR. The time of the gentleman has again expired.

Mr. RUSH. Mr. Chairman, I yield 30 seconds to the gentleman from Maryland.

Mr. HOYER. The Senate has passed a highway bill in a bipartisan fashion with half of the Republicans in the United States Senate voting for it, and with a very conservative Republican ranking member, JIM INHOFE, and a very liberal chairwoman, BARBARA BOXER, who came together and had the ability to compromise and come to agreement.

I tell my friends on the Republican side, that's what the American people want us to do. If we do that, it will raise the confidence of our people, of our business community, of our country. That will be the best thing we can do for our country, to come together in a bipartisan fashion, as the United States Senate did, and act.

Mr. GARDNER. Mr. Chairman, I yield 1½ minutes to the gentlelady from Alabama (Mrs. ROBY).

Mrs. ROBY. I thank the gentleman from Colorado.

Mr. Chairman, I rise today in support of the Domestic Energy and Jobs Act.

Oil accounts for 37 percent of U.S. energy demand, with 71 percent directed to fuels that are used in transportation. Our energy policy is vitally important to our national and economic security. It's especially as important to the mother who drives her children to school as it is the business owner who operates a fleet of delivery vehicles. When the price of gasoline increases, Americans hurt.

Last year, the price of gasoline increased 81 cents per gallon. That is why I do support an all-of-the-above approach to energy. This includes opening up new areas for American energy exploration, transitioning to renewable and alternative energy, and using more clean and reliable nuclear.

The President in his last State of the Union stated the same belief, but this administration has done nothing to back up that statement. The executive branch is using the Strategic Petroleum Reserve for political purposes by imposing overburdensome regulations on refineries and placing obstacles to increasing permitting and leasing on Federal lands for gas and oil production.

During this administration, we have seen a drastic decrease of oil production on federally owned lands at a time with high gas prices. From 2010 to 2011, there has been a 14 percent decrease. The Domestic Energy and Jobs Act will enable job creators in the energy industry and increase domestic energy production here at home.

The legislation that is before us today will turn the tide on this administration's actions, or lack thereof, and allow our Nation to move forward on our Nation's energy production, thereby increasing jobs and bringing us closer to energy independence.

I urge all of my colleagues to vote in favor of this bill.

Mr. RUSH. Mr. Chairman, may I inquire as to how much time is remaining on this side?

The CHAIR. The gentleman from Illinois has 3 minutes remaining, and the gentleman from Colorado has 11½ minutes remaining.

Mr. RUSH. Mr. Chairman, I yield 2 minutes to the gentleman from Tennessee (Mr. COHEN).

Mr. COHEN. Thank you, Mr. RUSH. I appreciate the time.

Mr. Chairman, I rise in opposition to H.R. 4480. This is a bill that is totally a giveaway to Big Oil.

The fact is, if we want to be energy independent, we can't drill our way to energy independence. We can get there by having alternative green energies that will create jobs and make us independent. We can have wind and solar, and we can have higher fuel standards for automobiles. That's the best thing we can do is reduce the demand for oil by having higher fuel standards, which we don't have in this bill. Regarding the price of oil and making ourselves energy independent, it's not going to happen.

My colleagues on the other side—at least some of them—have for quite a while, about 2 or 3 months ago, blamed the rising prices of gasoline on President Obama. Gasoline has come down considerably since that time. Has one person had the veracity, the bipartisanship to say, Mr. President, thank you for bringing the price of oil down?

No, they haven't, because the President didn't bring the price of oil down, just like he didn't take the price of oil up. It's political rhetoric to say he caused the prices to go up, and it would be wrong to say he brought them down.

□ 1730

There are world markets, demand in China, demand in India, demand even in Bangkok; and those demands have put the price of oil up. The situation in Iran with Israel has created concerns about the future of oil shipments through the Strait of Hormuz. Because of that, prices went up. That situation has been rectified.

This bill is only a giveaway to Big Oil. It threatens people's First Amendment rights because it says they have to put up a $5,000 bond simply to protest. It threatens jobs. In many industries—the outdoors industry—it threatens public health and people's opportunity to be free from air pollution. It threatens hunting, fishing, and recreation and grazing because it violates the multiple-use doctrines established in the Federal Land Policy and Management Act.

This is not a good bill for America. And to be energy independent, we need to find green energy and green jobs.

Mr. GARDNER. Mr. Chairman, I yield 90 seconds to the gentleman from Texas (Mr. CONAWAY).

(Mr. CONAWAY asked and was given permission to revise and extend his remarks.)

Mr. CONAWAY. Mr. Chair, I rise today in strong support for the Domestic Energy and Jobs Act of 2012 because I personally know the importance of the oil and gas industry to the future of America.

I am fortunate to call West Texas home. Growing up in the Permian Basin has given me a better perspective on what it means to produce the raw resources that our Nation needs to power its industry. It is a perspective that has come from working on a drilling rig in Fort Stockton, Texas, drilling miles and miles below the surface of the Earth.

It's this pursuit of oil and gas miles below our feet that is reinvigorating pockets of the American economy from Texas to Pennsylvania to North Dakota. The work is hard, but the rewards can be great. Not just for the producers, but also for the roughnecks, the thousands of small and large firms that support the drilling activity, and the communities that host them.

Our Nation relies and prospers, Mr. Chairman, on affordable, abundant energy like oil and gas. This bill will ensure that not only do we have affordable energy, but that Americans are put back to work producing it.

The oil and gas industry on private lands is thriving in spite of this administration's attempt to slowly suffocate it. Today's legislation would reverse the glacial pace of permitting and the pointless regulations designed solely to slow down production on Federal lands.

Mr. Chairman, this bill will do the things that the President's stimulus act has failed to do. It will drive investment into American businesses and will put Americans back to work, just like the oil and gas industry has been doing in District 11 for over 80 years.

Mr. RUSH. Mr. Chairman, I intend to close, so I will reserve the balance of my time.

Mr. GARDNER. Mr. Chairman, at this time, I would like to yield 1½ minutes to another gentleman from Texas (Mr. FLORES).

Mr. FLORES. Mr. Chairman, I rise today in support of the Domestic Energy and Jobs Act of 2012.

Every developed economy in the world looks to their own resources as assets to fuel their economic growth. Yet many folks in Washington view our domestic energy resources as a liability. Unelected and unaccountable Federal bureaucrats continue to dream up ways to lock up, restrict, tax, or otherwise regulate these assets away from benefiting the American people.

This is an issue of critical importance for our economic security, our national security, our energy security, and most importantly for the opportunities that we hope to leave for future generations.

We desperately need the stability that comes from unlocking access and tapping into our American energy resources. The Domestic Energy and Jobs Act does just that by allowing us to pursue an all-of-the-above energy plan that removes unwarranted government roadblocks to domestic energy production and supply.

This bill will also help reduce our Federal deficits and our trade deficits. In the case of the former, it helps to reduce our Federal deficit in multiple ways: one, by growing the American economy and American jobs; two, by increasing royalties and lease payments to the Federal Treasury; and, three, by reducing the cost of our energy for the American economy. In the case of the latter, increased production of American energy will result in lower oil imports from foreign sources and reduced payments for those imports, thereby keeping more American money at home to rebuild our economy.

I urge my colleagues to support the Domestic Energy and Jobs Act, which would create jobs, grow our economy, reduce our dependence on unstable Middle Eastern oil, improve our national security, and restore the American Dream for future generations.

Mr. GARDNER. Mr. Chairman, at this point I would like to yield 1 minute to the gentleman from Louisiana (Mr. LANDRY), my freshman colleague.

Mr. LANDRY. Mr. Chairman, here are some facts: an estimated 13 million Americans are out of work. The State of Colorado's unemployment rate is 8.1 percent, which correlates with the national unemployment rate. Today, the State of Colorado's estimated reserves are 1 billion barrels of oil.

In 1995, the State of North Dakota's estimated reserves were 151 million barrels. Today, those reserves have been increased to 4.2 billion barrels of oil; yet today, the State of North Dakota's unemployment rate is 3 percent. What do those facts tell us? Those facts tell us that drilling equals jobs, Mr. Chairman. And it's very simple. In North Dakota, they are drilling on private lands. They are driving unemployment rates down.

Please, if the President wants a jobs plan, it is here. And I urge all Members to vote for this bill.

Mr. GARDNER. Mr. Chairman, at this time I would like to yield 2 minutes to the gentleman from California (Mr. ROHRABACHER).

Mr. ROHRABACHER. Mr. Chairman, I rise in strong support for H.R. 4480, a bill that promises to open up more public land to energy development and to streamline burdensome rules and heavy-handed regulations that now thwart new domestic energy development in the United States.

The President and the Democratic-led Senate continue to obstruct the utilization of America's enormous natural resources. What are they? These resources are a God-given asset that has elevated the well-being and prosperity of our people ever since the time of our Nation's founding. Now, when we need the wealth of those resources more than ever, we suffer the obstructionism of our own government.

The President has prevented the construction of the Keystone XL pipeline. The President has shut down oil and gas production offshore. And most recently, this administration—and perhaps most heinously—this administration has moved forward with plans to add onerous rules and regulations on a new and emerging technology. The efforts of this administration are mind-boggling because there is no evidence that this technology has done any harm to our people, and there is ample evidence that this technology would produce significant economic growth, thus jobs. And I am referring to, of course, fracking, which has clearly been targeted by the President and by his environmental gestapo friends.

While we are talking today and while we are trying to determine whether or not we are going to be using more resources, gasoline prices are changing the lifestyle of the American people. We're talking about people who are paying $3.50 a gallon and, in my State, $4 a gallon. Why are we allowing our people—13 million people who are currently out of work and suffering under these conditions—why are we adding such costs for them to bear?

The CHAIR. The time of the gentleman has expired.

Mr. GARDNER. I yield the gentleman an additional 30 seconds.

Mr. ROHRABACHER. What we need, Mr. Chair, is we need to make sure that we move forward, as this bill will do, to ensure that we are fulfilling our commitment to the American people to do

everything we can to make sure that they will live in prosperity and freedom and hope for a better life for their children.

This has always been tied to the utilization of natural resources, and this bill will ensure that our people will benefit from those gifts that God gave us underneath our ground and public lands.

Mr. GARDNER. Mr. Chairman, at this point I would like to yield 1 minute to another freshman, Mr. GOSAR from Arizona.

Mr. GOSAR. Mr. Chair, outside these walls people across our country are suffering. Electric bills and gasoline prices are increasing as we enter the heat of the summer.

□ 1740

Over 13 million Americans are still without work. Our constituents are counting on us to take action.

The Republican-led House has been leading the way with solutions to our country's energy problems. The bill before us today, the Domestic Energy and Jobs Act, is just another part of that agenda. It will remove government roadblocks and bureaucratic red tape that hinder onshore oil, natural gas, and renewable energy production and facilitate job creation. This act truly embraces an all-of-the-above approach that our country so desperately needs.

A country is only as strong as its people. Henry Ford II once said:

What's right about America is although we have a mess of problems, we have great capacity—intellect and resources—to do something about them.

Let's use that capacity to address our country's energy crisis and put people back to work. I urge my colleagues to vote in favor of the Domestic Energy and Jobs Act.

Mr. RUSH. I continue to reserve the balance of my time.

Mr. GARDNER. I am prepared to close. I have no further requests for time.

Mr. RUSH. I yield myself such time as I may consume.

There is widespread opposition to the Republican oil-above-all bill. The Obama administration opposes the Republican bill. Its Statement of Administration Policy says:

The administration strongly opposes H.R. 4480, which would undermine the Nation's energy security, roll back policies that support the continued growth of safe and responsible energy production in the United States, discourage environmental analysis and civic engagement in Federal decisionmaking, and impede progress on important Clean Air Act rules to protect the health of American families.

If the President were presented with H.R. 4480, his senior advisers would recommend that he veto the bill. Numerous public health organizations oppose this bill, including the American Academy of Pediatrics and various others.

Mr. Chair, this bill is nonsensical and is another bill in a long list of Big Oil giveaways pushed by the most anti-environmental House in the history of our Nation.

I yield back the balance of my time.

Mr. GARDNER. I would just inquire how much time I have remaining.

The CHAIR. The gentleman from California has 4 minutes remaining.

Mr. GARDNER. I thank the Chair and I yield myself the balance of my time.

Sixty four thousand eight hundred five jobs, $4.3 billion in wages, $14.9 billion in annual economic impact. That is the number of jobs, the amount of wages, and the economic impact that we would have seen today if not for the backlog of BLM projects over the past 3 years.

Sixty-five thousand jobs. There are 22 proposed projects in the Western United States that would create nearly 121,000 jobs.

Over the past few years, we have seen gas prices increase dramatically: $3.50, $3.60, $3.70. Since we've heard debate on the House floor tonight, they're going down. Even a flood can be lowered by a foot the next day, but it's still a flood. Our constituents who are paying $60, $70 to fill up with a tank of gas to drive their families to school, trying to put food on the table, to get to work, cannot afford high energy prices year after year.

This bill presents us with an opportunity to create jobs to build on American energy independence, to make sure that we are doing the one thing that we set out to do, and that is improve the economic chances of this country, our competitiveness, and the lives of our constituents. But they can't do it with gas prices exceeding $3, $4. What's next? Because here we are again.

The policies presented in this bill will allow us to cut through red tape and to increase exploration on our great lands in the Western United States across this country in an environmentally responsible fashion. It will allow us to make sure that when we access the Strategic Petroleum Reserve because of a supply problem that we're also addressing a long-term supply fix instead of just quick-fix politics.

We have an opportunity to make sure that when it comes to the regulations that are driving up the price of gasoline—and they have a real impact; we have both heard before our committee testimony from EPA administrators who say, yes, it will increase the price of gasoline—we stop and take a look before we leap to make sure that we are analyzing to understand the impact they will have on our constituents, who continue to suffer.

The best way to improve our economy is to make sure that we are unleashing every sector of our economy. And yes, that means renewable energy. This bill includes renewable energy. It takes a 4-year look at renewable energy on public lands, to take advantage of our opportunity with solar on Federal lands, with wind on Federal lands. But we will not sit idly by while our constituents pay thousands of dollars a more each year to put fuel in the tank, competing with the food on their table.

And so, Mr. Chair, this bill presents us all with a great chance to increase our energy supply, create American jobs, and make sure that we understand the full ramifications of regulations and drawdowns of the Strategic Petroleum Reserve before we act. And I think it's important that we send one strong message to our constituents that we've heard you. We've heard you loud and clear. And we are going to do everything we can to improve our economy, bring down the cost of energy, create jobs. That's when this Congress will do our job. This Congress will do our job when we pass this legislation, and I urge passage of H.R. 4480.

I yield back the balance of my time.

Mr. HASTINGS of Washington. I yield myself such time as I may consume.

Mr. Chairman, the legislation that we are debating and considering today is a clear all-of-the-above plan to increase American energy production, to lower gasoline prices, and to reduce our dependence on unstable foreign energy. But more than anything else, Mr. Chairman, this is a bill about creating jobs. The Domestic Energy and Jobs Act creates good-paying permanent jobs that will put people back to work and help grow our economy.

The only thing that the Obama administration has been more hostile to than American job creation, Mr. Chairman, is American energy production. Frankly, that shouldn't surprise anyone because the two do go hand-in-hand.

President Obama likes to talk about an all-of-the-above energy plan. But in reality, it's a nothing-from-America energy plan. This administration has consistently said ''no'' to new American energy production while happily forcing hardworking American taxpayers to spend over $1 million a minute on foreign energy.

President Obama doesn't want to drill for oil in Utah; perhaps he'd rather get it from Venezuela. President Obama doesn't want to drill for natural gas in New Mexico; perhaps he'd rather get it from Yemen.

□ 1750

President Obama doesn't want to develop our oil shale in Colorado; perhaps he'd rather get oil from OPEC.

President Obama doesn't want to import oil from our friends in Canada by approving the Keystone pipeline; perhaps he'd rather import oil from countries that aren't our friends in the Middle East.

Finally, President Obama doesn't want to drill off America's coasts, but he doesn't seem to mind Fidel Castro drilling 60 miles from America. And he doesn't seem to mind giving Brazil billions of dollars to help them drill off their coasts and then promise to be their ''best customer.''

The American people need to understand that this administration has

taken this country in exactly the wrong direction when it comes to developing our vast energy resources. While President Obama has been digging the United States into massive fiscal deficits, he has also gotten America into an energy deficit on Federal lands from which it could take years to recover.

Energy production on Federal lands is one of our best opportunities for job creation and energy security. But time and again, that production has been blocked or delayed by this administration. Under this administration, from 2010–2011, oil production on Federal lands fell by 14 percent. And natural gas production on these same lands fell by 11 percent. Mr. Chairman, this is in stark contrast to the oil and natural gas production on State and private lands because that production has boomed.

American energy equals American jobs. It's a simple formula for job creation and economic growth, but clearly it's one that this administration doesn't seem to understand. Maybe that's because they just don't know how desperate Americans are for jobs. Just a few weeks ago, with unemployment above 8 percent and 23 million Americans looking for work, our President told the American people that the private sector is doing ''just fine.'' Well, if you don't know what the problem is, how can you possibly know how to fix it?

Mr. Chairman, in summary, this is the same President that has issued the lowest number of onshore energy leases since 1984. This is the same President who talks about an all-of-the-above energy plan, but actively blocks ability to produce more oil and natural gas and coal, and specifically doing so on public lands. For President Obama, ''all of the above'' is just a politically convenient slogan. But for House Republicans, it's a real job-creating energy policy.

So I urge my colleagues to vote for the Domestic Energy and Jobs Act to put Americans back to work and make us less dependent on foreign sources.

I reserve the balance of my time.

Mr. MARKEY. Mr. Chairman, I yield myself such time as I may consume.

My colleagues, the short title of this bill, the Domestic Energy and Jobs Act, spells out the word D-E-J-A. But what we're seeing here is not just deja vu, the feeling that we've seen all these Big Oil giveaways before. No, this bill is a deja preview, a look ahead into what the Romney administration would do if elected and had a GOP House and Senate to fully implement the oil companies' legislative agenda and block all efforts to help clean energy.

There's been a lot of discussion of the DREAM Act recently, but the bill we have before us today is really the Big Oil dream act. This package represents everything Big Oil could ever possibly dream up to drill on our public lands and roll back public health protections.

As the world gathers in Rio de Janeiro right now to try to head off catastrophic global warming from the burning of fossil fuels, here we are in the House of Representatives looking for ways to give more benefits to fossil fuel industries.

And as America's wind and solar companies look to hire more American workers, here we are in the GOP-controlled House, where the Republican leadership refused to make my amendment in order to establish national goals for wind and solar, clean energy and energy efficiency. They won't even allow that debate to take place on the floor of the House of Representatives during what they say is the big energy debate for America. Can you imagine, it's 2012, we are having a big energy debate, big, big debate on the energy future of our country, and the words ''wind'' and ''solar'' are not going to be permitted by the Republicans to be out here on the House floor and being debated. And by the way, did I throw in biomass? Did I throw in geothermal? Did I throw in energy efficiency? They won't allow the words to be spoken. There's a gag order here, a big gag order by the Republicans. No debating that.

And then they have the temerity to call it an all-of-the-above bill. Oh, a comprehensive energy plan without wind, without solar, without geothermal, without biomass, without plug-in hybrids or energy efficiency debated out here because they have a gag order. They prohibit any debating of those issues on the House floor. And yet here they are, saying it's an all-of-the-above energy bill.

Great. Great. So fair. Fair and square. A real debate. Let all the Members decide what our energy future looks like.

But before the end of this year, the Republicans are allowing all of the tax breaks for the wind industry to expire. And what are they doing? They are actually going to continue the $4 billion a year that ExxonMobil and Chevron get. That's fair, huh? A gag order on even mentioning wind and solar out here as part of an amendment, a debate, $4 billion for the oil industry. And by the way, let's take a look at what's going on in oil production in the United States.

Oh, by the way, did you hear the news? It's now at an 18-year high. Obama, drill, baby, drill. Obama, what a great job. An 18-year high under Barack Obama, way better than George Bush. Way better. You have to go back to almost a time when a kid who's graduating from high school has no memory of. It's 18 years ago the last time there was this much oil drilling in the United States—Federal, State, private lands.

But if you listen to the Republicans, they're saying there's not enough breaks for ExxonMobil. No, no, no, we have to give them more. This poor, beleaguered company, and all of the other oil companies of the same size, they have been beleaguered as they are now at an 18-year peak in oil production in the United States. And you know who's beating them up—wind and solar, geothermal, biomass, plug-in hybrids. Very scary things to the Republican. So scary that because they control the Speakership, because they control the Rules Committee, we're not allowed to debate wind and solar. They're prohibiting it today. An absolute, all-out prohibition this week on the discussion of wind and solar. Huh?

When I asked to have an amendment be put in place that we could debate whether or not we had a national renewable electricity standard for the whole country, setting goals for what our country should have for wind and solar by the year 2020, you know what they said: No, we're gagging you. You can't have that debate out on the House floor. You can't even raise the words ''wind'' and ''solar.''

Yet they're going to keep coming out here saying we're for all of the above. All of the above that Exxon and Shell and BP want. Right on their list. And do you know where wind and solar are on the BP and ExxonMobil list? Oh, they just forgot to put it on their list. And that's what we get to debate out here, and it's going to be called an all-of-the-above energy future.

Well, let me tell you something—the American people deserve a lot better. They really do have a real sense that America has to be the leader in these new energy technologies. And President Obama has done his best or else we would not be at an 18-year high.

By the way, there are more oil rigs drilling in the United States for oil today—are you ready for this—than all of the other countries in the world combined. Barack Obama, drill, baby, drill. You are really doing the job. More oil rigs right here in the United States right now drilling than all the rest of the world combined.

But you're going to listen to these Republicans talk as though somehow or other, although ExxonMobil and BP and Shell are reporting the largest profits of any corporation in the history of the world, that they are being discriminated against.

□ 1800

What do ExxonMobil and BP expect? They expect there to be a gag applied out here on the floor so we cannot debate wind and solar, we cannot debate biomass and geothermal, we cannot debate energy efficiency. And yet we're supposed to sit over here in silence and listen to them say that they have an all-of-the-above energy strategy when we all know their entire strategy is oil above all—as a matter in fact, to exclude all else, exclude it, can't even debate it. They actually passed a rule here last night prohibiting us from debating wind and solar, from debating the future, from unleashing this technological revolution.

And why is that the case? I'll tell you why it's the case. Because in the last 5

years there have been 45,000 new megawatts of wind installed here in the United States. In this year, there will be 4,000 new megawatts of solar installed in the United States. Do you know who hates that? ExxonMobil hates that. Shell, BP, they hate it. Peabody Coal, Arch Coal, they hate it. They see this new clean energy future unfolding.

Out here on the floor of the House, as we debate the big energy bill here of 2012, I'm prohibited, as the senior Democrat, from bringing out an amendment that talks about wind and solar, that talks about geothermal and biomass, that talks about energy efficiency. I'm not allowed to bring it out here. So this is not an auspicious day for the United States Congress.

If there were any kernel of truth about Obama and his incredible work here, lifting us to an 18-year high in total oil production in the United States—by the way, since Bush left, since he left, we have dropped from being 57 percent dependent upon imported oil down to 45 percent dependent upon imported oil. Did Bush do that? No. Did Bush's father do that? No. Barack Obama did that, ladies and gentlemen. And what Barack Obama is saying, in addition to the dramatic decline in the amount of oil that we import from the Middle East, I would also like to add wind and solar and geothermal and biomass and energy efficiency. And they're saying, oh, no, it's already going too fast. This dependence thing is already happening much too fast for us.

And, by the way, this revolution in wind and solar and geothermal, people might start driving cars that are all electric and dependent upon wind and solar to give them the electricity so they don't even have to go into a gas station.

Do you know what they're really afraid of? They're afraid that what is going to happen to them is what happened to the typewriter, that in 20 years we went from everyone using a typewriter to everyone using a computer. People have to look into a history book to now find what a typewriter looks like. It only took 20 years. They can see this wind and solar revolution happening so fast that they're afraid that in 2030 a kid won't even know how to fill up a car with gasoline because they'll be plugging in the car at home with solar and wind-generated electricity. That's what they're most afraid of.

That's what this debate is really all about and that's why there's a gag on the Democrats, why we're not allowed to talk about wind and solar and geothermal and biomass and energy efficiency. Oh, I'm sorry, we're allowed to talk about it, we're just not allowed to have an amendment out here on the floor. We're just not allowed to put everyone on record as to where they stand on those issues. We're just not allowed to do that. You cannot have an amendment out here on the floor.

So this is the full extent of our ability to help those industries, those competitive industries, those Microsofts and Googles and eBays and Hulus and YouTubes of the energy industry get out there and reinvent the way in which we generate electricity here in our country. That's what this debate is really all about.

At this point, Mr. Chairman, I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I'm very pleased to yield 3 minutes to the gentleman from Colorado (Mr. LAMBORN), author of one of the provisions in this.

Mr. LAMBORN. Mr. Chairman, I rise in support of the Domestic Energy and Jobs Act. This energy package will unlock some of the vast resources this country has been blessed with, create stable jobs to put Americans back to work, and ensure America's energy security for the future.

While President Obama believes that the private sector is doing fine with an unemployment rate of over 8 percent and 23 million Americans looking for work, more Americans on food stamps than ever before, the U.S. Bureau of Labor Statistics tells us far too many Americans are not doing fine. And while private sector oil and gas are booming, our Federal lands are left behind.

Rather than encouraging and implementing policies that will create jobs for Americans, the Democrats and the Obama administration unfortunately support antienergy, job-destroying policies and have refused to act on or have reversed policies that would have created jobs for Americans and allowed for the development of American-made energy.

The Strategic Energy Production Act of 2012 takes the steps necessary to increase production of American-made energy and creates stable jobs for Americans. The plan, lease, permit provisions from the Natural Resources Committee in this legislation requires the administration to create a definitive, all-of-the-above, 4-year production plan to ensure American production of conventional—and, yes, renewable—energy to meet our energy needs.

While the administration has been unwilling to make land available for energy production, this legislation requires that they annually lease land for onshore development to ensure that the energy production process moves forward. It also streamlines the permitting process to ensure the expeditious and timely permitting of approvals. The legislation also ensures that understaffed and underfunded BLM field offices receive the funding they need to keep up with their workloads.

In addition to these reforms, this legislation opens one of our most promising areas for energy production: the National Petroleum Reserve-Alaska, which would expand American energy production and support current energy jobs for Alaska.

Finally, this legislation brings oil and natural gas leasing into the 21st century by allowing the BLM the authority to conduct Internet lease sales.

This legislation will take huge strides in securing our Nation's energy future. It will lessen our dependence on foreign sources of oil and create good-paying jobs for Americans across the country.

Mr. Chairman, I urge my colleagues to support the Domestic Energy and Jobs Act.

Mr. MARKEY. I yield 4 minutes to the gentleman from New York (Mr. TONKO).

Mr. TONKO. Mr. Chairman, I rise in opposition to H.R. 4480, which I heard my good friend and colleague from Massachusetts, Representative MARKEY, refer to as the ''Déjà Preview Act'' or the ''Big Oil Drain Act.''

Any student of history will tell you that the Congress was not designed to be efficient—while there were some good reasons for that—but deliberately celebrating that particular design of Congress with yet another partisan, short-sighted piece of legislation that moves United States energy policy backward is truly disappointing.

H.R. 4480 leaves our energy policy stuck somewhere in the 1950s. While other nations are making serious investments to diversify their energy supplies, support new clean energy businesses, and become less dependent on traditional fossil fuels, we are marching in place.

H.R. 4480, with its gag order on renewables and energy efficiency, is another missed opportunity and a waste of time. H.R. 4480 is nothing more than a wish list for Big Oil companies at a time when these companies are making record profits on the backs of America's taxpayers and her middle class.

Our energy crisis isn't that we need to drill for more oil. In fact, we're actually quite good at it as we saw in Representative MARKEY's presentation. This bill will only make us more dependent on a limited resource that is priced on the global market and enjoys a century-old taxpayer giveaway while making record profits on the backs of our middle class.

The answer to our energy crisis is to diversify our supply, support new clean energy businesses, become less dependent on fossil fuels—to focus on the demand side of the energy equation as much as we do our supply side.

While we consider this bill, policies that would provide modest assistance to companies that are working on solar, wind, fuel cells, combined heat and power, geothermal and energy efficiency, to name a few, are languishing in committee.

□ 1810

These are the technologies that will take us into the future, a bold future. True, they are not yet ready to provide all the energy we need, but that is all the more reason for us to help them move forward aggressively.

Jobs in the industries I've mentioned, good-paying jobs, are at risk

due to our failure to renew the production tax credit, the 1603 program, and the research and development tax credit. We are stifling job growth and innovation with this act.

Eventually, traditional fossil fuels will run out. Already, the human health and environmental costs of extracting and using these fuels have risen tremendously. We choose to ignore this at our peril, or at least at the peril of the next generation and generations to come.

Over the past 40 years, the Clean Air Act has shown we can have both clean air and a vibrant economy. Since 1960, air pollution has decreased by more than 70 percent, while the economy has grown by more than 200 percent.

But this bill is likely to eliminate jobs, while making the air we breathe more toxic. But that doesn't seem to matter to the majority in the House. It does so by eliminating standards for cleaner vehicles and cleaner fuels, likely costing nearly 25,000 jobs a year for 3 years. Yet more backward motion.

The public lands policy put forward today and in yesterday's legislation is an insult to the previous generations whose foresight and concern for future generations granted us a rich inheritance of natural resources in our wildlife refuges, wilderness areas, and national parks.

Mr. HASTINGS of Washington. Mr. Chairman, I am pleased to yield 3 minutes to the gentleman from Colorado (Mr. TIPTON), an author of one of the provisions of the bill.

Mr. TIPTON. Thank you, Chairman HASTINGS, for yielding me time.

America has always had a competitive advantage as a Nation. It's been the entrepreneurship, the hard work, the innovation of the American people. But we've also always had a different advantage as well—affordable energy in this country. We see that now imperiled.

In 1979, Jimmy Carter challenged this Nation to move to energy self-sufficiency. Decade after decade it has not been addressed. This piece of legislation is to move America fully into the 21st century, to be able to secure for us and for our children this land of liberty, opportunity, and growth. It comes with American energy.

The ranking member from Massachusetts, I have good news for you. When you read the actual legislation that is put forward, it states in my portion of the bill, the Planning for American Energy Act of 2012, page 16, line 16, calling on the Secretary of the Interior to develop a plan for American energy.

What does it say?

Creating the best estimate, based upon commercial and scientific data of the expected increase in megawatts for electricity production from each of the following sources: wind, solar, biomass, hydropower, and geothermal energy produced on Federal lands.

The very thing you asked for is in the bill. We have an opportunity to be able to create an American energy future in this Nation, to be able to secure for our children that birthright that many of us grew up believing was an American birthright—the right to be able to live that American Dream—to be able to put Americans back to work.

The Planning for American Energy Act of 2012, my portion of this bill, speaks to that commonsense, all-of-the-above proposal that we all seek: wind, solar, geothermal, hydroelectric, using the minerals, the resources, the natural gas, the oil that we find on American soil.

When we see what is happening right now in the Middle East, when we see at the gas pump our prices doubled from just 3 short years ago, when we talk to senior citizens on fixed incomes who are finding out when they turn on that light switch that their bill has increased, is it time, is it appropriate for us to seek an American energy solution? The time has come. The day has arrived.

The Acting CHAIR (Mr. STUTZMAN). The time of the gentleman has expired.

Mr. HASTINGS of Washington. I yield the gentleman an additional 30 seconds.

Mr. TIPTON. Rather than encouraging energy development off of our shores, as the President has done with his $2 billion loan guarantee to Brazil to develop their energy sources, if we're going to make those kind of investments, if we're going to look to that type of future, would it not be better for us to develop American energy on American soil to put Americans back to work and create American energy certainty? That day has come. The time is now.

This is a good piece of legislation for American security and American jobs.

Mr. MARKEY. I yield myself 1 minute.

I thank the gentleman from Colorado.

Yes, what the Republicans are saying is, in their bill, that they want a study for 4 years of wind and solar. A study?

Well, maybe they should study the fact that it's very sunny in Florida. It's very windy out in the Midwest and, as a matter of fact, so sunny and so windy that there have been 45,000 megawatts of wind installed over the last 6 years in the United States, that there's going to be 4,000 new megawatts of solar installed in the United States just this year.

So maybe the Republicans should study the studies that are already out there, and maybe they could actually look over and ask the coal industry what they're thinking as they've dropped from 51 percent of all electrical generation down to 36 percent of all electrical generation in the last 5 years.

Maybe they're looking at the wind industry. Maybe they're looking at the solar industry. Maybe you could call them. But you don't have to wait 4 years, because all you want to do is study it. What we want to do is give the incentive for the wind and solar industry to continue their revolution.

I yield 5 minutes, if I may, Mr. Chairman, to the gentleman from New Jersey (Mr. HOLT), the ranking member of the subcommittee.

Mr. HOLT. Mr. Chairman, I thank my friend from Massachusetts, and I thank him for laying out so clearly all the shortcomings of this legislation, this oil-above-all legislation. It really is nothing but a big giveaway to Big Oil.

The only jobs it will create will be in the boardrooms and the executive offices of the Big Oil companies because, since 2005, even as ExxonMobil, Chevron, BP, and Shell have made more than $650 billion in profits—need I repeat that? $650 billion in profits—they eliminated more than 11,000 jobs, U.S. jobs, American jobs. And this is even while wind and solar were creating 50,000 jobs.

Yes, there's a mismatch here. The bill before us presented by the Republicans says we'll study to see how much solar and wind energy might come from these lands in the future instead of saying let's get these energy sources of the 21st century rolling in these lands. It's not a plan of what we might get. The Markey amendment would have set standards for what we would get.

Now, the Republicans have a long record of protecting tax breaks for Big Oil while cutting clean energy initiatives. That's what we see here.

But what I wanted to talk about is the damage that would be done under this legislation. Health officials today here in Washington are warning people to avoid the heat and stay indoors. I don't think they had in mind that we stay indoors to pass legislation that chokes off public health protections, that modifies the Clean Air Act to make it ineffective, and yet that's what this bill does.

□ 1820

By rejecting clean energy and pushing only for more fossil fuels to blanket the world with heat-trapping pollution, the Republican majority is essentially turning off the world's air conditioner and turning on the heater.

There is a reason that the term ''fossil fuels'' applies—actually, two reasons. One is that these are derived from ancient plants that have decayed deep in the Earth and have produced petroleum. But there is another reason. ''Fossil'' means ''archaic.'' ''Fossil'' means ''out of date.'' ''Fossil'' does not mean ''21st century.''

Yet that's where this legislation is taking us—in the wrong direction and in the wrong direction with regard to environmental protection.

In the wake of the Deepwater Horizon disaster, we shouldn't be playing games with safety and the environment. The spill exposed a woefully inadequate environmental review process that was done prior to the oil and gas leasing. The environmental review done prior to the BP spill was so sloppy that response plans talked about protecting walruses. Obviously, they were

just, in an unthinking way, using old Alaska pages.

Tourism is the lifeblood of so many of our coastal communities. As the economy is struggling to recover, we can't risk the kind of environmental damage that derails economic progress in these areas. We should understand the risks of drilling, and we should strengthen the protections, not weaken them. Furthermore, there will be damage done to the whole leasing process.

For my colleagues on the other side of the aisle who are so worried that putting some real standards—some expecting of good performance from oil companies—would somehow interfere with their production, let me point out some good news. Today, the Interior Department announced the results of an oil and gas lease sale in the Gulf of Mexico.

The Acting CHAIR. The time of the gentleman has expired.

Mr. MARKEY. Would the Chair tell me how much time is remaining.

The Acting CHAIR. The gentleman from Massachusetts has 8½ minutes.

Mr. MARKEY. I yield an additional minute to the gentleman from New Jersey.

Mr. HOLT. I thank my friend.

According to the Interior Department, today's leases that were bid on today, which have some lease standards apply that require increasing rental rates and shorter lease terms—the very things that the folks on the other side of the aisle here say would be killers, would stop the drilling—were record-setting lease sales, bringing in $11.7 billion even with these new conditions for offshore drilling; and they're saying what works here offshore won't work on the lands that we are talking about in this legislation.

Now, I'll tell you what's a killer in this. A killer is the relaxing of the public health and environmental standards in the legislation. That's literally a killer.

Mr. HASTINGS of Washington. Mr. Chairman, I am very pleased to yield 2 minutes to the gentleman from Alaska (Mr. YOUNG), whose State has tremendous resources.

(Mr. YOUNG of Alaska asked and was given permission to revise and extend his remarks.)

Mr. YOUNG of Alaska. I support this legislation. It's long overdue. Title VI of this legislation is a good step forward in Pet 4 in Alaska, so it is with great amazement that I listened to the two previous speakers.

Wind power, you can take and cover every acre of the United States, including the parks and refuges, and put solar panels on them, but you'll only produce 20 percent of the consumption of energy we use today. Now, think about that—no parks, no refuges—all solar panels, and we're going to take care of the problem. By the way, it has to be transported to a battery, taken and made by rare earths from China.

That's what this is all about. It's nonsense.

The idea that wind is going to solve the problem and that solar is going to solve the problem, that's nonsense because, in reality, fossil fuel, to this day, is the only fuel that can move an object, ladies and gentlemen. It moves your car; it moves your truck; it moves your plane; it moves your train; and it moves your ship that brings all the product to and from the United States.

You're not going to do it with a beanie on your hat. You're not going to do it with solar panels that have to cover every acre of the United States of America. It's because we're collecting the power of the Sun down here at the bottom of the pyramid. We're not collecting from the source. If you want to go far, if you want to be really reaching into the future, collect it up there and beam it down to a point where we can create electricity.

This is a good bill because, ladies and gentlemen, Mr. TIPTON said it right. In his bill, we do have action on wind and solar, although it will not work, and we know it won't work. We need fossil fuels now until we have the time to produce another source of energy that does not need electrical batteries to run a car. We're going to plug a car in? Nonsense. It won't happen, because you need to produce energy from some other source to create the electricity. You're against nuclear power. You're against hydropower. By the way, you'd like to take and grow our way into new power by using corn—a food—for energy. That's absolutely nonsense.

Shame on you to say this is not a good bill. This is a good bill. It's not a nonsense bill.

Today, the NPRA remains in various stages of exploration, and experiences no shortage of interest from producers. However, there have been a series of bureaucratic delays that have impeded production from this vast area. This bill seeks to remedy that situation and give the American people the energy resources they need.

The Trans Alaska Pipeline System is running at one-third capacity. Soon, without the addition of increased oil supplies, that pipeline will no longer be economical to operate. Carrying 11% of our Nation's supply, TAPS is critical infrastructure for this nation that must be protected. This winter TAPS was shut down for a period of days and fuel prices on the West coast shot up immediately in a drastic manner. Luckily, NPRA is only tens of miles from existing pipeline infrastructure that leads into TAPS.

A few weeks ago, clearly acknowledging that increased supplies will bring down energy prices, President Obama released 30 million barrels of oil form the Strategic Petroleum reserve. The National Petroleum Reserve—Alaska has 2.7 billion barrels and already has infrastructure in place to bring the oil to market!

Title VI of H.R. 4480 is a good first step towards harnessing the potential that these federal lands in Alaska have to provide domestic energy supplies.

Mr. MARKEY. Again, I ask how much time is remaining on both sides.

The Acting CHAIR. The gentleman from Washington has 17½ minutes. The gentleman from Massachusetts has 7½ minutes.

Mr. MARKEY. I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I am very pleased to yield 2 minutes to the gentleman from South Carolina, a member of the Natural Resources Committee, Mr. DUNCAN.

Mr. DUNCAN of South Carolina. I thank the chairman.

There can be no national security without energy security. Let that sink in. There can be no national security without energy security.

House Republicans support a truly all-of-the-above energy policy, not one put forth by the Obama administration and House Democrats, which basically is an all-of-the-above, except for X, Y, and Z, policy, which blows through Americans' hard-earned tax dollars by chasing phantom solutions to our energy needs with companies like Solyndra. ''All of the above'' means opening up Federal lands for energy production and exploration, and it puts Americans to work.

Americans simply need to look to one western State to see a microcosm of what America could be with an energy-driven economy. That State is North Dakota. When you get off the plane in North Dakota, they give you a job whether you need one or not. They're approaching a zero percent unemployment rate—zero. It is an energy-driven economy. It is the microcosm of what this Nation could be if we would pursue an energy-driven economy.

Energy from Federal lands could be a reality. Energy from the Outer Continental Shelf could be a reality if we would embrace opening up American resources for production, which is like the folks in North Dakota have done on State and private lands. This is good policy for America. Energy policy works.

Mr. MARKEY. I continue to reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I am very pleased to yield 3 minutes to another member of the Natural Resources Committee, the gentleman from Ohio (Mr. JOHNSON).

Mr. JOHNSON of Ohio. Mr. Chairman, today I rise in strong support of H.R. 4480, the Domestic Energy and Jobs Act. This important legislation begins to put in place a true all-of-the-above energy plan, a type of plan that has been missing since this President came into office in 2009.

This legislation will expand oil, gas, and renewable energy development on Federal lands to help increase the supply of energy and lower energy prices for consumers. It will also give relief to drivers who are paying high prices at the pump every month due to very costly EPA regulations that are scheduled to go into place.

□ 1830

This legislation also contains a bill that I introduced, the BLM Live Internet Auctions Act. This section of the bill is supported by my friends on the

opposite side of the aisle here and even the administration. The BLM Live Internet Auctions Act will bring the BLM Lease Auction program into the 21st century by allowing BLM to conduct online leases just like the private sector has been doing for over 10 years.

We hear a lot about an all-of-the-above energy policy. The President even talked about an all-of-the-above energy policy in the State of the Union. I'm convinced that what the President means by an all-of-the-above energy policy is anything all and above the ground, because it seems like he doesn't want us going after our own natural resources.

If we had an energy policy that said, Look, we're going to draw a line in the sand, and over the next 10 years we're going to become energy independent and secure in America, we're going to go after the trillions of barrels of oil that we already own, we're going to harvest the vast volumes of natural gas and oil that we own, we're going to continue to mine and harvest coal and use it environmentally soundly, we're even going to expand our nuclear footprint because it's the safest and most reliable form of energy on the planet, and, yeah, we'll even look at wind and solar and find out where those renewable energy sources fit into an overall scheme, but we're not going to sit on the sidelines any longer and be beholden to foreign countries for our energy, if we had that kind of vision backed with regulatory reform that said to the regulatory agencies like the EPA and the Department of the Interior, Starting today, you become partners in progress with America's industries and businesses—if you've a got a national security or public health or public safety reason for saying ''no,'' then say ''no.'' But don't let ''no'' be the final answer.

I think the American people have an expectation that their elected officials and the bureaucracies that are sent here to manage the American system are partners in progress, not barriers to progress.

I urge my colleagues to support H.R. 4480, the Domestic Energy and Jobs Act. I certainly do, and I urge them to, as well.

Mr. MARKEY. I yield 2 minutes to the gentleman from Minnesota (Mr. ELLISON).

Mr. ELLISON. I would like to thank you, Mr. MARKEY, and Mr. HASTINGS, as well, for the time.

Mr. Chairman, my friends on the other side of the aisle keep on using this mantra, ''all of the above, all of the above.'' I think they should really name it ''oil above all.'' Oil above all would be a better name because it's very clear that this bill is really just a wish list and a checkoff for the big oil industry. It weakens public health protections, it forces arbitrary giveaways on public land, and it puts energy drilling ahead of all uses of Federal land. This is not a long-term strategy solution. It is an oil-above-all strategy.

The oil, gas, and coal industry are already getting billions in corporate welfare while they're making record profits. How much of the American taxpayers' money do they need? They will receive at least $110 billion in subsidies over the next 10 years. These subsidies have been won by decades of lobbying. In 2011, the oil, gas, and coal industry spent $167 million lobbying. But in comparison to the return on their investment, $167 million is small because they got subsidies of $110 billion. It is lucrative for them to do so.

They don't even need our help, Mr. Chairman. In 2011, just last year, the Big Five oil companies made $137 billion in profits. That's good by any measure. Why in the world would an industry that makes $137 billion in profits need the help of the American people with these tax breaks that the Republican majority won't even agree to get rid of?

This bill is simply checking off from Big Oil's wish list.

It weakens public health protections.

It forces arbitrary giveaways of public land.

It puts energy drilling ahead of all other uses of federal land.

This is not a long-term energy solution.

The oil, gas, and coal industries are already getting billions in corporate welfare.

They will receive at least $110 billion in subsidies over the next 10 years.

These subsidies have been won by decades of lobbying.

In 2011, the oil, gas, and coal industries spent $167 million lobbying the federal government.

They don't need our help.

In 2011, the Big Five oil companies made $137 billion in profits.

But the renewable energy industry does need investment.

Renewable energy is an emerging industry that can create thousands of new jobs.

Yet we are subsidizing the fossil fuel industry at 6 times the rate we are supporting renewable energy.

I offered a simple amendment to this bill.

It was a sense of Congress that fossil fuel subsidies should be reduced to help control the budget deficit.

Unfortunately, it seems the Republicans are too beholden to Big Oil to even allow a vote on my amendment.

I hope my colleagues on the other side—especially fiscal conservatives—agree that $110 billion in fossil fuel subsidies to profitable companies makes no sense.

We need a true ''All of the above bill'' that invests in clean, renewable energy—not this ''Oil above all'' bill.

I urge my colleagues to oppose this bill.

Mr. HASTINGS of Washington. Mr. Chairman, I am very pleased to yield 2 minutes to the gentleman from Georgia, Dr. GINGREY, a member of the Energy and Commerce Committee.

Mr. GINGREY. Mr. Chairman, I thank the chairman for yielding.

The previous speaker, the gentleman from Minnesota, it sounds like his policy on his side of the aisle is: No oil, no matter what.

This is a very good bill. If it becomes law, H.R. 4480, the Domestic Energy and Jobs Act, will put people back to work. It will be a great giant step toward creating energy independence for this country. And, yes, indeed, my colleagues, it will bring down the price of gasoline at the pump, which has actually doubled in 3½ years under President Obama's watch.

As a member of the Energy and Commerce Committee, let me focus on one specific title of this legislation: The Strategic Energy Production Act. The Strategic Petroleum Reserve that we have in this country is about 700 million barrels of oil. Mr. Chairman, that reserve is there for a situation of a domestic crisis, not a political crisis. We use 20 million barrels of oil a day in this country. If you assume that 60 percent of it was domestically produced and we had to import 8 million barrels of oil a day, then think about how many days it would last if we truly had a crisis and OPEC cut us off completely from what we import. That reserve would last about 90 days. That is a 3-month period of time. Yet, President Obama wants to take that reserve and use it for political purposes.

This title of the bill, Mr. Chairman, just simply says that every ounce of oil that he takes out of the strategic reserve, we would increase that same amount on Federal lands.

The Acting CHAIR. The time of the gentleman has expired.

Mr. HASTINGS of Washington. I yield an additional 30 seconds to the gentleman.

Mr. GINGREY. I thank the gentleman.

Here is an important point, my colleagues. What this President has done has simply cut the production on Federal lands by 11 percent on his watch.

Let's pass this bill so that we do create jobs, we put people back to work, we become independent in this country, and not dependent on nations that hate us.

Mr. MARKEY. Mr. Chair, I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I am very pleased to yield 2 minutes to the gentleman from Tennessee (Mr. ROE).

Mr. ROE of Tennessee. Mr. Chairman, I rise today in support of H.R. 4480.

The average American family buys 1,100 gallons of gasoline per year. If the price of gas fell just $1 from the current national average of $3.49, families would save $1,100 a year.

For far too long, this administration has prioritized politics over the needs of the American people, and today in this body we have an opportunity to work together and do what's right for the future of this country. The Domestic Energy and Jobs Act will help ease the pain at the pump, create jobs, and push this country towards energy independence.

This commonsense legislation would put several costly and potential burdensome EPA regulations on hold while an analysis of the potential costs and consequences of these rules is

done. To me, it is unthinkable that we wouldn't ask agencies to consider the impact of a regulation on jobs and the economy, particularly at a time of such economic uncertainty.

To boost our energy production, the Domestic Energy and Jobs Act will require the Secretary of the Interior to act on oil and natural gas lease applications and will cut red tape on opening up new reserves in Alaska. This legislation would also restrict the Strategic Petroleum Reserve from being tapped unless the administration develops a plan to explore for additional sources of oil.

Let me put this in perspective. As a young Army officer in Korea in 1973 and 1974, there was an oil embargo. OPEC cut off oil production and sending it to the U.S. We only got heat 3 hours a day. We had to keep the heat for our tanks and our aircraft to protect this Nation. So it is one of strategic importance, and energy is a very important source of that.

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To obtain energy independence is not only a key component to our domestic recovery, but it's also an issue of national security, as I just mentioned. Becoming energy independent is far too important for the future of this country to continue to put politics above people.

I encourage my colleagues to join in supporting the Domestic Energy and Jobs Act.

Mr. MARKEY. May I ask again, Mr. Chairman, that we review where the majority and minority are in terms of time remaining in debate?

The Acting CHAIR. The gentleman from Massachusetts has 5½ minutes. The gentleman from Washington has 8½ minutes.

Mr. MARKEY. I will yield myself 1 minute at this time.

I would just like to review, once again, the Republican ''all-of-the-above'' plan: One, light, sweet crude oil. Two, sour, high sulfur oil. Three, heavy oil. Four, tar sands oil. Five, oil shale. And oh, just to mix it up, a little natural gas. What they forgot was, of course, wind, solar, geothermal, and biomass. And they won't even allow us to have an amendment out here on the floor in order to have a debate over it.

But that ''oil above all'' agenda you have, it is very comprehensive, and I give you credit for figuring out every single way that we can help all the oil companies in the United States at the expense of all the renewable energy industries.

I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I am pleased to yield 2 minutes to the gentleman from Mississippi (Mr. NUNNELEE).

Mr. NUNNELEE. I would like to thank the chairman for yielding.

I rise in support of the Domestic Energy and Jobs Act. You know, America's been blessed with an abundance of natural resources under our feet and off our shores. We have the largest coal reserves in the world. New technologies are making it possible to unlock vast new reserves of oil and natural gas. We need to do everything possible to safely and responsibly develop those natural resources because doing so will create good, high-paying jobs, and it will improve national security by reducing our dependence on energy from unstable regions of the world.

Higher gas prices are a cruel tax. They're a cruel tax on hardworking men and women who are trying to find a way to get back and forth to work. Higher gas prices are a cruel tax on seniors living on a fixed income.

And unfortunately, this administration is full of people that are pushing a radical environmental agenda that's hostile to energy development. They believe the solution is to force the price of traditional energy supplies to skyrocket so that alternative green energy becomes artificially competitive.

Alternative energy should be a part of the mix. But the reality is that fossil fuels will be the main source of our energy for at least the next two generations, and it's fantasy to suggest otherwise.

Now we do support an all-of-the-above strategy, but that all-of-the-above strategy also includes an all-of-the-below strategy. We support developing those resources that are below our feet and off our shores. That's why I am proud to support the Domestic Energy and Jobs Act.

Mr. MARKEY. At this time I yield myself 2 minutes.

You know, I hate giving all the bad news to the Republicans. But I'll give you some more bad news. You hate to hear it, but I will give it to you anyway.

In 2011, in terms of new electrical generation in the United States, 33 percent came from natural gas, 29 percent from wind, 20 percent from coal, and 8 percent from solar. Got that again? Wind and solar were about 37 percent of all new electrical generating capacity in the United States in the year 2011. But you guys want to study it. You want to have more information about this technology.

And by the way, in that study, you should also throw a few other things—a single device from which you can talk to your family, send emails, and watch videos. That's a concept some people have. You might want to study that as well. Oh, no, we already have that.

Sending a man to the Moon and returning him safely to the Earth. Oh, I guess that's something else we already did. How about studying the possibility of mapping the entire human genome so we can have an idea of what material humanity is made out of, to kind of break a breakthrough. Oh, I think we've already done that. And there may be many other things that we can throw into that solar and wind study that we also don't need to have studied that you can also throw in there as part of your technological and scientific phobia that refuses to have you admit that things are already happening.

And by the way, something else you are refusing to admit that happened—during Bush's term as President, the production of oil went down, down, down, down from 2001–2008. Do you know what happened once Obama took over? Up, up, up, up. So much oil drilling, in fact, that all the rigs in the world combined are not matching what Obama has done in terms of total oil rigs out there. And we are now at an 18-year high in oil.

Maybe you should study this. Maybe this is hard for you to understand. I've heard all the Members out here saying that there is a jihad against oil being waged by the Obama administration. It just doesn't match any of the evidence.

I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I will advise my very good friend from Massachusetts that I am prepared to close if he is prepared to close.

Mr. MARKEY. I will yield myself the balance of my time.

Let me just say that I know it's not anything that has been observed by the Republicans. But the price of gasoline has dropped for the last 11 weeks in a row, ever since the President threatened to use the Strategic Petroleum Reserve, because it was never about supply and demand. It was always about fear and greed. It was what Wall Street was doing and manipulating the price of oil and the commodities futures of the marketplace. It was about the fear that people had about a war in Iran breaking out.

But what's the response from the Republicans? Well, they have a brilliant amendment inside of their bill. What they say here is that if, God forbid, the Ayatollah ever attacked the United States, a Middle Eastern war ever broke out, and the President deployed the Strategic Petroleum Reserve, 10 million barrels worth of the Strategic Petroleum Reserve, you know what their bill says? That we, the Federal Government—if the Republican bill passes today—would then have to sell to ExxonMobil and the other Big Oil companies 200 million acres of Federal lands for ExxonMobil and the other Big Oil companies to drill on.

Understand that? That the Ayatollah attacks us, there's a war in the Middle East, and who do we have to pay the ransom to? To the Big Oil companies of the United States, if we deploy the Strategic Petroleum Reserve.

Now how nonsensical is that? That is an absolutely crazy idea, that the oil companies become the beneficiaries of a Middle Eastern conflict. They get the public lands of the United States, 200 million acres that we have to sell them simultaneously. It's almost a trigger that occurs inside of their legislation. That's how meshuggah this all is.

This is an absolutely crazy set of concepts, where we can't have an

amendment on wind and solar, geothermal, biomass, plug-in hybrids, all new technologies and efficiency that back out the need for all this oil to ever come in in the first place. And as a penalty, the country will use this Strategic Petroleum Reserve as a weapon of our national security against OPEC, that if the President uses it, we have to sell 200 million acres of American land to the oil companies so that they can even drill for bargain basement prices here in the country.

This bill is absolutely the wrong recipe for our country as we head into the 21st century. I urge a ''no'' vote.

I yield back the balance of my time.

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Mr. HASTINGS of Washington. I yield myself the balance of my time.

The Acting CHAIR. The gentleman is recognized for 7 minutes.

Mr. HASTINGS of Washington. Mr. Chairman, it is hard to know where to start as I close the debate on this portion of the bill because there's been so much information out there and so much information that, frankly, I won't say it's untrue, but it's not exactly accurate.

Let me start with the idea that the price of gasoline has dropped with this administration. In January of 2009, the average price of gasoline in this country was $1.82 a gallon. Now what is magic about January 2009? Well, that was the month that the President was inaugurated and the price of gasoline was $1.82 a gallon. Today, the average price of gasoline is $3.48. Now if your math is such that the price of gasoline drops when it starts at $1.82 and ends at $3.48, you've got fuzzy math. But that's what we keep hearing.

Furthermore, we have heard I don't know how many Members on the other side speak, but I dare say every one of them said that this is a giveaway to oil and gas. If they didn't say it, they implied it, trying to get that message across.

Now, I wondered when I heard the debate here about there's no reference to renewables if they read the bill. I am now convinced they did not read the bill, Mr. Chairman. And let me tell you why. Because when we talk about renewables, we're talking about Federal lands and we say that the Secretary—and I'm reading from page 15, title III, section 44, paragraph 3. It says:

The Secretary shall determine a domestic strategic production objective for the development of energy resources from Federal onshore lands.

Now that's the directive.

So on page 16 we make reference to renewable energy. And they said, Oh, it's just a study. What do you mean it's just a study? Well, if you read, Mr. Chairman, we are asking for a study for the estimates of what? On subsection A, it's oil and natural gas. What? We're asking for a study of oil and natural gas on Federal lands. Then, you go to C. It talks about the critical minerals. Then it goes on to renewables.

In other words, the point I'm making, Mr. Chairman—and this is very important—if this is a giveaway to oil and gas companies and not helping renewables, then why is it the precise same language for the type of production of energy on Federal lands? You can't have it both ways.

So I think, Mr. Chairman, that this is a very good bill because we're focusing on where the greatest resources we have in this country are on Federal lands. That's where the greatest potential resources are. This bill is aimed at those resources. That's why this bill is so important.

Let's set production goals on all energy development. And that means all-of-the-above. That means above ground. That means underground, as my friend from Mississippi said. That's what we are attempting to do. But to suggest that this is a giveaway when precisely the same language applies to all energy production, frankly, is inaccurate.

So with that, Mr. Chairman, I urge my colleagues to support this piece of legislation.

I yield back the balance of my time.

Mr. GENE GREEN of Texas. I rise today in opposition to H.R. 4480, the Domestic Energy and Jobs Act.

While I support pieces of H.R. 4480, unfortunately I am not able to vote for the bill because I believe it will actually create more regulatory confusion and impediments for our domestic producers. Title I, for example, requires the Secretary of Energy to develop a plan to increase domestic oil and gas leasing from onshore and offshore federal lands that are under the jurisdiction of the Departments of Agriculture, Energy, Interior, and Defense within 180 days of a release of petroleum from the Strategic Petroleum Reserve. A new government bureaucracy at the Department of Energy would develop this plan, which duplicates the oil and gas leasing programs at the Departments of Interior and Agriculture. During a House Energy and Commerce Hearing on the bill, the Secretary of Energy expressed many concerns about their ability to effectively do this.

I am also concerned with Title III of the bill, which would overturn the multiple-use principle established in the Federal Land Policy and Management Act of 1976. This would undermine the basic principal which has guided the management of public lands for 35 years.

I also have concerns with Section 206 of the bill, which would require the Environmental Protection Agency to consider industry costs when determining what level of air pollution is "safe." By doing this we would be rolling back one of the core aspects of the Clean Air Act—a requirement that was passed on a bipartisan basis over 40 years ago, signed into law by a Republican President and unanimously upheld by the Supreme Court in 2001. I plan to offer an amendment that would strike section 206 and I hope that my colleagues will support it.

As a strong supporter of policies that encourage and support domestic energy production, my hope is that in the future, the House takes up legislation that deals with this important issue without including controversial policy riders that prevent bipartisan support in the House and movement in the Senate.

The CHAIR. All time for general debate has expired.

Pursuant to the rule, the bill shall be considered for amendment under the 5-minute rule.

In lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce, printed in the bill, it shall be in order to consider as an original bill for the purpose of amendment under the 5-minute rule an amendment in the nature of a substitute consisting of the text of Rules Committee Print 112–24. That amendment in the nature of a substitute shall be considered as read.

The text of the amendment in the nature of a substitute is as follows:

H.R. 4480

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Domestic Energy and Jobs Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—INCREASING DOMESTIC IN RESPONSE TO STRATEGIC PETROLEUM RESERVE DRAWDOWNS

SEC. 101. SHORT TITLE.

This title may be cited as the ''Strategic Energy Production Act of 2012''.

SEC. 102. PLAN FOR INCREASING DOMESTIC OIL AND GAS EXPLORATION, DEVELOPMENT, AND PRODUCTION FROM FEDERAL LANDS IN RESPONSE TO STRATEGIC PETROLEUM RESERVE DRAWDOWN.

Section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241) is amended by adding at the end the following new subsection:

''(k) PLAN.—

''(1) CONTENTS.—

''(A) IN GENERAL.—Not later than 180 days after the date on which the Secretary executes, in accordance with the provisions of this section, the first sale after the date of enactment of this subsection of petroleum products in the Reserve the Secretary shall develop a plan to increase the percentage of Federal lands (including submerged lands of the Outer Continental Shelf) under the jurisdiction of the Secretary of Agriculture, the Secretary of Energy, the Secretary of the Interior, and the Secretary of Defense leased for oil and gas exploration, development, and production. The percentage of the total amount of the Federal lands described in the preceding sentence by which the plan developed under this paragraph will increase leasing for oil and gas exploration, development, and production shall be the same as the percentage of petroleum in the Strategic Petroleum Reserve that was drawn down.

''(B) REQUIREMENTS.—The plan developed under this paragraph shall—

''(i) be consistent with a national energy policy to meet the present and future energy needs of the Nation consistent with economic goals; and

''(ii) promote the interests of consumers through the provision of an adequate and reliable supply of domestic transportation fuels at the lowest reasonable cost.

''(C) ENERGY INFORMATION.—The Secretary shall base the determination of the present and future energy needs of the Nation, for purposes of subparagraph (B)(i), on information from the Energy Information Administration.

''(2) LIMITATION.—The plan developed under paragraph (1) shall not provide for oil and gas exploration, development, and production leasing of a total of more than 10 percent of the Federal lands described in paragraph (1)(A).

''(3) CONSULTATION.—The Secretary shall develop the plan required by paragraph (1) in consultation with the Secretary of Agriculture, the Secretary of the Interior, and the Secretary of Defense. Additionally, in developing the plan, the Secretary shall consult with the American Association of Petroleum Geologists and other State, environmentalist, and oil and gas industry stakeholders to determine the most geologically promising lands for production of oil and natural gas liquids.

''(4) COMPLIANCE WITH REQUIREMENTS.—Each Federal agency described in paragraph (1)(A) shall comply with any requirements established by the Secretary pursuant to the plan, except that no action shall be taken pursuant to the plan if in the view of the Secretary of Defense such action will adversely affect national security or military activities, including preparedness and training.

''(5) EXCLUSIONS.—The lands referred to in paragraph (1)(A) shall not include lands managed under the National Park System or the National Wilderness Preservation System.

''(6) SAVINGS CLAUSE.—Nothing in this subsection shall be construed to limit or affect the application of existing restrictions on offshore drilling or requirements for land management under Federal, State, or local law.''.

TITLE II—IMPACTS OF EPA RULES AND ACTIONS ON ENERGY PRICES

SEC. 201. SHORT TITLE.

This title may be cited as the ''Gasoline Regulations Act of 2012''.

SEC. 202. TRANSPORTATION FUELS REGULATORY COMMITTEE.

(a) ESTABLISHMENT.—The President shall establish a committee to be known as the Transportation Fuels Regulatory Committee (in this title referred to as the ''Committee'') to analyze and report on the cumulative impacts of certain rules and actions of the Environmental Protection Agency on gasoline, diesel fuel, and natural gas prices, in accordance with sections 203 and 204.

(b) MEMBERS.—The Committee shall be composed of the following officials (or their designees):

(1) The Secretary of Energy, who shall serve as the Chair of the Committee.

(2) The Secretary of Transportation, acting through the Administrator of the National Highway Traffic Safety Administration.

(3) The Secretary of Commerce, acting through the Chief Economist and the Under Secretary for International Trade.

(4) The Secretary of Labor, acting through the Commissioner of the Bureau of Labor Statistics.

(5) The Secretary of the Treasury, acting through the Deputy Assistant Secretary for Environment and Energy of the Department of the Treasury.

(6) The Secretary of Agriculture, acting through the Chief Economist.

(7) The Administrator of the Environmental Protection Agency.

(8) The Chairman of the United States International Trade Commission, acting through the Director of the Office of Economics.

(9) The Administrator of the Energy Information Administration.

(c) CONSULTATION BY CHAIR.—In carrying out the functions of the Chair of the Committee, the Chair shall consult with the other members of the Committee.

(d) TERMINATION.—The Committee shall terminate 60 days after submitting its final report pursuant to section 204(c).

SEC. 203. ANALYSES.

(a) SCOPE.—The Committee shall conduct analyses, for each of the calendar years 2016 and 2020, of the cumulative impact of all covered rules, in combination with covered actions.

(b) CONTENTS.—The Committee shall include in each analysis conducted under this section the following:

(1) Estimates of the cumulative impacts of the covered rules and covered actions with regard to—

(A) any resulting change in the national, State, or regional price of gasoline, diesel fuel, or natural gas;

(B) required capital investments and projected costs for operation and maintenance of new equipment required to be installed;

(C) global economic competitiveness of the United States and any loss of domestic refining capacity;

(D) other cumulative costs and cumulative benefits, including evaluation through a general equilibrium model approach; and

(E) national, State, and regional employment, including impacts associated with changes in gasoline, diesel fuel, or natural gas prices and facility closures.

(2) Discussion of key uncertainties and assumptions associated with each estimate under paragraph (1).

(3) A sensitivity analysis reflecting alternative assumptions with respect to the aggregate demand for gasoline, diesel fuel, or natural gas.

(4) Discussion, and where feasible an assessment, of the cumulative impact of the covered rules and covered actions on—

(A) consumers;

(B) small businesses;

(C) regional economies;

(D) State, local, and tribal governments;

(E) low-income communities;

(F) public health; and

(G) local and industry-specific labor markets, as well as key uncertainties associated with each topic listed in subparagraphs (A) through (G).

(c) METHODS.—In conducting analyses under this section, the Committee shall use the best available methods, consistent with guidance from the Office of Information and Regulatory Affairs and the Office of Management and Budget Circular A–4.

(d) DATA.—In conducting analyses under this section, the Committee is not required to create data or to use data that is not readily accessible.

(e) COVERED RULES.—In this section, the term ''covered rule'' means the following rules (and includes any successor or substantially similar rules):

(1) ''Control of Air Pollution From New Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards'', as described in the Unified Agenda of Federal Regulatory and Deregulatory Actions under Regulatory Identification Number 2060–AQ86.

(2) Any rule proposed after March 15, 2012, establishing or revising a standard of performance or emission standard under section 111 or 112 of the Clean Air Act (42 U.S.C. 7411, 7412) that is applicable to petroleum refineries.

(3) Any rule proposed after March 15, 2012, for implementation of the Renewable Fuel Program under section 211(o) of the Clean Air Act (42 U.S.C. 7545(o)).

(4) ''National Ambient Air Quality Standards for Ozone'', published at 73 Federal Register 16436 (March 27, 2008); ''Reconsideration of the 2008 Ozone Primary and Secondary National Ambient Air Quality Standards'', as described in the Unified Agenda of Federal Regulatory and Deregulatory Actions under Regulatory Identification Number 2060–AP98; and any subsequent rule revising or supplementing the national ambient air quality standards for ozone under section 109 of the Clean Air Act (42 U.S.C. 7409).

(f) COVERED ACTIONS.—In this section, the term ''covered action'' means any action, to the extent such action affects facilities involved in the production, transportation, or distribution

of gasoline, diesel fuel, or natural gas, taken on or after January 1, 2009, by the Administrator of the Environmental Protection Agency, a State, a local government, or a permitting agency as a result of the application of part C of title I (relating to prevention of significant deterioration of air quality), or title V (relating to permitting), of the Clean Air Act (42 U.S.C. 7401 et seq.), to an air pollutant that is identified as a greenhouse gas in the rule entitled ''Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act'' published at 74 Federal Register 66496 (December 15, 2009).

SEC. 204. REPORTS; PUBLIC COMMENT.

(a) PRELIMINARY REPORT.—Not later than 90 days after the date of enactment of this Act, the Committee shall make public and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works of the Senate a preliminary report containing the results of the analyses conducted under section 203.

(b) PUBLIC COMMENT PERIOD.—The Committee shall accept public comments regarding the preliminary report submitted under subsection (a) for a period of 60 days after such submission.

(c) FINAL REPORT.—Not later than 60 days after the close of the public comment period under subsection (b), the Committee shall submit to Congress a final report containing the analyses conducted under section 203, including any revisions to such analyses made as a result of public comments, and a response to such comments.

SEC. 205. NO FINAL ACTION ON CERTAIN RULES.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency shall not finalize any of the following rules until a date (to be determined by the Administrator) that is at least 6 months after the day on which the Committee submits the final report under section 204(c):

(1) ''Control of Air Pollution From New Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards'', as described in the Unified Agenda of Federal Regulatory and Deregulatory Actions under Regulatory Identification Number 2060–AQ86, and any successor or substantially similar rule.

(2) Any rule proposed after March 15, 2012, establishing or revising a standard of performance or emission standard under section 111 or 112 of the Clean Air Act (42 U.S.C. 7411, 7412) that is applicable to petroleum refineries.

(3) Any rule revising or supplementing the national ambient air quality standards for ozone under section 109 of the Clean Air Act (42 U.S.C. 7409).

(b) OTHER RULES NOT AFFECTED.—Subsection (a) shall not affect the finalization of any rule other than the rules described in such subsection.

SEC. 206. CONSIDERATION OF FEASIBILITY AND COST IN REVISING OR SUPPLEMENTING NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE.

In revising or supplementing any national primary or secondary ambient air quality standards for ozone under section 109 of the Clean Air Act (42 U.S.C. 7409), the Administrator of the Environmental Protection Agency shall take into consideration feasibility and cost.

TITLE III—QUADRENNIAL STRATEGIC FEDERAL ONSHORE ENERGY PRODUCTION STRATEGY

SEC. 301. SHORT TITLE.

This title may be cited as the ''Planning for American Energy Act of 2012''.

SEC. 302. ONSHORE DOMESTIC ENERGY PRODUCTION STRATEGIC PLAN.

(a) IN GENERAL.—The Mineral Leasing Act (30 U.S.C. 181 et seq.) is amended by redesignating section 44 as section 45, and by inserting after section 43 the following:

''SEC. 44. QUADRENNIAL STRATEGIC FEDERAL ONSHORE ENERGY PRODUCTION STRATEGY.

''(a) IN GENERAL.—

''(1) The Secretary of the Interior (hereafter in this section referred to as 'Secretary'), in consultation with the Secretary of Agriculture with regard to lands administered by the Forest Service, shall develop and publish every 4 years a Quadrennial Federal Onshore Energy Production Strategy. This Strategy shall direct Federal land energy development and department resource allocation in order to promote the energy security of the United States.

''(2) In developing this Strategy, the Secretary shall consult with the Administrator of the Energy Information Administration on the projected energy demands of the United States for the next 30-year period, and how energy derived from Federal onshore lands can put the United States on a trajectory to meet that demand during the next 4-year period. The Secretary shall consider how Federal lands will contribute to ensuring national energy security, with a goal for increasing energy independence and production, during the next 4-year period.

''(3) The Secretary shall determine a domestic strategic production objective for the development of energy resources from Federal onshore lands. Such objective shall be—

''(A) the best estimate, based upon commercial and scientific data, of the expected increase in domestic production of oil and natural gas from the Federal onshore mineral estate, with a focus on lands held by the Bureau of Land Management and the Forest Service;

''(B) the best estimate, based upon commercial and scientific data, of the expected increase in domestic coal production from Federal lands;

''(C) the best estimate, based upon commercial and scientific data, of the expected increase in domestic production of strategic and critical energy minerals from the Federal onshore mineral estate;

''(D) the best estimate, based upon commercial and scientific data, of the expected increase in megawatts for electricity production from each of the following sources: wind, solar, biomass, hydropower, and geothermal energy produced on Federal lands administered by the Bureau of Land Management and the Forest Service;

''(E) the best estimate, based upon commercial and scientific data, of the expected increase in unconventional energy production, such as oil shale; and

''(F) the best estimate, based upon commercial and scientific data, of the expected increase in domestic production of oil, natural gas, coal, and other renewable sources from tribal lands for any federally recognized Indian tribe that elects to participate in facilitating energy production on its lands.

''(4) The Secretary shall consult with the Administrator of the Energy Information Administration regarding the methodology used to arrive at its estimates for purposes of this section.

''(5) The Secretary has the authority to expand the energy development plan to include other energy production technology sources or advancements in energy on Federal lands.

''(b) TRIBAL OBJECTIVES.—It is the sense of Congress that federally recognized Indian tribes may elect to set their own production objectives as part of the Strategy under this section. The Secretary shall work in cooperation with any federally recognized Indian tribe that elects to participate in achieving its own strategic energy objectives designated under this subsection.

''(c) EXECUTION OF THE STRATEGY.—The relevant Secretary shall have all necessary authority to make determinations regarding which additional lands will be made available in order to meet the production objectives established by strategies under this section. The Secretary shall also take all necessary actions to achieve these production objectives unless the President determines that it is not in the national security and economic interests of the United States to increase Federal domestic energy production and to further decrease dependence upon foreign sources of energy. In administering this section, the relevant Secretary shall only consider leasing Federal lands available for leasing at the time the lease sale occurs.

''(d) STATE, FEDERALLY RECOGNIZED INDIAN TRIBES, LOCAL GOVERNMENT, AND PUBLIC INPUT.—In developing each strategy, the Secretary shall solicit the input of affected States, federally recognized Indian tribes, local governments, and the public.

''(e) REPORTING.—The Secretary shall report annually to the Committee on Natural Resources of the House of Representatives and the Committee on Energy and Natural Resources of the Senate on the progress of meeting the production goals set forth in the strategy. The Secretary shall identify in the report projections for production and capacity installations and any problems with leasing, permitting, siting, or production that will prevent meeting the goal. In addition, the Secretary shall make suggestions to help meet any shortfalls in meeting the production goals.

''(f) PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT.—Not later than 12 months after the date of enactment of this section, in accordance with section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)), the Secretary shall complete a programmatic environmental impact statement. This programmatic environmental impact statement will be deemed sufficient to comply with all requirements under that Act for all necessary resource management and land use plans associated with the implementation of the strategy.

''(g) CONGRESSIONAL REVIEW.—At least 60 days prior to publishing a proposed strategy under this section, the Secretary shall submit it to the President and the Congress, together with any comments received from States, federally recognized Indian tribes, and local governments. Such submission shall indicate why any specific recommendation of a State, federally recognized Indian tribe, or local government was not accepted.''.

(b) FIRST QUADRENNIAL STRATEGY.—Not later than 18 months after the date of enactment of this Act, the Secretary of the Interior shall submit to Congress the first Quadrennial Federal Onshore Energy Production Strategy under the amendment made by subsection (a).

SEC. 303. DEFINITIONS.

For purposes of this title, the term ''strategic and critical energy minerals'' means those that are necessary for the Nation's energy infrastructure including pipelines, refining capacity, electrical power generation and transmission, and renewable energy production and those that are necessary to support domestic manufacturing, including but not limited to, materials used in energy generation, production, and transportation.

TITLE IV—ONSHORE OIL AND GAS LEASING CERTAINTY

SEC. 401. SHORT TITLE.

This title may be cited as the ''Providing Leasing Certainty for American Energy Act of 2012''.

SEC. 402. MINIMUM ACREAGE REQUIREMENT FOR ONSHORE LEASE SALES.

In conducting lease sales as required by section 17(a) of the Mineral Leasing Act (30 U.S.C. 226(a)), each year the Secretary of the Interior shall perform the following:

(1) The Secretary shall offer for sale no less than 25 percent of the annual nominated acreage not previously made available for lease. Acreage offered for lease pursuant to this paragraph shall not be subject to protest and shall be eligible for categorical exclusions under section 390 of the Energy Policy Act of 2005 (42 U.S.C. 15492), except that it shall not be subject to the test of extraordinary circumstances.

(2) In administering this section, the Secretary shall only consider leasing of Federal lands that

are available for leasing at the time the lease sale occurs.

SEC. 403. LEASING CERTAINTY.

Section 17(a) of the Mineral Leasing Act (30 U.S.C. 226(a)) is amended by inserting ''(1)'' before ''All lands'', and by adding at the end the following:

''(2)(A) The Secretary shall not withdraw any covered energy project issued under this Act without finding a violation of the terms of the lease by the lessee.

''(B) The Secretary shall not infringe upon lease rights under leases issued under this Act by indefinitely delaying issuance of project approvals, drilling and seismic permits, and rights of way for activities under such a lease.

''(C) No later than 18 months after an area is designated as open under the current land use plan the Secretary shall make available nominated areas for lease under the criteria in section 2.

''(D) Notwithstanding any other law, the Secretary shall issue all leases sold no later than 60 days after the last payment is made.

''(E) The Secretary shall not cancel or withdraw any lease parcel after a competitive lease sale has occurred and a winning bidder has submitted the last payment for the parcel.

''(F) Not later than 60 days after a lease sale held under this Act, the Secretary shall adjudicate any lease protests filed following a lease sale. If after 60 days any protest is left unsettled, said protest is automatically denied and appeal rights of the protestor begin.

''(G) No additional lease stipulations may be added after the parcel is sold without consultation and agreement of the lessee, unless the Secretary deems such stipulations as emergency actions to conserve the resources of the United States.''.

SEC. 404. LEASING CONSISTENCY.

Federal land managers must follow existing resource management plans and continue to actively lease in areas designated as open when resource management plans are being amended or revised, until such time as a new record of decision is signed.

SEC. 405. REDUCE REDUNDANT POLICIES.

Bureau of Land Management Instruction Memorandum 2010–117 shall have no force or effect.

TITLE V—STREAMLINED ENERGY PERMITTING

SEC. 501. SHORT TITLE.

This title may be cited as the ''Streamlining Permitting of American Energy Act of 2012''.

Subtitle A—Application for Permits to Drill Process Reform

SEC. 511. PERMIT TO DRILL APPLICATION TIMELINE.

Section 17(p)(2) of the Mineral Leasing Act (30 U.S.C. 226(p)(2)) is amended to read as follows:

''(2) APPLICATIONS FOR PERMITS TO DRILL REFORM AND PROCESS.—

''(A) TIMELINE.—The Secretary shall decide whether to issue a permit to drill within 30 days after receiving an application for the permit. The Secretary may extend such period for up to 2 periods of 15 days each, if the Secretary has given written notice of the delay to the applicant. The notice shall be in the form of a letter from the Secretary or a designee of the Secretary, and shall include the names and titles of the persons processing the application, the specific reasons for the delay, and a specific date a final decision on the application is expected.

''(B) NOTICE OF REASONS FOR DENIAL.—If the application is denied, the Secretary shall provide the applicant—

''(i) in writing, clear and comprehensive reasons why the application was not accepted and detailed information concerning any deficiencies; and

''(ii) an opportunity to remedy any deficiencies.

''(C) APPLICATION DEEMED APPROVED.—If the Secretary has not made a decision on the application by the end of the 60-day period beginning on the date the application is received by the Secretary, the application is deemed approved, except in cases in which existing reviews under the National Environmental Policy Act of 1969 or Endangered Species Act of 1973 are incomplete.

''(D) DENIAL OF PERMIT.—If the Secretary decides not to issue a permit to drill in accordance with subparagraph (A), the Secretary shall—

''(i) provide to the applicant a description of the reasons for the denial of the permit;

''(ii) allow the applicant to resubmit an application for a permit to drill during the 10-day period beginning on the date the applicant receives the description of the denial from the Secretary; and

''(iii) issue or deny any resubmitted application not later than 10 days after the date the application is submitted to the Secretary.

''(E) FEE.—

''(i) IN GENERAL.—Notwithstanding any other law, the Secretary shall collect a single $6,500 permit processing fee per application from each applicant at the time the final decision is made whether to issue a permit under subparagraph (A). This fee shall not apply to any resubmitted application.

''(ii) TREATMENT OF PERMIT PROCESSING FEE.—Of all fees collected under this paragraph, 50 percent shall be transferred to the field office where they are collected and used to process protests, leases, and permits under this Act subject to appropriation.''.

SEC. 512. SOLAR AND WIND RIGHT-OF-WAY RENTAL REFORM.

Notwithstanding any other provision of law, each fiscal year, of fees collected as annual wind energy and solar energy right-of-way authorization fees required under section 504(g) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1764(g)), 50 percent shall be retained by the Secretary of the Interior to be used, subject to appropriation, by the Bureau of Land Management to process permits, right-of-way applications, and other activities necessary for renewable development, and, at the discretion of the Secretary, by the U.S. Fish and Wildlife Service or other Federal agencies involved in wind and solar permitting reviews to facilitate the processing of wind energy and solar energy permit applications on Bureau of Land Management lands.

Subtitle B—Administrative Protest Documentation Reform

SEC. 521. ADMINISTRATIVE PROTEST DOCUMENTATION REFORM.

Section 17(p) of the Mineral Leasing Act (30 U.S.C. 226(p)) is further amended by adding at the end the following:

''(4) PROTEST FEE.—

''(A) IN GENERAL.—The Secretary shall collect a $5,000 documentation fee to accompany each protest for a lease, right of way, or application for permit to drill.

''(B) TREATMENT OF FEES.—Of all fees collected under this paragraph, 50 percent shall remain in the field office where they are collected and used to process protests subject to appropriation.''.

Subtitle C—Permit Streamlining

SEC. 531. IMPROVE FEDERAL ENERGY PERMIT COORDINATION.

(a) ESTABLISHMENT.—The Secretary of the Interior (referred to in this section as the ''Secretary'') shall establish a Federal Permit Streamlining Project (referred to in this section as the ''Project'') in every Bureau of Land Management field office with responsibility for permitting energy projects on Federal land.

(b) MEMORANDUM OF UNDERSTANDING.—

(1) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary shall enter into a memorandum of understanding for purposes of this section with—

(A) the Secretary of Agriculture;

(B) the Administrator of the Environmental Protection Agency; and

(C) the Chief of the Army Corps of Engineers.

(2) STATE PARTICIPATION.—The Secretary may request that the Governor of any State with energy projects on Federal lands to be a signatory to the memorandum of understanding.

(c) DESIGNATION OF QUALIFIED STAFF.—

(1) IN GENERAL.—Not later than 30 days after the date of the signing of the memorandum of understanding under subsection (b), all Federal signatory parties shall, if appropriate, assign to each of the Bureau of Land Management field offices an employee who has expertise in the regulatory issues relating to the office in which the employee is employed, including, as applicable, particular expertise in—

(A) the consultations and the preparation of biological opinions under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536);

(B) permits under section 404 of Federal Water Pollution Control Act (33 U.S.C. 1344);

(C) regulatory matters under the Clean Air Act (42 U.S.C. 7401 et seq.);

(D) planning under the National Forest Management Act of 1976 (16 U.S.C. 472a et seq.); and

(E) the preparation of analyses under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).

(2) DUTIES.—Each employee assigned under paragraph (1) shall—

(A) not later than 90 days after the date of assignment, report to the Bureau of Land Management Field Managers in the office to which the employee is assigned;

(B) be responsible for all issues relating to the energy projects that arise under the authorities of the employee's home agency; and

(C) participate as part of the team of personnel working on proposed energy projects, planning, and environmental analyses on Federal lands.

(d) ADDITIONAL PERSONNEL.—The Secretary shall assign to each Bureau of Land Management field office identified in subsection (a) any additional personnel that are necessary to ensure the effective approval and implementation of energy projects administered by the Bureau of Land Management field offices, including inspection and enforcement relating to energy development on Federal land, in accordance with the multiple use mandate of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.).

(e) FUNDING.—Funding for the additional personnel shall come from the Department of the Interior reforms identified in sections 511, 512, and 521.

(f) SAVINGS PROVISION.—Nothing in this section affects—

(1) the operation of any Federal or State law; or

(2) any delegation of authority made by the head of a Federal agency whose employees are participating in the Project.

(g) DEFINITION.—For purposes of this section the term ''energy projects'' includes oil, natural gas, coal, and other energy projects as defined by the Secretary.

SEC. 532. ADMINISTRATION OF CURRENT LAW.

Notwithstanding any other law, the Secretary of the Interior shall not require a finding of extraordinary circumstances in administering section 390 of the Energy Policy Act of 2005.

SEC. 533. POLICIES REGARDING BUYING, BUILDING, AND WORKING FOR AMERICA.

(a) CONGRESSIONAL INTENT.—It is the intent of Congress that—

(1) this title will support a healthy and growing United States domestic energy sector that, in turn, helps to reinvigorate American manufacturing, transportation, and service sectors by employing the vast talents of United States workers to assist in the development of energy from domestic sources; and

(2) Congress will monitor the deployment of personnel and material onshore under this title to encourage the development of American technology and manufacturing to enable United

States workers to benefit from this title through good jobs and careers, as well as the establishment of important industrial facilities to support expanded access to American energy resources.

(b) REQUIREMENT.—The Secretary of the Interior shall, when possible and practicable, encourage the use of United States workers and equipment manufactured in the United States in all construction related to mineral resource development under this title.

Subtitle D—Judicial Review

SEC. 541. DEFINITIONS.

In this title—

(1) the term ''covered civil action'' means a civil action containing a claim under section 702 of title 5, United States Code, regarding agency action (as defined for the purposes of that section) affecting a covered energy project on Federal lands of the United States; and

(2) the term ''covered energy project'' means the leasing of Federal lands of the United States for the exploration, development, production, processing, or transmission of oil, natural gas, wind, or any other source of energy, and any action under such a lease, except that the term does not include any disputes between the parties to a lease regarding the obligations under such lease, including regarding any alleged breach of the lease.

SEC. 542. EXCLUSIVE VENUE FOR CERTAIN CIVIL ACTIONS RELATING TO COVERED ENERGY PROJECTS.

Venue for any covered civil action shall lie in the district court where the project or leases exist or are proposed.

SEC. 543. TIMELY FILING.

To ensure timely redress by the courts, a covered civil action must be filed no later than the end of the 90-day period beginning on the date of the final Federal agency action to which it relates.

SEC. 544. EXPEDITION IN HEARING AND DETERMINING THE ACTION.

The court shall endeavor to hear and determine any covered civil action as expeditiously as possible.

SEC. 545. STANDARD OF REVIEW.

In any judicial review of a covered civil action, administrative findings and conclusions relating to the challenged Federal action or decision shall be presumed to be correct, and the presumption may be rebutted only by the preponderance of the evidence contained in the administrative record.

SEC. 546. LIMITATION ON INJUNCTION AND PROSPECTIVE RELIEF.

In a covered civil action, the court shall not grant or approve any prospective relief unless the court finds that such relief is narrowly drawn, extends no further than necessary to correct the violation of a legal requirement, and is the least intrusive means necessary to correct that violation. In addition, courts shall limit the duration of preliminary injunctions to halt covered energy projects to no more than 60 days, unless the court finds clear reasons to extend the injunction. In such cases of extensions, such extensions shall only be in 30-day increments and shall require action by the court to renew the injunction.

SEC. 547. LIMITATION ON ATTORNEYS' FEES.

Sections 504 of title 5, United States Code, and 2412 of title 28, United States Code, (together commonly called the Equal Access to Justice Act) do not apply to a covered civil action, nor shall any party in such a covered civil action receive payment from the Federal Government for their attorneys' fees, expenses, and other court costs.

SEC. 548. LEGAL STANDING.

Challengers filing appeals with the Department of the Interior Board of Land Appeals shall meet the same standing requirements as challengers before a United States district court.

TITLE VI—EXPEDITIOUS PROGRAM OF OIL AND GAS LEASING IN THE NATIONAL PETROLEUM RESERVE IN ALASKA

SEC. 601. SHORT TITLE.

This title may be cited as the ''National Petroleum Reserve Alaska Access Act''.

SEC. 602. SENSE OF CONGRESS AND REAFFIRMING NATIONAL POLICY FOR THE NATIONAL PETROLEUM RESERVE IN ALASKA.

It is the sense of Congress that—

(1) the National Petroleum Reserve in Alaska remains explicitly designated, both in name and legal status, for purposes of providing oil and natural gas resources to the United States; and

(2) accordingly, the national policy is to actively advance oil and gas development within the Reserve by facilitating the expeditious exploration, production, and transportation of oil and natural gas from and through the Reserve.

SEC. 603. NATIONAL PETROLEUM RESERVE IN ALASKA: LEASE SALES.

Section 107(a) of the Naval Petroleum Reserves Production Act of 1976 (42 U.S.C. 6506a(a)) is amended to read as follows:

''(a) IN GENERAL.—The Secretary shall conduct an expeditious program of competitive leasing of oil and gas in the reserve in accordance with this Act. Such program shall include at least one lease sale annually in those areas of the reserve most likely to produce commercial quantities of oil and natural gas each year in the period 2011 through 2021.''.

SEC. 604. NATIONAL PETROLEUM RESERVE IN ALASKA: PLANNING AND PERMITTING PIPELINE AND ROAD CONSTRUCTION.

(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of the Interior, in consultation with the Secretary of Transportation, shall facilitate and ensure permits, in an environmentally responsible manner, for all surface development activities, including for the construction of pipelines and roads, necessary to—

(1) develop and bring into production any areas within the National Petroleum Reserve in Alaska that are subject to oil and gas leases; and

(2) transport oil and gas from and through the National Petroleum Reserve in Alaska to existing transportation or processing infrastructure on the North Slope of Alaska.

(b) TIMELINE.—The Secretary shall ensure that any Federal permitting agency shall issue permits in accordance with the following timeline:

(1) Permits for such construction for transportation of oil and natural gas produced under existing Federal oil and gas leases with respect to which the Secretary has issued a permit to drill shall be approved within 60 days after the date of enactment of this Act.

(2) Permits for such construction for transportation of oil and natural gas produced under Federal oil and gas leases shall be approved within 6 months after the submission to the Secretary of a request for a permit to drill.

(c) PLAN.—To ensure timely future development of the Reserve, within 270 days after the date of the enactment of this Act, the Secretary of the Interior shall submit to Congress a plan for approved rights-of-way for a plan for pipeline, road, and any other surface infrastructure that may be necessary infrastructure that will ensure that all leasable tracts in the Reserve are within 25 miles of an approved road and pipeline right-of-way that can serve future development of the Reserve.

SEC. 605. DEPARTMENTAL ACCOUNTABILITY FOR DEVELOPMENT.

(a) IN GENERAL.—The Secretary of the Interior shall issue regulations within 180 days after the date of enactment of this Act that establish clear requirements to ensure that the Department of the Interior is supporting development of oil and gas leases in the National Petroleum Reserve in Alaska.

(b) DEADLINES.—At a minimum, the regulations shall—

(1) require the Department to respond within 5 business days acknowledging receipt of any permit application for such development; and

(2) establish a timeline for the processing of each such application, that—

(A) specifies deadlines for decisions and actions on permit applications; and

(B) provide that the period for issuing each permit after submission of such an application shall not exceed 60 days without the concurrence of the applicant.

(c) ACTIONS REQUIRED FOR FAILURE TO COMPLY WITH DEADLINES.—If the Department fails to comply with any deadline under subsection (b) with respect to a permit application, the Secretary shall notify the applicant every 5 days with specific information regarding the reasons for the permit delay, the name of the specific Department office or offices responsible for issuing the permit and for monitoring the permit delay, and an estimate of the time that the permit will be issued.

SEC. 606. UPDATED RESOURCE ASSESSMENT.

(a) IN GENERAL.—The Secretary of the Interior shall complete a comprehensive assessment of all technically recoverable fossil fuel resources within the National Petroleum Reserve in Alaska, including all conventional and unconventional oil and natural gas.

(b) COOPERATION AND CONSULTATION.—The resource assessment required by subsection (a) shall be carried out by the United States Geological Survey in cooperation and consultation with the State of Alaska and the American Association of Petroleum Geologists.

(c) TIMING.—The resource assessment required by subsection (a) shall be completed within 24 months after the date of the enactment of this Act.

(d) FUNDING.—The United States Geological Survey may, in carrying out the duties under this section, cooperatively use resources and funds provided by the State of Alaska.

TITLE VII—INTERNET-BASED ONSHORE OIL AND GAS LEASE SALES

SEC. 701. SHORT TITLE.

This title may be cited as the ''BLM Live Internet Auctions Act''.

SEC. 702. INTERNET-BASED ONSHORE OIL AND GAS LEASE SALES.

(a) AUTHORIZATION.—Section 17(b)(1) of the Mineral Leasing Act (30 U.S.C. 226(b)(1)) is amended—

(1) in subparagraph (A), in the third sentence, by inserting '', except as provided in subparagraph (C)'' after ''by oral bidding''; and

(2) by adding at the end the following:

''(C) In order to diversify and expand the Nation's onshore leasing program to ensure the best return to the Federal taxpayer, reduce fraud, and secure the leasing process, the Secretary may conduct onshore lease sales through Internet-based bidding methods. Each individual Internet-based lease sale shall conclude within 7 days.''.

(b) REPORT.—Not later than 90 days after the tenth Internet-based lease sale conducted under the amendment made by subsection (a), the Secretary of the Interior shall analyze the first 10 such lease sales and report to Congress the findings of the analysis. The report shall include—

(1) estimates on increases or decreases in such lease sales, compared to sales conducted by oral bidding, in—

(A) the number of bidders;

(B) the average amount of bid;

(C) the highest amount bid; and

(D) the lowest bid;

(2) an estimate on the total cost or savings to the Department of the Interior as a result of such sales, compared to sales conducted by oral bidding; and

(3) an evaluation of the demonstrated or expected effectiveness of different structures for lease sales which may provide an opportunity to

better maximize bidder participation, ensure the highest return to the Federal taxpayers, minimize opportunities for fraud or collusion, and ensure the security and integrity of the leasing process.

The CHAIR. No amendment to that amendment in the nature of a substitute shall be in order except those printed in House Report 112–540. Each such amendment may be offered only in the order printed in the report, by a Member designated in the report, shall be considered read, shall be debatable for the time specified in the report, equally divided and controlled by the proponent and an opponent, shall not be subject to amendment, and shall not be subject to a demand for division of the question.

AMENDMENT NO. 1 OFFERED BY MR. HASTINGS OF WASHINGTON

The Acting CHAIR. It is now in order to consider amendment No. 1 printed in House Report 112–540.

Mr. HASTINGS of Washington. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 3, line 1, insert ''**OIL AND GAS EXPLORATION, DEVELOPMENT, AND PRODUCTION**'' after ''**DOMESTIC**''.

Page 5, after line 19, insert the following (and redesignate the subsequent quoted paragraphs accordingly):

''(4) CONCURRENCE.—The plan required by paragraph (1) shall not take effect without the concurrence of each of the Secretary of Agriculture, the Secretary of the Interior, and the Secretary of Defense with respect to elements of the plan within the jurisdiction, respectively, of the Department of Agriculture, the Department of the Interior, and the Department of Defense.

Page 31, strike lines 1 through 3 and insert the following:

(g) DEFINITION.—For purposes of this section the term ''energy projects'' means oil, natural gas and renewable energy projects.

At the end of section 605 (page 39, after line 4) add the following:

(d) ADDITIONAL INFRASTRUCTURE.—Within 180 days after the date of enactment of this Act, the Secretary of the Interior shall approve, after consultation with the State of Alaska and public comment, right-of-way corridors for the construction of 2 separate additional bridges and pipeline rights-of-way to help facilitate timely oil and gas development of the Reserve.

At the end of title VI (page 39, after line 22), insert the following:

SEC. ___. COLVILLE RIVER DESIGNATION.

The designation by the Environmental Protection Agency of the Colville River Delta as an Aquatic Resource of National Importance shall have no force or effect.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Washington (Mr. HASTINGS) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Washington.

Mr. HASTINGS of Washington. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, the Natural Petroleum Reserve-Alaska, or NPR–A, was specifically designated as a petroleum reserve back in 1923. It's a place that we can develop our resources for energy and national security. Title VI of this bill will ensure that production can occur on NPR–A by requiring at least one annual lease sale, streamline the permitting process to ensure lease sales lead to energy production, and ensure a right-of-away plan to allow for the transportation of the product out of NPR–A.

In addition to making technical corrections, this amendment aims to accomplish two vital goals that are imperative for facilitating development at NPR–A. First, it would require, at the request of the State of Alaska, up to two additional rights-of-way planned in and out of NPR–A. This would prepare for future development by providing approved rights-of-way in and out of this area.

Secondly, it would repeal the designation of the Colville River as an Aquatic Resource of National Importance. This designation was blatantly used by the anti-energy EPA as nothing more than a tool to stop energy development on this area.

While the President touts his energy record and speaks of his support for leasing and energy development in the NPR–A, he fails to mention that due to red tape from his administration, Alaskans have waited for years and years for approval to build a simple bridge across the Colville River to begin production in NPR–A. What you do not hear is that the EPA has paid no attention to the Colville River until after ConocoPhillips filed its application for a bridge. It was shortly after that application that EPA declared it was an Aquatic Resource of Natural Importance. And it was that action that stopped the development and production for nearly a decade before approval of this simple bridge and pipeline.

What the Obama administration says and what the administration does to promote energy development in Alaska are entirely two different things.

So those two things that I mention in this amendment would give Alaskans the assurance they need to create jobs and encourage development of the NPR–A.

I reserve the balance of my time.

Mr. MARKEY. Mr. Chairman, I rise to claim time in opposition to this amendment.

The Acting CHAIR. The gentleman from Massachusetts is recognized for 5 minutes.

Mr. MARKEY. Mr. Chairman, when manager's amendments making technical changes to legislation are presented, such amendments are accepted and we move on to amendments making substantive changes to the bill. In this instance, however, among the technical changes made by this manager's amendment is a controversial provision flatly overturning an EPA ruling in Alaska. This change should not be made at all, but it certainly should not be made as part of a manager's amendment.

As part of the review process for beginning energy production in the National Petroleum Reserve in Alaska, the EPA designated the Colville River, the largest Arctic river in Alaska, as an Aquatic Resource of National Importance. To be clear, this designation did not stop the proposed project. ConocoPhillips has already received approval to build a gravel road, including a bridge over the Colville to access their oil field. The National Importance designation simply required a heightened level of review before the project moved forward. For Congress to overturn this EPA finding through a provision buried in what is supposed to be a technical manager's amendment is not appropriate.

Mr. Chairman, I doubt a single Member of this House has an informed opinion regarding whether the Colville River is an Aquatic Resource of National Importance. But I will tell you who does have an informed position on that question, and that is the scientists in Alaska working for the Environmental Protection Agency.

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This provision is an ill-informed sneak attack on an agency decision, and for the purposes of this debate, it has no place in a manager's amendment. It should be a stand-alone amendment that we're debating. Because of the inappropriateness of it being inside of the manager's amendment, I would have to oppose this provision.

I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I advise my friend that I have no more requests for time, and I am prepared to close if the gentleman is prepared to close.

Mr. MARKEY. I yield myself the balance of my time just to say that I don't have a problem in debating this issue, but I just think it should be done in an appropriate way. It is an important issue. It overturns an EPA decision of some significance and I urge a ''no'' vote.

I yield back the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I yield myself the balance of my time.

Mr. Chairman, just briefly, there are technical amendments in here which I acknowledge and the gentleman did acknowledge, and there are two substantive changes, and I acknowledge both of those.

Now, I just want to repeat, he talked about the issue that the Colville River was an aquatic resource of national importance. He's basing that as the reason why we should not adopt this amendment.

I want to point out again, and I made this observation in my remarks, the Colville River was not designated this until after—and I want to say this again very slowly; sometimes you don't hear things in this echo chamber—after Conoco wanted to develop the NPR–A. When they developed the NPR-A, they

had to have access across the Colville River. But the EPA said all of a sudden: Wait a second, this might be a good time to make that change. That's pure politics, Mr. Chairman.

And I will say this. I was up in Alaska last year, and I stood right at the spot where they want to build a bridge across the Colville River. The Colville River there is not very large, and to suggest it falls into that category and we should not adopt this amendment flies right in the face of common sense.

So with that, I urge my colleagues to adopt this amendment, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Washington (Mr. HASTINGS).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. MARKEY. I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Washington will be postponed.

AMENDMENT NO. 2 OFFERED BY MR. POLIS

The Acting CHAIR. It is now in order to consider amendment No. 2 printed in House Report 112–540.

Mr. POLIS. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of title I (page 6, after line 6) insert the following:

SEC. ___. LIMITATION ON HYDRAULIC FRACTURING.

No lease or other authorization may be issued under a plan required by subsection (k) of section 161 of the Energy Policy and Conservation Act, as amended by section 102 of this Act, for the conduct of any activity related to hydraulic fracturing within 1,000 feet of a primary or secondary school.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Colorado (Mr. POLIS) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Colorado.

Mr. POLIS. Mr. Chairman, I yield myself 2 minutes.

Mr. Chairman, my amendment would better protect the health of children by providing for a 1,000-foot buffer between schools and oil or gas drilling using the technique commonly known as fracking.

Hydraulic fracturing is a national issue, and natural gas is an important part of our national energy policy. According to the Interstate Oil and Gas Compact Commission, currently oil or gas production occurs in 33 States. Fracking occurs on more than 90 percent of oil and natural gas wells in the U.S.

Advances in unconventional oil and natural gas extraction have led to an increase in fracking near where people live, work, and play in my district, across Colorado, and across the United States. That means increased exposure to toxic chemicals for kids in school and the air that researchers have found near wells, as well as noise and the nuisance of heavy truck traffic.

A recent report by the Colorado School of Public Health indicated that residents living less than half of a mile from wells were at a greater risk of acute and chronic health problems than those who live more than half of a mile from drilling sites; including exposure to air pollutants like benzene, a known carcinogen, at a level five times higher than the Federal hazard standard.

Given this risk and the need for more information, we should obviously err on the side of caution, particularly when it comes to children. We need additional studies to better understand the health impacts; but, given what we know, frankly, it's time to act.

Now, we've already set some basic standards when we know pollutants may put children at risk. As an example, in my district in Colorado, commercial diesel vehicles are prohibited from idling for more than 5 minutes within 1,000 feet of a school. In New York, fracking operations may be placed 100 feet from a home and 150 feet from a public building.

A review of active and prospective wells in four northern Colorado counties found 26 schools that have drilling wells operational emitting toxic gases within 1,000 feet of schools.

In Erie, Colorado, I met with homeowners and parents who are increasingly concerned about the impacts of fracking on their health and their children's health. We should be listening to their voices and not just the demands of energy companies. We need to find a reasonable compromise to address the concerns of families in Erie and across America.

I would like to yield 2 minutes to the gentleman from New York (Mr. HINCHEY).

Mr. HINCHEY. Mr. Chairman, I rise in strong support of the gentleman's amendment, which would prohibit hydraulic fracturing on public lands from taking place within 1,000 feet of our schools. This major industrial activity has significant public health risks and has no business being near our kids.

Hydraulically fractured wells emit huge quantities of smog-forming chemicals, volatile organic compounds, hazardous air pollutants like benzene, as well as methane. These pollutants cause serious health problems.

This past March, the Colorado School of Public Health released a report based on 3 years of monitoring that found higher cancer, respiratory, and neurological health risks among people living closest to drilling sites. The analysis found volatile organic chemicals to be five times the level at which the emissions are considered potentially harmful to public health, according to EPA's hazard index.

The Medical Society of New York has recently urged caution with expanded drilling because of concerns about health impacts. And data collected by the National Oceanic and Atmospheric Administration has shown increased ground level ozone and other pollution as a result of fracking.

But the risks go beyond just air quality. In April 2010, there was a major blowout in Pennsylvania at a hydraulic fracturing well site. Gas and tainted brine spewed 75 feet in the air for 16 hours. These kinds of blowouts happen far too often.

Even the best regulated activities have accidents; but fracking, as we all know, is far from the best regulated activities. We need to keep it away from our kids. It shouldn't be done near our schools, and I urge support for the gentleman's amendment.

Mr. POLIS. Mr. Chairman, I yield myself the remainder of my time.

I would ask my colleagues to ask themselves, would they want their kids to be 300 feet, 500 feet, every day from a fracking site? Three hundred feet is the size of one football field. Fracking is scientifically documented as producing air pollution. We know the level of air pollution that is promoted, and it is measured.

Advances in technology make reasonable accommodations possible. Directional drilling means we can actually locate wells miles from schools and still extract the oil and natural gas resources we need and make sure that our children remain healthy.

I'm hopeful that my colleagues on both sides of the aisle support this commonsense amendment that will protect public health, ensure the safe development of natural gas and promote domestic energy production.

I urge a ''yes'' vote on this amendment, I urge my colleagues to join me in keeping our children safe, and I yield back the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. HASTINGS of Washington. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, this amendment would really restrict the ability to produce energy on Federal lands, and I think, quite frankly, it is purely a political amendment.

Rather than allow existing environmental protections and reviews to ensure that we have safe drilling operations, this amendment seeks to use an arbitrary standard that, frankly, is more of a scare tactic than good science; and it would actually harm school districts, principally those in the Intermountain West, that take advantage of their large landholder status to lease their lands for energy development.

□ 1910

In addition, it would infringe upon the ability of Native American tribes

to manage their lands and their resources. It's bad policy, particularly for the consequences of tribal lands that are trying to develop their energy resources. This would restrict their ability to do that.

Now, we've heard the other side talk about why we need to do this, and the implication is that we need to do this to protect drinking water at our children's schools that may become contaminated from hydraulic fracturing. Now, Mr. Chairman, I want to say this very emphatically. This information of contamination is based on absolutely no science or factual evidence. As a matter of fact, to put an exclamation point on that, earlier this week, the gentleman who is offering this amendment, his governor, Governor Hickenlooper of Colorado—who, I might add, is a Democrat—was quoted as saying—and I'll say the whole quote here, and I'll say it as slowly as I can so everybody can understand what Governor Hickenlooper said:

There have been tens of thousands of wells in Colorado, and we can't find anywhere in Colorado a single example of the process of fracking that has polluted groundwater.

Now, I didn't say this. I am quoting the governor of the gentleman who offered the amendment, his State.

Mr. Chairman, I just have to say, I believe this is a politically motivated amendment, and it, frankly, does not even deserve debate on that. So I urge rejection of this amendment, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Colorado (Mr. POLIS).

The amendment was rejected.

The Acting CHAIR. The Chair understands that amendment No. 3 will not be offered.

AMENDMENT NO. 4 OFFERED BY MR. QUIGLEY

The Acting CHAIR. It is now in order to consider amendment No. 4 printed in House Report 112–540.

Mr. QUIGLEY. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of title I (page 6, after line 11) add the following:

SEC. ___. PROTECTIVE APPROACH TO OIL AND GAS LEASING, EXPLORATION, AND DEVELOPMENT ON THE OUTER CONTINENTAL SHELF.

The Secretary of the Interior—

(1) shall not conduct or authorize any leasing, exploration, or development of oil and gas resources of the Outer Continental Shelf under a plan required by subsection (k) of section 161 of the Energy Policy and Conservation Act, as amended by section 102 of this Act, unless—

(A) sound science shows that such activities can proceed with minimal risk to the health of the marine environment and coastal environment.

(B) the Secretary has a thorough understanding of the marine environment and coastal environment impacted by the activity and an environmental baseline, the risks of exploration or development, and the potential consequences of accidents and other emergencies; and

(C) the Secretary determines, on the basis of sound science, that risks are minimal, rigorous safety measures are in place and will be enforced, and there is a demonstrated ability to mount an effective response to accidents in real-world conditions;

(2) shall not make available for oil and gas leasing under such a plan any area of the outer Continental Shelf that, by itself or in a network, has distinguishing ecological characteristics, is important for maintaining habitat heterogeneity or the viability of a species, or contributes disproportionately to the health of an ecosystem, including its biodiversity, function, structure, or resilience; and

(3) in determining whether an area is described in paragraph (2), should give particular consideration to—

(A) areas of high productivity or diversity;

(B) areas that are important for feeding, migration, or the lifecycle of species; and

(C) areas of biogenic habitat, structure forming habitat, or habitat for endangered or threatened species.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Illinois (Mr. QUIGLEY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Illinois.

Mr. QUIGLEY. Mr. Chairman, 2 years ago, the largest accidental marine oil spill in the history of the petroleum industry ravaged the gulf coast. We passed legislation, we convened commissions, and we swore that we would learn. Have we? I fear the answer is no, and I'm not the only one.

In April of this year, the Presidential panel that investigated the explosion gave the Obama administration a B, the oil industry a C-plus, and Congress a D for refusing to act on any of the recommendations of the commission.

The bill that stands before us today seeks to increase domestic oil and gas production and reduce regulation of the energy industry. I've said it before and I'll say it again, sometimes this place feels like Groundhog Day, and I am Bill Murray. So, in the spirit of déjà vu, I am offering an amendment today that mirrors legislation I introduced in the 111th Congress as a response to the BP oil catastrophe.

The amendment would reconfigure the existing presumption that extraction comes first and conservation comes second. The measure would change our Nation's Outer Continental Shelf policy and mandate precaution from a derivative that may imply that protection of the environment is secondary to expeditious development; declares that protection and maintenance—and where appropriate, restoration—of ocean ecosystems and coastal environment is of primary importance; makes clear that OCS leasing, exploration, and development will be authorized in limited areas of the ocean only when science shows that those initiatives can proceed with minimal risk to the health of ocean ecosystems; protects Important Ecological Areas, or IEAs, by requiring the Secretary to consider geographical, geological, and ecological characteristics of the OCS areas. And finally, it amends the Outer Continental Shelf Lands Act to require specific precautions for areas with particular physical or environmental characterizations from OCS leasing.

In the Commission's review, one of the chairmen stated:

Across the board, we are disappointed with Congress' lack of action. Two years have passed since the explosion on the Deepwater Horizon killed 11 workers, and Congress has yet to enact one piece of legislation to make drilling safer.

Let us do one thing to make our public safe, to keep them healthy, and to spur economic development through conservation and the creation of green jobs.

I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I rise to claim time in opposition to this amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. HASTINGS of Washington. I yield myself such time as I may consume.

Mr. Chairman, developing our Nation's Outer Continental Shelf is all about achieving a balance. The Federal agencies involved have to balance the needs of the coastal community and the environment while also providing for safe energy production. This is how you preserve the multiple-use aspect that we have for Federal land management, and I endorse that concept.

Fortunately for the gentleman, the author of this amendment, the purpose of his amendment is already the law of the land. No leasing occurs in the Outer Continental Shelf without extensive environmental assessment. Now, I'll give you an example.

The Bureau of Ocean Energy Management conducts an environmental impact statement, or an EIS, before leasing any area, then another EIS for the specific lease sale area, and then another environmental assessment must be conducted before a company can even begin development. So, with that process that you have to go through, I can only conclude that this amendment is offered not about protecting the environment, but it's really about stopping offshore energy production. Of course, if we do that, obviously what does that do to American energy jobs?

Like I said earlier, fortunately, all these protections exist if indeed we're going to have energy production. So I don't think we need this amendment, and I would urge my colleagues to reject it.

With that, I reserve the balance of my time.

Mr. QUIGLEY. Having respectfully heard the argument, I would stand on the statements we have made and yield back the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I am pleased to yield 1 minute to the gentleman from Colorado (Mr. GARDNER).

Mr. GARDNER. Mr. Chairman, we had a discussion on this very issue in the Energy and Commerce Committee,

and we made very clear that the language dealing with the Strategic Petroleum Reserve did not affect existing land management policies or management policies, or those policies in place to protect our resources.

So, again, we actually adopted an amendment by Chairman DINGELL, the gentleman from Michigan, the chairman emeritus, to make sure that we restated that this does not change or affect our Federal land management policies and those intended to protect our Federal resources. So we made that clear in the Energy and Commerce provisions in this bill as well.

Mr. HASTINGS of Washington. With that, then, Mr. Chairman, the arguments have been made. I urge rejection of this amendment, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Illinois (Mr. QUIGLEY).

The amendment was rejected.

AMENDMENT NO. 5 OFFERED BY MR. MCKINLEY

The Acting CHAIR. It is now in order to consider amendment No. 5 printed in House Report 112–540.

Mr. MCKINLEY. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 8, line 6, redesignate subsection (d) as subsection (e).

Page 8, after line 5, insert the following:

(d) CONSULTATION BY COMMITTEE.—In carrying out this title, the Committee shall consult with the National Energy Technology Laboratory.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from West Virginia (Mr. MCKINLEY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from West Virginia.

Mr. MCKINLEY. Mr. Chairman, under this legislation, Congress creates a Transportation Fuels Regulatory Committee with the Secretary of Energy chairing the committee.

□ 1920

My amendment is simple. It will require the Secretary and the committee, during their deliberation, to consult and receive input from the National Energy Technology Laboratory.

If we're going to analyze and report on the impacts of the rules and actions of the EPA on our Nation's fossil fuels, then we should make sure that the committee established under this legislation consults with our Nation's fossil energy laboratory. NETL is our only governmental research, design, and developmental laboratory dedicated to domestic energy sources. It's only fitting we make that they are included in this process.

NETL works with academia on over 275 projects across this country, as well as private entities, having provided over 450 projects in 2011, nearly 400 private sector projects, and over 100 not-for-profit laboratories. NETL's work in 2011 alone provided over 2,000 projects, 89,000 jobs, and over $18 billion in total funding in every State in every congressional district.

NETL's research and development into our transportation fuel sector began back in 1918 in Bartlesville, Oklahoma, with petroleum research. In fact, synthetic gas research began at NETL in 1946.

To note some other successes, NETL worked in conjunction with academia and private industry to develop horizontal drilling in our Nation's natural gas fields.

Now, some say that Secretary Chu, being the chairman of this committee, will consult with his own fossil energy team. Maybe that's true, Mr. Chairman, but this is the same Secretary of Energy who has worked with President Obama to slash our fossil energy research budget by 40 percent over each of the last 2 years. This is the same Secretary of Energy who should be promoting coal, oil and gas, but, instead, makes derogatory comments, such as ''coal is my worst nightmare.''

What we can do here today is ensure that the Transportation Fuels Committee and the Secretary consult with our government's fossil energy experts. If you support having input from government, private sector, and academia experts, then support of this amendment would be appreciated.

Mr. Chairman, I also wish to thank Chairman UPTON for his support of this.

I yield back the balance of my time.

Mr. WAXMAN. Mr. Chairman, I rise to claim the time in opposition to the amendment.

The Acting CHAIR. The gentleman from California is recognized for 5 minutes.

Mr. WAXMAN. This amendment highlights, Mr. Chairman, the absurdity of title II of the Republican bill. The bill will create a new government bureaucracy to conduct an unrealistic and burdensome study of several clean air rules, none of which have even been proposed. This is a fundamentally flawed approach. The scope and timing of the new government committee's analysis simply are not feasible.

The bill requires a new interagency committee to estimate a host of cumulative impacts of multiple unrelated potential rules. The committee is supposed to estimate impacts on gasoline prices, capital investments, projected maintenance and operation of new equipment, refinery capacity, employment at the national, State and regional levels, other cumulative costs and benefits, and even the overall global economic competitiveness of the United States.

Since none of the rules that are supposed to be analyzed have even been proposed, this complex analysis required by the bill would be full of guesswork and assumptions. It's unclear how this new government bureaucracy could estimate the level of pollution control that may be required, predict compliance options, or assess the specified effects.

Given all of the uncertainties and guess work inherent in such an analysis, it's unclear how the committee could produce an economic analysis of the rules with any measure of credibility.

EPA Assistant Administrator Gina McCarthy testified:

> It is unclear how the new committee would analyze rules that have not yet been proposed, or how the public could comment on that analysis in an informed way.

She also noted that such analysis would be redundant and a waste of government resources, given the extensive analysis EPA already completes as part of the rulemaking process and the interagency review conducted by OMB.

The bill provides an unrealistic deadline, as well, for completing this report, doesn't create an additional job in the private sector. All it will do is devote taxpayers' money to create another government committee in order to provide it with the hopeless task of conducting a host of complex analyses that probably could not be completed with any credibility, even if the necessary data did exist and the committee had years to work.

So the whole thing is a pointless waste of taxpayers' money required by the bill.

Now, Mr. MCKINLEY's amendment adds some additional consultation to that already absurd requirement. The Department of Energy is already represented on this new government committee the Republicans want to establish. In fact, the Secretary of Energy chairs the committee.

Mr. MCKINLEY's amendment adds a requirement that the committee consult with part of the Department of Energy. This adds another layer of unnecessary, superfluous consultation on an already unwieldy process.

I urge my colleagues to vote ''no'' on the amendment and ''no'' on the underlying bill.

I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from West Virginia (Mr. MCKINLEY).

The amendment was agreed to.

AMENDMENT NO. 6 OFFERED BY MR. MCKINLEY

The Acting CHAIR. It is now in order to consider amendment No. 6 printed in House Report 112–540.

Mr. MCKINLEY. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 9, line 6, strike ''and''.

Page 9, line 10, strike the period and insert ''; and''.

Page 9, after line 10, insert the following:

(F) any other matters affecting the growth, stability, and sustainability of the Nation's oil and gas industries, particularly relative to that of other nations.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman

from West Virginia (Mr. MCKINLEY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from West Virginia.

Mr. MCKINLEY. By the way, I'm just a little happy right now. I just got a text that my grandson won his baseball game tonight, 15–14. It's a tournament he's playing in. So be nice over there now.

Mr. Chairman, once again I would like to reference the Transportation Fuels Regulatory Committee created by H.R. 4480. My amendment will look at the analysis that the committee will develop.

One of the problems our oil and gas industry faces is the vast, ideologically motivated regulations they must endure. However, other nations do not seem to impose such overburdensome policies and regulations upon them. Instead, countries in the Middle East and Asia promote their oil and gas industries and work to make it easier for these countries to get their gas products to market.

This amendment would require the committee to conduct an analysis of other nations' regulations, policies and enforcements, or lack thereof, of their oil and gas industries. Saudi Arabia, China, and India do not overwhelm their oil and gas industries with excessive regulations. They help them to thrive.

This committee needs to look at what these other nations are doing to grow, stabilize and sustain their oil and gas industries, and ultimately compare it to what we're doing here in the United States. We ought to help our industry, and this amendment helps to show how we can improve and stop hindering development of our natural resources.

Ultimately, I offered this amendment because we are supposed to be a Nation leading by example over the rest of the world. With this economy and millions of people unemployed or underemployed we really ought to be saying to our regulators, just because you can doesn't mean you should. Just because you can doesn't mean you should.

Mr. Chairman, again, I wish to thank Chairman UPTON for his support of this amendment and the opportunity to offer it here.

I yield back the balance of my time.

□ 1930

Mr. WAXMAN. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman from California is recognized for 5 minutes.

Mr. WAXMAN. In the previous amendment, we discussed title II, the Gasoline Regulations Act, which creates a new government committee to do the impossible: conduct an analysis of EPA air quality rules that have not yet even been proposed, using data that does not exist.

The interagency committee cannot possibly provide a credible assessment of the potential impact of these potential rules on energy prices. It would simply require too much guesswork. Moreover, the Energy Information Administration told our committee staff that it does not have the capability to conduct much of the analysis required by this title. The agency would have to devote significant new staff and contractor time to complete the analysis.

The CBO estimates that the Gasoline Regulations Act would cost $3 million to implement. That's $3 million to produce a report that will not be reliable, credible, or valuable to anyone. Mr. MCKINLEY's amendment would make this report even less credible by significantly expanding its scope. His amendment would require that this new interagency committee examine ''any other matters affecting the growth, stability, and sustainability of the Nation's oil and gas industries, particularly relative to that of other nations.'' This language suggests that the new committee will have to take into account events and regulations in other countries as well as our own. Now, that's certainly going to send the price tag well above $3 million.

For example, will the new interagency committee have to examine Nigerian labor law? What about oil company business practices in the Amazon or the concerns of indigenous communities in Canada's tar sands? Will the committee have to take into account the health of Hugo Chavez and the potential impact on Venezuelan oil prices? Political upheaval in the Middle East has a profound impact on the oil market. Will the new committee have to delve into that?

If the interagency committee were serious about examining ''any other matters'' affecting the stability and sustainability, then it would have to look at a whole Pandora's box of issues here in the United States.

For example, shouldn't the committee have to examine what Congress is doing to give coal a competitive advantage over natural gas by weakening air pollution laws and blocking action on climate change?

The CEO of Chesapeake Energy has been in the news lately for some questionable business decisions that have helped put the country's second-largest natural gas company on the brink of bankruptcy. Certainly, the new interagency committee would have to examine that issue as part of this inquiry into matters relevant to the sustainability of the oil and gas industry.

All of this is to say that Mr. MCKINLEY's amendment is extremely broad and that it would make a deeply flawed report even less reliable and credible, if that's even possible. I urge my colleagues to oppose this amendment.

I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from West Virginia (Mr. MCKINLEY).

The amendment was agreed to.

AMENDMENT NO. 7 OFFERED BY MR. WAXMAN

The Acting CHAIR. It is now in order to consider amendment No. 7 printed in House Report 112–540.

Mr. WAXMAN. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 14, after line 9, at the end of title II, add the following new section:

SEC. 207. PROTECTION AGAINST ASTHMA AND OTHER HEALTH EFFECTS OF AIR POLLUTION.

Notwithstanding any other provision of this title, the Administrator of the Environmental Protection Agency shall not delay finalization of any of the rules described in section 205(a) to establish standards for clean air and to reduce air pollution, if the pollution that would be controlled by the finalized rule is contributing to asthma attacks, acute and chronic bronchitis, heart attacks, cancer, birth defects, neurological damage, premature death, or other serious harms to human health.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from California (Mr. WAXMAN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from California.

Mr. WAXMAN. Mr. Chairman, title II of this bill blocks the EPA from finalizing several important air quality rules until after a new government bureaucracy produces a new analysis of these and other EPA actions. But it's a fool's errand because a new government bureaucracy is required to conduct an impossible analysis of rules that haven't even been proposed using data that doesn't exist.

The bill would block the EPA from issuing new tier 3 standards for motor vehicles and fuels to reduce harmful tailpipe emissions that cause smog and deadly particle pollution. Smog and soot pollution can trigger asthma attacks, heart attacks, and even premature death.

The bill would block the EPA from issuing long overdue rules to require refineries to use modern technology to reduce their emissions of toxic air pollutants. The pollutants cause cancer, birth defects, neurological damage, and other serious health problems.

The bill would also block the EPA from issuing rules necessary for States and localities to implement the 2008 ozone standard. This would leave the outdated 1997 ozone standard in place. Even the Bush administration thought this standard was too weak. In addition, the bill would block the EPA from updating the ozone standard to reflect the best available science on the health effects of breathing dirty air.

During the legislative hearing on this bill, Chairman WHITFIELD stated, ''It is not the intent of this legislation to roll back any existing health protections.''

That claim is laughable for a bill that radically changes the Clean Air Act by barring the EPA from setting

air quality goals based on what the science tells us is safe to breathe. But if Republicans want to claim that this bill is not an attack on the Clean Air Act and public health, there should be no objection to my amendment.

My amendment simply states that, notwithstanding the bill's provisions and notwithstanding all that's in this bill, the EPA administrator cannot delay implementing any of the rules targeted by the bill if the air pollution that would be controlled by those rules causes serious harm to human health, including asthma attacks and other respiratory disease, heart attacks, cancer, birth defects, brain damage, or premature death.

This is a simple choice between oil industry profits and Americans' health. The top five oil companies earned $137 billion in profits last year. They can afford to clean up their pollution.

Instead, this bill would make Americans pick up the tab for the oil companies, and it would make Americans pay that tab with their health and even their lives. The air quality protections blocked by this bill are especially important for the most vulnerable among us—our babies, kids, old people.

Oil refineries are among the largest emitters of toxic air pollution, and they are often located near where people live, but this bill would indefinitely delay the EPA's ability to require oil refineries to clean up pollution such as benzene, which causes cancer and contributes to birth defects and developmental harm in babies.

Republicans argue these rules would only be delayed for a while, but many of these rules have already been delayed for far too long. The Republicans' claim assumes that the interagency committee can actually complete the impossible study required by this bill. Even if that were possible, there would still be no deadlines for these new rules as the bill eliminates existing deadlines and sets no new ones.

Americans rely on the Environmental Protection Agency to hold polluters responsible for cleaning up their pollution. It's just common sense. If you stop the EPA from doing its job, public health will suffer.

So it's time to come clean. If you want to pass a bill to stop the EPA from doing its job and allow polluters to pollute with impunity, be honest with the American people. Tell them you think that we have done enough to reduce air pollution and that you want to stop any further efforts to clean up air pollution, but don't pretend that this get-out-of-jail-free card for oil industry polluters won't hurt the health of Americans, especially our children and the elderly.

If, on the other hand, you don't want to block efforts to clean up air pollution that is contributing to asthma attacks, heart attacks, lung disease, cancer, birth defects, neurological damage, and premature death, then support my amendment. My amendment will make it perfectly clear that the EPA can continue to clean up air pollution that causes serious health effects.

I urge my colleagues to support this amendment.

I yield back the balance of my time.

□ 1940

Mr. GARDNER. Mr. Chairman, I rise in opposition to this amendment.

The Acting CHAIR. The gentleman from Colorado is recognized for 5 minutes.

Mr. GARDNER. Mr. Chairman, we heard a lot of powerful words there: ban, bar, block. The fact is that this bill does not ban, bar, or block these regulations. In fact, nothing prevents and nothing bars, bans, or blocks the EPA from developing rules on their current schedule. And nothing bars, bans, or blocks the EPA from protecting the public health and the environment as the law requires them to do so. In fact, it's quite commonly known that the EPA is unlikely to even finalize these rules prior to the completion of the study.

We've already got tremendous protections in current law, stringent regulations, some of which were just issued in the past few months. But I think we ought to take a look to understand what impact regulations are going to have on the cost of people's energy.

Our colleague mentioned picking up the tab. I'll tell you who else is picking up the tab: people in poverty are picking up the tab of increasing energy costs, which is making it more and more difficult for them to make ends meet. They are picking up the tab of rising gas prices, costing $50, $60, $70 a tank to fill up with gas to drive to work. That's who is picking up the tab, our constituents who are trying to lift themselves up and out of poverty and are having difficulty trying to make ends meet because of rising energy prices, because this Congress refuses to enact legislation that says, Hey, let's look before we leap and understand the impact these regulations are going to have on the price of gasoline.

Again, the purpose of the bill is to require a study. Nothing in this bill relieves the administrator of the EPA from the responsibility to issue rules required by the Clean Air Act or any other legal obligation. Nothing in this bill changes the EPA's obligation to protect the public health. Nothing in this bill prevents the EPA from developing and proposing new regulations, taking public comments, or from preparing a final rule, a process that typically requires at least a year. In fact, it would be highly unlikely, as I said before, that they could even both propose and finalize this rule before the study was finished.

Our colleague also mentioned that we don't know enough information about proposed regulations to study them. EPA's own action development process—the internal ways that the EPA works, their own internal action development process—requires that the analysis of a regulation start early in the rule development. So they're already talking about what impact these have, including the President's own executive orders that require agencies to perform analysis and consider the cumulative effects of regulations. So this is an unnecessary amendment.

Our colleague mentioned some of the most toxic emitters of air pollution. There's a lot of people around the country that believe the most toxic emitter of air pollution is Congress. In this case, some of those arguments have been used in the bill on this amendment.

I would just urge my colleagues to vote ''no'' on this amendment.

Mr. WAXMAN. Will the gentleman yield?

Mr. GARDNER. I would be happy to yield to the gentleman from California.

Mr. WAXMAN. There is a regulation for Tier 3 standards for automobiles that will reduce sulfur and other emissions that are very harmful. EPA's analysis says that will contribute a penny per gallon for gasoline. That is the kind of rule that would be stopped under the existing bill, and there is an enormous health impact.

When you talk about people in poverty, they can afford a penny a gallon on gasoline and the oil companies can afford to absorb a penny a gallon, especially with all of the health and lives that can be enhanced by removing some of these very dangerous chemicals.

Mr. GARDNER. Reclaiming my time, again, I'm not in a position to tell constituents who may find it tough to make ends meet that it's okay if we increase your price of gasoline by a penny here and a penny there, a couple of pennies, maybe even a nickel.

Mr. WAXMAN. But you claim that it's going to increase it by many dollars, and I think you're incorrect.

Mr. GARDNER. Reclaiming my time, we know that a penny increase in a gallon of gasoline, the Federal Trade Commission has said, can be a significant burden, meaning as much as $4 million to individuals and businesses around the country for every single penny in the increase of the price of gasoline.

Again, this does not prevent the EPA from developing rules on the current schedule. It says, Look before you leap. That's why I object to this amendment, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from California (Mr. WAXMAN).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. GARDNER. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from California will be postponed.

AMENDMENT NO. 8 OFFERED BY MR. CONNOLLY OF VIRGINIA

The Acting CHAIR. It is now in order to consider amendment No. 8 printed in House Report 112–540.

Mr. CONNOLLY of Virginia. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

On page 14, after line 9, insert the following:

SEC. 207. CORPORATIONS ARE NOT PEOPLE.

Section 302 of the Clean Air Act (42 U.S.C. 7602) is amended by adding at the end the following:

''(aa) PUBLIC HEALTH.—The term 'public health'—

''(A) refers to the health of members of the species homo sapiens; and

''(B) does not refer to the health of corporations or any other non-living entities.''.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Virginia (Mr. CONNOLLY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Virginia.

Mr. CONNOLLY of Virginia. Mr. Chairman, throughout the 112th Congress, the Republican leadership has invested a staggering amount of time and effort into gutting our Nation's clean water and air protections. As of this month, this House has voted 247 times in support of anti-environmental bills, amendments, and riders, including 77 votes devoted to dismantling the Clean Air Act alone.

As we debate yet another bill that seeks to gut the public health and welfare protections provided by that act and as we witness Democratic attempts to protect public health get defeated time and again on party-line votes, one is tempted to cynically dismiss H.R. 4480 as the Republican leadership's latest offering to their good friends in Big Oil. However, this bill contains an interesting provision that gave me pause, frankly, since it seems to hint that disagreements over protecting public health, when setting national ambient air quality standards, may actually stem from fundamental philosophical differences between the two parties.

One provision in particular begs for clarification since it's not every day that Republicans starkly disagree with Justice Antonin Scalia in regard to statutory interpretation as they do in section 206 of this bill. As written, that section would amend section 109(b) of the Clean Air Act to require the administrator of the EPA to take feasibility and costs into consideration when prescribing air quality standards that are requisite to protect public health.

Now, I'm aware that the author of this provision believes that this language merely clarifies supposed ambiguity in the act, going so far as to assert during the May 17 markup:

The only reason costs are not being considered in setting standards there today is because the Supreme Court said the language was ambiguous.

Mr. Chairman, I must respectfully disagree with that interpretation since Justice Scalia's statutory interpretation of section 109(b) was anything but ambiguous.

To quote Justice Scalia's unanimous opinion in Whitman v. American Trucking Associations, Inc., in regard to potentially considering cost when setting ambient air quality standards to protect public health, he said:

The cost factor is both so indirectly related to public health and so full of potential for canceling the conclusions drawn from direct health effects, that it would have been expressly mentioned in sections 108 and 109 had Congress meant it to be considered.

Even more to the point, the very first sentence of Justice Scalia's opinion says:

Section 109(b) does not permit the administrator to consider implementation costs in setting national ambient air quality standards.

This would seem to put aside any ambiguity.

That brings us to my simple amendment. Since Justice Scalia's opinion was crystal clear that the costs cannot be considered when setting those standards to protect public health, I couldn't figure out why my Republican colleagues were so committed to forcing the administrator to take those very factors into account. But then it dawned on me that since the Clean Air Act actually never defines the term ''public health,'' perhaps there is some confusion concerning who or what comprises the public. After all, if one believes that corporations are people, then the term ''public health'' would obviously have a different meaning to that individual compared to my own or Justice Scalia's.

Thus, my simple amendment would clarify the term ''public health'' in the Clean Air Act only as it pertains to the health of people and not corporations or other nonliving entities, and it's a simple fix to clear any confusion and restate congressional intent. By adopting this amendment, Mr. Chairman, Congress can reaffirm the principle that corporations are not people and ensure the lack of definition for the term ''public health'' in the Clean Air Act does not cause any confusion, particularly for certain individuals who may be under the misguided impression that corporations are, indeed, people.

□ 1950

I urge my colleagues to support this simple amendment, and I yield back the balance of my time.

Mr. GARDNER. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman from Colorado is recognized for 5 minutes.

Mr. GARDNER. Again, I believe this amendment is unnecessary, talking about ambiguities and the silence in the law when it comes to the Clean Air Act in the determination of cost. Here the issue of cost was silent, and we are simply saying we ought to have the issue of cost brought into this.

When the term ''public health'' appeared in the first Federal Clean Air legislation in 1955, its ordinary meaning was ''the health of the community.'' In the American Trucking decision, as you pointed out, the Supreme Court affirmed that the definition of public health is ''the health of the public'' and does not refer to the health of nonliving entities.

The Clean Air Act requires that ambient air quality standards be established to protect the public health with an adequate margin of safety. Nothing—nothing—in H.R. 4480 changes the definition of ''public health.'' Again, let me say that: Nothing in H.R. 4480 changes the definition of ''public health'' in the Clean Air Act or any obligations. It doesn't change any obligations to set such human health-based standards.

So I would urge a ''no'' vote on this amendment, and with that, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Virginia (Mr. CONNOLLY).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. CONNOLLY of Virginia. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Virginia will be postponed.

AMENDMENT NO. 9 OFFERED BY MR. GENE GREEN OF TEXAS

The Acting CHAIR. It is now in order to consider amendment No. 9 printed in House Report 112–540.

Mr. GENE GREEN of Texas. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 14, lines 1 through 9, strike section 206 (relating to consideration of feasibility and cost in revising or supplementing national ambient air quality standards for ozone).

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Texas (Mr. GENE GREEN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Texas.

Mr. GENE GREEN of Texas. Mr. Chairman, I rise in support of my amendment.

I would like to vote for this bill, but it goes way too far.

Mr. Chairman, I represent five large refineries and 20-plus chemical plants, so I'm very sensitive to what regulatory compliance can mean to a company's economic success. But for over 40 years, the Clean Air Act has required the Environmental Protection Agency to set the level of each ambient air quality standard based on what is necessary to protect public health. They do this because EPA's job is health, not economic impacts.

Again, for over 40 years, Republicans and Democrats have agreed to this principle, which was passed on a bipartisan basis in the 1970s and signed into law by a Republican President and unanimously upheld by the U.S. Supreme Court in 2001.

This amendment would strike section 206 of the bill, which would require the EPA to consider industry costs when determining what level of air pollution is ''safe.'' But economic and compliance costs are already considered several times throughout the regulatory process, which is why section 206 is not necessary.

The EPA conducts a regulatory impact analysis for a range of emission standards when they propose the standard. Then they do a second regulatory impact analysis when they choose the final standard before it is sent to the Office of Management and Budget for review.

The regulatory process works. Last September, the Office of Management and Budget did not allow EPA to move forward with a revised ozone NAAQS standard because they felt that the costs of compliance would be too high for the regulated industries at this point in our economic recovery. To use a Texas saying, let's not throw out the baby with the bathwater.

Section 206 is a policy rider that undermines 40 years of bipartisan agreement, and I encourage my colleagues to support my amendment that would strike it.

I reserve the balance of my time.

Mr. GARDNER. Mr. Chairman, I rise to claim time in opposition to the amendment.

The Acting CHAIR. The gentleman from Colorado is recognized for 5 minutes.

Mr. GARDNER. Mr. Chairman, I have great respect for my colleague from Texas. We've worked on a couple of pieces of legislation together over the year and a half that I have been on the committee. I have the honor of serving with him on the Energy and Commerce Committee. But I also must rise again to oppose the amendment from our colleague from Texas.

Once again, under this bill, nothing in the gasoline regulations act stops the EPA from developing rules on their current schedule. Nothing in this prevents the EPA from protecting the public health and the environment, as the law requires them to do.

But as we talked in the previous amendment, consideration of the cost and the feasibility of these major rules is elsewhere throughout the law. And it is warranted because, in this case, a failure to consider those costs could hurt jobs and the economy. We need to know.

In fact, costs are required in other parts of the Clean Air Act. And EPA must consider costs in the context of setting New Source Performance Standards, automobile emission standards, aircraft emission standards, fuel additives, and reformulated gasoline standards. And it's also a matter that you have to consider costs when setting future drinking water standards in the Safe Drinking Water Act.

And if you hearken back to last year when President Obama decided that he was going to withdraw his last ozone rule, one of the comments that he made when he was withdrawing that ozone rule, which we argued would have greatly imperiled our economy—here's a quote from President Obama:

I have continued to underscore the importance of reducing regulatory burdens and regulatory uncertainty, particularly as our economy continues to recover.

So when the President was talking about the Clean Air Act, he recognized ozone; he recognized the importance of taking a look at our economic uncertainty and the economic uncertainty of his last ozone rule.

So I appreciate our colleague's amendment, but I certainly have to oppose it at this time. I urge the rest of my colleagues to oppose it as well.

With that, I reserve the balance of my time.

Mr. GENE GREEN of Texas. Mr. Chairman, I want to thank my colleague from Colorado because the system does work. Even the President used economics. But that's the President's job, not the EPA.

I would like to yield 2 minutes to the ranking member of the Energy and Commerce Committee, the gentleman from California (Mr. WAXMAN).

Mr. WAXMAN. I thank the gentleman for yielding to me.

The Clean Air Act was adopted in 1970, signed by President Nixon. Changes were made in 1990, signed by President George H.W. Bush. The heart of the Clean Air Act has been that EPA relies on the best science possible to determine what level of pollution is harmful for people to breathe. They decide what is safe. And based on the science, EPA sets a quality standard. This is the standard to protect public health. Then they take into consideration, at the State and local level, the costs of how to achieve that. They may give more time; they may do it in different ways.

But section 206 of the bill would end this commonsense approach, the main part of the Clean Air Act, because it would make cost a factor in what is supposed to be a scientific decision about how much pollution is safe for a child to breathe. In setting a public health standard, it would give as much weight to a polluter's accountant as to a scientist. This is like going to your doctor, asking for a diagnosis, and he wants to tell you what your diagnosis is based on the cost of treatment. You want to know what's most important for your health. That's what's required of the EPA.

You will hear over and over again Republicans saying, We've done well in reducing pollution. And we have because of a Clean Air Act that's based on setting a standard to protect health and then allowing costs to determine how to achieve that standard, but not setting the goal based on costs that could be wildly out of sync with the reality of what it would take and how much to spend to achieve that health-based standard.

This is a very, very radical provision in the bill. I want to commend my colleague Mr. GREEN for seeking to strike it. It would be consistent with the law as we have always known it, not to go back and change it as this bill would do.

Mr. GARDNER. Mr. Chairman, again, to repeat, to reiterate, to restate this point: Nothing in this bill—nothing in this bill—changes the EPA's obligation to protect the public health with an adequate safety margin. Nothing changes the obligation to protect the public health.

And with that, Mr. Chairman, I yield back the balance of my time.

□ 2000

Mr. GENE GREEN of Texas. I yield myself the balance of my time.

The Acting CHAIR. The gentleman is recognized for 1½ minutes.

Mr. GENE GREEN of Texas. I appreciate my colleague and your work on the committee, but that's why we need to remove 206. That provision actually takes away health and safety as EPA's primary responsibility. That's what it was created for in 1970. We already have a system that will work to deal with the economic problems. We go to OMB. But even more so, we can go to the States. Because once EPA and OMB approves that rule, then they go to the States to work out the compliance. And in our district, where I have a huge industrial capacity, we actually work with our State agency and EPA to make sure we can economically do that within a timeframe.

That's why this amendment should be acceptable, Mr. Chairman, and I would encourage Members to vote for this amendment when it comes up for a vote tomorrow.

I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Texas (Mr. GENE GREEN).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. GENE GREEN of Texas. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Texas will be postponed.

AMENDMENT NO. 10 OFFERED BY MR. TERRY

The Acting CHAIR. It is now in order to consider amendment No. 10 printed in House Report 112–540.

Mr. TERRY. I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

On page 14, after line 9, insert the following new section:

SEC. 207. FUEL REQUIREMENTS WAIVER AND STUDY.

(a) WAIVER OF FUEL REQUIREMENTS.—Section 211(c)(4)(C) of the Clean Air Act (42 U.S.C. 7545(c)(4)(C)) is amended—

(1) in clause (ii)(II), by inserting ''a problem with distribution or delivery equipment necessary for the transportation or delivery of fuel or fuel additives,'' after ''equipment failure,'';

(2) in clause (iii)(II), by inserting before the semicolon at the end the following: ''(except that the Administrator may extend the effectiveness of a waiver for more than 20 days if the Administrator determines that the conditions under clause (ii) supporting a waiver determination will exist for more than 20 days)'';

(3) by redesignating the second clause (v) (relating to the authority of the Administrator to approve certain State implementation plans) as clause (vi); and

(4) by adding at the end the following:

''(vii) PRESUMPTIVE APPROVAL.—Notwithstanding any other provision of this subparagraph, if the Administrator does not approve or deny a request for a waiver under this subparagraph within 3 days after receipt of the request, the request shall be deemed to be approved as received by the Administrator and the applicable fuel standards shall be deemed to be waived for the period of time requested.''.

(b) FUEL SYSTEM REQUIREMENTS HARMONIZATION STUDY.—Section 1509 of the Energy Policy Act of 2005 (Public Law 109–58; 119 Stat. 1083) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(A), by inserting ''biofuels,'' after ''oxygenated fuel,'';

(B) in paragraph (2)—

(i) in subparagraph (B)—

(I) by redesignating clause (ii) as clause (iii);

(II) in clause (i), by striking ''and'' after the semicolon; and

(III) by inserting after clause (i) the following:

''(i) the renewable fuel standard; and''; and

(IV) in subparagraph (G), by inserting ''or Tier III'' after ''Tier II''; and

(2) in subsection (b)(1), by striking ''2008'' and inserting ''2014''.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Nebraska (Mr. TERRY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Nebraska.

Mr. TERRY. Thank you, Mr. Chairman.

My amendment is a rather simple one and I hope all of my colleagues can support it.

Many of us remember the devastation brought on by Hurricanes Katrina and Rita. But even more folks outside of the gulf region remember the meteoric rise in gas prices and the threat of having no gas at all. When supplies are interrupted, it's critical to restore fuel for consumers as soon as possible. We continue to operate in an environment in which the fuel required in one market may not satisfy the requirement set by the EPA in another market, i.e., the fuel in Chicago may be different from the fuel in St. Louis, especially in the summertime.

If supplies of fuel are disrupted, whether from a national emergency or from a simple equipment failure, the consumers can be affected in a very significant and adverse way. When gas stations run out of gas, our constituents suffer. When suppliers run short of fuel and the market drives up prices, the constituents suffer. Not every supply disruption is covered in the existing statute. But every supply disruption can hurt our consumers. That is what this amendment is doing: Ensuring that the Administrator has the authority to serve the best interests of our constituents—our consumers—when fuel prices are affected.

Further, asking these consumers to wait a prolonged period of time before issuing a ruling that could restore supplies to their market is unacceptable. Time is of the essence when we are trying to avert these fuel shortages and price spikes. It's important that the decisions regarding the economic welfare of our constituents are made in a timely manner.

The underlying bill that we have here before us is about doing what we can to keep the prices as low as we can. This amendment would broaden the times where EPA can grant a waiver to an area to use whatever fuel they have on hand when there is a disruption. Right now, the authority only exists for natural disasters and other larger emergencies. Not all disruptions are covered. This amendment expands upon the waiver to include any disruption. Because we have refineries closing in the Northeast and we have a limited ability to move product due to Jones Act requirements, we need to ensure that any region is never in a position of doing without fuel.

The second part of my amendment calls for the EPA and DOE to conduct the Fuel Harmonization Study that EPACT 05 directed them to complete by June, 2008. And here we are in 2012 and we don't have the study. It simply tells them to get on it. We want the Harmonization Study completed.

I reserve the balance of my time.

Mr. WAXMAN. Mr. Chairman, I rise to claim time in opposition to this amendment.

The Acting CHAIR (Mr. CRAWFORD). The gentleman from California is recognized for 5 minutes.

Mr. WAXMAN. This amendment would change the law—the Clean Air Act—that authorizes EPA to waive pollution control requirements for motor vehicle fuels where there's an extremely unusual fuel supply circumstance. Well, we want that ability to waive that law. And EPA is already allowed to do that.

But the Terry amendment provides that if EPA doesn't act in 3 days, it's automatically granted. And that's not enough time for EPA to act. Often, a request for a waiver is incomplete. We don't know exactly why they're asking for the waiver. They haven't come up with all the information. It may not specify the area that could be covered. It may not be clear on exactly which fuel parameters are waived.

So under this amendment the EPA would have to choose between two bad options. They could reject the waiver and then perhaps approve a revised version a few days later when EPA gets the necessary information. Well, that doesn't make any sense. Fuel suppliers are going to be confused. They may be concerned that EPA won't address a situation where they need some rule. Or, EPA can allow an ambiguous and confusing waiver request to become effective. Again, this would just leave fuel suppliers confused and uncertain about what they have to do. Since the waiver would become effective automatically, how would fuel suppliers even find out it had gone into effect? It's also unclear what constitutes a waiver of request.

I think there's a lot of confusion in this proposal. I don't know why existing law should be changed. If there's been a problem, we haven't heard any testimony on this. We haven't had any hearings on this in our committee.

Requiring laws and regulations to be waived hastily, based on incomplete information, and for potentially long periods of time, is simply bad policy. Regulations are adopted through a public process which allows all parties to participate and all relevant information to be considered. But without limits, waivers could effectively rewrite regulations without public input. That's why the Clean Air Act waiver provisions, which were adopted in 2005, are narrowly crafted.

So I have a lot of misgivings about this policy. I don't know why we need it. We haven't had any testimony on it. It can lead to some very bad results.

I reserve the balance of my time.

Mr. TERRY. I appreciate the gentleman's remarks, but it's really not as draconian a measure as it may appear from his comments. When a waiver is requested, it's usually by a government entity for a region, usually with Governors, and there still has to be a disruption. If there's a disruption to the point where a government entity has to request a waiver from the oxygen requirements for the summer fuel for that particular region, that disruption is going to be well known and well documented. It won't take them more than 3 days to do it, unless they're intentionally dragging their feet.

Three days is sufficient. And if they refuse to act on that within that certain period of time, I think it's completely appropriate that they're able to keep the blend with the supply that they would have.

So this is really a simple request, a simple amendment to make sure that price spikes don't occur, that time is of the necessity.

I reserve the balance of my time.

Mr. WAXMAN. Mr. Chairman, a waiver request does not have to come from a public entity. It can come from elsewhere as well.

I yield the balance of my time to the gentleman from Massachusetts (Mr. MARKEY).

□ 2010

Mr. MARKEY. I thank the gentleman. This is just another example

that Congress knows best. It is a Republican solution to everything. Let's not let the agency professionals do their jobs on a case-by-case basis. Let's have a one-size-fits-all, 3-day shot clock that we put on a request that could have significant impacts environmentally in areas.

And by the way, if the agency is not ready, they might just reject it on day two because there's not enough information, rather than having an orderly process that makes it possible for the agency to be able to determine in a conversation with perhaps a government entity, but perhaps not, all of the details of what the implications are, what the ramifications of this request would be.

But it's not different than the shot clock that you want to put on the Department of the Interior in 60 days having to approval drilling in sensitive offshore or onshore lands in our country. All of these things are basically part of a Republican agenda to ensure that the hands of the government are actually tied in protecting the health and environment of our country.

What the gentleman from Nebraska is doing, which is part and parcel of a systematic approach to undermine the ability of those agencies that are tasked with the job of protecting the health, of protecting the environment, of protecting the safety of individual citizens, is to have handcuffs put on them so they cannot discharge their responsibility.

I urge in the strongest possible terms a ''no'' vote on the Terry amendment.

Mr. TERRY. Mr. Chairman, I yield myself the balance of my time.

The Acting CHAIR. The gentleman from Nebraska is recognized for 1 minute.

Mr. TERRY. I would just state that I think the rhetoric far exceeds the facts here. This is a simple amendment just to say when there's a disruption, instead of waiting around, when we know there's a problem, let's take care of the problem, allow the available fuel to be used so there aren't price spikes that hurt people.

And so I ask that my colleagues support this amendment, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Nebraska (Mr. TERRY).

The amendment was agreed to.

AMENDMENT NO. 11 OFFERED BY MR. RUSH

The Acting CHAIR. It is now in order to consider amendment No. 11 printed in House Report 112–540.

Mr. RUSH. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 14, after line 9, at the end of title II, add the following new section:

SEC. 207. IMPACT ON GASOLINE PRICES AND JOBS IN THE UNITED STATES.

(a) DETERMINATION OF IMPACT.—Not later than 90 days after the date of enactment of this Act, the Administrator of the Energy Information Administration shall make a determination as to whether implementation of this title is projected to lower gasoline prices or create jobs in the United States within 10 years.

(b) SUNSET IF IMPLEMENTATION NOT PROJECTED TO LOWER GASOLINE PRICES OR CREATE JOBS.—Sections 205 and 206 shall cease to be effective if the Administrator of the Energy Information Administration, pursuant to subsection (a), determines that implementation of this title is not projected to lower gasoline prices and create jobs in the United States within 10 years.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Illinois (Mr. RUSH) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Illinois.

Mr. RUSH. Mr. Chairman, while gas prices have subsided over the past few months, Americans are still very concerned about the issue of jobs and high unemployment. In my district and in the African American community in general, joblessness is far higher than the national average with some communities experiencing unemployment rates of up to 60 percent. Yet even with these staggering figures, we are here today debating a bill that will do absolutely nothing to address this critical issue that the American people are facing. Nada, zip, zero will it do.

Mr. Chairman, the House will only be in session a little over 20 more days before we recess in August; and after that, this House will barely be in session until after the November elections. During this limited time, we should be focusing our attention on legislation that will create jobs and move America forward towards a smarter energy future that is less vulnerable to the whims of the world's oil market.

However, there is nothing in this bill, H.R. 4480, that will do anything to address the issues most important to the American people. Neither jobs nor gas prices are dealt with in this bill.

Mr. Chairman, my amendment, the amendment that I'm offering today, gets right to the heart of the matter and simply states that:

Not later than 90 days after the date of enactment of this Act, the administrator of the Energy Information Administration shall make a determination as to whether implementation of this Act is projected to lower gasoline prices or create jobs within the United States within 10 years.

That's what my amendment says—clearly, simply, concisely.

However, if the administrator of the EIA determines that implementation of this act is not projected to lower prices or create jobs in 10 years, then the most egregious provisions of this bill, sections 205 and 206, which attack existing Clean Air Act protections, will sunset and cease to be in effect.

Mr. Chairman, provisions in this bill, such as title II, the Gasoline Regulations Act, use the backdrop of high unemployment and fluctuating gas prices as a ruse to once again attack the EPA and the Clean Air Act, without doing a single thing to actually reduce the cost that Americans are paying at the pump or to deliver more jobs to the American people.

Mr. Chairman, Congress should not remove long-standing Clean Air Act requirements for EPA to set ambient air quality standards at the level necessary to protect human health.

Nor should the majority attempt to block and delay several EPA air quality and public health provisions under the guise of falsely claiming that these attacks on EPA will actually create jobs or reduce gas prices. Time and time again over the past year and a half, this Congress, under the majority party's leadership, has voted to roll back provisions of the Clean Air Act.

Mr. Chairman, I urge all of my colleagues to vote for the Rush amendment, and I yield back the balance of my time.

Mr. GARDNER. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman from Colorado is recognized for 5 minutes.

Mr. GARDNER. Mr. Chairman, I want to tell a little bit of a story. I grew up and live in a very small town in the eastern plains of Colorado. There are about 3,000 people who live in this small town. And when I was growing up, there was a mother and her daughter who lived across the street from where I was growing up in a little home. They had an older car. And in this small town, the grocery stores, gosh, can't be more than four blocks away. But when they went to the grocery store, they walked.

As the years went by and the mother got older, they still walked to the grocery store. In the winter, a lot of times they walked. And in the summer, they walked. I remember asking them one time, they have a car, how come they're not driving? It's just four blocks away. And as she got older and it was more difficult to walk, her response was because we can't afford the gas. That's four blocks of driving. It can't use much gasoline. But the fact is, the price of gas mattered to that family. It made the difference of getting groceries, putting food on the table.

We talk about people's ability to afford health care. If you're left with the option of getting to work or buying health care insurance, what are you going to do? What choice are you going to make?

By making sure that we have abundant, affordable energy, we are making sure that families can make ends meet easier, that they can make those choices to go see the doctor when they need to, because high prices of energy certainly impact the ability of families to lift themselves out of poverty to make sure that they're improving their own lives.

□ 2020

Your amendment would stop the look that we're asking to take at what regulations do when it comes to the price of

gasoline, when it comes to the price of energy. Nothing in this bill prevents the EPA from developing rules on their current schedule, but it does say we need to understand the impact that they are going to have on the price of gasoline, because I bet those neighbors of mine are very interested in what government is doing to increase the cost of them getting to the grocery store or not, and maybe they could drive when it's cold outside.

Mr. RUSH. Will the gentleman yield?

Mr. GARDNER. I yield to the gentleman from Illinois.

Mr. RUSH. I am so glad you used the story and told the story of your neighbor, because your neighbor is not unlike my neighbors. They're suffering from unemployment; they're suffering from high gas prices. But what confuses me and what's gotten me astounded is the fact that in this bill, your neighbor, her problems, my neighbor's problems, the problems of all the Members of this body, all of our neighbors' problems, our problems aren't addressed.

All I'm asking for is that if the EIA—a fairly knowledgeable agency, an agency that is respected—if they determine after looking at the provisions of this bill and say that this bill will not create one job, this bill doesn't address rising gasoline prices——

Mr. GARDNER. Mr. Chairman, if I could reclaim my time so that I can have the ability to close on my amendment, and I appreciate my colleague's debate on this.

But again, this issue is not about stopping or blocking the EPA from doing it, because they're fully able to develop rules on their current schedule. Nothing prevents them from protecting the public health and the environment as the law requires them to do—nothing. So your amendment, though, when you talk about rules affecting gas prices should be delayed until the report is completed because those rules could increase gas prices; that's all we're trying to do. Allowing a single member of this committee, which your amendment would do, to circumvent the analysis would defeat the purpose of the act.

Gas prices impact, as we know, all parts of our economy, and we need to have multiple experts. But the EIA, of which your amendment deals with, doesn't have the expertise in national competitiveness. They don't have the expertise in job impacts or agriculture or health benefits analysis.

Again, I think we have just got to be at the point where we let the American people know what's happening to the price of gasoline because of these regulations.

With that, Mr. Chairman, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Illinois (Mr. RUSH).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. RUSH. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Illinois will be postponed.

AMENDMENT NO. 12 OFFERED BY MR. HOLT

The Acting CHAIR. It is now in order to consider amendment No. 12 printed in House Report 112–540.

Mr. HOLT. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 17, after line 17, insert the following:

''(6) The Strategy under this subsection should seek to ensure that that the percentage of onshore Federal oil and gas leases under which production is not occurring is reduced during the next 4-year period.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from New Jersey (Mr. HOLT) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from New Jersey.

Mr. HOLT. Mr. Chairman, the bill before us tonight would elevate energy production above all other uses of public lands in, really, contradiction of the principles of multiple use under the Federal Land Management and Policy Act. This would be to the detriment of grazing, hunting, fishing, and other recreation activities. Yet the plan envisioned by the majority's bill does not even require that the Interior Department consider the tens of millions of acres of public lands that oil companies are just sitting on and not using.

Right now, oil companies have roughly 25 million acres of public land onshore on which they are not producing oil. Even worse, oil companies are not even beginning drilling activities on the vast majority of these nonproducing areas. In fact, last month the Interior Department released a new report which found that oil companies have nearly 21 million acres onshore under lease on which they have not even begun conducting exploration activities.

Well over half of the public lands that oil companies have under lease onshore are idle. They are warehousing these leases. They are sitting on these leases. My amendment would require that the Secretary reduce the number of nonproducing leases as part of the plan for energy development on public lands that would be established under the underlying bill.

Before we risk disrupting additional public lands, let's begin by getting the oil and gas industry to use the leases they have. It's simple: No seconds while your plate is still full. It's the height of cynicism that the industry would be squatting on these leases at the same time it is asking us to give them more land that belongs to the Americans.

I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I rise to claim time in opposition to this amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. HASTINGS of Washington. I yield myself such time as I may consume.

Mr. Chairman, we've heard this argument and this debate and this issue before. This is nothing but a recycled version of the old use-it-or-lose-it argument that we've heard so many times, but this time it's disguised as an effort to reduce nonproducing leases.

This amendment is based on a completely unsubstantiated premise, which is that oil companies are sitting on oil and gas leases, therefore rendering them inactive—at least that's how the claim goes—if they are not diligently drilling for and producing oil.

This is important, Mr. Chairman. Use it or lose it is already the law of the land. Why? Because every lease on Federal land currently includes development language requiring moving forward by the energy companies, and if a company does not produce within those lease terms, then the lease reverts back to the government.

Now, keep in mind, picture this: A company is paying money for a lease and there are certain conditions in this lease for them to produce in a time period. If they don't produce in that time period, it reverts back to the government. Is that not use it or lose it? That's the law of the land as it is a part of the lease sales.

So, just because a lease sale is not actively producing, that doesn't mean that there's not work on that lease sale. Leases can be held for up to 7 or 10 years because studies or permitting or even lawsuits slow that process down.

In addition, it isn't possible to drill every lease at the same time. Think of leases like homebuilding. A homebuilder doesn't start building every home at the same time. You have roofers, you have framers, you have plumbers, you have drywalls, you have electricians all working at different times on different parts of the house. Oil and natural gas is the same way. You have geologists, drillers, production, permitting, and environmental studies. All those things happen in different steps.

So the argument that use it or lose it—which is already in place—is something that we should even be debating here is nonsensical. It ignores the realities of oil and gas, the years of exploring, the drilling and permitting that it takes to bring something to the floor.

Not only has a use-it-or-lose-it argument failed many times when it's been brought to the floor of this House, but in the House Natural Resources Committee on legislation dealing with this, it lost on a bipartisan vote. Frankly, Mr. Chairman, I suspect if there's a vote called on this, it, too, will lose on a bipartisan vote. So to encourage that, I would urge my colleagues to reject this amendment.

I reserve the balance of my time.

Mr. HOLT. Mr. Chairman, may I ask the time remaining on this amendment?

The Acting CHAIR. The gentleman from New Jersey has 3 minutes remaining.

Mr. HOLT. I would be pleased to yield 2½ minutes to the coauthor of this amendment, the ranking member, Mr. MARKEY.

Mr. MARKEY. I thank the gentleman.

I have a suggestion to succinctly tell the whole story about the tens of millions of acres that oil companies are allowing to sit idle. Fox should create a new TV show for the oil companies holding all these idle wells, and it could be called ''American Idle,'' with Exxon and Chevron and BP and all those companies as the contestants. Every week, the oil companies can come and sing their sad tune about needing more taxpayer-owned land to drill even as their lease blocks are left lonely for years at a time and they don't drill at all.

□ 2030

ExxonMobil and BP could sing songs like ''Not Taking Care of Business'' or ''Sitting on a Block in the Bay,'' where the refrain sung by the oil company executives would, of course, be ''wastin' time.''

And Simon Cowell could come back to the show he created so we can all watch as he mocks these companies for their subpar drilling performance. And of course, in typical fashion for the oil industry, they'll still demand to be advanced to the next round of leasing, even though they're doing nothing.

And by the way, in this bill, the Republicans actually have a provision that if the President, because Iran attacked us, deployed 10 percent of the Strategic Petroleum Reserve, that we, the American people, would then have to lease 200 million acres, an area the size of Texas to the oil companies to drill because the President deployed the Strategic Petroleum Reserve, even though the oil companies already have an area the size of Kentucky in public lands that they are not drilling on.

So this whole American Idle thing really plays perfectly into the Republican plan because right now the oil companies pay $1.50 per year per acre not to drill while at the same time bleating that they are being discriminated against, even as the President now has us at the highest rate of oil production in the United States in 18 years, which is a very hard thing for the Republicans to finally come here to the floor and admit.

Vote for the Holt amendment. That is the solution to this problem. Then we'll get America and the oil companies back to work and away from their idle ways, which is hurting the national security of this country.

Mr. HASTINGS of Washington. Could I inquire how much time remains on both sides?

The Acting CHAIR. The gentleman from Washington has 2 minutes. The gentleman from New Jersey has 30 seconds.

Mr. HASTINGS of Washington. I reserve the balance of my time.

Mr. HOLT. Mr. Chairman, let me just repeat. Right now, the oil companies have 25 million acres of public land onshore on which they are not producing. They have 21 million acres of public land onshore under lease on which they are not even conducting exploration activities.

I rest my case.

I yield back the balance of my time.

Mr. HASTINGS of Washington. I yield myself the balance of the time.

Mr. Chairman, once again, to repeat, the nature of the lease sales that companies enter into is ''use it or lose it'' because if they don't, within the time period of that lease, utilize that for production, they give it back. That's ''use it or lose it.'' That's the law right now.

But let me respond here in the short time I have about comments that have been made earlier about increased American production. That's true, Mr. Chairman, and I'm glad for that. But the implication of that statement being made by my friends on the other side of the aisle is that it's because of the policies of this administration.

Mr. Chairman, nothing could be further from the truth. It takes a while to get land or offshore up to speed and in production, sometimes many years. But the reason production is increasing in some areas and has been increasing—it's now going down on Federal lands—is because of actions of prior administrations. That is never said. It's because of prior administrations' actions, because the last 2 years of this administration, oil and natural gas, the production on Federal lands, has gone down.

And finally, the main reason why oil production has increased in this country is because it's happening principally in North Dakota and in west Texas, and it's on private land and/or State land. The Federal Government and this administration had absolutely nothing to do with the increase of that production. As a matter of fact, I think there were probably some efforts to try to slow that down.

But, at any rate, I had to make that point, Mr. Chairman. This amendment, again, has been around a few times. I suspect that if a vote is called on it that it will fail on a bipartisan basis again. I urge rejection.

I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from New Jersey (Mr. HOLT).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. HOLT. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from New Jersey will be postponed.

AMENDMENT NO. 13 OFFERED BY MR. CONNOLLY OF VIRGINIA

The Acting CHAIR. It is now in order to consider amendment No. 13 printed in House Report 112–540.

Mr. CONNOLLY of Virginia. Mr. Chairman, on behalf of myself and Mr. LEWIS, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 27, line 17, strike the closing quotation marks and the following period, and after line 17 insert the following:

''(C) RIGHT TO PETITION PRESERVED.—This paragraph shall not be construed to abridge the right of the people to petition for the redress of grievances, in violation of the first article of amendment to the Constitution of the United States.''.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Virginia (Mr. CONNOLLY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Virginia.

Mr. CONNOLLY of Virginia. Mr. Chairman, I rise to offer this amendment on behalf of my colleague, Congressman JOHN LEWIS.

Before I begin, I'd like to invite my colleagues on the other side of the aisle to refer to their pocket Constitutions, specifically page 21. There they'll find the First Amendment, which reads, and I quote:

Congress shall make no laws respecting an establishment of religion, or prohibiting the free exercise thereof, or abridging the freedom of speech, or of the press, or the right of people peaceably to assemble and to petition the government for a redress of grievances.

I may be mistaken, Mr. Chairman, but when we read the Constitution, read it aloud here on the floor at the start of this Congress, a bipartisan exercise in which I was privileged to participate, I don't recall there being an asterisk at the end of the First Amendment saying, except, of course, if your petition stands in the way of Big Oil. Yet, the language in this bill creates a brand new, $5,000 protest fee for any American citizen to challenge the granting of a drilling lease, right of way or permit.

I don't know about my colleagues, but that seems like we're abridging the freedom of speech and the right to petition the government for redress of a grievance. Once again, the Republicans in the House are happy to rush by the rights of the public to benefit their big friends in Big Oil. This is a capricious tax, at best, on the peaceable right to protest an act of the government that someone believes might harm the environment.

Not surprisingly, the bill does not apply a similar protest fee on someone who might want to protest the denial of a drilling lease or permit. One wonders why? Could it be that would be a tax on industry?

Mr. Chairman, the Bureau of Land Management objected to this fee in its testimony to the committee on this legislation, citing it as an inappropriate economic barrier to the public to seek judicial review or redress of an agency decision.

I agree with that statement, but I don't think it goes far enough. It doesn't fully capture the full ramifications of it. It would trample on the First Amendment rights of the public. So much for the other side's commitment to being strict constructionists when it comes to the Constitution.

Mr. Chairman, I urge my colleagues to support this amendment and reject this assault on the Constitution and the First Amendment.

I reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman I rise to claim the time in opposition to this amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. HASTINGS of Washington. I yield myself as much time as I may consume.

Mr. Chairman, I just want to clarify something. Absolutely nothing in this legislation, or this entire legislation, takes away the right of people to protest or petition for the redress of grievances. That is something that is held sacred, I think by all Americans, certainly all Members of this House.

During the oil and natural gas leasing exploration and development process, there are over a dozen opportunities for citizens to protest, to appeal, to comment, or to even completely halt energy development on public land.

Since the 1990s, however, the use of protests on Federal lands has increased by 700 percent through a considered effort by special interest groups to halt oil and natural gas development on our Federal lands. This explosion of protests has crippled the Bureau of Land Management, or BLM, offices while they are working to handle the wave of new protests.

A formal protest of leasing is a legitimate step in oil and natural gas leasing process. However, and this is something that I think most people recognize, the abuse of protest to halt that development is something I think needs to be addressed.

□ 2040

So the $5,000 protest documentation fee in this legislation goes directly then towards helping the BLM process the onslaught of protests that are currently being paid by taxpayer dollars. It does not take away anyone's right to protest, nor does it interfere with the other nearly 15 ways someone can participate in government's decision regarding Federal energy leasing or development.

This provision, as a matter of fact, will ensure that taxpayers' dollars that are going through the normal process are spent protecting the environment and in the planning and the leasing, not tied up in processing paperwork related to endless protests filed by special interests with an agenda, which one has to conclude, of stopping oil and natural gas leasing.

I do want to mention, too, Mr. Chairman, that this amendment was also offered in legislation in the Natural Resources Committee, and it, too, was defeated on a bipartisan basis. I suspect that if this is brought to the floor it will probably be beaten on a bipartisan basis again, so I urge the rejection of this amendment.

I reserve the balance of my time.

Mr. CONNOLLY of Virginia. Mr. Chairman, I would inquire as to how much time remains on this side.

The Acting CHAIR. The gentleman has 2½ minutes remaining.

Mr. CONNOLLY of Virginia. I would yield the balance of my time to the gentleman from Massachusetts (Mr. MARKEY).

Mr. MARKEY. I thank the gentleman.

Mr. Chairman, this provision reminds me of something that French author Anatole France once said. He said that the law, in its majestic equality, forbids the rich as well as the poor to sleep under bridges, to beg in the streets and to steal bread.

So, yes, under the bill's petroleum protest poll tax, the rich as well as the poor are charged $5,000 as a fee to protest an oil company drilling plant that could undermine the environment or the safety or the view of a particular individual; but the law is clearly targeted against the poor.

So if you are one of the super-rich like, say, Mitt Romney, having to pay a $5,000 fee to protest is nothing. It's less than half of what you offer up when you make a friendly little bet with a friend. If you're the Koch brothers and you want to stop the Cape Wind project from blocking your view out on the ocean, that's a small price to pay to be able to undermine a project that you're not happy with. For everyone else, this is basic economic discrimination. This $5,000 fee isn't just a tollbooth on the highway of justice. It is a brick wall.

Just by contrast, the United States Supreme Court—the highest court in the land—charges $300 to appeal a case. For an American citizen who is earning minimum wage, it would take 4 months of working full time and forgoing food and shelter in order to pay this protest fee which the Republicans want to put on the books. So, ordinary people, they're going to have to pay up now if they want to protest, and the environmental justice that has been denied poor people in our country over the last several generations just continues under this. This is what it's all about—environmental justice.

What you're doing is you're imposing a poll tax—an environmental poll tax, a polluter's poll tax, a petroleum poll tax—on ordinary families. It is just wrong, unnecessary, but oh so obvious in what the agenda is. It's not to block the Koch brothers from trying to block Cape Wind but, rather, just ordinary citizens from having their days in court so they can make their protests in a way that doesn't bankrupt the families.

I yield back the balance of my time.

The Acting CHAIR. The gentleman from Washington has 2½ minutes remaining.

Mr. HASTINGS of Washington. I yield myself the balance of the time.

Mr. Chairman, I want to point out this poster behind me. I know one can't read all of the details here, but this is the process by which somebody goes through a lease process to try to develop some activity on Federal lands. This is the process that one goes through, which, of course, is pretty long.

Now, I mentioned in my opening remarks that there are 15 different ways there can be a protest made or a voice heard, or whatever, in that whole lease process. At the back of me on this chart, it is denoted by the red dots. You can see all the way along, starting way over to my right, where right at the start there are places you can have input and that continues throughout, all the way to virtually the end.

When you have a process like this—and I will say it—in many cases, some of these red dots are used for frivolous purposes. Well, if they're used for frivolous purposes, there has to be a way, it would seem, to mitigate that in some way so that the government can do its job and do its work under the law as to those who are trying to lease public lands. That's simply what the fee does because the fee goes to the agency that processes this.

That means you can ensure, from my point of view at least, that you'll have a process that's fair and open. Nothing is taken away. There are no red dots taken away whatsoever. We're just simply saying there has to be a means by which we finance this process. I think this is a way to do it, so I would urge the rejection of this amendment. As I mentioned, it has been rejected several times before. It was rejected in committee, and I hope it will be rejected on the House floor.

With that, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Virginia (Mr. CONNOLLY).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. CONNOLLY of Virginia. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Virginia will be postponed.

AMENDMENT NO. 14 OFFERED BY MR. AMODEI

The Acting CHAIR. It is now in order to consider amendment No. 14 printed in House Report 112–540.

Mr. AMODEI. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end the following:

TITLE ___—MISCELLANEOUS PROVISIONS

SEC. ___. LIMITATION ON TRANSFER OF FUNCTIONS UNDER THE MINING LAW PROGRAM OR THE SOLID MINERALS LEASING PROGRAM.

The Secretary of the Interior may not transfer to the Office of Surface Mining Reclamation and Enforcement any responsibility or authority to perform any function performed immediately before the enactment of this Act under the Solid Minerals Program of the Department of the Interior, including—

(1) any such function under—

(A) the laws popularly known as the Mining Law of 1872 (30 U.S.C. 22 note);

(B) the Act of July 31, 1947 (chapter 406; 30 U.S.C. 601 et seq.), popularly known as the Materials Act of 1947;

(C) the Minerals Leasing Act (30 U.S.C. 181 et seq.); or

(D) the Mineral Leasing Act for Acquired Lands (30 U.S.C. 351 et seq.); and

(2) any such function relating to management of mineral development on Federal lands and acquired lands under section 302 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1732); and

(3) any function performed under the Mining Law Program.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Nevada (Mr. AMODEI) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Nevada.

Mr. AMODEI. Mr. Chairman, the Domestic Energy and Jobs Act, in addition to developing our abundant oil and natural gas reserves, is also important for the purposes of recognizing another part of the energy sector, which are our mineral resources. An often-forgotten component of America's economic engine and comparative advantage over other nations is our mineral and, yes, coal production. Minerals and mine materials are the raw ingredients needed by every sector of our economy.

This amendment is simple. It would prohibit the Secretary of the Interior from moving any aspect of the Solid Minerals program administered by the Bureau of Land Management and merging it with the Office of Surface Mining Reclamation and Enforcement, the OSM. This amendment is necessary because, currently, the administration continues to proceed with plans to combine these two entities despite the fact that it has met with heavy bipartisan resistance and also resistance from stakeholders, including, yes, even environmental groups.

Last year, Secretary Salazar announced his intent to combine the OSM and a portion of BLM's Solid Minerals program through a secretarial order. It appears to be in vogue these days—executive orders, secretarial orders. The problem missing here is: resort to Congress. Previous administrations have looked at this and have concluded in the record that congressional action is needed to do this. So here we are, trying to forestall yet another secretarial or executive order that flies in the face of congressional authority.

In March of this year, the Department of the Interior indicated a desire to continue to evaluate this. This will result in unnecessary costs to taxpayers as it is duplicative and flies in the face of previous administrations.

More importantly, OSM should not have the responsibility for leasing Federal coal. Under the Surface Mining Control and Reclamation Act, which was passed by this House, States are responsible for the permitting and the regulation of coal mining and abandoned-mine land cleanup. Additionally, the Surface Mining Control and Reclamation Act expressly prohibits the commingling of employees of any Federal agency that promotes the development or use of coal—responsibilities of the Solid Minerals division of the BLM. It is a clear conflict of interest.

Finally, the OSM does not have offices in all Federal Western States, and hard-rock mining does not fall under their jurisdiction, nor does it have any experience in the broad range of mineral commodities regulated by the BLM.

I ask for the Chamber's support of this amendment that would stop the Department of the Interior from merging the operations of the BLM and OSM.

Mr. HASTINGS of Washington. Will the gentleman yield?

Mr. AMODEI. I yield to the gentleman.

Mr. HASTINGS of Washington. I thank the gentleman for yielding.

I think you have a very good amendment, and I support that amendment. I thank the gentleman for bringing it to the floor.

Mr. AMODEI. Mr. Chairman, I reserve the balance of my time.

□ 2050

Mr. MARKEY. Mr. Chairman, I rise in opposition to this amendment.

The Acting CHAIR. The gentleman from Massachusetts is recognized for 5 minutes.

Mr. MARKEY. Mr. Chairman, we know that the Republican majority thinks current law governing hard rock mining in this country is about as close to perfect as they can get, and we know that international mining giants like Barrick Gold and Rio Tinto agree with our Republican colleagues. The status quo is really ideal from their perspective. That is because the status quo allows these multinational companies to mine billions of dollars worth of gold, silver, and other minerals on Federal lands without paying a dime in royalties. What's not to like if you're a multinational offshore company coming into our country?

The law allowing this disgraceful windfall was signed by Ulysses S. Grant in 1872, and there it sits immune from change, immune from improvement or update for 140 years. What we did not realize was just how far this majority will go to make sure even the smallest corner of the current setup is never, ever changed.

The administration has announced plans to consider whether merging some of the functions of the Office of Surface Mining and the Bureau of Land Management might lead to efficiencies and save the American taxpayers some money. The jury is still out on that idea, but we must ensure that we can continue to exercise proper oversight of mining activities on public lands and ensure that American taxpayers and States can continue to receive a proper return on these minerals.

A February report to Secretary Salazar recommended that the two agencies stay largely independent of each other. The merger plans have yet to be developed or announced and would likely be limited to money-saving ideas like combining human resource divisions, employee training programs, and fleet management operations. This streamlining could reportedly save as much as $5 million annually of taxpayers' money, something that the GSA, perhaps, could take as a lesson as to how they should operate.

At the very least, the administration deserves the time to fully develop and present a plan that can be debated on its merits. But this amendment says ''no.'' This amendment would specifically prohibit the administration from even considering whether aspects of this idea have merit and would save the taxpayers money, which is the goal of the plan that the Department of the Interior is considering.

Not only do our Republican colleagues reject any and all efforts to bring the Federal mining law into the 21st century—I would even take the 20th century, for that matter—but they bristle at the very idea of thinking about ways to better organize the agencies overseeing mining on Federal lands.

We should let the administration do its job. We should also get serious about ending royalty-free mining on public lands. This amendment really misses the point entirely. We need to be more efficient. We have to save the taxpayers money, and we also have to make sure that these multinationals pay more to mine the minerals of the American people.

With that, I reserve the balance of my time.

Mr. AMODEI. Mr. Chairman, may I inquire as to how much time I have remaining?

The Acting CHAIR. The gentleman from Nevada has 2 minutes remaining.

Mr. AMODEI. I yield 1½ minutes to my colleague from the Buckeye State.

Mr. JOHNSON of Ohio. Mr. Chairman, today I rise in support of the Amodei amendment that would ensure that the Secretary of the Interior does not combine the two agencies with competing missions into the same agency.

Late last year, the Secretary of the Interior tried to merge the Office of

Surface Mining into the Bureau of Land Management. After spending months of time and valuable taxpayer dollars to look at the issue and holding multiple public meetings, the Secretary of the Interior realized two things: First, he realized that he didn't have the power to merge the two agencies; and secondly, he realized it was simply a bad idea. Now there are reports that the Secretary is looking at taking portions of Bureau of Land Management and moving them under the purview of the Office of Surface Mining.

The two facts that I just mentioned still hold true today. The Secretary doesn't have the power without it first being authorized by Congress, and the two agencies have competing missions. It simply doesn't make sense to combine the two agencies.

During a markup at Natural Resources earlier this year, I offered an amendment similar to this that stopped the Secretary of the Interior from combining the two agencies, and it passed on a voice vote. I would hope that this amendment passes in a similar fashion.

I am all for streamlining overlapping government functions and cutting wasteful government spending. However, in this case there are no overlapping functions or wasteful spending. For that reason, I urge all of my colleagues to support this amendment.

The Acting CHAIR. The gentleman from Massachusetts has 1½ minutes remaining, and the gentleman from Nevada has 30 seconds remaining.

Mr. MARKEY. Mr. Chairman, I yield back the balance of my time.

Mr. AMODEI. Mr. Chairman, I would just say that the goal of the amendment is to keep from picking up the newspaper in the morning and reading about a secretarial or executive order that has combined two agencies that the record is replete with evidence that the executive branch and the Secretary does not have the authority to.

So when we talk about oversight and the proper thing to do in these instances and when we talk about debate it on its merits, as my colleague from the Bay State has indicated, I would love to do that. That requires that Congress act, not the Secretary of the Interior and not the President of the United States.

Thank you, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Nevada (Mr. AMODEI).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. AMODEI. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Nevada will be postponed.

AMENDMENT NO. 15 OFFERED BY MR. MARKEY

The Acting CHAIR. It is now in order to consider amendment No. 15 printed in House Report 112–540.

Mr. MARKEY. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end the following:

TITLE—MISCELLANEOUS PROVISIONS

SEC. ___1. REQUIREMENT TO OFFER FOR SALE ONLY IN THE UNITED STATES.

The Secretary of the Interior shall require that all oil and gas produced under a lease issued under this Act, the amendments made by this Act, or any plan, strategy, or program under this Act shall be offered for sale only in the United States.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Massachusetts (Mr. MARKEY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Massachusetts.

Mr. MARKEY. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, this amendment is quite simple. It prohibits the export of oil and natural gas produced from leases on the public lands of the United States that are going to be authorized under this bill.

America's number one export last year was American fuel—number one. No other product did we export more of last year than the fuel that is produced here in the United States. More than $100 billion in American-made fuels was sent overseas to China, to Morocco, to Singapore, and other countries.

This infuriates Americans pulling up to the pump and paying more than $3.50 a gallon to fill up. Not only do oil companies want to continue exporting American fuel, but they're now talking about lifting restrictions on exporting America's crude oil as domestic production continues to increase.

Just this week, the President of the American Petroleum Institute announced that exporting America's crude oil should be a serious consideration. Let me say that again: Big Oil is now stating publicly, in no uncertain terms, that they want to be able to export crude oil produced in the United States.

Earlier, the majority whip said that this bill will make us energy independent. Well, without the Markey amendment, there is no way that an oil company just won't export the fuel and the natural gas, and now the head of the American Petroleum Institute says Big Oil also wants to start exporting America's crude oil, as well.

As American men and women are on the ground in the Middle East fighting and dying to protect oil supply lines coming from the Middle East into the United States, Big Oil wants to export oil produced here in America to China, to other countries around the world. That is truly frightening, and it's wrong, ladies and gentlemen. It is wrong in terms of our relationship with the young men and women who fight for us, who defend us around the world.

□ 2100

Big Oil is beholden to shareholder interests only. They do not care about American national security, and they certainly don't like Americans to enjoy low energy prices, which is what's happening right now with natural gas. They want a bigger cut. They want to create a global national gas market and a global price, just like they have for oil. That's the plan.

And the companies are lining up at the Department of Energy right now to get permits to export American natural gas. There are 15 applications seeking to export 28 percent of our current natural gas, American natural gas, natural gas here in the United States all around the world.

And why do they want to do that? Well, they want to do that—even though the Energy Department says it could lead to a 54 percent increase in the price of natural gas for Americans—they want to do it for a very simple reason. The price of natural gas in Japan right now is seven times higher than the price of natural gas here in America. American companies want to sell the natural gas to the Japanese rather than to Americans because they can make seven times as much money. In Europe, it's four times as high. They want to sell the natural gas of America overseas rather than keep the prices low for people to keep their homes heated, to keep our industries growing. The petrochemical industry, the fertilizer industry, the plastics industry, all those industries are dependent upon these fuels.

No, that's good for the oil industry. It's very bad for the American manufacturing sector because low-priced natural gas is what's fueling the increase in manufacturing all across this country.

So I just totally reject the premise of the majority in allowing for the sale of our oil and gas out of our land across the country.

At this point, I am going to reserve the balance of my time.

Mr. HASTINGS of Washington. Mr. Chairman, I rise to claim the time in opposition.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. HASTINGS of Washington. I yield myself as much time as I may consume.

Mr. Chairman, I'm afraid from at least my reading of the amendment that this displays a lack of understanding regarding existing Federal laws and the realities of the oil and natural gas markets because oil produced on Federal lands is already subject to the Export Administration Act. In order to export crude oil, a producer would have to apply for authorization from the President. That's the law right now. Currently, no crude oil produced in the United States is exported, with the exception of a small quantity that goes to a Canadian refinery.

So I just think that what this is, more than anything else, is an effort to

make production on Federal lands more challenging and, thus, less valuable. And as a matter of fact, that would hurt the economy and American jobs.

But there is another aspect to it. And again, it's the way the amendment is reading. What about products that are made from oil? We know there is a vast array of products that are made from oil and natural gas, for that matter.

I think of a product that's made in my State. One of the biggest manufacturers in my home State of Washington is Boeing. There was a big fanfare. And in fact, I think a couple of weeks ago, they had their latest product on display down at Reagan National. It's called the 787 Dreamliner, which, of course, is made of composites, composites made of natural resources, i.e., oil and natural gases and others.

Now the way this amendment is written, because there are no restrictions, that means that Boeing probably could not export 787s. And frankly, their biggest market is the international market.

But let's not just confine it to Boeing. What about other byproducts that we manufacture? One comes to mind because my wife and I were using it to do some home repairs this weekend, WD–40, a petroleum-based product. I understand that that company exports a lot of that product overseas. The way this amendment is written, one could assume that that too would be restricted. What would that, then, do to the job market and our economy if we restrict what is a result of oil and natural gas being exported overseas?

I just want to repeat: There are restrictions for crude oil on Federal lands. That's existing law. This amendment adds nothing to it. But what I am concerned about, I guess, would be the unintended consequences. Let's not get ourselves into a situation where we have to pass a bill before we know what's in it. We've painfully gone through that in this country.

So I don't think this amendment is a good amendment, and I urge my colleagues to reject it.

I am prepared to close, so I will reserve the balance of my time.

Mr. MARKEY. I will, then, yield myself the remainder of the time.

The Acting CHAIR. The gentleman from Massachusetts is recognized for 30 seconds.

Mr. MARKEY. In summary, Price Waterhouse estimates that U.S. manufacturing companies could employ 1 million more workers if they continued to have low-priced natural gas. Exporting natural gas, exporting crude oil is only going to hurt our domestic economy, except for one industry: the oil industry.

American oil production right now is at its highest level since Bill Clinton. Natural gas production is at its all-time high ever. And what the American petroleum industry is now saying is that we want to start exporting this crude oil, start exporting this natural gas around the planet.

Keep American oil and natural gas here in America. Do not export it to other countries. It should be for Americans, and it should be for American companies. Vote ''aye'' on the Markey amendment.

Mr. HASTINGS of Washington. I yield myself the balance of my time.

First, I will urge people to reject the Markey amendment.

Now I made an observation. And maybe somebody is saying, Boy, you are really stretching it if you are going to byproducts. And I referenced the way the amendment was written. And the amendment is written where it says very specifically, ''all oil and gas.''

Well, let's see. If a product is made from oil and gas, wouldn't that qualify? So I think this is a very, very serious concern. And once again, it is the unintentional consequences of this amendment. So I urge rejection of the Markey amendment.

With that, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Massachusetts (Mr. MARKEY).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. MARKEY. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Massachusetts will be postponed.

AMENDMENT NO. 16 OFFERED BY MR. LANDRY

The Acting CHAIR. It is now in order to consider amendment No. 16 printed in House Report 112–540.

Mr. LANDRY. I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end the following:

TITLE—MISCELLANEOUS PROVISIONS

SEC. ___1. AMOUNT OF DISTRIBUTED QUALIFIED OUTER CONTINENTAL SHELF REVENUES.

Section 105(f)(1) of the Gulf of Mexico Energy Security Act of 2006 (title I of division C of Public Law 109-432; (43 U.S.C. 1331 note)) is amended by striking ''2055'' and inserting ''2022, and shall not exceed $750,000,000 for each of fiscal years 2023 through 2055''.

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Louisiana (Mr. LANDRY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Louisiana.

Mr. LANDRY. Mr. Chairman, this amendment is very simple. It seeks to improve the environment by ensuring that those States that allow offshore drilling are allowed to keep more of the revenue generated off of their shores.

In 2007, Congress passed a historic Gulf of Mexico Energy Security Act, or GOMESA. This historic legislation for the first time allows States to share in the royalties generated from offshore drilling. However, GOMESA only provided 37.5 percent of the revenue to the States and then capped the States at no more than a collective $500 million per year. Conversely, the Mineral Leasing Act required the Federal Government to give 50 percent of the energy revenue generated on Federal lands to States in which it is generated.

□ 2110

In Louisiana, we wholly support offshore drilling. We are proud to supply 80 percent of our Nation's offshore energy. But why should we not share in the funding generated by this drilling?

My amendment simply moves offshore royalty sharing more in line with the benefit experienced from onshore States by moving the GOMESA cap from $500 million to $750 million per year. My amendment does not impact onshore-producing States. If your State is receiving revenue from onshore energy production now, my amendment does nothing to change that. All the amendment does is move Louisiana, Texas, Mississippi, and Alabama a little closer to what those onshore States currently enjoy.

This amendment is nearly identical to the amendment that both myself and the gentleman from Louisiana (Mr. RICHMOND) offered during consideration of H.R. 3408, the PIONEERS Act, of which that amendment passed by bipartisan support of 266–159.

Mr. HASTINGS of Washington. Will the gentleman yield?

Mr. LANDRY. I yield to the gentleman.

Mr. HASTINGS of Washington. I thank the gentleman for yielding.

I think the gentleman has a good amendment. As he pointed out, it already has passed on a bipartisan basis on the floor, and I think it's worthy to be passed in this instance. I support the amendment.

Mr. LANDRY. I reserve the balance of my time.

Mr. MARKEY. I rise to claim the time in opposition to this amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. MARKEY. Mr. Chairman, every day will be Mardi Gras down in Louisiana if the gentleman's amendment is adopted. We—that is all the rest of us in the country—are already going to be sending $150 billion to these four States over the next 60 years. I don't blame the gentleman for coming back to try to get another bite at the apple, or, in this case, another bite at the king cake.

But I would say to the gentleman from Louisiana that his State already won the baby in the king cake when the GOMESA giveaway was enacted back in 2006, and you're already entitled to $150 billion worth of revenue coming out of the Federal Government and heading your way. And so I just think it's time for your region to give

a little back to the other 46 States in the Union that didn't benefit from that 2006 giveaway to you. We're not begrudging that. What's done is done and you get the $150 billion. But I just think it's time for us to start thinking about starting to reduce the Federal deficit and starting to spend some of this money that comes in from the revenues from the drilling, and that it helps out the whole country. And so I would just make that case to everyone else.

By the way, if you come from one of those four States, vote for the gentleman from Louisiana's amendment. It's a good amendment for you if come from one of those four States. But if you come from one of the other 46 States, you've got rocks in your head if you're voting for that amendment because it's just another $6 billion going from your pockets into the pockets of those four States down there. And it just makes no sense at all after the $150 billion we gave them just 6 years ago.

I reserve the balance of my time.

Mr. LANDRY. I would only remind the gentleman from Massachusetts that this is, if you are an environmentalist and you want to help protect the environment like I know the gentleman from Massachusetts so desperately wants to do—I have served with him in committee and enjoyed his passion for taking care of the environment—this is an environmental amendment.

The citizens of Louisiana have passed a constitutional amendment that dedicates all of the proceeds from offshore royalty to go to wetlands restoration, coastal restoration, and hurricane protection. This is buying us an insurance policy that the other 46 States, who I know have been so generous to help us when hurricanes ravage our coast, this helps to protect us. And I know that the gentleman from Massachusetts would love to protect the environment in Louisiana.

I yield back the balance of my time.

Mr. MARKEY. I yield myself such time as I may consume.

Again, I'd be willing to have a conversation with the gentleman from Louisiana about what the proper way is of dealing with the funding for the preservation of the wetlands and the other environmentally sensitive areas down in the Gulf of Mexico, but this isn't the way to do it. This is just another permanent entitlement that we're building into the law here unattached to the hearings and the evidence that we need in order to make sure that whatever expenditures are made by the Federal Government are actually going for the intended purpose. And that's not what this discussion is here tonight with a 5-minute amendment that we're debating.

Six billion dollars should come under closer scrutiny than the debate we're having at quarter past 9 at night on the House floor where the only people who are watching the debate really need to get a life, because that's about the level of public scrutiny this is getting right now. I just think the $6 billion that the gentleman is seeking to request from the public has to be dispensed in a way that actually has a better process.

Again, I oppose the gentleman's amendment. I understand its intention. But for the other 46 States, I just don't think it's a good idea at this time.

I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Louisiana (Mr. LANDRY).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. MARKEY. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Louisiana will be postponed.

AMENDMENT NO. 17 OFFERED BY MR. RIGELL

The Acting CHAIR. It is now in order to consider amendment No. 17 printed in House Report 112–540.

Mr. RIGELL. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end the following:

TITLE ___—MISCELLANEOUS PROVISIONS

SEC. _01. LEASE SALE 220 AND OTHER LEASE SALES OFF THE COAST OF VIRGINIA.

(a) INCLUSION IN LEASING PROGRAMS.—The Secretary of the Interior shall—

(1) upon enactment of this Act, revise the proposed Outer Continental Shelf oil and gas leasing program for the 2012–2017 period to include in such program Lease Sale 220 off the coast of Virginia; and

(2) include the Outer Continental Shelf off the coast of Virginia in the leasing program for each 5-year period after the 2012–2017 period.

(b) CONDUCT OF LEASE SALE.—As soon as practicable, but not later than 1 year after the date of enactment of this Act, the Secretary of the Interior shall carry out under section 8 of the Outer Continental Shelf Lands Act (43 U.S.C. 1337) Lease Sale 220.

(c) BALANCING MILITARY AND ENERGY PRODUCTION GOALS.—

(1) JOINT GOALS.—In recognition that the Outer Continental Shelf oil and gas leasing program and the domestic energy resources produced therefrom are integral to national security, the Secretary of the Interior and the Secretary of Defense shall work jointly in implementing this section in order to ensure achievement of the following common goals:

(A) Preserving the ability of the Armed Forces of the United States to maintain an optimum state of readiness through their continued use of the Outer Continental Shelf.

(B) Allowing effective exploration, development, and production of our Nation's oil, gas, and renewable energy resources.

(2) PROHIBITION ON CONFLICTS WITH MILITARY OPERATIONS.—No person may engage in any exploration, development, or production of oil or natural gas off the coast of Virginia that would conflict with any military operation, as determined in accordance with the Memorandum of Agreement between the Department of Defense and the Department of the Interior on Mutual Concerns on the Outer Continental Shelf signed July 20, 1983, and any revision or replacement for that agreement that is agreed to by the Secretary of Defense and the Secretary of the Interior after that date but before the date of issuance of the lease under which such exploration, development, or production is conducted.

(3) NATIONAL DEFENSE AREAS.—The United States reserves the right to designate by and through the Secretary of Defense, with the approval of the President, national defense areas on the Outer Continental Shelf pursuant to section 12(d) of the Outer Continental Shelf Lands Act (43 U.S.C. 1341(d)).

The Acting CHAIR. Pursuant to House Resolution 691, the gentleman from Virginia (Mr. RIGELL) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Virginia.

Mr. RIGELL. Mr. Chairman, this is a job-creating amendment. It reflects the wisdom and truly the will of the good folks of the Commonwealth of Virginia, and specifically within the great district that I have the privilege of serving and representing, the Second Congressional District of Virginia.

The House of Delegates of the Commonwealth of Virginia have made it clear that they really believe we need to move forward with coastal Virginia energy. The same is true of the Virginia Senate. And just today, we received a letter of strong support from Governor McDonnell, of which I'm very grateful for his support of this amendment. It has tremendous opportunity to put folks to work.

In this very Chamber, Mr. Chairman, I recall vividly our President, President Obama, saying that he was an all-of-the-above President, and I truly think I was one of the first to leap to my feet in full support. We have really failed the American people over the last many decades in moving this country toward energy independence. So I leapt to my feet. I was clapping. Yet I'm unable to reconcile what he's saying with the painful reality—and Virginia, too.

There's a full moratorium on the responsible exploration and harvesting of Virginia's coastal Virginia energy. In my view, Mr. Chairman, this is a full moratorium on job creation, and that means there's a full moratorium on the tax revenues that we need for healthier schools and better roads. So this amendment is directed right at that to break through and create action where, at present, there's a full moratorium.

The way the amendment works is very simple. It requires the Secretary of the Interior to include Virginia in the 5-year oil and leasing plan. My amendment requires the Secretary of the Interior to conduct Lease Sale 220 within 1 year of enactment.

Again, the word that comes to my mind is ''action''—''definitive action.'' This is what the American people want. This is what the good folks of Virginia's Second Congressional District want. It helps, in part, to move us

away from the dependence on countries for our oil, many of which their values are diametrically opposed to ours, and we can do this in an environmentally responsible way.

Mr. HASTINGS of Washington. Will the gentleman yield?

Mr. RIGELL. I will yield to the chairman.

Mr. HASTINGS of Washington. I think the gentleman has a very good lease. And I've been talking about where Virginia has been shortchanged, from my point of view. I think this amendment goes a long way to advance that debate, and, actually, what we all want is the action.

I support the gentleman's amendment.

Mr. RIGELL. I thank the chairman for his support. I urge my colleagues to join us in supporting this bill. These are life-changing jobs. There's tremendous potential, and we can do this in a very environmentally responsible way.

I reserve the balance of my time.

□ 2120

Mr. MARKEY. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman from Massachusetts is recognized for 5 minutes.

Mr. MARKEY. This amendment would order the Secretary of the Interior to conduct oil and gas leasing offshore in Virginia. In the wake of the *Deepwater Horizon* disaster, which was a lesson to all of us about the risks inherent in deepwater drilling, the Obama administration wisely canceled the proposed lease sale.

The overwhelming majority of the Virginia lease sale area infringes on critical training areas for the United States Navy. The Department of Defense itself has concluded that over 78 percent of the lease sale area would occur in areas where military operations would be impeded by drilling structures and related activities.

This area is already home to a number of critical military actions, including live ordnance tests, aircraft carrier qualifications, sensitive undersea and surface operations, and shipboard qualification tests. The military's continued activities in this area would torpedo drilling in most of this land.

Of the remaining 22 percent of the lease area, the majority of the unrestricted waters available for leasing would occur in the main shipping channel for Norfolk and the Chesapeake Bay, as well as the main channel used by submarines. So in the end, drilling could only even conceivably occur in about 10 percent of the area that the majority is talking about off the Virginia coast. When this Congress still has not passed a single legislative reform to improve the safety of offshore drilling, this just doesn't seem like it's worth of risk.

While some States may support offshore drilling, New Jersey and Maryland both oppose it, along with many other States along the Eastern Seaboard. These States' economies depend on the tourism that comes to see pristine, oil-free beaches and fishing that happens in their waters. And we are talking about their waters. As we saw during the BP disaster, drilling off the coast of Virginia could affect Maryland, New Jersey, and many other States up and down the East Coast because of oil spills which do not respect State boundaries.

This Congress has yet to enact a single safety reform following the *Deepwater Horizon* disaster. The independent, blue ribbon BP Spill Commission recently gave Congress a grade of ''D'' on its legislative response to the worst environmental disaster offshore in American history, and only refrained from handing out an ''F'' because, and these are the words of the BP Spill Commission, it did not want ''to insult the whole institution.''

The gentleman's amendment would place the entire East Coast at risk of a spill in order to open up an area where drilling may only be able to occur in about 10 percent of the area. That doesn't make any sense for our coastal States and their economies. The risks that we run are much higher than the very small benefits that can be derived.

I urge rejection of this amendment, and I yield back the balance of my time.

Mr. RIGELL. I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Virginia (Mr. RIGELL).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. MARKEY. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Virginia will be postponed.

Mr. HASTINGS of Washington. Mr. Chairman, I move that the Committee do now rise.

The motion was agreed to.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. GARDNER) having assumed the chair, Mr. CRAWFORD, Acting Chair of the Committee of the Whole House on the state of the Union, reported that that Committee, having had under consideration the bill (H.R. 4480) to provide for the development of a plan to increase oil and gas exploration, development, and production under oil and gas leases of Federal lands under the jurisdiction of the Secretary of Agriculture, the Secretary of Energy, the Secretary of the Interior, and the Secretary of Defense in response to a drawdown of petroleum reserves from the Strategic Petroleum Reserve, had come to no resolution thereon.

HOUR OF MEETING ON TOMORROW

Mr. HASTINGS of Washington. Mr. Speaker, I ask unanimous consent that when the House adjourns today, it adjourn to meet at 9 a.m. tomorrow.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Washington?

There was no objection.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. BACHUS (at the request of Mr. CANTOR) for today on account of attending the funeral of his father-in-law Royl Eron ''Roy'' Bevill with his wife, Linda Bachus.

SENATE ENROLLED BILLS SIGNED

The Speaker announced his signature to enrolled bills of the Senate of the following titles:

S. 404. An act to modify a land grant patent issued by the Secretary of the Interior.

S. 684. An act to provide for the conveyance of certain parcels of land to the town of Alta, Utah.

S. 997. An act to authorize the Secretary of the Interior to extend a water contract between the United States and the East Bench Irrigation District.

ADJOURNMENT

Mr. HASTINGS of Washington. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 9 o'clock and 25 minutes p.m.), under its previous order, the House adjourned until tomorrow, Thursday, June 21, 2012, at 9 a.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

6515. A letter from the Acting Under Secretary, Department of Defense, transmitting Report to Congress on Corrosion Policy and Oversight Budget Materials for FY 2013; to the Committee on Armed Services.

6516. A letter from the Acting Under Secretary, Department of Defense, transmitting a review of the Joint Land Attack Cruise Missile Defense Elevated Netted Sensor System (JLENS) program; to the Committee on Armed Services.

6517. A letter from the Acting Under Secretary, Department of Defense, transmitting a letter on the approved retirement of Lieutenant General Ronald L. Burgess, Jr., United States Army, and his advancement to the grade of lieutenant general on the retired list; to the Committee on Armed Services.

6518. A letter from the Assistant Secretary, Department of Defense, transmitting a copy of the Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) Annual Report to Congress for 2012; to the Committee on Armed Services.

6519. A letter from the Director, Defense Procurement and Acquisition Policy, Department of Defense, transmitting the Department's final rule — Defense Federal Acquisition Regulation Supplement: Contracting with the Canadian Commercial Corporation (DFARS Case 2011-D049) (RIN: 0750-

AH42) received May 22, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Armed Services.

6520. A letter from the Acting Under Secretary, Department of Defense, transmitting a report on the Defense Production Act (DPA) Title III fund for Fiscal Year 2011; to the Committee on Financial Services.

6521. A letter from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting the Commission's final rule — Innovation in the Broadcast Television Bands: Allocations, Channel Sharing and Improvements to VHF [ET Docket No.: 10-235] received May 10, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6522. A letter from the Deputy Director, Defense Security Cooperation Agency, transmitting Transmittal No. 12-27, pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended; to the Committee on Foreign Affairs.

6523. A letter from the Director, Defense Security Cooperation Agency, transmitting Transmittal No. 12-06, pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended; to the Committee on Foreign Affairs.

6524. A letter from the Director, Defense Security Cooperation Agency, transmitting Transmittal No. 12-09, pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended; to the Committee on Foreign Affairs.

6525. A letter from the Assistant Legal Advisor for Treaty Affairs, Department of State, transmitting report prepared by the Department of State concerning international agreements other than treaties entered into by the United States to be transmitted to the Congress within the sixty-day period specified in the Case-Zablocki Act; to the Committee on Foreign Affairs.

6526. A letter from the Assistant Secretary, Legislative Affairs, Department of State, transmitting the Department's final rule — Implementation of the Defense Trade Cooperation Treaty between the United States and the United Kingdom (RIN: 1400-AC95) received May 25, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Foreign Affairs.

6527. A letter from the Assistant Secretary for Civil Rights, Department of Agriculture, transmitting the Department's fiscal year 2011 annual report prepared in accordance with Section 203 of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act), Public Law 107-174; to the Committee on Oversight and Government Reform.

6528. A letter from the Secretary, Department of Agriculture, transmitting the Department's semiannual report from the office of the Inspector General for the period ending March 31, 2012; to the Committee on Oversight and Government Reform.

6529. A letter from the Deputy Secretary, Department of the Interior, transmitting the Department's semiannual report from the office of the Inspector General for the period October 1, 2011 through March 31, 2012; to the Committee on Oversight and Government Reform.

6530. A letter from the Assistant Secretary for Management and Chief Financial Officer, Department of the Treasury, transmitting the Department's annual report for Fiscal Year 2011 prepared in accordance with Section 203 of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act), Public Law 107-174; to the Committee on Oversight and Government Reform.

6531. A letter from the Assistant General Counsel, General Law, Ethics, and Regulation, Department of the Treasury, transmitting six reports pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

6532. A letter from the Chairman, Railroad Retirement Board, transmitting the semiannual report on activities of the Office of Inspector General for the period of October 1, 2011 through March 31, 2012; to the Committee on Oversight and Government Reform.

6533. A letter from the Clerk of Court, Court of Appeals, transmitting an opinion of the United States Court of Appeals for the Seventh Circuit, Soppet, et al v. Enhanced Recovery Company, LLC, No. 11-3819; to the Committee on the Judiciary.

6534. A letter from the Assistant Attorney General, Department of Justice, transmitting the Department's report providing an estimate of the dollar amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals will be paid for in 2013, pursuant to 42 U.S.C. 233(o); to the Committee on the Judiciary.

6535. A letter from the Assistant Attorney General, Department of Justice, transmitting Activities of the Review Panel on Prison Rape in Calendar year 2011; to the Committee on the Judiciary.

6536. A letter from the Attorney Advisor, Department of Homeland Security, transmitting the Department's final rule — Drawbridge Operation Regulation; Long Island, New York Inland Waterway from East Rockaway Inlet to Shinnecock Canal, NY [Docket No.: USCG-2011-1132] (RIN: 1625-AA09) received May 14, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6537. A letter from the Attorney Advisor, Department of Homeland Security, transmitting the Department's final rule — Safety Zone; Matlacha Bridge Construction, Matlacha Pass, Matlacha, FL [Docket No.: USCG-2011-1115] (RIN: 1625-AA00) received May 14, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6538. A letter from the Attorney Advisor, Department of Homeland Security, transmitting the Department's final rule — Special Local Regulations; Emerald Coast Super Goat Grand Prix; Saint Andrew Bay; Panama City, FL [Docket No.: USCG-2012-0085] (RIN: 1625-AA08) received May 14, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6539. A letter from the Attorney, Department of Homeland Security, transmitting the Department's final rule — Safety Zone; 2012 Mavericks Invitational, Half Moon Bay, CA [Docket No.: USCG-2011-1146] (RIN: 1625-AA08) received May 14, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6540. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; The Boeing Company Airplanes [Docket No.: FAA-2011-0566; Directorate Identifier 2010-NM-271-AD; Amendment 39-16975; AD 2012-05-03] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6541. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Pratt & Whitney Turbofan Engines [Docket No.: FAA-2007-27023; Directorate Identifier 98-ANE-47-AD; Amendment 39-16971; AD 2012-04-15] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6542. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; 328 Support Services GmbH Airplanes [Docket No.: FAA-2011-1318; Directorate Identifier 2010-NM-274-AD; Amendment 39-17009; AD 2012-07-01] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6543. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Fokker Services B.V. Model [Docket No.: FAA-2011-1226; Directorate Identifier 2011-NM-006-AD; Amendment 39-17001; AD 2012-06-20] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6544. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Rolls-Royce plc Turbofan Engines [Docket No.: FAA-2010-0821; Directorate Identifier 2010-NE-30-AD; Amendment 39-17004; AD 2012-06-23] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6545. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; DG Flugzeugbau GmbH Gliders [Docket No.: FAA-2012-0017; Directorate Identifier 2011-CE-039-AD; Amendment 39-16994; AD 2012-06-13] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6546. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Pilatus Aircraft Ltd. Airplanes [Docket No.: FAA-2012-0018; Directorate Identifier 2011-CE-042-AD; Amendment 39-16997; AD 2012-06-16] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6547. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Airbus Airplanes [Docket No.: FAA-2012-0294; Directorate Identifier 2011-NM-047-AD; Amendment 39-16992; AD 2012-06-11] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6548. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Airbus Airplanes [Docket No.: FAA-2012-0295; Directorate Identifier 2011-NM-057-AD; Amendment 39-16993; AD 2012-06-12] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6549. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; DASSAULT AVIATION Airplanes [Docket No.: FAA-2011-1164; Directorate Identifier 2011-NM-084-AD; Amendment 39-17002; AD 2012-06-21] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6550. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Airbus Airplanes [Docket No.: FAA-2012-0297; Directorate Identifier 2011-NM-093-AD; Amendment 39-17003; AD 2012-06-22] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6551. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Bombardier, Inc. Airplanes [Docket No.: FAA-2011-1088; Directorate Identifier 2011-NM-099-AD; Amendment 39-16985; AD 2012-06-04] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6552. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Goodrich Evacuation Systems Approved Under Technical Standard Order (TSO) TSO-C69b and Installed on Airbus Airplanes [Docket No.: FAA-2011-0223; Directorate Identifier 2010-NM-161-AD; Amendment 39-17006; AD 2012-06-25] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6553. A letter from the Commissioner, Social Security Administration, transmitting the Administration's sixteenth 2012 Annual Report of the Supplemental Security Income Program, pursuant to Public Law 104-193, section 231 (110 Stat. 2197); to the Committee on Ways and Means.

6554. A letter from the General Counsel, Office of Compliance, transmitting the Office's biennial report entitled ''Safety and Health in the Congressional Workplace — Report on the 111th Congress Biennial Occupational Safety and Health Inspections''; jointly to the Committees on House Administration and Education and the Workforce.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and references to the proper calendar, as follows:

Mr. LATHAM: Committee on Appropriations. H.R. 5972. A bill making appropriations for the Department of Transportation, and Housing and Urban Development, and related agencies for the fiscal year ending September 30, 2013, and for other purposes (Rept. 112–541). Referred to the Committee of the Whole House on the state of the Union.

Mr. KINGSTON: Committee on Appropriations. H.R. 5973. A bill making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2013, and for other purposes (Rept. 112–542). Referred to the Committee of the Whole House on the state of the Union.

Mr. RYAN of Wisconsin: Committee on the Budget. Activities and Summary Report of the Committee on the Budget Third Quarter 112th Congress (Rept. 112–543). Referred to the Committee of the Whole House on the state of the Union.

Mr. BACHUS: Committee on Financial Services. H.R. 4264. A bill to help ensure the Fiscal solvency of the FHA mortgage insurance programs of the Secretary of Housing and Urban Development, and for other purposes (Rept. 112–544). Referred to the Committee of the Whole House on the state of the Union.

PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XII, public bills and resolutions of the following titles were introduced and severally referred, as follows:

By Mr. LEVIN (for himself, Mr. RANGEL, Mr. STARK, Mr. MCDERMOTT, Mr. LEWIS of Georgia, Mr. NEAL, Mr. BECERRA, Mr. THOMPSON of California, Mr. LARSON of Connecticut, Mr. BLUMENAUER, Mr. KIND, Mr. PASCRELL, Ms. BERKLEY, Mr. CROWLEY, and Mr. VAN HOLLEN):

H.R. 5974. A bill to amend the Internal Revenue Code of 1986 to extend bonus depreciation, and for other purposes; to the Committee on Ways and Means.

By Ms. BONAMICI:

H.R. 5975. A bill to amend the Workforce Investment Act of 1998 to provide for the establishment of the Small Business Liaison Pilot Program; to the Committee on Education and the Workforce.

By Ms. WATERS (for herself, Ms. RICHARDSON, Ms. BASS of California, Ms. HAHN, Ms. ROYBAL-ALLARD, Ms. LEE of California, Mr. HINCHEY, Mr. FILNER, Mr. CARNAHAN, Mr. CONYERS, Ms. FUDGE, Mr. CLARKE of Michigan, Mr. HASTINGS of Florida, Mr. RUSH, Mr. CLAY, Mr. LEWIS of Georgia, Mr. RYAN of Ohio, Mr. CICILLINE, Mr. KUCINICH, Ms. JACKSON LEE of Texas, Ms. PINGREE of Maine, Mr. RANGEL, Mr. MCDERMOTT, Mr. ELLISON, Ms. SCHAKOWSKY, Ms. ZOE LOFGREN of California, Mr. TOWNS, Mr. CLEAVER, Ms. SEWELL, Ms. CLARKE of New York, Ms. SLAUGHTER, Ms. EDWARDS, Mr. DOYLE, Mr. BACA, Ms. WILSON of Florida, Ms. MCCOLLUM, Mr. BUTTERFIELD, Mr. MICHAUD, Mr. SCOTT of Virginia, Mr. JOHNSON of Georgia, and Ms. MATSUI):

H.R. 5976. A bill making supplemental appropriations for fiscal year 2012 for the TIGER Discretionary Grant program, and for other purposes; to the Committee on Appropriations, and in addition to the Committee on the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. SMITH of Texas (for himself and Mr. UPTON):

H.R. 5977. A bill to amend the Hobby Protection Act to make unlawful the provision of assistance or support in violation of that Act, and for other purposes; to the Committee on Energy and Commerce.

By Ms. DELAURO (for herself, Ms. CHU, Mr. COHEN, Mr. CONYERS, Ms. DEGETTE, Mr. ELLISON, Mr. FARR, Mr. FILNER, Mr. HINCHEY, Ms. HIRONO, Mr. JACKSON of Illinois, Mr. JOHNSON of Georgia, Ms. KAPTUR, Ms. LEE of California, Mrs. LOWEY, Mrs. MALONEY, Ms. MCCOLLUM, Mr. MCDERMOTT, Mr. GEORGE MILLER of California, Ms. MOORE, Mr. MORAN, Mr. NADLER, Ms. NORTON, Ms. RICHARDSON, Ms. ROYBAL-ALLARD, Mr. RUSH, Ms. SCHAKOWSKY, Ms. SLAUGHTER, Mr. STARK, Ms. WATERS, Ms. WOOLSEY, Ms. ZOE LOFGREN of California, Ms. ESHOO, Ms. WASSERMAN SCHULTZ, Mr. GRIJALVA, Mr. DEUTCH, Mr. LARSEN of Washington, Mr. SERRANO, and Ms. JACKSON LEE of Texas):

H.R. 5978. A bill to restore the effective use of group actions for claims arising under title VII of the Civil Rights Act of 1964, title I of the Americans with Disabilities Act of 1990, title V of the Rehabilitation Act of 1973, section 1977 of the Revised Statutes, and the Genetic Information Nondiscrimination Act of 2008, and for other purposes; to the Committee on the Judiciary.

By Mr. CASSIDY:

H.R. 5979. A bill to amend title XIX of the Social Security Act to reform payment to States under the Medicaid program; to the Committee on Energy and Commerce.

By Mr. PETERSON:

H.R. 5980. A bill to amend the National Trails System Act to revise the route of the North Country National Scenic Trail in northeastern Minnesota to include existing hiking trails along Lake Superior's north shore and in Superior National Forest and Chippewa National Forest, and for other purposes; to the Committee on Natural Resources.

By Mr. PETRI (for himself and Mr. ANDREWS):

H.R. 5981. A bill to amend title IV of the Employee Retirement Income Security Act of 1974 to provide for a guarantee by the Pension Benefit Guaranty Corporation for qualified preretirement survivor annuities under insolvent or terminated multiemployer pension plans; to the Committee on Education and the Workforce.

By Mr. SHULER:

H.R. 5982. A bill to amend the Internal Revenue Code of 1986 to provide that the value of certain historic property shall be determined using an income approach in determining the taxable estate of a decedent; to the Committee on Ways and Means.

By Mr. STIVERS:

H.R. 5983. A bill to designate the facility of the United States Postal Service located at 2539 Dartmoor Road in Grove City, Ohio, as the ''Master Sergeant Shawn T. Hannon and Veterans Memorial Post Office Building''; to the Committee on Oversight and Government Reform.

By Mr. STIVERS:

H.R. 5984. A bill to designate the facility of the United States Postal Service located at 25 South Oak Street in London, Ohio, as the ''Lance Corporal Joshua B. McDaniels and Veterans Memorial Post Office Building''; to the Committee on Oversight and Government Reform.

By Mr. STIVERS:

H.R. 5985. A bill to designate the facility of the United States Postal Service located at 3700 Riverside Drive in Columbus, Ohio, as the ''Master Sergeant Jeffery J. Rieck and Veterans Memorial Post Office''; to the Committee on Oversight and Government Reform.

By Mrs. MALONEY (for herself, Ms. FUDGE, Ms. MOORE, Ms. NORTON, Ms. LEE of California, Ms. WILSON of Florida, Ms. MCCOLLUM, Ms. RICHARDSON, Mr. TOWNS, Mr. CARNAHAN, Ms. WOOLSEY, Mr. MCDERMOTT, and Mr. MCGOVERN):

H. Res. 694. A resolution recognizing the 40th anniversary of title IX, the Federal law that prohibits sex discrimination in education, including high school and college sports and other activities; to the Committee on Education and the Workforce.

By Mr. QUAYLE (for himself and Mr. GOWDY):

H. Res. 695. A resolution expressing the sense of the House of Representatives on the appointment by the Attorney General of an outside special counsel to investigate certain recent leaks of apparently classified and highly sensitive information on United States military and intelligence plans, programs, and operations; to the Committee on the Judiciary.

By Mr. SMITH of Washington (for himself and Mr. MCKEON):

H. Res. 696. A resolution recognizing the 70th anniversary of the Guadalcanal campaign during World War II; to the Committee on Foreign Affairs, and in addition to the Committee on Armed Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 7 of rule XII of the Rules of the House of Representatives, the following statements are submitted regarding the specific powers granted to Congress in the Constitution to enact the accompanying bill or joint resolution.

By Mr. LATHAM:

H.R. 5972.

Congress has the power to enact this legislation pursuant to the following:

The principal constitutional authority for this legislation is clause 7 of section 9 of article I of the Constitution of the United States (the appropriation power), which states: ''No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . .'' In addition, clause 1 of section 8 of article I of the Constitution (the spending power) provides: ''The Congress shall have the Power . . . to pay the Debts and provide for the common Defence and general Welfare of the United States . . . .'' Together, these specific constitutional provisions establish the congressional power of the purse, granting Congress the authority to appropriate funds, to determine their purpose, amount, and period of availability, and to set forth terms and conditions governing their use.

By Mr. KINGSTON:

H.R. 5973.

Congress has the power to enact this legislation pursuant to the following:

The principal constitutional authority for this legislation is clause 7 of section 9 of article I of the Constitution of the United States (the appropriation power), which states: ''No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . .'' In addition, clause 1 of section 8 of article I of the Constitution (the spending power) provides: ''The Congress shall have the Power . . . to pay the Debts and provide for the common Defence and general Welfare of the United States . . . .'' Together, these specific constitutional provisions establish the congressional power of the purse, granting Congress the authority to appropriate funds, to determine their purpose, amount, and period of availability, and to set forth terms and conditions governing their use.

By Mr. LEVIN:

H.R. 5974.

Congress has the power to enact this legislation pursuant to the following:

The Congress enacts this bill pursuant to Sections 7 & 8 of Article I of the United States Constitution and Amendment XVI of the United States Constitution.

By Ms. BONAMICI:

H.R. 5975.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 1 of the United States Constitution.

By Ms. WATERS:

H.R. 5976.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, clause 1 of the U.S. Constitution and

Article 1, Section 9, clause 7 of the U.S. Constitution.

By Mr. SMITH of Texas:

H.R. 5977.

Congress has the power to enact this legislation pursuant to the following:

The authority to enact this bill is derived from, but may not be limited to, Article I, Section 8, Clause 3 of the United States Constitution.

By Ms. DELAURO:

H.R. 5978.

Congress has the power to enact this legislation pursuant to the following:

Fourteenth Amendment, Section 5

By Mr. CASSIDY:

H.R. 5979.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 1 [the Spending Clause] of the United States Constitution states that 'The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay for Debts and provide for the common Defence and general Welfare of the United States.'

By Mr. PETERSON:

H.R. 5980.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 18 (Necessary and Proper Clause)

The Congress shall have Power * * * To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by the Constitution in the Government of the United States, or in any Department or Officer thereof.

By Mr. PETRI:

H.R. 5981.

Congress has the power to enact this legislation pursuant to the following:

Clauses 1 and 3 of Section 8 of Article I of the Constitution of the United States.

By Mr. SHULER:

H.R. 5982.

Congress has the power to enact this legislation pursuant to the following:

Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 1.

By Mr. STIVERS:

H.R. 5983.

Congress has the power to enact this legislation pursuant to the following:

The constitutional authority on which this bill rests is the power of Congress to establish Post Offices and post roads, as enumerated in Article I, Section 8, Clause 7 of the United States Constitution.

By Mr. STIVERS:

H.R. 5984.

Congress has the power to enact this legislation pursuant to the following:

The constitutional authority on which this bill rests is the power of Congress to establish Post Offices and post roads, as enumerated in Article I, Section 8, Clause 7 of the United States Constitution.

By Mr. STIVERS:

H.R. 5985.

Congress has the power to enact this legislation pursuant to the following:

The constitutional authority on which this bill rests is the power of Congress to establish Post Offices and post roads, as enumerated in Article I, Section 8, Clause 7 of the United States Constitution.

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions as follows:

H.R. 192: Mr. MORAN.

H.R. 459: Mr. HUNTER and Mr. MCHENRY.

H.R. 687: Mr. TONKO.

H.R. 831: Ms. WILSON of Florida and Mr. ELLISON.

H.R. 904: Mr. GIBSON.

H.R. 930: Mr. HIMES.

H.R. 1044: Ms. SPEIER.

H.R. 1054: Ms. ESHOO.

H.R. 1093: Mr. KIND.

H.R. 1192: Ms. BONAMICI.

H.R. 1307: Mr. ROKITA.

H.R. 1322: Ms. PINGREE of Maine.

H.R. 1370: Ms. HERRERA BEUTLER, Mr. KELLY, Mr. NUGENT, and Mr. HASTINGS of Washington.

H.R. 1375: Mr. NEAL, Mr. CLAY, Mr. CARNEY, and Mr. CICILLINE.

H.R. 1381: Ms. BALDWIN.

H.R. 1386: Mr. MILLER of North Carolina and Mr. DANIEL E. LUNGREN of California.

H.R. 1426: Mr. BISHOP of Georgia.

H.R. 1653: Mr. RUNYAN.

H.R. 1681: Ms. EDWARDS and Mr. KUCINICH.

H.R. 1733: Mr. KILDEE.

H.R. 1802: Mr. CLAY.

H.R. 1842: Mr. VAN HOLLEN, Ms. RICHARDSON, Mr. MILLER of North Carolina, and Mr. FALEOMAVAEGA.

H.R. 1867: Mr. TIERNEY, Mr. NADLER, and Mr. CONYERS.

H.R. 1878: Mr. KILDEE.

H.R. 1912: Mr. TOWNS and Mr. CLAY.

H.R. 2141: Mr. FARR.

H.R. 2464: Mr. WELCH.

H.R. 2493: Ms. BASS of California.

H.R. 2794: Ms. ZOE LOFGREN of California, Mr. SIRES, Ms. LEE of California, Mr. KUCINICH, and Ms. NORTON.

H.R. 2885: Mr. HARRIS.

H.R. 2978: Mr. COLE.

H.R. 3044: Mr. HUIZENGA of Michigan and Mr. MANZULLO.

H.R. 3059: Mr. COOPER.

H.R. 3125: Mr. BILBRAY and Mr. MCNERNEY.

H.R. 3187: Ms. HERRERA BEUTLER, Mr. BUTTERFIELD, Mr. HARRIS, and Mr. SULLIVAN.

H.R. 3192: Mr. RICHMOND and Mr. MCNERNEY.

H.R. 3307: Mr. MILLER of North Carolina.

H.R. 3338: Mr. HOLT.

H.R. 3352: Mr. OLVER and Mr. HINCHEY.

H.R. 3359: Mr. KEATING, Ms. ROYBAL-ALLARD, and Mr. KILDEE.

H.R. 3432: Mr. HONDA.

H.R. 3481: Mr. WALSH of Illinois.

H.R. 3506: Mr. KING of Iowa.

H.R. 3619: Mr. FRANK of Massachusetts and Mr. BUTTERFIELD.

H.R. 3767: Mr. COHEN and Mr. BRALEY of Iowa.

H.R. 3790: Mr. RYAN of Ohio.

H.R. 3798: Mr. TONKO.

H.R. 3816: Mr. HARRIS, Ms. JENKINS, and Mr. HULTGREN.

H.R. 3993: Mr. POLIS.

H.R. 4021: Mr. HONDA, Ms. BORDALLO, Ms. LEE of California, and Mr. SABLAN.

H.R. 4066: Mr. BUCHANAN.

H.R. 4070: Mr. OWENS.

H.R. 4112: Mr. DANIEL E. LUNGREN of California.

H.R. 4134: Mr. WATT.

H.R. 4160: Mr. BRADY of Texas and Mr. SCALISE.

H.R. 4164: Mr. CRITZ and Mr. SMITH of New Jersey.

H.R. 4202: Ms. ZOE LOFGREN of California and Ms. HOCHUL.

H.R. 4227: Mr. CRITZ, Mr. HINCHEY, and Ms. CHU.

H.R. 4269: Mr. GRIFFIN of Arkansas and Mr. HURT.

H.R. 4271: Mr. LOEBSACK.

H.R. 4296: Mr. WEBSTER.

H.R. 4342: Mr. HULTGREN.

H.R. 4362: Mr. PIERLUISI.

H.R. 4367: Mr. YODER, Mr. CAPUANO, Mr. CARNEY, Mr. LATHAM, Mr. DUFFY, Mr. NUGENT, and Mr. GALLEGLY.

H.R. 4378: Mr. POLIS, Mr. LANGEVIN, Ms. SLAUGHTER, Mr. HASTINGS of Washington, Mr. LEWIS of Georgia, and Mr. DEUTCH.

H.R. 4406: Mr. KILDEE.

H.R. 4816: Mr. HASTINGS of Florida.

H.R. 4965: Mr. CASSIDY, Mr. HUELSKAMP, and Mr. GRIFFIN of Arkansas.

H.R. 4972: Mr. CROWLEY.

H.R. 5381: Mr. LANKFORD and Mr. CAMPBELL.

H.R. 5542: Mr. HOLT and Mr. BISHOP of Georgia.

H.R. 5646: Mr. LAMBORN.
H.R. 5707: Mr. TONKO.
H.R. 5872: Mr. MCCLINTOCK, Mr. WALBERG, and Mr. WESTMORELAND.
H.R. 5894: Mr. ROSS of Florida and Mr. WESTMORELAND.
H.R. 5910: Mr. WALSH of Illinois and Mr. BACHUS.
H.R. 5912: Mr. ROKITA.
H.R. 5925: Mr. ROONEY, Mr. ROSS of Florida, and Mr. NUGENT.
H.R. 5943: Mr. TONKO.
H.R. 5953: Mr. CRAVAACK, Mr. WESTMORELAND, Mr. SCALISE, Mr. WILSON of South Carolina, Mr. AUSTIN SCOTT of Georgia, Mr. SCHWEIKERT, Mr. STUTZMAN, Mr. ROE of Tennessee, Mr. FRANKS of Arizona, Mr. FLEMING, Mr. DUNCAN of South Carolina, Mrs. ELLMERS, Mr. HARRIS, Mr. CAMPBELL, Mr. GRIFFIN of Arkansas, and Mr. GINGREY of Georgia.
H.R. 5957: Mrs. BLACK, Mr. GINGREY of Georgia, Mr. CRAVAACK, Mr. WESTMORELAND, Mr. WILSON of South Carolina, Mr. CHABOT, Mr. GARRETT, Mr. ROE of Tennessee, Mr. FRANKS of Arizona, Mr. HUELSKAMP, Mr. FLEMING, Mr. DUNCAN of South Carolina, Mr. BROOKS, Mr. BILBRAY, Mr. MARCHANT, and Mr. MULVANEY.
H.R. 5961: Mr. REHBERG.
H.J. Res. 72: Mr. SMITH of Washington.
H. Con. Res. 63: Mr. ELLISON.
H. Con. Res. 110: Mr. BENISHEK.
H. Con. Res. 114: Mr. BENISHEK.
H. Con. Res. 129: Mr. BENISHEK, Mr. UPTON, Mr. TONKO, Mr. DINGELL, and Mr. AMODEI.
H. Res. 25: Ms. HOCHUL.
H. Res. 134: Mr. WILSON of South Carolina.
H. Res. 298: Mr. KILDEE.
H. Res. 351: Mr. JOHNSON of Georgia.
H. Res. 397: Mr. SHULER, Mr. BISHOP of Georgia, Mr. COSTA, and Mr. PETERSON.
H. Res. 613: Mr. COLE.
H. Res. 618: Mr. BOSWELL.
H. Res. 623: Mr. ALTMIRE, Mr. GARDNER, Mr. CANSECO, Mr. ROSS of Florida, Mr. STEARNS, and Mr. RIVERA.
H. Res. 662: Mr. COLE.