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Senate

The Senate was not in session today. Its next meeting will be held on Thursday, May 31, 2012, at 12 p.m.

House of Representatives

WEDNESDAY, MAY 30, 2012

The House met at 2 p.m. and was called to order by the Speaker.

PRAYER

The Chaplain, the Reverend Patrick J. Conroy, offered the following prayer:

We give You thanks, God of the universe, for giving us another day.

As the various Members of this people's House return, we ask Your blessing upon each as they resume the difficult responsibilities that await them. Give each the wisdom and good judgment needed to give credit to the office they have been honored by their constituents to fill.

Bless the work of all who serve in their various capacities here in the United States Capitol.

Bless all those who visit the Capitol this very day, be they American citizens or visitors or guests of our Nation. May they be inspired by this monument to the noble idea of human freedom and its guarantee by the democratic experiment that is the United States.

God, bless America, and may all that is done this day be for Your greater honor and glory.

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 gentlewoman from Minnesota (Ms. MCCOLLUM) come forward and lead the House in the Pledge of Allegiance.

Ms. MCCOLLUM 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.

GOVERNMENT ENERGY PLAN: MORE AIR

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

Mr. POE of Texas. Mr. Speaker, recently I met with some people in Texas in the trucking industry. We discussed the administration's domestic energy policy—how the administration is against using more American coal; how the administration is against drilling in ANWR; how the administration is stonewalling the drilling on Federal lands; how the administration has delayed offshore-drilling permits; and how the administration uses the EPA to block domestic energy production.

Since the administration is against so much, what is it in favor of? Then Dalton handed me this—yes, a tire gauge—and reminded me that the President touted his energy plan when he said this: We could save all the oil they are talking about getting off drilling if everybody would just inflate their tires and get tune-ups.

Really? That's it, more air in our tires? Now, you know, Mr. Speaker, more hot air will save us all. Now there's an energy plan we can all be proud of.

And that's just the way it is.

HONORING MILLE LACS BAND CHIEF EXECUTIVE MARGE ANDERSON

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

Ms. MCCOLLUM. Mr. Speaker, today I rise to honor my dear friend and outstanding tribal leader, Mille Lacs Band Chief Executive Marge Anderson. After 30 years of service to our community, Marge is retiring. I know I'm not alone in saying she will be missed.

Ms. Anderson first reached out to me when I was in the Minnesota State house. The education she provided on Indian treaty rights and the U.S. Constitution's guarantees of tribal sovereignty are lessons I still carry with me.

The first woman elected to serve as chief executive for the Mille Lacs Band, Marge promoted tribal self-governance, economic development, education, health care, and infrastructure. Chief Executive Anderson has also been recognized for her dedication to the welfare of Native American children, families, and communities by regional tribal organizations all around this country. I thank her for her inspired leadership, for her protection of tribal sovereignty, for her guidance and her

friendship. Marge, Miigwetch—thank you.

PROVIDING FOR VETERANS—AND STILL TRIMMING SPENDING

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

Mr. HULTGREN. Mr. Speaker, I rise today in support of the 2013 Military Construction and Veterans Affairs appropriations bill.

Most of the time, when budgets are cut and cuts are made, someone somewhere is upset about them. But as a wise Governor once said: you'll be amazed how much government you'll never miss.

In the case of this bill, efficiencies were found within programs to trim billions in spending, while still providing for our warfighters and veterans in the most effective and efficient ways. The fact that funding for so many vital programs for our veterans were actually increased is a testament to the significant savings made in other areas of the bill. For example, it will provide disability compensation for almost 4 million veterans and their survivors, and it will provide post-9/11 GI Bill education benefits for more than 600,000 veterans.

I ask my colleagues to join me in voting in favor of this important bill later this week.

STUDYING TOWARD ADJUSTED RESIDENCY STATUS ACT

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

Mr. RIVERA. Mr. Speaker, many young immigrants have found themselves stuck in limbo due to our failure to address immigration reform. Such is the plight of my constituent, Daniela Pelaez, who came here from Colombia with her family when she was four. They overstayed their visas, and she has now been ordered deported. Next week, Daniela, who is here with us today in the gallery, will graduate as valedictorian from North Miami High. Having maintained a 6.7 GPA, she has received a full scholarship to Dartmouth College.

In order to assist students like Daniela today, I am introducing the Studying Toward Adjusted Residency Status, or STARS, Act. The STARS Act would allow undocumented students who arrive here at a young age, graduate from high school, and are accepted into a university to apply for a 5-year conditional nonimmigrant status. During that 5-year period, they can focus on their college education and, once they graduate, have their conditional status extended and work toward achieving residency.

This legislation can make the American Dream a reality for young people like Daniela, who through no fault of their own are prevented from realizing their full potential in this land of opportunity.

I ask my colleagues to join me in supporting this legislation to help Daniela and others like her who are as American as anyone born in the United States and who simply need a chance to continue being productive Americans.

PRENATAL NONDISCRIMINATION ACT

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

Mr. PITTS. Mr. Speaker, today, the House of Representatives will consider the Prenatal Nondiscrimination Act, a bill to ban the practice of sex-selection abortions.

If you talk to most expectant couples, you'll hear a common refrain: we don't care whether it's a boy or a girl; we just want a healthy baby. In fact, even with advanced ultrasound technology, many parents choose to wait until birth to discover the sex of their child. Unfortunately, there are exceptions. Some couples will do anything to choose the sex of their child. In the majority of these cases, boys are favored and girls are aborted.

I know most Americans think this is something that happens overseas in places like China and India. However, a Columbia University study found evidence that sex selection at the prenatal level is happening right here in the United States.

Just yesterday, the group Live Action released undercover video of a Planned Parenthood clinic in Austin, Texas, counseling a woman on how to choose the sex of her child. We shouldn't wait any longer to ban this barbaric and socially unhealthy practice. It's time to pass the bill.

□ 1410

PAT HEAD SUMMITT HONORED WITH THE PRESIDENTIAL MEDAL OF FREEDOM

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

Mr. COHEN. Yesterday, there was a historic program at the White House where 13 great people of the world were recognized with Presidential Medals of Freedom. They ranged from former Supreme Court Justice John Paul Stevens to Bob Dylan to John Glenn and others. But nobody stood out more than Pat Head Summitt, the great athletic coach for the University of Tennessee Lady Vols—greatest basketball coach of all time.

But now, facing her greatest battle, Alzheimer's, she stands as a public statement that a cure must be found, and the caregivers must be recognized and taken care of. She's raising money for Alzheimer's. She's raising money for those that face this problem, like she does, but she's facing it with courage and trying to help others.

This is her greatest battle. She is a great American. I thank the world for Pat Head Summitt, not for her coaching ability but for her courage as a human being.

RECESS

The SPEAKER pro tempore (Mr. BISHOP of Utah). Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until approximately 3:30 p.m. today.

Accordingly (at 2 o'clock and 10 minutes p.m.), the House stood in recess.

□ 1532

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. BISHOP of Utah) at 3 o'clock and 32 minutes p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions 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.

Record votes on postponed questions will be taken later.

PRENATAL NONDISCRIMINATION ACT (PRENDA) OF 2012

Mr. FRANKS of Arizona. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3541) to prohibit discrimination against the unborn on the basis of sex or race, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3541

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 ''Prenatal Nondiscrimination Act (PRENDA) of 2012''.

SEC. 2. FINDINGS AND CONSTITUTIONAL AUTHORITY.

(a) FINDINGS.—The Congress makes the following findings:

(1) Women are a vital part of American society and culture and possess the same fundamental human rights and civil rights as men.

(2) United States law prohibits the dissimilar treatment of males and females who are similarly situated and prohibits sex discrimination in various contexts, including the provision of employment, education, housing, health insurance coverage, and athletics.

(3) Sex is an immutable characteristic ascertainable at the earliest stages of human development through existing medical technology and procedures commonly in use, including maternal-fetal bloodstream DNA sampling, amniocentesis, chorionic villus sampling or ''CVS'', and obstetric ultrasound. In addition to medically assisted

sex determination, a growing sex determination niche industry has developed and is marketing low cost commercial products, widely advertised and available, that aid in the sex determination of an unborn child without the aid of medical professionals. Experts have demonstrated that the sex-selection industry is on the rise and predict that it will continue to be a growing trend in the United States. Sex determination is always a necessary step to the procurement of a sex-selection abortion.

(4) A ''sex-selection abortion'' is an abortion undertaken for purposes of eliminating an unborn child based on the sex or gender of the child. Sex-selection abortion is barbaric, and described by scholars and civil rights advocates as an act of sex-based or gender-based violence, predicated on sex discrimination. Sex-selection abortions are typically late-term abortions performed in the 2nd or 3rd trimester of pregnancy, after the unborn child has developed sufficiently to feel pain. Substantial medical evidence proves that an unborn child can experience pain at 20 weeks after conception, and perhaps substantially earlier. By definition, sex-selection abortions do not implicate the health of the mother of the unborn, but instead are elective procedures motivated by sex or gender bias.

(5) The targeted victims of sex-selection abortions performed in the United States and worldwide are overwhelmingly female. The selective abortion of females is female infanticide, the intentional killing of unborn females, due to the preference for male offspring or ''son preference''. Son preference is reinforced by the low value associated, by some segments of the world community, with female offspring. Those segments tend to regard female offspring as financial burdens to a family over their lifetime due to their perceived inability to earn or provide financially for the family unit as can a male. In addition, due to social and legal convention, female offspring are less likely to carry on the family name. ''Son preference'' is one of the most evident manifestations of sex or gender discrimination in any society, undermining female equality, and fueling the elimination of females' right to exist in instances of sex-selection abortion.

(6) Sex-selection abortions are not expressly prohibited by United States law or the laws of 47 States. Sex-selection abortions are performed in the United States. In a March 2008 report published in the Proceedings of the National Academy of Sciences, Columbia University economists Douglas Almond and Lena Edlund examined the sex ratio of United States-born children and found ''evidence of sex selection, most likely at the prenatal stage''. The data revealed obvious ''son preference'' in the form of unnatural sex-ratio imbalances within certain segments of the United States population, primarily those segments tracing their ethnic or cultural origins to countries where sex-selection abortion is prevalent. The evidence strongly suggests that some Americans are exercising sex-selection abortion practices within the United States consistent with discriminatory practices common to their country of origin, or the country to which they trace their ancestry. While sex-selection abortions are more common outside the United States, the evidence reveals that female feticide is also occurring in the United States.

(7) The American public supports a prohibition of sex-selection abortion. In a March 2006 Zogby International poll, 86 percent of Americans agreed that sex-selection abortion should be illegal, yet only 3 States proscribe sex-selection abortion.

(8) Despite the failure of the United States to proscribe sex-selection abortion, the United States Congress has expressed repeatedly, through Congressional resolution, strong condemnation of policies promoting sex-selection abortion in the ''Communist Government of China''. Likewise, at the 2007 United Nation's Annual Meeting of the Commission on the Status of Women, 51st Session, the United States delegation spearheaded a resolution calling on countries to condemn sex-selective abortion, a policy directly contradictory to the permissiveness of current United States law, which places no restriction on the practice of sex-selection abortion. The United Nations Commission on the Status of Women has urged governments of all nations ''to take necessary measures to prevent . . . prenatal sex selection''.

(9) A 1990 report by Harvard University economist Amartya Sen, estimated that more than 100 million women were ''demographically missing'' from the world as early as 1990 due to sexist practices, including sex-selection abortion. Many experts believe sex-selection abortion is the primary cause. Current estimates of women missing from the world range in the hundreds of millions.

(10) Countries with longstanding experience with sex-selection abortion—such as the Republic of India, the United Kingdom, and the People's Republic of China—have enacted restrictions on sex-selection, and have steadily continued to strengthen prohibitions and penalties. The United States, by contrast, has no law in place to restrict sex-selection abortion, establishing the United States as affording less protection from sex-based feticide than the Republic of India or the People's Republic of China, whose recent practices of sex-selection abortion were vehemently and repeatedly condemned by United States congressional resolutions and by the United States Ambassador to the Commission on the Status of Women. Public statements from within the medical community reveal that citizens of other countries come to the United States for sex-selection procedures that would be criminal in their country of origin. Because the United States permits abortion on the basis of sex, the United States may effectively function as a ''safe haven'' for those who seek to have American physicians do what would otherwise be criminal in their home countries—a sex-selection abortion, most likely late-term.

(11) The American medical community opposes sex-selection. The American Congress of Obstetricians and Gynecologists, commonly known as ''ACOG,'' stated in its 2007 Ethics Committee Opinion, Number 360, that sex-selection is inappropriate because it ''ultimately supports sexist practices.'' The American Society of Reproductive Medicine (commonly known as ''ASRM'') 2004 Ethics Committee Opinion on sex-selection notes that central to the controversy of sex-selection is the potential for ''inherent gender discrimination'', . . . the ''risk of psychological harm to sex-selected offspring (i.e., by placing on them expectations that are too high),''. . . and ''reinforcement of gender bias in society as a whole.'' Embryo sex-selection, ASRM notes, remains ''vulnerable to the judgment that no matter what its basis, [the method] identifies gender as a reason to value one person over another, and it supports socially constructed stereotypes of what gender means.'' In doing so, it not only ''reinforces possibilities of unfair discrimination, but may trivialize human reproduction by making it depend on the selection of non-essential features of offspring.'' The ASRM ethics opinion continues, ''ongoing problems with the status of women in the United States make it necessary to take account of concerns for the impact of sex-selection on goals of gender equality.'' The American Association of Pro-Life Obstetricians and Gynecologists, an organization with hundreds of members - many of whom are former abortionists - makes the following declaration: ''Sex selection abortions are more graphic examples of the damage that abortion inflicts on women. In addition to increasing premature labor in subsequent pregnancies, increasing suicide and major depression, and increasing the risk of breast cancer in teens who abort their first pregnancy and delay childbearing, sex selection abortions are often targeted at fetuses simply because the fetus is female. As physicians who care for both the mother and her unborn child, the American Association of Pro-Life Obstetricians and Gynecologists vigorously opposes aborting fetuses because of their gender.'' The President's Council on Bioethics published a Working Paper stating the council's belief that society's respect for reproductive freedom does not prohibit the regulation or prohibition of ''sex control,'' defined as the use of various medical technologies to choose the sex of one's child. The publication expresses concern that ''sex control might lead to . . .dehumanization and a new eugenics.''

(12) Sex-selection abortion results in an unnatural sex-ratio imbalance. An unnatural sex-ratio imbalance is undesirable, due to the inability of the numerically predominant sex to find mates. Experts worldwide document that a significant sex-ratio imbalance in which males numerically predominate can be a cause of increased violence and militancy within a society. Likewise, an unnatural sex-ratio imbalance gives rise to the commoditization of humans in the form of human trafficking, and a consequent increase in kidnapping and other violent crime.

(13) Sex-selection abortions have the effect of diminishing the representation of women in the American population, and therefore, the American electorate.

(14) Sex-selection abortion reinforces sex discrimination and has no place in a civilized society.

(15) The history of the United States includes examples of sex discrimination. The people of the United States ultimately responded in the strongest possible legal terms by enacting a constitutional amendment correcting elements of such discrimination. Women, once subjected to sex discrimination that denied them the right to vote, now have suffrage guaranteed by the 19th amendment. The elimination of discriminatory practices has been and is among the highest priorities and greatest achievements of American history.

(16) Implicitly approving the discriminatory practice of sex-selection abortion by choosing not to prohibit them will reinforce these inherently discriminatory practices, and evidence a failure to protect a segment of certain unborn Americans because those unborn are of a sex that is disfavored. Sex-selection abortions trivialize the value of the unborn on the basis of sex, reinforcing sex discrimination, and coarsening society to the humanity of all vulnerable and innocent human life, making it increasingly difficult to protect such life. Thus, Congress has a compelling interest in acting—indeed it must act—to prohibit sex-selection abortion.

(b) CONSTITUTIONAL AUTHORITY.—In accordance with the above findings, Congress enacts the following pursuant to Congress' power under—

(1) the Commerce Clause;

(2) section 5 of the 14th amendment, including the power to enforce the prohibition on government action denying equal protection of the laws; and

(3) section 8 of article I to make all laws necessary and proper for the carrying into

execution of powers vested by the Constitution in the Government of the United States.

SEC. 3. DISCRIMINATION AGAINST THE UNBORN ON THE BASIS OF SEX.

(a) IN GENERAL.—Chapter 13 of title 18, United States Code, is amended by adding at the end the following:

"§ 250. Discrimination against the unborn on the basis of sex

''(a) IN GENERAL.—Whoever knowingly—

''(1) performs an abortion knowing that such abortion is sought based on the sex or gender of the child;

''(2) uses force or the threat of force to intentionally injure or intimidate any person for the purpose of coercing a sex-selection abortion;

''(3) solicits or accepts funds for the performance of a sex-selection abortion; or

''(4) transports a woman into the United States or across a State line for the purpose of obtaining a sex-selection abortion;

or attempts to do so, shall be fined under this title or imprisoned not more than 5 years, or both.

''(b) CIVIL REMEDIES.—

''(1) CIVIL ACTION BY WOMAN ON WHOM ABORTION IS PERFORMED.—A woman upon whom an abortion has been performed pursuant to a violation of subsection (a)(2) may in a civil action against any person who engaged in a violation of subsection (a) obtain appropriate relief.

''(2) CIVIL ACTION BY RELATIVES.—The father of an unborn child who is the subject of an abortion performed or attempted in violation of subsection (a), or a maternal grandparent of the unborn child if the pregnant woman is an unemancipated minor, may in a civil action against any person who engaged in the violation, obtain appropriate relief, unless the pregnancy resulted from the plaintiff's criminal conduct or the plaintiff consented to the abortion.

''(3) APPROPRIATE RELIEF.—Appropriate relief in a civil action under this subsection includes—

''(A) objectively verifiable money damages for all injuries, psychological and physical, including loss of companionship and support, occasioned by the violation of this section; and

''(B) punitive damages.

''(4) INJUNCTIVE RELIEF.—

''(A) IN GENERAL.—A qualified plaintiff may in a civil action obtain injunctive relief to prevent an abortion provider from performing or attempting further abortions in violation of this section.

''(B) DEFINITION.—In this paragraph the term 'qualified plaintiff' means—

''(i) a woman upon whom an abortion is performed or attempted in violation of this section;

''(ii) any person who is the spouse or parent of a woman upon whom an abortion is performed in violation of this section; or

''(iii) the Attorney General.

''(5) ATTORNEYS FEES FOR PLAINTIFF.—The court shall award a reasonable attorney's fee as part of the costs to a prevailing plaintiff in a civil action under this subsection.

''(c) LOSS OF FEDERAL FUNDING.—A violation of subsection (a) shall be deemed for the purposes of title VI of the Civil Rights Act of 1964 to be discrimination prohibited by section 601 of that Act.

''(d) REPORTING REQUIREMENT.—A physician, physician's assistant, nurse, counselor, or other medical or mental health professional shall report known or suspected violations of any of this section to appropriate law enforcement authorities. Whoever violates this requirement shall be fined under this title or imprisoned not more than 1 year, or both.

''(e) EXPEDITED CONSIDERATION.—It shall be the duty of the United States district courts, United States courts of appeal, and the Supreme Court of the United States to advance on the docket and to expedite to the greatest possible extent the disposition of any matter brought under this section.

''(f) EXCEPTION.—A woman upon whom a sex-selection abortion is performed may not be prosecuted or held civilly liable for any violation of this section, or for a conspiracy to violate this section.

''(g) PROTECTION OF PRIVACY IN COURT PROCEEDINGS.—

''(1) IN GENERAL.—Except to the extent the Constitution or other similarly compelling reason requires, in every civil or criminal action under this section, the court shall make such orders as are necessary to protect the anonymity of any woman upon whom an abortion has been performed or attempted if she does not give her written consent to such disclosure. Such orders may be made upon motion, but shall be made sua sponte if not otherwise sought by a party.

''(2) ORDERS TO PARTIES, WITNESSES, AND COUNSEL.—The court shall issue appropriate orders under paragraph (1) to the parties, witnesses, and counsel and shall direct the sealing of the record and exclusion of individuals from courtrooms or hearing rooms to the extent necessary to safeguard her identity from public disclosure. Each such order shall be accompanied by specific written findings explaining why the anonymity of the woman must be preserved from public disclosure, why the order is essential to that end, how the order is narrowly tailored to serve that interest, and why no reasonable less restrictive alternative exists.

''(3) PSEUDONYM REQUIRED.—In the absence of written consent of the woman upon whom an abortion has been performed or attempted, any party, other than a public official, who brings an action under this section shall do so under a pseudonym.

''(4) LIMITATION.—This subsection shall not be construed to conceal the identity of the plaintiff or of witnesses from the defendant or from attorneys for the defendant.

''(h) DEFINITIONS.—

''(1) The term 'abortion' means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child, unless the act is done with the intent to—

''(A) save the life or preserve the health of the unborn child;

''(B) remove a dead unborn child caused by spontaneous abortion; or

''(C) remove an ectopic pregnancy.

''(2) The term 'sex-selection abortion' is an abortion undertaken for purposes of eliminating an unborn child based on the sex or gender of the child.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 13 of title 18, United States Code, is amended by adding after the item relating to section 249 the following new item:

''250. Discrimination against the unborn on the basis of sex.''.

SEC. 4. SEVERABILITY.

If any portion of this Act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect the portions or applications of this Act which can be given effect without the invalid portion or application.

SEC. 5. RULE OF CONSTRUCTION.

Nothing in this Act shall be construed to require that a healthcare provider has an affirmative duty to inquire as to the motivation for the abortion, absent the healthcare provider having knowledge or information that the abortion is being sought based on the sex or gender of the child.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. FRANKS) and the gentleman from Michigan (Mr. CONYERS) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

Mr. FRANKS of Arizona. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous materials on H.R. 3541, as amended, currently under consideration.

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

There was no objection.

Mr. FRANKS of Arizona. I yield myself such time as I may consume.

The Prenatal Nondiscrimination Act we are debating at this moment simply says that an unborn child cannot be discriminated against by subjecting him to an abortion based on the sex of the child. Because between 40 and 50 percent of African American babies—nearly one in two—are killed by abortion, which is five times, Mr. Speaker, the rate of white children, I believe with all of my heart that this bill should also prohibit race-targeted abortion as it did when the bill was first introduced.

It is my hope that by protecting unborn children from being aborted based on their sex that one day very soon we will also recognize the humanity and justice of protecting unborn children regardless of their race or color as well, and simply because we recognize them as fellow human beings.

Mr. Speaker, worldwide sex-selection abortion has now left the human family on Earth with approximately 200 million missing baby girls. Various United Nations organizations have battled sex-selection abortion for years. These agencies routinely refer to sex-selection abortion as ''an extreme form of violence against women.''

In the New Atlantis magazine, political economist Nicholas Eberstadt, of the American Enterprise Institute, said:

> In terms of its sheer toll in human numbers, sex-selective abortion has assumed a scale tantamount to a global war against baby girls.

In 2007, the United States spearheaded a U.N. resolution to condemn sex-selection abortion worldwide; yet here in the land of the free and the home of the brave, we are the only advanced country left in the world that still doesn't restrict sex-selection abortion in any way.

Mr. Speaker, a number of academic papers have now published evidence that the practice of sex-selection abortion is demonstrably increasing here in the United States, especially, but not exclusively, in the Asian immigrant community.

A study by researchers at the University of Connecticut, which was published in Prenatal Diagnosis, found that the male-to-female live birth sex ratio in the United States for Chinese, Asian Indians, and Koreans clearly exceeded biological variation for third births and beyond. Mr. Speaker, deliberate prenatal sex selection is the only plausible explanation.

Dr. Sunita Puri and three other researchers at the University of California interviewed 65 immigrant Indian women in the United States who had sought or were seeking sex-selection abortion. They found that 40 percent of the women interviewed had deliberately aborted unborn baby girls previously and that nearly 90 percent of the women who were currently carrying unborn baby girls were also currently seeking to abort them.

This was an incredibly powerful study, Mr. Speaker. It discussed in detail the multiple forms of pressure and outright coercion to which these women are often subjected. Sixty-two percent of the women described verbal abuse from their husbands or female in-laws, and fully one-third of women described past physical abuse and neglect, all related specifically to their failing to produce a male child. As a result, these women reported aborting multiple unborn baby girls in a row because of the pressure that was put on them to have a male child.

Mr. Speaker, sex-selection abortion is extreme violence against both unborn baby girls and their mothers. It has been a primary enforcement mechanism for China's forced abortion and ''one child'' policy for many years. It has dramatically increased sex trafficking and violence against women due to the imbalanced sex ratios left in its wake across the world, and we now know that it is a tragic circumstance into which many women are also being coerced. This evil practice has now allowed thousands of little girls in America and millions of little girls across the world to be brutally dismembered, most of them in their second or third trimester and when they are capable of feeling extreme pain, simply because they were little girls instead of little boys, Mr. Speaker.

Sex selection is violence against women, and it is the truest kind of war against women, and it has now brought humanity to a place where the three deadliest words on this Earth are ''it's a girl.'' What in God's name have we come to, Mr. Speaker? I've often asked myself what finally enlightened and changed the hearts of those across history who have either perpetrated or supported or ignored the atrocities and human genocides of their day.

While I probably will never fully understand, I believe I caught a glimpse of the answer from my 3-year-old little girl, Gracie. As I was holding her and we were watching her favorite laughing baby videos on YouTube, I inadvertently clicked on a video that showed a young man from China who was playing poignant and beautiful music on the piano with his feet because both of his arms had been amputated when he was a child.

In trying to seize on a teaching moment, Mr. Speaker, I said, ''Look at that, Gracie. He's playing the piano with his feet. Isn't that amazing?''

But with a stricken little look on her face, Gracie said, ''But, Daddy, he doesn't have any arms.''

I said, ''I know, Baby, and that's very sad, isn't it?''

And she said, ''Oh, Daddy, it is very sad. We've got to help him. We've just got to. We've got to get some arms and give it to him.''

I said, ''But, Baby, there aren't any extra arms. They're all hooked onto other people.''

And she thought for a moment and looked at me with wet little eyes and pulled up her sleeve and held up her little arm and said, ''But, Daddy, can I give him one of my arms if it will fit on him?''

Across human history, the greatest and most loving voices among us have always emphasized the critical responsibility each of us has to recognize and cherish the light of divine, eternal humanity shining in the soul of every last one of our fellow human beings. I believe there is an answer to some of these seemingly unanswerable questions, Mr. Speaker, that face the human families and how we see each other. On that YouTube video, I saw an amazing young man who played heart-stirring music with his feet, but my little girl saw a child of God who had no arms and wanted to give him one of hers.

And how very thankful I am that my little Gracie was not one of the hundreds of millions of little girls whose lives and hearts were torn from this world before they ever saw the light of sunrise simply because they were little girls instead of little boys.

I know that this Congress deals with many controversial issues where it is sometimes difficult for Republicans and Democrats to find common ground, but I refuse to believe that we cannot find enough humanity in this body to conclude together that it is wrong to knowingly kill unborn children because they are baby girls instead of baby boys.

With that, Mr. Speaker, I reserve the balance of my time.

□ 1540

Mr. CONYERS. Mr. Speaker, I yield myself such time as I may consume.

Members of the House, I want to thank the leadership on the other side for requiring that the chairman of the Subcommittee on the Constitution, the gentleman from Arizona, drop ''race'' from this Prenatal Nondiscrimination Act, so-called. So it's now just sex selection.

This is the latest in a long series of measures intended to chip away at a woman's right to seek safe and legal medical care. It tramples the rights of women under the guise of nondiscrimination while doing absolutely nothing to provide women with the needed resources so that their babies—female and male—can come into the world healthy, and so that both mother and child can thrive.

I am grateful that the proponents of this bill have stopped making the ridiculous charge that I used to hear, that reproductive freedom is worse than slavery, and invoking at the same time the name of the great abolitionist leader Frederick Douglass in the service of their cause. It was deeply offensive, and I'm glad that we won't have to listen to that anymore.

Mr. Speaker, at this point, I reserve the balance of my time.

Mr. FRANKS of Arizona. Mr. Speaker, I yield 1½ minutes to the gentlewoman from Florida (Mrs. ADAMS), a member of the Judiciary Committee.

Mrs. ADAMS. Mr. Speaker, I rise today in support of H.R. 3541, the Prenatal Nondiscrimination Act, PRENDA, introduced by Representative TRENT FRANKS.

As the mother of a daughter, I am disturbed by what I am hearing about sex selection occurring in the United States. A 2008 Columbia University report found that there is strong son bias and there is clear evidence of sex selection, most likely at the prenatal stage. The victims of sex-selection abortions are predominantly female and most are later term, which means that these gruesome abortions are occurring after the child becomes pain capable.

In 2007, the United States spearheaded an international resolution to condemn sex selection; however, there are no laws preventing or prohibiting the practice in the United States. And while I stand here, I think about just yesterday as I watched as my little granddaughter—inside her mother's womb—turned towards that ultrasound.

This issue of life is a divisive one in politics, but I think all Americans can agree aborting babies because they are the wrong sex is just plain wrong.

Let's put a stop to this egregious practice, and let's pass this legislation.

Mr. CONYERS. Mr. Speaker, I am pleased now to yield as much time as he may consume to the ranking member of the Constitution Subcommittee, the distinguished gentleman from New York, JERRY NADLER.

Mr. NADLER. I thank the gentleman.

Mr. Speaker, I rise in opposition to the so-called ''Prenatal Nondiscrimination Act.''

Today, the Republican majority continues its war on women in a new and creative way, by attempting to couch legislation that would destroy women's fundamental constitutional rights as a women's rights law. It is cynical, but creative.

Trying to destroy women's constitutional rights, and pretending that it is somehow being pro-woman, plays well to the far-right wing base, but does nothing to help American families get

on their feet and put people back to work.

This bill criminalizes abortion prior to viability. It makes pre-viability abortions a crime under certain circumstances, a flagrantly unconstitutional provision under Roe v. Wade.

Under this bill, a relative who disagreed with a woman's choice would be able to sue a doctor simply by alleging that the woman had an impermissible motive. The doctor would face years of litigation at great expense. A relative could even obtain an injunction blocking an abortion from going forward merely by alleging that the abortion is being done for the purposes of sex selection. While the matter is being litigated, the pregnancy would go forward so that, regardless of the merits, a woman would be compelled by a court injunction to proceed with her pregnancy against her will, perhaps to have an abortion at a much later stage with a much more mature fetus.

Any clinic employee who suspected—merely suspected—that a woman's motives ran afoul of this law would have a legal obligation, under penalty of prison, to report that suspicion to law enforcement.

How would this affect the basic practice of medicine?

H.R. 3541 would force health care providers to inquire into women's reasons for seeking abortion services. Physicians would have to consider whether women seeking routine non-abortion services, such as determining the sex of the fetus, might then use that information in deciding whether to continue a pregnancy.

Given the severe civil and criminal penalties in this bill, doctors would be forced to police their patients, read their minds, and conceal information from them. The failure to do so would put medical professionals at risk of prosecution and lawsuits.

This bill is facially unconstitutional. The Supreme Court has held, beginning with Roe v. Wade and in Casey and subsequent cases, that the decision of whether to have a child or whether to end a pregnancy is a private one. Up until the point of viability, the government may not make that decision for a woman. Following viability, the government may regulate or bar an abortion, except when the abortion is necessary to protect the life or health of the woman.

The preference for male children is a real, if limited, phenomenon in the United States. Some women face familial and community preference to have male children, and that pressure can increase with each subsequent birth. But this bill does nothing to help those women.

This bill cites the United Nations Commission on the Status of Women as urging governments to prevent sex-selective abortions, but it ignores the concerns of those who work on this problem, such as the U.N. Population Fund, the Office of the U.N. High Commissioner for Human Rights, the U.N. Children's Fund, the U.N. Women, and the World Health Organization, that abortion restrictions are not the solution because they put women's health and lives in jeopardy and violate women's human and reproductive rights.

Where is the legislation providing women with the means to achieve independence so that they are not subject to community and family pressures? My Republican colleagues opposed the Lilly Ledbetter Fair Pay Act that would have done just that. We all had to watch the charade recently where Republicans pretended they weren't going after the Violence Against Women Act with a meat-ax. Where is the support for family planning services so we have fewer unplanned pregnancies and, therefore, fewer abortions? Where is the commitment to maternal and child health programs?

But all this costs money, it won't do anything to undermine Roe v. Wade, and it doesn't play well in the world of abortion politics.

I urge the Members of this House to reject this cynical, dishonest, and hypocritical legislation.

Mr. Speaker, I rise in opposition to the so-called ''Prenatal Nondiscrimination Act.''

Today, the Republican majority continues the war on women in a new and creative way, by attempting to couch legislation that would destroy women's fundamental constitutional rights as a women's rights law. It is cynical, but creative.

Our nation's economy is struggling to recover. Families are struggling to keep their homes, and provide a better future for their children.

And what is the majority doing about it? Nothing. Today we have yet another radical foray into divisive social issues. Trying to destroy women's constitutional rights, and pretending that it is somehow being ''pro-woman,'' plays well to the far right-wing base, but does nothing to help American families get on their feet, and put people back to work.

This is election-year politics at its absolute worst.

Despite the fact that this bill is couched in the language of civil rights, indeed it amends the civil rights crimes chapter of the federal Criminal Code, it is nothing more than yet another attack on the fundamental constitutional rights of women. It does not improve their ability to choose to have a healthy and successful pregnancy. It does not improve the prospects for their children once those children come into the world. It does nothing to help women who are subject to community pressure to have sons. It does nothing to improve the lot of women who may really need our help.

This bill criminalizes abortion, prior to viability; it makes previability abortions a crime under certain circumstances, a flagrantly unconstitutional provision under Roe.

Under this bill, a relative who disagreed with a woman's choice would be able to sue a doctor simply by alleging that the woman had an impermissible reason. The doctor would face years of litigation at great expense.

A relative could even obtain an injunction blocking an abortion from going forward merely by alleging that the abortion is being done for the purposes of sex selection. While the matter is being litigated, the pregnancy would go forward so that, regardless of the merits, a woman would be compelled by a court injunction to proceed with her pregnancy against her will.

Any clinic employee who suspected—merely suspected—that a woman's motives ran afoul of this law would have a legal obligation, under penalty of prison, to report that suspicion to law enforcement.

How would this affect the basic practice of medicine?

H.R. 3541 would force health care providers to inquire into a woman's reasons for seeking abortion services. Physicians would have to consider whether women seeking routine non-abortion services, such as determining the sex of the fetus, would then use that information in deciding whether to continue a pregnancy.

The more information the doctor has, and the more he shares with his patient, the greater the risk that someone could argue that the abortion was for a prohibited purpose, and that he knew it.

Given the severe civil and criminal penalties in this bill, doctors would be forced to police their patients, read their patients' minds, and conceal information from them. The failure to do so would put medical professionals at risk of prosecution and lawsuits.

Do you want to see defensive medicine? Try making this law.

This bill is facially unconstitutional. The Supreme Court has held, beginning with Roe v. Wade, and in Casey and subsequent cases, that the decision whether to have a child, or whether to end a pregnancy, is a private one. Up until the point of viability, the government may not make that decision for a woman. Following viability, the government may regulate or bar an abortion, except when the abortion is necessary to protect the life or health of the woman.

This bill would bar a woman from having an abortion at any time on the basis of her motives.

While this bill may be an unconstitutional intrusion into women's private choices, it does nothing to help women or their children. That sort of legislation is not on the agenda here, or in this Republican controlled Congress.

The bill contains flat out lies. For example, it contains a ''finding'' that a fetus can feel pain after 20 weeks, even though this is a fringe position rejected by the mainstream of medical science. A survey of available research published in the Journal of the American Medical Association in 2005 concluded that ''[e]vidence regarding the capacity for fetal pain is limited but indicates that fetal perception of pain is unlikely before the third trimester.'' Similarly, a detailed survey by the Royal Academy of Obstetricians and Gynecologists concluded:

> In reviewing the neuroanatomical and physiological evidence in the fetus, it was apparent that connections from the periphery to the cortex are not intact before 24 weeks of gestation and, as most neuroscientists believe that the cortex is necessary for pain perception, it can be concluded that the fetus cannot experience pain in any sense prior to this gestation.

But why let the facts get in the way of some nice rhetoric?

The preference for male children is a real if limited phenomenon in the United States. Some women face familial and community preference to have male children and that pressure can increase with each subsequent birth.

But this bill does nothing to help those women.

While H.R. 3541 cites the United Nations Commission on the Status of Women as urging governments to prevent sex selective abortions, it ignores the concerns expressed by those who work on this problem—such as the United Nations Population Fund, the Office of the United Nations High Commissioner for Human Rights, the United Nations Children's Fund, United Nations Women, and the World Health Organization—that abortion restrictions are not the solution because they put women's health and lives in jeopardy and violate women's human and reproductive rights.

The Judiciary Committee heard from Miriam Yeung, of the National Asian Pacific American Women's Forum, who discussed how Congress could address the male child preference issue in a manner that is effective and that supports women rather than stigmatizing them. She explained:

Son preference is a symptom of deeply rooted social biases and stereotypes about gender. Gender inequity cannot be solved by banning abortion. The real solution is to change the values that create the preference for sons. . . . We are working with members of our own community to empower women and girls, thereby challenging norms and transforming values.

Where is the legislation providing women with the means to achieve independence so that they are not subject to community and familial pressures? My Republican colleagues opposed the Lilly Ledbetter Fair Pay Act that would have done just that. We all had to watch the charade recently where Republicans pretended they weren't going after the Violence Against Women Act with a meat-ax. Where is the support for family planning services so we have fewer unplanned pregnancies and, therefore, fewer abortions? Where is the commitment to maternal and child health programs?

There are many things Congress could do to assist women, including women who are under pressure from their families or communities to terminate a pregnancy—strategies that have worked and that assist women rather than turn them into suspects or pariahs. We can work with their doctors and provide necessary resources to women and their families.

But that costs money, it won't do anything to undermine Roe v. Wade, and it doesn't play well in the world of abortion politics.

I urge the members of this House to reject this cynical and destructive legislation.

Mr. FRANKS of Arizona. Mr. Speaker, I yield 1½ minutes to the gentleman from Iowa (Mr. KING), the vice chairman of the Judiciary Immigration Subcommittee.

Mr. KING of Iowa. Mr. Speaker, I thank the gentleman from Arizona for his leadership on this issue and many other issues, and I come to the floor here in strong support of the PRENDA Act.

The very idea of sex-selection abortion, gendercide, as it was so aptly named, brought back to mind for me a story that I heard from a man whom I admired. His name was Gil Copper. Sadly, we lost him back in 2010.

Gil Copper was a World War II veteran who volunteered with Merrill's Marauders in Asia and marched across those areas in India and Burma to take on the Japanese behind the scenes. Gil Copper picked up and was awarded one Silver Star, two Bronze Stars, one Combat Infantry Badge, and one Purple Heart.

Gil Copper spent his time off in Asia under the bridge in New Delhi, India, standing in the Ganges River listening for the splash. Standing there day or night, any time he had off, he was listening for the splash of a little baby girl that would often and regularly be tossed off the bridge into the river to drown because the culture in India cherished boys and didn't cherish girls. Gil Copper would swim out there and pick up those little girls that were floating then in the filthy Ganges River and swim back with them and dry them off and carry them to the Catholic orphanage in New Delhi. He saved scores of lives during that period of time.

That culture has arrived here in this country, and this bill puts an end to that kind of culture that would select baby girls for death.

Mr. CONYERS. Mr. Speaker, I am pleased now to yield 3 minutes to the gentleman from Georgia, HANK JOHNSON, a distinguished member of the House Judiciary Committee.

Mr. JOHNSON of Georgia. Mr. Speaker, this bill is not about civil rights, but it's simply another attempt to chip away at a woman's right to choose. It's part of the Republican war on women, also known as WOW. I'm like, Wow, why are we continuing to attack women like this? Wow, it's men against women.

What's happening is we're in a political year, ladies and gentlemen, and politics has been good to the Republicans as of late. They have pitted people who favor immigration against those who do not support it. They have divided people on affirmative action from African Americans. They have divided people on the issue of gays living in America. These are all diversionary issues. They've been attacking labor and saying that it is because of labor that you don't have what you should have.

□ 1550

It's a political season, and so this is what they are doing with this bill. It's pitting the men against the women.

This bill seeks to prohibit discrimination against the unborn on the basis of gender, but it's really part of the divide-and-conquer approach that has been hugely successful for these Republicans. It would require doctors to become mind readers, ladies and gentlemen, and require them to determine what the sex of the child is and whether or not that is a factor in a woman's determination to have an abortion. It's ridiculous.

It's shameful many of the supporters of this bill are the same ones who voted to eliminate funding for Planned Parenthood and the Teen Pregnancy Prevention Initiative. That's funding that would have helped prevent unintended pregnancies. They also voted, ladies and gentlemen, to repeal, and repeatedly they have voted to repeal, the Affordable Care Act, which has improved the health of uninsured women and children. Recently, they supported Rush Limbaugh in his attack on women and access to contraception.

You see, this is part of the war on women. Wow. The record is shameful and it's clear.

Instead of divisive attacks on a woman's right to choose, we should unite behind policies that prevent unintended pregnancies in the first place. I urge a ''no'' vote.

Mr. FRANKS of Arizona. Mr. Speaker, I yield 1 minute to the gentlewoman from New York (Ms. BUERKLE), a member of the Oversight & Government Reform Committee.

Ms. BUERKLE. I thank the gentleman from Arizona for his excellent work on this important bill.

I rise this afternoon in support of H.R. 3541 as a woman, as a mother of four daughters, and as a grandmother of three granddaughters.

Mr. Speaker, there can be no rights for women if we don't allow them the right to life. What we are hearing from the other side this afternoon is about money and about political campaigns and about the rhetoric of the war on women. This is the ultimate war on women, Mr. Speaker. If we don't allow women to be born, we cannot talk about any other rights.

So I stand here today, and I urge all of my female colleagues in this House of Representatives to stand together and support H.R. 3541.

Mr. CONYERS. Mr. Speaker, I yield 2 minutes to the distinguished physician, the gentleman from Washington, the Honorable Dr. MCDERMOTT.

(Mr. MCDERMOTT asked and was given permission to revise and extend his remarks.)

Mr. MCDERMOTT. Mr. Speaker, as I listen to this debate, I am not sure if we are talking about India or China, but where are we talking about here? The Republicans have set up another straw man.

This bill is another Republican attack on women's rights at the same time it's masquerading as an anti-discrimination bill. It's about as cynical and deceptive as anything I've seen on the floor.

I ask the proponents of this bill: If you care, Mr. Speaker, if they care about discrimination against women, why did they vote in the last Congress against women's rights to challenge gender-based pay discrimination? Why did you also vote to allow health insurers to continue charging women higher premiums based on their sex?

These votes are on the record. That's what you think of women.

My friend, this bill is not what it claims to be. It is not about fighting discrimination against women. It is the opposite. It is another Republican intrusion into a woman's right to choose. Women should be able to make such

sensitive and private decisions with their families, their doctors, and their God, free from the fear of the police.

What are you going to do, set up a registry every time they do a sonogram and they decide what the baby is, girl or boy, they are going to post it and then they are going to follow? If that woman then decides to have an abortion, well, she is getting rid of a girl, so we are going to criminally charge her with making that decision on the basis of the sex of the child. That's what kind of nonsense you are setting up.

For people who don't want government in people's lives, who argue over and over and over about keeping the government—in fact, we don't want ObamaCare. We don't want government in our lives at all. But in this one, you want them to go right into the personal mind of the woman and decide and criminally charge her.

Do you think that's going to do any good? You simply are attacking women's rights.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair will remind Members to speak in the third person, not in the second person, in their remarks on the floor.

Mr. FRANKS of Arizona. Of course, the gentleman knows there's no criminal thing in this bill for the women. That's an unfortunate fallacy.

I yield 1½ minutes to the gentleman from Louisiana, Dr. FLEMING, a member of the Armed Services Committee.

Mr. FLEMING. I want to thank the gentleman, Mr. FRANKS of Arizona, for authoring this fine bill.

You know, I find that gender-oriented abortion is problematic for two reasons. Number one is very obvious. The taking of an innocent life merely because that child happens to be a boy or a girl certainly goes against all the values that we hold true in America. But, secondly, because of the technology requiring that you are well into the second trimester even to determine the gender of the fetus means that we're talking about a mid- to late-term abortion, something that is so brutal.

Mr. Speaker, as a family physician and a father of four, two boys and two girls, I have delivered over 300 babies in my career. Each and every child, regardless of his or her gender, is a unique individual, deserving of equal protection under the law. The American people agree with me on this. In fact, polls show that over two-thirds of Americans are supportive of eliminating abortion practices tailored to destroy babies because of their gender.

Gender aside, which is really what this is, the deliberate annihilation of a particular sex, often unborn female children, as we know, generally occurs midway through pregnancy. These late-term abortions are grisly procedures, where the condemned is often poisoned or dismembered before being extracted from the womb, sometimes in pieces. Medical evidence shows that, at a minimum, unborn babies can experience pain at 20 weeks.

I ask my colleagues to support this bill, H.R. 3541.

Mr. CONYERS. Mr. Speaker, I yield 3 minutes to the former chair of the Congressional Black Caucus, the gentlewoman from Oakland, California, BARBARA LEE.

Ms. LEE of California. First, let me thank Congressman CONYERS for yielding the time, but also for your very bold and relentless leadership as our ranking member on the House Judiciary Committee.

I rise today as a member of the Congressional Pro-Choice Caucus and also as the Health Care Task Force chair of the Congressional Asian Pacific American Caucus. I rise in strong opposition to this bill.

□ 1600

Supporters of this bill claim that the legislation would combat sex-selection abortion and prevent the United States from becoming a safe haven for women seeking an abortion based on the sex of the pregnancy.

Here we go again. This war on women continues. And this, quite frankly, is a shocking battle in this war. It really is shock and awe.

Don't get me wrong. Of course we all are opposed to sex-selection abortion based on gender. That's not what this is about. This is about women's health care and gender discrimination.

Let me read a paragraph from a letter signed by the American Congress of Obstetricians and Gynecologists and other groups:

> If passed into law, this bill would require that medical and mental health professionals violate doctor-patient confidentiality and report known or suspected violations of the law to law enforcement authorities. The penalty for failure to report is a fine or incarceration of up to 1 year.

Shock and awe. This is a continuation of the war on women.

There are those who have been actively working to reverse much of the progress women have made by declaring this war on women that includes stripping reproductive rights for women and cutting critical Title X funding and for the WIC nutrition program for low-income infants and pregnant women. And yes, this war on women continues with slashed funding for food stamps and day care spending.

Let's call it what it is, Mr. Speaker. Supporters of this bill really are exploiting serious issues like racism and sexism in a backdoor attempt to make abortion illegal. It would also lead to further stigmatization of women, especially Asian Pacific American women, who seek their constitutional rights to an abortion.

The ramifications are real, and they are very dangerous. Attempts to restrict or deny access to safe abortions is harmful to women's health and would ultimately take us back to the days of back-alley abortions.

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

Mr. CONYERS. I yield the gentlelady 1 additional minute.

Ms. LEE of California. I thank the gentleman.

If this bill passes, it would forever change the doctor-patient relationship as we know it by casting suspicion on doctors that serve communities facing the greatest health disparities, many of which are minority communities.

As a woman of faith, I have always believed that decisions about whether to choose adoption, end a pregnancy, or raise a child must be left to a woman, her family, and her faith, with the counsel of her doctor or health professional. Politics—government—has no place preventing doctors and other health professionals from informing patients about all their health care options, and doctors should not be criminalized for providing constitutionally protected care.

If supporters are really serious about advancing the real interest of women, I urge them to vote ''no'' on this bill. We need to work together to ensure that all women have meaningful access to the health care that they need to stay healthy and to improve their own lives and their children's lives.

We need to make sure that women get equal pay for equal jobs.

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

Mr. CONYERS. I yield the gentlewoman an additional 15 seconds.

Ms. LEE of California. I just want to conclude by saying if you really care about women and their children and their families, we need to work to end wage discrimination in this country. We need to work to end domestic violence that's tearing apart families across this country and reauthorize a real Violence Against Women's Act. We need to reject this insidious attack on Roe v. Wade.

Mr. FRANKS of Arizona. Mr. Speaker, I yield 2½ minutes to the gentleman from Florida (Mr. STEARNS), a member of the Energy and Commerce Committee.

Mr. STEARNS. Let me say to the gentlelady and to Mr. JOHNSON and Mr. NADLER: This is a war on ethics or WOE. You talk about a war on women. This is a war on ethics. Woe to you if you vote against this bill.

Mr. NADLER was down here talking about this bill and how he's going to vote against it. But let me ask you: Is there anybody in this Chamber that wants to vote against sex-selection abortion? Is that what you want to do? The coercion of sex-selection abortion, is that what you want to do? The solicitation or acceptance of funds for sex-selection abortion, you want to vote against that? And lastly, the transportation of a woman into the country to obtain a sex-selection abortion, you want to vote against that?

Woe to you. War on ethics. This is wrong for you to do that.

In a recent letter, the Planned Parenthood has once again chosen to put profits before women's well-being and is encouraging Members of Congress to

oppose this legislation, reinforcing sex discrimination and positioning the United States of America as a safe haven for those who cannot legally acquire a sex-selection abortion in their own home countries. But this is not surprising, considering Planned Parenthood's record.

As chairman of the Energy and Commerce Committee's Subcommittee on Oversight and Investigations, I have led an investigation into Planned Parenthood's use of the more than $1 million of Federal funds they receive every day and their compliance with sexual assault and child abuse reporting laws. This was the first ever such investigation in Planned Parenthood's history.

Planned Parenthood has an extensive and well-documented record of improper Medicaid billing practices—all of you know that; you can go to the State of California and New York and read about those indictments—and violating State sexual assault and child abuse reporting laws and of encouraging young girls to simply lie about their ages to circumvent State reporting laws.

These four things in this bill, woe to you—war on ethics—if you vote against this bill. And I am just amazed that people of strong religious belief would come on this floor and say that you're going to believe that sex-selection abortion is okay. I can't even comprehend what you're doing.

So let me just close by saying I encourage all of my colleagues, both Democrats and Republicans, to support this lifesaving legislation and ban sex-selection abortions and to send a clear message that each and every girl is valued in our society.

My colleagues, with passage of this critical legislation, the United States will finally join the rest of the industrialized world in prohibiting the barbaric practice of using abortion as a method of sex selection. It is astounding that in a country that prohibits discrimination on the basis of sex in various contexts, such as employment, education, and housing, it is legal to abort a child simply because she's a girl.

Pure and simple, these abortions are female infanticide. The victims of sex-selection abortion are overwhelmingly female, and most sex-selection abortions are grisly, later-term abortions, likely occurring after the child becomes capable of feeling pain.

In a recent letter, Planned Parenthood has once again chosen to put profits before women's well-being and is encouraging Members of Congress to oppose this legislation, reinforcing sex discrimination and positioning the U.S. as a safe haven for those who cannot legally acquire a sex-selection abortion in their home countries. But this is not surprising considering Planned Parenthood's record.

A recent undercover investigation by Live Action once again exposed Planned Parenthood's hypocrisy and anti-life ideology by showing a Planned Parenthood facility located in Austin, Texas knowingly facilitating the sex-selective abortion of a baby girl. Even going so far as to coach a late term abortion, in order to confirm that the baby was the unwanted sex. The video also shows the Planned Parenthood employee instructing a young woman about how to commit Medicaid fraud.

As Chairman of the Energy and Commerce Committee's Subcommittee on Oversight and Investigations, I have led an investigation into Planned Parenthood's use of the more than $1 million federal dollars they receive everyday and their compliance with sexual assault and child abuse reporting laws. This was the first ever such investigation in Planned Parenthood's history. Planned Parenthood has an extensive and well-documented record of improper Medicaid billing practices, violating state sexual assault and child abuse reporting laws, and of encouraging young girls to lie about their ages to circumvent state reporting laws.

I encourage all of my colleagues to support this life-saving legislation and ban sex-selective abortions and to send the clear message that each and every girl is valued in our society.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair will again remind all Members to address their remarks to the Chair, not to one another, and to avoid references in the second person.

Mr. CONYERS. I reserve the balance of my time.

Mr. FRANKS of Arizona. Mr. Speaker, can I inquire as to the remainder of the time?

The SPEAKER pro tempore. The gentleman from Arizona has 5 minutes remaining. The gentleman from Michigan has 5¼ minutes remaining.

Mr. FRANKS of Arizona. I yield 2 minutes to the gentlelady from Tennessee (Mrs. BLACKBURN), a member of the Energy and Commerce Committee.

Mrs. BLACKBURN. I rise in support of the Prenatal Nondiscrimination Act, and I thank the gentleman from Arizona for his leadership on the issue.

Simply put, this bill gives baby girls the same chance at life as our baby boys, Mr. Speaker. I think it's hypocrisy to say that one is pro-woman and that it's okay to end the life of an unborn child just because of its gender. Since when did America subscribe to the idea that males are worth more than females?

We know that sex-selection abortions happen all over the world, as was evidenced and certainly brought to light by human rights activists like Mr. Chen, who fled to America this month. But according to at least six academic studies published in the past 4 years, this tragic reality is playing out in our own backyard. Just this week, an undercover video showed a Planned Parenthood employee encouraging a woman to obtain a late-term abortion because she was purportedly carrying a girl, and she wanted to have a boy instead.

A vote against ending sex-selection abortion is a vote in favor of gender bias and female gendercide. A vote against is a vote for organized and systematic subtraction of women in America through targeted abortions. It's sick, it's discriminatory, it's sexist, and it's blatantly antiwoman and antihuman.

It's no surprise that a poll conducted this month by the Charlotte Lozier Institute showed 80 percent of women in this country support a law banning abortion in cases where the sole reason for seeking an abortion is that the developing baby is female.

I support the legislation, and I urge my colleagues to do the same.

□ 1610

Mr. CONYERS. Mr. Speaker, I yield myself such time as I may consume.

I would just like to remind my colleagues that from the Leadership Conference on Civil and Human Rights, we have this warning:

> We oppose this bill because it does not in any way adjust discrimination on the basis of sex or race. Rather, it is a veiled attempt to restrict health care for women of color under the guise of civil rights.

This is the Leadership Conference on Civil and Human Rights.

This bill tramples the rights of women under the guise of nondiscrimination while doing absolutely nothing to provide women with needed resources for their babies, female and male, so they can come into this world healthy and so both the mother and the child can thrive.

This measure before us does absolutely nothing to empower women to make important life choices free from any family or community pressures they now face either to have an abortion, or to carry the pregnancy to term. In fact, it fails to employ the tested solutions that will reduce the pressures brought to bear on women to have sons. Experience around the world has shown that supporting women, providing them with tools to become independent and to be safe from violence, rather than criminal prohibitions, helps them resist the pressures of son preference. International organizations such as the United Nations Population Fund, the Office of the United Nations High Commissioner for Human Rights, the United Nations Children's Fund, United Nations Women, and the World Health Organization have all said that abortion restrictions are not the solution because they put women's health and lives at risk and violate their human and reproductive rights.

Please, join us and these organizations who are familiar with the phenomenon of son preference and oppose H.R. 3541.

I reserve the balance of my time.

Mr. FRANKS of Arizona. Mr. Speaker, I would now yield 2½ minutes to the distinguished gentleman from New Jersey (Mr. SMITH) who is a member of the Foreign Affairs Committee, where he is the chairman of the Africa, Global Health, and Human Rights Subcommittee.

Mr. SMITH of New Jersey. Mr. Speaker, I thank my good friend TRENT FRANKS for his extraordinary leadership and courage. He is a pro-life champion.

Mr. Speaker last year, an undercover videotaped sting operation by Live Action exposed several Planned Parenthood affiliates who are eager, ready,

and willing to facilitate secret abortions for underage sex trafficking victims—some as young or younger than 14.

As the prime sponsor of the Trafficking Victims Protection Act, I found the on-the-record willingness of Planned Parenthood personnel to exploit young girls and partner with sex traffickers to be absolutely appalling.

Now Live Action has released another sting operation video—part of a new series, ''Gendercide: Sex Selection in America''—showing Planned Parenthood advising an undercover female investigator how to procure a sex-selection abortion.

Caught on tape, Planned Parenthood tells the investigator to wait until the baby is 5 months along to get an ultrasound that reveals the sex of the child. Then, if it's a girl, kill it.

Yesterday, The Huffington Post reported: ''No Planned Parenthood clinic will deny a woman an abortion based on her reasons for wanting one, except in States that explicitly prohibit sex-selection abortions.''

In other words, Planned Parenthood is okay with exterminating a child in its huge network of clinics simply because she's a girl. What a dangerous place for little girls. Let's not forget that Planned Parenthood aborts approximately 330,000 children every year. This, Mr. Speaker, is the real war on women.

For most of us, Mr. Speaker, ''it's a girl'' is cause for enormous joy, happiness, and celebration. But in many countries, including our own, it can be a death sentence. Today, the three most dangerous words in China and India are ''it's a girl.'' We can't let that happen here.

In her book ''Unnatural Selection,'' Mara Hvistendahl traces the sordid history of sex-selection abortion as a means of population control. She writes that by August of 1969, ''sex selection had become a pet scheme''—fewer girls, fewer future mothers, fewer future children.

At a 1969 conference, Christopher Tietze co-presented sex-selection abortion as one of the 12 new strategies representing the future of population control. He, by the way, got the Margaret Sanger Award 4 years later.

Sex-selection abortion is cruel, it's discriminatory, and it's legal. It is violence against women. Most people in government are unaware that it is part of a deliberate plan of population control. Support the Prenatal Nondiscrimination Act, sponsored by Mr. FRANKS.

Last year, an undercover video-taped sting operation by Live Action (liveaction.org) exposed several Planned Parenthood affiliates who were eager, ready and willing to facilitate secret abortions for underage sex trafficking victims—some as young or younger than 14—to get them on the streets again.

As the prime sponsor of the Trafficking Victims Protection Act, I found the on-the-record willingness of Planned Parenthood personnel to exploit young girls and partner with sex traffickers to be absolutely appalling.

Now Live Action has released another sting operation video—part of a new series, Gendercide: Sex Selection in America—showing Planned Parenthood staff advising an undercover female investigator how to procure a sex-selection abortion.

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By now most people know that the killing of baby girls by abortion or at birth is pervasive in China due to the One Child policy and a preference for sons. China and India are ''missing'' tens of millions of daughters.

In her book, Unnatural Selection: Choosing Boys Over Girls, and the Consequences of a World Full of Men, Mara Hvistendahl, traces the sordid history of sex-selection abortion as a means of population control. ''By August 1969, when the National Institute of Child Health and Human Development and the Population Council convened another workshop on population control, sex selection had become a pet scheme . . . Sex selection, moreover, had the added advantage of reducing the number of potential mothers . . . if a reliable sex determination technology could be made available to a mass market,'' there was ''rough consensus'' that sex selection abortion ''would be an effective, uncontroversial and ethical way of reducing the global population.''

Fewer women, fewer mothers, fewer future children.

At the conference, one abortion zealot, Christopher Tietze co-presented sex selection abortion as one of twelve new strategies representing the future of global birth control. Planned Parenthood honored Tietze four years later with the Margaret Sanger Award.

(I would note parenthetically, in March of 2009, Secretary of State Hillary Clinton also received the Margaret Sanger Award and said in her acceptance speech that she was ''in awe'' of Margaret Sanger, the founder of Planned Parenthood. To our distinguished Secretary of State, I respectfully ask: Are you kidding? In ''awe'' of Margaret Sanger, who said in 1921, ''Eugenics . . . is the most adequate and thorough avenue to the solution of racial, political, and social problems.'' And who also said in 1922, ''The most merciful thing that a family does to one of its infant members is to kill it.''

Secretary Clinton in her speech said that Margaret Sanger's ''life and leadership'' was ''one of the most transformational in the entire history of the human race.'' Mr. Speaker, transformational, yes, but not for the better if one happens to be a woman, poor, disenfranchised, weak, a person of color, vulnerable, or among the many so-called undesirables who Sanger would exclude and exterminate from the human race.)

Mr. Speaker, these cruel, anti-woman policies have had horrific consequences.

Hvistendahl writes that today ''there are over 160 million females ''missing'' from Asia's population. That's more than the entire female population of the United States. And gender imbalance—which is mainly the result of sex selective abortion—is no longer strictly an Asian problem. In Azerbaijan and Armenia, in Eastern Europe, and even among some groups in the United States, couples are making sure at least one of their children is a son. So many parents now select for boys that they have skewed the sex ratio at birth of the entire world.''

In the Global War Against Baby Girls renowned AEI demographer Nicholas Eberstadt wrote in The New Atlantis last Fall; ''over the past three decades the world has come to witness an ominous and entirely new form of gender discrimination: sex-selective feticide, implemented through the practice of surgical abortion with the assistance of information gained through prenatal gender determination technology. All around the world, the victims of this new practice are overwhelmingly female—in fact, almost universally female. The practice has become so ruthlessly routine in many contemporary societies that it has impacted their very population structures, warping the balance between male and female births and consequently skewing the sex ratios for the rising generation toward a biologically unnatural excess of males. This still-growing international predilection for sex-selective abortion is by now evident in the demographic contours of dozens of countries around the globe—and it is sufficiently severe that it has come to alter the overall sex ratio at birth of the entire planet, resulting in millions upon millions of new ''missing baby girls'' each year. In terms of its sheer toll in human numbers, sex-selective abortion has assumed a scale tantamount to a global war against baby girls.''

As far back as 1990, Nobel Prize winner Amartya Sen wrote in The New York Review of Books that ''More than 100 Million Women are Missing.'' In 2003 Sen wrote that sex-selection abortion was the primary cause.

A 2008 study by Douglas Almond and Lena Edlund of Columbia University documented ''male-biased sex ratios among U.S. born children of Chinese, Korean and Asian Indian parents in the 2000 U.S. census. The male bias is particularly evident for third children: If there was no previous son, sons outnumbered daughters by 50 percent . . . We interpret the found deviation in favor of sons to be evidence of sex selection, most likely at the prenatal stage.''

A study published in 2011 by Sunita Pun and three other researchers undertook ''in-depth interviews with 65 immigrant Indian women in the United States who had pursued fetal sex selection on the East and West Coasts of the United States between September 2004 and December 2009 . . .'' and found ''that 40% of the women interviewed had terminated prior pregnancies with female fetuses and that 89% of women carrying female fetuses in their current pregnancy pursued an abortion.''

Many European nations including the UK as well as several Asian countries ban sex selection abortion. Only four US states—Arizona, Illinois, Oklahoma and Pennsylvania—proscribe it.

The United States is a destination country for sex selection abortion. According to the House Judiciary Committee Report, ''women cross the border from Canada (where it is illegal) to obtain sex selection abortions in the United States.''

The Prenatal Nondiscrimination Act, authored by pro-life champion Congressman TRENT FRANKS, seeks an end to this pernicious form of violence against women by prescribing criminal and civil penalties on abortionists who knowingly perform an abortion based on sex or gender of the child.

If enacted, the Act will also penalize anyone who uses force or the threat of force to intentionally injure or intimidate any person for the purpose of coercing a sex selection abortion. This anti-coercion provision is an extremely important protection for women.

According to the House Judiciary Committee Report; ''sex-selection abortions are oftentimes coerced.'' The Report notes ''women who refuse sex-selection abortions are sometimes physically abused. A woman may be denied food, water, and rest to induce abortion where it is determined that the woman is carrying a female unborn child. Some women described being hit, pushed, choked and kicked in the abdomen in a husband's attempt to terminate a female unborn child. Pregnancy is already a vulnerable time for women; the most common cause of death for pregnant women in the United States is homicide, often at the hands of the unborn child's father.''

And the Act will hold accountable anyone who knowingly solicits or accepts funds for the performance of a sex selection abortion or transports a woman into the U.S. or across a state line for a sex selection abortion.

Sex-selection abortion is cruel and discriminatory and legal. It is violence against women. Most people in and out of government remain woefully unaware of the fact that sex-selection abortion was—a violent, nefarious and deliberate policy imposed on the world by the pro-abortion population control movement—it's not an accident. The Congress can—and must—defend women from this vicious assault today.

Mr. CONYERS. Mr. Speaker, I yield myself the balance of my time.

Ladies and gentlemen of the House, if this measure is passed into law, we would then require that medical and mental health professionals violate doctor-patient confidentiality and report ''known or suspected violations'' of the law to law enforcement authorities. The penalty for failure to report would be a fine or incarceration.

Now, it is not by accident, Members of the House, that this measure is opposed by these outstanding organizations: the American Congress of Obstetricians and Gynecologists; American Public Health Association; Association of Reproductive Health Professionals; American Society for Reproductive Medicine; Medical Students for Choice; National Abortion Federation; National Association of Nurse Practitioners in Women's Health; National Family Planning and Reproductive Health Association; Physicians for Reproductive Health and Choice; and Planned Parenthood Federation of America.

Now, this is something that would chill communications between doctors and patients because doctors might hear something that would put them at risk for criminal prosecution, and patients because they would fear that their conversations with their doctors would not remain private. And so what we're doing here is taking the most drastic step that would cause these nine organizations to oppose this legislation.

Mr. Speaker, I yield back the balance of my time.

Mr. FRANKS of Arizona. Mr. Speaker, I don't have time to correct all of the misinformation that my friends on the other side of the aisle have said here today. They've talked about everything but what this bill does.

If I thought that America really supported aborting little girls because they were little girls as a people, then I guess I would conclude that the light of human compassion had gone out in our society and it was time to board this place up and go home and be done with it. But, fortunately, Mr. Speaker, I know that 86 percent of the American people favor protecting little girls from sex-selection abortion, and that gives me great hope. I wish I had time to mention all of the groups that are in favor of this bill, but I know that this is going to be the first step, and we're going to be on the right side of history and the right side of justice, and I urge a ''yes'' vote on this bill.

I yield back the balance of my time.

Mr. PAUL. Mr. Speaker, as an OB-GYN who has delivered over 4,000 babies, I certainly abhor abortion. And I certainly share my colleagues' revulsion at the idea that someone would take an innocent unborn life because they prefer to have a child of a different gender.

However, I cannot support H.R. 3541, the Prenatal Nondiscrimination Act, because this bill is unconstitutional. Congress's jurisdiction is limited to those areas specified in the Constitution. Nowhere in that document is Congress given any authority to address abortion in any manner. Until 1973, when the Supreme Court usurped the authority of the States in the Roe v. Wade decision, no one believed or argued abortion was a Federal issue.

I also cannot support H.R. 3541 because it creates yet another set of Federal criminal laws, even though the Constitution lists only three Federal crimes: piracy, treason, and counterfeiting. All other criminal matters are expressly left to States under the Ninth and Tenth Amendments, and criminal laws relating to abortion certainly should be legislated by States rather than Congress.

I have long believed that abortion opponents make a mistake by spending their energies on a futile quest to make abortion a Federal crime. Instead, pro-life Americans should work to undo Roe v. Wade and give the power to restrict abortion back to the States and the people. It is particularly disappointing to see members supporting this bill who rightfully oppose ludicrous interpretations of the Commerce Clause when it comes to the national health care law, which also abuses the Commerce Clause to create new Federal crimes.

Pro-life Americans believe all unborn life is precious and should be protected. Therefore we should be troubled by legislation that singles out abortions motivated by a ''politically incorrect'' reason for special Federal punishment. To my conservative colleagues who support this bill: what is the difference in principle between a Federal law prohibiting ''sex selection'' abortions and Federal hate crimes laws? After all, hate crime laws also criminalize thoughts by imposing additional stronger penalties when a crime is motivated by the perpetrator's animus toward a particular race or gender.

I also question whether this bill would reduce the number of abortions. I fear instead that every abortion provider in the Nation would simply place a sign in their waiting room saying ''It is a violation of Federal law to perform an abortion because of the fetus' gender. Here is a list of reasons for which abortion is permissible under Federal law.''

Mr. Speaker, instead of spending time on this unconstitutionally, ineffective, and philosophically flawed bill, Congress should use its valid authority to limit the jurisdiction of activist Federal courts and (thereby) protect state laws restoring abortion. This is the constitutional approach to effectively repealing Roe v. Wade. Instead of focusing on gimmicks and piecemeal approaches, true conservatives should address the horror of abortion via the most immediate, practical, and effective manner possible: returning jurisdiction over abortion to the States.

Mr. STARK. Mr. Speaker, I rise in opposition to the so-called Prenatal Non-Discrimination Act, H.R. 3541. This legislation is the latest Republican attack on women's health and would actually criminalize doctors who provide reproductive health care to women.

Proponents of this bill claim the mantle of civil rights, arguing it will prevent abortions based on the gender of the fetus, particularly when female. We should not be fooled by this claim. The true goal of this legislation is to erode women's reproductive choices and Constitutional rights while further stigmatizing women who've had—or are seeking—an abortion.

Restricting reproductive health services to women will not eliminate or even lessen gender bias. If we truly want to end gender discrimination, there are rational, effective ways to do so: ensuring our communities have the resources they need to address cultural preferences for male children, educating individuals about contraception and family planning, and providing access to quality health care. This bill addresses none of these worthy goals. Not surprisingly, the sponsors of this legislation don't support funding for family planning, comprehensive sex education, access to affordable birth control, or pay equity.

In addition to undercutting women's rights, this bill punishes health care providers who perform abortions. Specifically, this legislation imposes criminal penalties on doctors who perform abortions if the sex of the fetus is found to be a factor in a woman's decision to terminate her pregnancy. Furthermore, abortion providers would receive a one-year prison term and lose Federal funding if they fail to report a ''suspected'' gender-based abortion. In other words, Republicans want to criminalize health care professionals who cannot guess a

woman's very personal reasons to have an abortion or who refuse to violate the doctor-patient relationship by telling the government about private conversations with patients.

Let's be clear: this bill is not about ending sex selection or protecting women's rights. It is about Republicans trying to take away a woman's right to choose. To claim this legislation is about ''civil rights'' is reprehensible. I urge my colleagues to join me in opposing this bill and to work toward actual gender equality.

Mr. FARR. Mr. Speaker, the bill we are debating today, the Prenatal Nondiscrimination Act, purports to address gender discrimination by preventing abortions on the basis of sex. While one of the most effective ways to end gender discrimination is to empower women, H.R. 3541 only serves to marginalize women even further. Today, minority women have to overcome additional hurdles to receive the quality healthcare they deserve and this legislation only serves to subject them to even further scrutiny when making healthcare decisions.

This legislation restricts women's access to reproductive healthcare by threatening doctors with up to five years in prison and other penalties if they perform sex selection abortions. If the drafters of H.R. 3541 were really trying to end sex-selective abortions, wouldn't they also be prosecuting those who sought an abortion for these reasons, not only doctors? With doctors fearful of yet even more restrictions to their practice, many will simply refuse to treat women who want to obtain a safe and legal abortion. After all, abortion is still a constitutionally guaranteed right in this country.

In addition, this bill includes language requiring any medical or mental health professional to report known or suspected sex-selective abortions. However, in virtually all circumstances, it would be impossible for reproductive healthcare providers to determine whether a woman seeks a sex-selective abortion, thus amounting to a ''witch hunt''.

I am lucky enough to be surrounded by women in my family. I have a wife, a sister, a daughter, and a granddaughter. I am deeply troubled by gender discrimination. I support legislation to address the real issues in low-income communities of color, and to promote women's rights, including: S. 1925, the reauthorization of the Violence Against Women Act; H.R. 1519, the Paycheck Fairness Act; and H.J. Res. 69, proposing an amendment to the Constitution on the equal rights for men and women. Since the Majority is so concerned with gender discrimination, I look forward to the day when the Republican leadership decides to bring these bills on the floor for a vote.

Mr. Speaker, I am completely opposed to sex-selective abortions but H.R. 3541 will not prevent these and, in fact, will do far more harm than good.

Mr. DAVIS of Illinois. Mr. Speaker, I cannot support H.R. 3541, the Republican bill that rolls back critical protections for a women's right to choose under the guise of preventing prenatal discrimination. While the bill's title includes the names of anti-discrimination activists Susan B. Anthony and Frederick Douglas, its anti-discrimination premise is disingenuous—the bill actually reverses the rights that these leaders fought so hard for centuries ago. Rather than protecting women, this bill is just another thinly-veiled attack on women's rights.

H.R. 3541 is legislation for a fictional problem. Statistics demonstrate that sex selection does not happen with regularity in our nation. Specifically, the Centers for Disease Control reported that 91.4% of abortions in 2008 occurred prior to the 13th week of pregnancy, whereas gender identification by the most-common method of ultrasound is not available until between weeks 16 to 20. Further, gender ratios within the U.S. reflect a gender balance consistent with what one would expect it to be. The CIA's World Factbook indicates that the gender ratio at birth 1.05 males to females, which the Guttmacher Institute indicates is ''squarely within biologically normal parameters.'' The United States simply does not have a gender imbalance that would indicate that sex-selection occurs with any regularity. So, if gender selection is not a problem in the United States, one must wonder why the Republican leadership purports it to be one. The answer is that the bill before us simply is a deceptive effort to limit women's choice.

Gender inequity should concern all of us. That we still live in a society that provides preferential treatment to men is deeply disturbing, and Congress should feel compelled to act to correct these inequities. Unfortunately, rather than promoting equal pay for women, advancing protections for all women from domestic violence, increasing access to affordable health care for all women, or addressing racial disparities in health care among women, the Republican leadership offers H.R. 3541 that would undermine the constitutional rights of women under a false cry of gender discrimination. This bill would encourage racial profiling, create additional barriers for women to access comprehensive health care, allow the government to interfere with confidential communications between doctors and their patients, and threaten physicians with criminal penalties for open, honest communication with their patients.

So, I stand with dozens of diverse organizations—including the American Congress of Obstetricians and Gynecologists, American Society for Reproductive Medicine, NAACP, the American Civil Liberties Union, the American Public Health Association, Presbyterian Voices for Justice, and the National Women's Law Center—to strongly oppose House Republican bill H.R. 3541. As twenty-first-century policymakers, we should advance the rights of women and minorities, not weaken them. I vehemently oppose this dangerous and discriminatory bill that would limit women's health care options.

Mr. SMITH of Texas. Mr. Speaker, I would like to thank Chairman FRANKS for introducing the Prenatal Nondiscrimination Act, also called PRENDA. This legislation prohibits abortions based on the sex of the unborn child.

The bill also prohibits the solicitation or acceptance of funds for such purposes and prohibits the federal funding of abortions based on sex.

As the New York Times has reported, ''There is evidence that some Americans want to choose their babies' sex'' through abortions.

U.S. Census numbers and national vital statistics show that certain communities achieve unnatural sex ratios at birth that are statistically impossible without medically assisted sex-selection, with the cheapest option being abortion.

These sex-selection abortions discriminate strongly against females and are overwhelmingly opposed by the American people. According to a recent Charlotte Lozier Institute poll, 77% of those surveyed support a law that bans abortion in cases where ''the fact that the developing baby is a girl is the sole reason for seeking an abortion.''

Regardless of one's views on abortion generally, everyone should be able to agree that no abortions should occur based on the sex of the unborn child.

It is time to end the practice of using sex as an excuse for abortion. I thank Chairman FRANKS again for his leadership on this issue.

Ms. RICHARDSON. Mr. Speaker, I rise today in opposition to H.R. 3541, the Prenatal Nondiscrimination Act of 2011. I stand with the more than 200 leading organizations that oppose this bill as an unwanted and punitive burden on American women. I stand with those who are focused on women's empowerment and the protection of their civil liberties.

This bill is a misguided proposal that would put additional barriers between women and their healthcare providers rather than seriously tackling gender discrimination. It is an unworkable bill designed with a purely political agenda that will have a damaging effect on women's health and autonomy.

This legislation imposes criminal penalties on healthcare providers who perform certain abortions and requires them to report suspicions of sex-selective abortion. The bill lacks clear definitions and is so dangerously vague that it will force all healthcare providers to stop offering these services due to fear of jail time and civil damages claims. For instance, prosecutors could use shaky circumstantial evidence to suggest gender bias, including routine ultrasounds or profiling based on race or culture.

There rarely exists evidence strong enough to conclude that an abortion is motivated by the sex or any other singular factor. The World Health Organization has analyzed similar laws around the world that criminalize sex-selective abortions but has found that it is nearly impossible to prosecute such cases. The United Nations has argued that the most effective way to fight a pervasive preference for sons is to instead dedicate ourselves to ending economic and social inequalities. By passing H.R. 3541, we would stand at odds with the international community.

As a representative of the 37th District of California, I am particularly concerned that this bill will unfairly subject Asian American women to additional scrutiny and racial profiling. It is unclear to what extent sex-selection abortions exist in the United States; however, the law specifically targets women of Asian descent and places them under a cloud of suspicion. Minority communities already face difficulties in accessing healthcare, and this bill will cause further marginalization.

We should be uniting around healthcare reform, not legislation that erodes trust on both sides of the patient-doctor relationship. Honest dialogue between women and medical professionals is critical in ensuring safe and appropriate care, and I cannot vote for any bill that does not protect open communication. Medical practices are already governed by strict codes of conduct and regulations. This bill simply adds unnecessary government interference. It puts physicians at risk for criminal penalties while doing absolutely nothing to address root causes of gender biases and inequalities.

There are many proven investments that support women and girls and help them to

lead safe and healthy lives. Those include policies that promote equal pay and employment, access to healthcare, and protection from gender-based violence. Nevertheless, in the 112th Congress, House Republicans have voted in favor of reducing protections against gender-based violence and limiting access to reproductive healthcare and birth control.

H.R. 3541 continues this pattern of perpetuating gender inequalities by allowing the state to scrutinize the private decisions made by women and their doctors, notwithstanding the recent lip service being paid to gender discrimination. Additionally, this legislation will have no effect on the rates of abortions and unwanted pregnancies as long as the House Republican majority continues its unbroken and disturbing record of cutting public funding for sex education, family planning, and maternal health services.

Mr. Speaker, the sponsors of H.R. 3541 are continuing to attack the rights of women, albeit now under the disguise of gender equality. I urge my colleagues to see the hypocrisy of this bill and to join me in voting against this legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. FRANKS) that the House suspend the rules and pass the bill, H.R. 3541, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. FRANKS of Arizona. 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.

□ 1620

DIVISIONAL REALIGNMENT ACT OF 2012

Mr. COBLE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5512) to amend title 28, United States Code, to realign divisions within two judicial districts, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5512

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 ''Divisional Realignment Act of 2012''.

SEC. 2. REALIGNMENT WITHIN THE EASTERN DISTRICT OF MISSOURI.

Section 105(a) of title 28, United States Code, is amended—

(1) in paragraph (1), by striking ''Iron,'' and ''Saint Genevieve,''; and

(2) in paragraph (3)—

(A) by inserting ''Iron,'' after ''Dunklin,''; and

(B) by inserting ''Saint Genevieve,'' after ''Ripley,''.

SEC. 3. REALIGNMENT WITHIN THE NORTHERN DISTRICT OF MISSISSIPPI.

Section 104 of title 28, United States Code, is amended by striking subsection (a) and inserting the following:

''(a) The northern district comprises three divisions.

''(1) The Aberdeen Division comprises the counties of Alcorn, Chickasaw, Choctaw, Clay, Itawamba, Lee, Lowndes, Monroe, Oktibbeha, Prentiss, Tishomingo, Webster, and Winston.

''Court for the Aberdeen Division shall be held at Aberdeen, Ackerman, and Corinth.

''(2) The Oxford Division comprises the counties of Benton, Calhoun, DeSoto, Lafayette, Marshall, Panola, Pontotoc, Quitman, Tallahatchie, Tate, Tippah, Tunica, Union, and Yalobusha.

''Court for the Oxford Division shall be held at Oxford.

''(3) The Greenville Division comprises the counties of Attala, Bolivar, Carroll, Coahoma, Grenada, Humphreys, Leflore, Montgomery, Sunflower, and Washington.

''Court for the Greenville Division shall be held at Clarksdale, Cleveland, and Greenville.''.

SEC. 4. EFFECTIVE DATE.

The amendments made by this Act take effect on the 60th day after the date of the enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from North Carolina (Mr. COBLE) and the gentleman from Georgia (Mr. JOHNSON) each will control 20 minutes.

The Chair recognizes the gentleman from North Carolina.

GENERAL LEAVE

Mr. COBLE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous materials on H.R. 5512, as amended, currently under consideration.

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

There was no objection.

Mr. COBLE. Mr. Speaker, I yield myself such time as I may consume.

I support H.R. 5512, the Divisional Realignment Act of 2012, sponsored by Representative BENNIE THOMPSON.

On March 13, 2012, the Judicial Conference of the United States adopted a draft bill that realigns divisions within the Eastern District of Missouri and the Northern District of Mississippi. The Divisional Realignment Act of 2012 reflects the draft developed by the Judicial Conference which the Judiciary Committee marked up on May 16. The realignments equalize workloads among divisions, maximize the use of court facilities, and shorten commutes for jurors and attorneys.

The bill is supported by the judges and attorneys from the two judicial districts and affected Members from Missouri and Mississippi.

The Congressional Budget Office states that H.R. 5512 will have ''only minimal administrative costs and thus no significant impact on the Federal budget.''

The only changes to the bill subsequent to our markup is the effective date. The local judges and the Judicial Conference asked Representative BENNIE THOMPSON, the bill's sponsor, and the other members of the committee to include a 60-day delayed effective date. This provides the local judges in Mississippi and Missouri with more time to adjust their jury wheels to account for the new realignments. This is a good, commonsense change that helps with the administration of justice in the Northern District of Mississippi and the Eastern District of Missouri.

I hope, Mr. Speaker, that the Divisional Realignment Act of 2012 will be adopted by my colleagues, and I reserve the balance of my time.

Mr. JOHNSON of Georgia. Mr. Speaker, I yield myself such time as I may consume, and I rise in support of H.R. 5512, the Divisional Realignment Act of 2012, as amended.

This noncontroversial measure, which the Judiciary Committee ordered reported by voice vote, simply reorganizes divisions within the two Federal judicial districts, namely the Eastern District of Missouri and the Northern District of Mississippi. I hope I pronounced ''Missourah'' correctly. Some say ''Missourah,'' some say ''Missouri.'' I'll stick with ''Missourah'' right now—I'm feeling kind of down home.

This divisional realignment is being done at the request of these two districts to improve judicial administration and access to court for jurors and litigants. These proposals were formally adopted by the Judicial Conference of the United States on March 13, 2012, and transmitted to the House Judiciary Committee.

According to the Judicial Conference, these changes are supported by the judicial councils of the circuits in which these districts are located, as well as the United States Attorneys for the affected districts.

Under H.R. 5512, two counties in the Eastern District of Missouri will be shifted from its Eastern Division to its Southeastern Division. The bill also eliminates one of the four divisions within the Northern District of Mississippi and reallocates the counties within the eliminated division among the remaining three divisions.

The Members whose districts would be affected by these divisional changes—that being Representatives BENNIE THOMPSON, GREGG HARPER, ALAN NUNNELEE, JO ANN EMERSON, and RUSS CARNAHAN—have all sponsored or cosponsored this bill. In deference to these Members' familiarity with local conditions, therefore, we do not oppose these changes.

We have made one revision to H.R. 5512 at the request of the Judicial Conference. To give the judges in the two affected districts some additional time to implement the bill's new divisional realignments, the version of the bill that we are considering today includes a 60-day delayed effective date.

I thank Chairman LAMAR SMITH and Subcommittee Chairman HOWARD COBLE for their assistance in moving this bipartisan legislation that should improve the administration of justice in these judicial districts.

I reserve the balance of my time.

Mr. COBLE. I thank the gentleman from Georgia for his generous remarks.

Mr. Speaker, I am prepared to close, and I reserve the balance of my time.

Mr. JOHNSON of Georgia. Mr. Speaker, I yield as much time as he may consume to the gentleman from Mississippi (Mr. THOMPSON), the sponsor of this bill.

Mr. THOMPSON of Mississippi. Mr. Speaker, today I rise in support of my bill, H.R. 5512, the Divisional Realignment Act of 2012, which will improve court management for the United States District Courts in the Northern District of Mississippi and the Eastern District of Missouri.

I introduced this bill to help realign counties in those Federal judicial districts, which includes a change that affects counties within my own congressional district. I am pleased to have my colleagues in the Mississippi delegation who represent impacted counties join me as original cosponsors, Congressman HARPER and NUNNELEE. In Missouri, Representatives EMERSON and CARNAHAN, whose congressional districts overlay the counties affected by the change there, also joined as original cosponsors.

H.R. 5512 will primarily eliminate the Delta Division—one of four existing statutory divisions—in the Northern District of Mississippi. To accomplish this, the eight counties in the Delta Division will be absorbed into the other divisions, while some counties from the other divisions will be realigned.

The proposed also renames the Eastern Division as the Aberdeen Division and the Western Division as the Oxford Division. The two places authorized to hold court now for the Delta Division would continue to exist under the realignment within the Greenville division.

The Delta Division, unlike the other three divisions, is not serviced by a Federal courthouse. This fact has created unnecessary issues regarding venue and jury selection. The realignment will ensure that all counties in the district are statutorily linked to divisions with courthouses. It will also be more economical for jury travel and will more fairly balance the caseload in the Northern District.

This realignment is supported by the judges of the Northern District of Mississippi, the Fifth Circuit Judicial Council, and the Judicial Conference of the United States. In addition, the proposal is backed by the United States Attorney for the Northern District of Mississippi.

Regarding the Eastern District of Missouri, H.R. 5512 simply shifts two counties from the Eastern Division to the Southeastern Division.

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This adjustment will enhance convenient access to court services for the public and improve judicial administration of the case load.

More specifically, the realignment will allow cases for those two counties to be held in Cape Girardeau, which has a new state-of-the-art Federal courthouse. This location is also closer for citizens in those counties than in the St. Louis location where the court is now held. As a result, the change will lessen the burden on jurors traveling, as well as lessen the cost of mileage expenses. In addition, a shift will better align the places of holding court with the total population served today.

This realignment is supported by the judges of the Eastern District of Missouri, the Eighth Judicial Circuit Council, and the Judicial Conference of the United States. In addition, it is supported by the United States Attorney for the Eastern District of Missouri.

Lastly, I note that the bill under consideration today has been amended by adding a section that establishes a 60-day delayed effective date. This will ensure that both courts have sufficient time to transition court operations through local orders and scheduling.

Mr. Speaker, the House Judiciary Committee reported the Divisional Realignment Act favorably by a voice vote on May 16. I urge my colleagues to support this necessary, bipartisan and noncontroversial bill, which would help constituents and improve Federal court operations in my home State of Mississippi and in the State of Missouri.

Mr. JOHNSON of Georgia. Mr. Speaker, I yield back the balance of my time.

Mr. COBLE. I yield back the balance of my time.

Mr. Speaker, I rise today to debate H.R. 5512, the "Division Realignment Act of 2012." The Division Realignment Act of 2012 proposes to amend title 28, United States Code, to adjust divisions within two judicial districts. The realignment will occur between Missouri and Mississippi boundaries within the U.S. District Court. In response to population shifts and other factors, this legislation will transfer counties divisions in an effort to ensure more resourceful productivity on the district court level.

In particular, H.R. 5512 will separate the Northern District of Mississippi into three divisions consisting of, Aberdeen, Oxford and Greenville. Additionally, it seeks to amend Iron and Saint Genevieve Counties, in Missouri, from the eastern subdivision to the southeastern subdivision.

This legislation will aid in the equitable distribution of cases and administration functions for a faster and more efficient processing within the courts.

H.R. 5512 is necessary in maintaining the regulation of Federal statutory authority governing the Federal judicial system. The passage of this bill will assist in reducing case loads, promoting speedy trials, and ensuring that there is accurate jurisdiction within the federal districts among the states.

It is essential that we continue to aim for judicial effectiveness and sufficiency while adjusting to the continued growth and shifts within our communities.

Consistency is critical when the issue of judicial efficiency arises. It should be noted that while this legislation was acted upon swiftly, other important acts have failed to follow it its path. Proficiency within our courts is imperative therefore I encourage the Senate to act on President Obama's nominees so that American citizens can rely on an organized and effective judicial system.

As noted by Senator LEAHY, Chairman of the Senate Judiciary Committee, despite the political party of the President in office, nominations to fill the positions of federal district court judges have always been confirmed quickly with deference given to the home state Senators who best know the nominees and their states. Never before in the Senate's history have the district court nominees been blocked for months as we have seen since President Obama's election.

Like many of my colleagues, it is my hope that both Republicans and Democrats in the Senate can end the damage of filibusters and quickly work toward the purpose of easing the burdens on our Federal courts that risk delaying justice.

Federal district court judges play an essential role in ensuring that Federal courts are able to provide fair hearings for all Americans. Similar to H.R. 5512, this is the same judiciary efficiency that the American people deserve.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from North Carolina (Mr. COBLE) that the House suspend the rules and pass the bill, H.R. 5512, 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.

FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5651) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for 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 bill is as follows:

H.R. 5651

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 ''Food and Drug Administration Reform Act of 2012''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. 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 such 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 such fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for each 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)(A) 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)(A);

''(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 language preceding subparagraph (A), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(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 subparagraph 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 ''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; and

''(vii) the number of applications filed for orphan-designated products per 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 (21 U.S.C. 379g; 379h) are repealed October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 736B (21 U.S.C. 379h–2) is repealed January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 106 of the Prescription Drug User Fee Amendments of 2007 (Title I 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 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—MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This Act 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.—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):

''(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 YEAR 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) in paragraph (3), by amending 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 Website 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 (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 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) is repealed January 31, 2018.

(b) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 217 of the Medical Device User Fee Amendments 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)(1), 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 three 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 cause to be published 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 cause to be published 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 cause to be published 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 cause to be published 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 cause to be published 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 cause to be published 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 cause to be published 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 part, 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; and

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

''(B) 24 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) 56 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) 14 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 cause to be published 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 an 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 the 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.

''(1) 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.—

''(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 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.

''(2) REGULATORY SCIENCE ACCOUNTABILITY METRICS.—The report required by paragraph (1) shall describe the amounts spent, data generated, and activities undertaken, including any FDA Advisory Committee consideration, by the Secretary for each of the local acting bioequivalence topics (Topics 1–3) in the Regulatory Science Plan described in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012.

''(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, as added by section 302 of this Act, are repealed October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 744C, as added by section 303 of this Act, is repealed 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).''.

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 five 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 defined 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, by 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 of this Act, 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, as added by section 402 of this Act, are repealed October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 744I, as added by section 403 of this Act, is repealed 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)''.

TITLE V—REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT

SEC. 501. PERMANENT EXTENSION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT.

(a) 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 subsection (c)(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)(i) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) 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'';

(2) in subsection (c)(2)—

(A) in the heading of paragraph (2), 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''; and

(3) in subsection (e)(1), by striking ''to carry out this section'' and all that follows through the end of paragraph (1) and inserting ''$25,000,000 for each of fiscal years 2013 through 2017.''.

(b) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A (21 U.S.C. 355a) is amended—

(1) in subsection (d)(1)(A), 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.'';

(2) by amending subsection (h) 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.'';

(3) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(4) 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.'';

(5) in subsection (n)—

(A) in the subsection heading, by striking ''COMPLETED'' and inserting ''SUBMITTED''; and

(B) in paragraph (1)—

(i) in the text preceding subparagraph (A), by striking ''have not been completed'' and inserting ''have not been submitted by the date specified in the written request issued and agreed upon''; and

(ii) by revising subparagraphs (A) and (B) to read as follows:

''(A) For a drug for which there remains any listed patent or exclusivity protection eligible for extension under subsection (b)(1) or (c)(1) of this section, or any exclusivity protection eligible for extension under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act, the Secretary shall make a determination regarding whether an assessment shall be required to be submitted under section 505B(b).

''(B) For a drug that has no remaining listed patents or exclusivity protection eligible for extension under subsection (b)(1) or (c)(1) of this section, or any exclusivity protection eligible for extension under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.'';

(6) 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.''; and

(7) by striking subsection (q) (relating to a sunset).

(c) 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)'';

(B) in paragraph (3)—

(i) by redesignating subparagraph (B) as subparagraph (D); and

(ii) by inserting after subparagraph (A) the following:

''(B) DEFERRAL EXTENSION.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral under subparagraph (A) if—

''(i) the Secretary finds that the criteria specified in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

''(ii) the applicant submits the materials required under subparagraph (A)(ii).

''(C) CONSIDERATION DURING DEFERRAL PERIOD.—If the Secretary has under this paragraph deferred the date by which an assessment must be submitted, then until the date specified in the deferral under subparagraph (A) (including any extension of such date under subparagraph (B))—

''(i) the assessment shall not be considered late or delayed; and

''(ii) the Secretary shall not classify the assessment as late or delayed in any report, database, or public posting.''; and

(iii) in subparagraph (D), as redesignated, by amending clause (ii) to read as follows:

''(ii) PUBLIC AVAILABILITY.—Not later than 60 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 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

(C) 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 partial waiver'' and inserting ''a partial waiver'';

(2) in subsection (b)(1), by striking ''After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary'' and inserting ''The Secretary'';

(3) by amending subsection (d) to read as follows:

''(d) FAILURE TO MEET REQUIREMENTS.—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)—

''(1)(A) the Secretary shall issue a letter to such person informing such person of such failure;

''(B) not later than 30 calendar days after the issuance of a letter under subparagraph (A), the person who receives such letter shall submit to the Secretary a written response to such letter; and

''(C) not later than 45 calendar days after the issuance of a letter under subparagraph (A), the Secretary shall make such letter, and any response to such letter under subparagraph (B), available to the public on the Web site of the Food and Drug Administration, with appropriate redactions made to protect trade secrets and confidential commercial information, except that, if the Secretary determines that the letter under subparagraph (A) was issued in error, the requirements of this subparagraph shall not apply with respect to such letter; and

''(2)(A) the drug or biological product that is the subject of the required assessment, applicable requirements in subsection (a)(3), or required 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

''(B) the failure to submit the required assessment, meet the applicable requirements in subsection (a)(3), or submit the required request for approval of a pediatric formulation shall not be the basis for a proceeding—

''(i) to withdraw approval for a drug under section 505(e); or

''(ii) to revoke the license for a biological product under section 351 of the Public Health Service Act.'';

(4) by amending subsection (e) to read as follows:

''(e) INITIAL PEDIATRIC PLAN.—

''(1) IN GENERAL.—

''(A) SUBMISSION.—An applicant who is required to submit an assessment under subsection (a)(1) shall submit an initial pediatric plan.

''(B) 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 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.

''(C) CONTENTS.—The initial pediatric plan shall include—

''(i) an outline of the pediatric studies that the applicant plans to conduct;

''(ii) any request for a deferral, partial waiver, or waiver under this section, along with supporting information; and

''(iii) other information the Secretary determines necessary, including any information specified in regulations under paragraph (5).

''(2) MEETING.—

''(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 calendar days after receiving an initial pediatric plan under paragraph (1), the Secretary shall meet with the applicant to discuss the plan.

''(B) WRITTEN RESPONSE.—If the Secretary determines that a written response to the initial pediatric plan is sufficient to communicate comments on the initial pediatric plan, and that no meeting is necessary the Secretary shall, not later than 90 days after receiving an initial pediatric plan under paragraph (1)—

''(i) notify the applicant of such determination; and

''(ii) provide to the applicant the Secretary's written comments on the plan.

''(3) AGREED INITIAL PEDIATRIC PLAN.—

''(A) SUBMISSION.—The applicant shall submit to the Secretary a document reflecting the agreement between the Secretary and the applicant on the initial pediatric plan (referred to in this subsection as an 'agreed initial pediatric plan').

''(B) CONFIRMATION.—Not later than 30 days after receiving the agreed initial pediatric plan under subparagraph (A), the Secretary shall provide written confirmation to the applicant that such plan reflects the agreement of the Secretary.

''(C) DEFERRAL AND WAIVER.—If the agreed initial pediatric plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under subparagraph (B) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

''(D) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed initial pediatric plan may be amended at any time. The requirements of paragraph (2) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric plan under paragraph (1). The requirements of subparagraphs (A) through (C) of this paragraph 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 plan.

''(4) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric plan, greed initial pediatric plan, and any amendments to such plans.

''(5) MANDATORY RULEMAKING.—Not later than one year after the date of enactment of the Food and Drug Administration Reform Act of 2012, the Secretary shall promulgate proposed regulations and guidance to implement the provisions of this subsection.

''(6) EFFECTIVE DATE.—The provisions of this subsection shall take effect 180 calendar days after the date of enactment of the Food and Drug Administration Reform Act of 2012, irrespective of whether the Secretary has promulgated final regulations to carry out this subsection by such date.'';

(5) in subsection (f)—

(A) in the subsection heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,'';

(B) in paragraph (4)—

(i) in the paragraph heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,''; and

(ii) in the second sentence, by inserting '', deferral extensions,'' after ''deferrals''; and

(C) in paragraph (6)(D)—

(i) by inserting ''and deferral extensions'' before ''requested and granted''; and

(ii) by inserting ''and deferral extensions'' after ''the reasons for such deferrals'';

(6) in subsection (g)—

(A) in paragraph (1)(A), by striking ''after the date of the submission of the application or supplement'' and inserting ''after the date of the submission of an application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review''; and

(B) in paragraph (2), by striking ''the label of such product'' and inserting ''the labeling of such product'';

(7) in subsection (h)(1)—

(A) by inserting ''an application (or supplement to an application) that contains'' after ''date of submission of''; and

(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,'';

(8) 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.'';

(9) by striking subsection (m) (relating to integration with other pediatric studies); and

(10) by redesignating subsection (n) as subsection (m).

(d) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS IN PHSA.—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)''.

(e) 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.

(f) CONFORMING AMENDMENT.—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) PUBLIC MEETING ON PEDIATRIC CANCERS.—Not later than December 31, 2013, the Secretary of Health and Human Services shall hold a public meeting on the impact of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) on the development of new therapies for children with cancer.

SEC. 502. FOOD AND DRUG ADMINISTRATION REPORT.

(a) IN GENERAL.—Not later than four years after the date of enactment of this Act and every five years thereafter, the Secretary of Health and Human Services 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 Web site of the Food and Drug Administration, a report on the implementation of section 505A and 505B.

(b) CONTENTS.—The report described in paragraph (1) shall include—

(1) an assessment of the effectiveness of sections 505A and 505B in improving information about pediatric uses for approved drugs and biologics, including the number and type of labeling changes made since the date of enactment of this Act;

(2) the number of waivers and partial waivers granted under section 505B since the date of enactment of this Act, and the reasons such waivers and partial waivers were granted;

(3) the number of deferrals and deferral extensions granted under section 505B since the date of enactment of this Act, and the reasons such deferrals and deferral extensions were granted;

(4) the number of letters issued under section 505B(d);

(5) an assessment of the timeliness and effectiveness of pediatric study planning since the date of enactment of this Act, including the number of pediatric plans not submitted in accordance with the requirements of section 505B(e) and any resulting rulemaking;

(6) the number of written requests issued, accepted, and declined under 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;

(7) a description and current status of referrals made under section 505A(n);

(8) an assessment of the effectiveness of studying drugs for rare diseases under 505A;

(9) an assessment of the effectiveness of studying drugs for children with cancer under 505A and 505B, and any recommendations for modifications to the programs under such sections that would lead to new and better therapies for children with cancer;

(10) an assessment of the effectiveness of studying drugs in the neonate population under 505A and 505B;

(11) an assessment of the effectiveness of studying biological products in pediatric populations under 505A and 505B;

(12) an assessment of the Secretary's efforts to address the suggestions and options described in the report required under 505A(p); and

(13) any suggestions for modification to the programs that would improve pediatric drug research and increase pediatric labeling of drugs and biologics that the Secretary determines to be appropriate.

(c) STAKEHOLDER COMMENT.—At least 180 days prior to the submission of the report required in paragraph (1), 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 study and report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biologics.

SEC. 503. 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''.

SEC. 504. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.

Section 6(c) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(c)) is amended—

(1) in paragraph (1), by striking ''and'' at the end;

(2) by redesignating paragraph (2) as paragraph (4);

(3) by inserting after paragraph (1) the following:

''(2) one or more additional individuals with expertise in neonatology;

''(3) one or more additional individuals with expertise in pediatric epidemiology; and''.

SEC. 505. CONTINUATION OF OPERATION OF 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))''.

SEC. 506. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS 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—

(1) in paragraph (1)(D), by striking ''section 505B(f)'' and inserting ''section 505C''; and

(2) in paragraph (3), 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 Subcommittee's responsibilities under this section''.

TITLE VI—FOOD AND DRUG ADMINISTRATION ADMINISTRATIVE REFORMS

SEC. 601. PUBLIC PARTICIPATION IN ISSUANCE OF FDA GUIDANCE DOCUMENTS.

Section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended by striking subparagraph (C) and inserting the following:

''(C) For any guidance document that sets forth initial interpretations of a statute or regulation, sets forth changes in interpretation or policy that are of more than a minor nature, includes complex scientific issues, or covers highly controversial issues—

''(i) the Secretary—

''(I) at least 30 days before issuance of a draft of such guidance document, shall publish notice in the Federal Register of the Secretary's intent to prepare such guidance document; and

''(II) during preparation and before issuance of such guidance document, may meet with interested stakeholders, including industry, medical, and scientific experts and others, and solicit public comment;

''(ii) if the Secretary for good cause finds that, with respect to such guidance document, compliance with clause (i) is impracticable, unnecessary, or contrary to the public interest—

''(I) the Secretary shall publish such finding and a brief statement of the reasons for such finding in the Federal Register;

''(II) clause (i) shall not apply with respect to such guidance document; and

''(III) during a 90-day period beginning not later than the date of issuance of such guidance document, the Secretary may meet with interested stakeholders, including industry, medical, and scientific experts and others, and shall solicit public comment;

''(iii) beginning on the date of enactment of the Food and Drug Administration Reform Act of 2012, upon issuance of a draft guidance

document under clause (i) or (ii), the Secretary shall—

''(I) designate the document as draft or final; and

''(II) not later than 18 months after the close of the comment period for such guidance, issue a final version of such guidance document in accordance with clauses (i) and (ii);

''(iv) the Secretary may extend the deadline for issuing final guidance under clause (iii)(II) by not more than 180 days upon submission by the Secretary of a notification of such extension in the Federal Register;

''(v) if the Secretary issues a draft guidance document and fails to finalize the draft by the deadline determined under clause (iii)(II), as extended under clause (iv), the Secretary shall, beginning on the date of such deadline, treat the draft as null and void; and

''(vi) not less than every 5 years after the issuance of a final guidance document in accordance with clause (iii), the Secretary shall—

''(I) conduct a retrospective analysis of such guidance document to ensure it is not outmoded, ineffective, insufficient, or excessively burdensome; and

''(II) based on such analysis, modify, streamline, expand, or repeal the guidance document in accordance with what has been learned.

''(D) With respect to devices, a notice to industry guidance letter, a notice to industry advisory letter, and any similar notice that sets forth initial interpretations of a statute or regulation or sets forth changes in interpretation or policy shall be treated as a guidance document for purposes of subparagraph (C).

''(E) The following shall not be treated as a guidance document for purposes of subparagraph (C):

''(i) Any document that does not set forth an initial interpretation or a reinterpretation of a statute or regulation.

''(ii) Any document that sets forth or changes a policy relating to internal procedures of the Food and Drug Administration.

''(iii) Agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or communications directed to individual persons or firms.''.

SEC. 602. 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 Website 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 Website 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.''; and

(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.''.

(b) APPLICABILITY.—The amendments made by subsection (a) apply beginning on October 1, 2012.

SEC. 603. 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, pre-submissions 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 pre-submissions or submissions, shall include an electronic copy of such pre-submissions 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. 604. NOTIFICATION OF FDA INTENT TO REGULATE LABORATORY-DEVELOPED TESTS.

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.

TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

SEC. 701. 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. 702. 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. 703. 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 completely document 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 complete documentation 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. 704. TRANSPARENCY IN CLEARANCE PROCESS.

(a) PUBLICATION OF DETAILED DECISION SUMMARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended by adding at the end the following:

''(5) Subject to subsection (c) and section 301(j), the Secretary shall regularly publish detailed decision summaries for each clearance of a device under section 510(k) requiring clinical data.''.

(b) APPLICATION.—The requirement of section 520(h)(5) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to clearance of a device occurring after the date of the enactment of this Act.

SEC. 705. 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 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.''.

Subtitle B—Patients Come First

SEC. 711. ESTABLISHMENT OF SCHEDULE AND PROMULGATION OF REGULATION.

(a) ESTABLISHMENT OF SCHEDULE.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish the schedule referred to in section 515(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

(b) REGULATION.—Not later than one year after the date that the schedule is established under such section 515(i)(3) (as required by subsection (a)) the Secretary shall issue a final regulation under section 515(b) of such Act for each device that the Secretary requires to remain in class III through a determination under section 515(i)(2) of such Act.

SEC. 712. 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) 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).''.

Subtitle C—Novel Device Regulatory Relief

SEC. 721. 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 of a device pursuant to a request under clause (ii) if the Secretary—

''(I) identifies a legally marketed device that would permit a substantial equivalence determination under paragraph (1) for the device; or

''(II) determines that the device submitted is not of low-moderate risk or special controls to mitigate the risks cannot be developed for the device.

''(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) of such Act (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).''.

Subtitle D—Keeping America Competitive Through Harmonization

SEC. 731. HARMONIZATION OF DEVICE PREMARKET REVIEW, INSPECTION, AND LABELING SYMBOLS; REPORT.

(a) IN GENERAL.—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.''.

(b) REPORT.—Not later than 3 years 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 the Food and Drug Administration's harmonization activities, itemizing methods and approaches that have been harmonized pursuant to section 803(c)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a).

SEC. 732. 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.''.

Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

SEC. 741. 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. 742. 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''.

Subtitle F—Humanitarian Device Reform

SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DEVICES.

(a) IN GENERAL.—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''subparagraph (D)'' and inserting ''subparagraph (C)'';

(ii) 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.'';

(iii) 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 number of such devices needed to treat, diagnose, or cure a population of 4,000 individuals in the United States (referred to in this paragraph as the 'annual distribution number').''; and

(iv) in clause (iv), by striking ''2012'' and inserting ''2017'';

(B) by striking subparagraph (C);

(C) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively; and

(D) in subparagraph (C), as so redesignated, by striking ''and modified under subparagraph (C), if applicable,'';

(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 paragraph (6)(A)(i) of such section 520(m) (as amended by subsection (a)). If the Secretary determines that such subclause (I) or (II) applies with respect to a device, then clauses

(ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), and (D) of paragraph (6) of such section 520(m) shall apply to such device.

(c) REPORT.—Not later than January 1, 2017, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a) in stimulating innovation with respect to medical devices, including any favorable or adverse impact on pediatric device development;

(2) the impact of such amendments on pediatric device approvals for devices that received a humanitarian use designation under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) prior to the date of enactment of this Act;

(3) the status of public and private insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m) and costs to patients of such devices;

(4) the impact that paragraph (4) of such section 520(m) has had on access to and insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m); and

(5) the effect of the amendments made by subsection (a) on patients described in such section 520(m).

Subtitle G—Records and Reports on Devices

SEC. 761. UNIQUE DEVICE IDENTIFICATION SYSTEM REGULATIONS.

Not later than 120 days after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate the regulations required by section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

SEC. 762. EFFECTIVE DEVICE SENTINEL PROGRAM.

(a) INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Section 519 (21 U.S.C. 360i) is amended by adding at the end the following:

''(h) INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(1) IN GENERAL.—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.

''(2) DATA.—In expanding the system as described in paragraph (1), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, which may include claims data, patient survey data, and standardized analytic files that allow for the pooling and analysis of data from disparate data environments.

''(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.''.

(b) AMENDMENTS TO POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Section 505(k)(3)(C)(i) (21 U.S.C. 355(k)(3)(C)(i)) is amended—

(1) by striking subclause (II);

(2) by redesignating subclauses (III) through (VI) as subclauses (II) through (V), respectively; and

(3) in item (bb) of subclause (II), as so redesignated, by striking ''pharmaceutical purchase data and health insurance claims data'' and inserting ''medical device utilization data, health insurance claims data, and procedure and device registries''.

Subtitle H—Miscellaneous

SEC. 771. CUSTOM DEVICES.

Section 520(b) (21 U.S.C. 360j) 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. 772. PEDIATRIC DEVICE REAUTHORIZATION.

(a) 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.

(b) DEMONSTRATION GRANTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.—Section 305(e) of the Pediatric Medical Device Safety and Improvement Act of 2007 (Title III of Public Law 110–85) is amended by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

SEC. 773. REPORT ON REGULATION OF HEALTH INFORMATION TECHNOLOGY.

(a) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, 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 submit to the Committee on Energy and Commerce of the House of Representatives and the appropriate committees of the Senate a report that contains—

(1) a strategy for coordinating the regulation of health information technology in order to avoid regulatory duplication; and

(2) recommendations on an appropriate regulatory framework for health information technology, including a risk-based framework.

(b) DEFINITION.—In this section, the terms ''health information technology'' has the meaning given such term in section 3000(5) of the Public Health Service Act and includes technologies such as electronic health records, personal health records, mobile medical applications, computerized health care provider order entry systems, and clinical decision support.

TITLE VIII—DRUG REGULATORY IMPROVEMENTS

Subtitle A—Drug Supply Chain

SEC. 801. REGISTRATION OF PRODUCERS OF DRUGS.

(a) TIMING.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)(1), by striking ''On or before'' and inserting ''During the period beginning on October 1 and ending on''; and

(2) in subsection (i)(1)(B)(i), by striking ''on or before'' and inserting ''during the period beginning on October 1 and ending on''.

(b) ESTABLISHMENTS NOT DULY REGISTERED; MISBRANDING.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking ''in any State''.

SEC. 802. INSPECTION OF DRUGS.

Subsection (h) of section 510 (21 U.S.C. 360) is amended—

(1) by striking ''(h)'' and inserting ''(h)(1)'';

(2) by inserting ''with respect to the manufacture, preparation, propagation, compounding, or processing of a device'' after ''registered with the Secretary pursuant to this section'';

(3) by striking ''of a drug or drugs or''; and

(4) by adding at the end the following:

''(2) INSPECTIONS WITH RESPECT TO DRUG ESTABLISHMENTS.—With respect to the manufacture, preparation, propagation, compounding, or processing of a drug:

''(A) 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.

''(B) RISK-BASED SCHEDULE.—In the case of an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as a 'drug establishment'), the inspections required under subparagraph (A) shall be conducted by officers or employees duly designated by the Secretary, on a risk-based schedule established by the Secretary.

''(C) RISK FACTORS.—In establishing the risk-based schedule under subparagraph (B), the Secretary shall allocate resources to inspect establishments according to the known safety risks of such establishments, based on the following factors:

''(i) The compliance history of the establishment.

''(ii) The inspection frequency and history of the establishment, including whether it has been inspected pursuant to section 704 within the last four years.

''(iii) The record, history, and nature of recalls linked to the establishment.

''(iv) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

''(v) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(D) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under subparagraph (B), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b)(1).

''(E) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit to Congress a report that contains the following:

''(i) The number of domestic and foreign establishments registered pursuant to this section in the previous calendar year.

''(ii) The number of such registered domestic and foreign establishments that the Secretary inspected in the previous calendar year.

''(iii) The number of such registered establishments that list one or more drugs approved pursuant to an application filed under section 505(j).

''(iv) The number of such registered establishments that list one or more drugs approved pursuant to an application filed under section 505(b).

''(v) The number of registered establishments that list both drug products approved pursuant to an application filed under section 505(j) and drug products approved pursuant to an application filed under section 505(b).

''(vi) A description of how the Secretary implemented the risk-based schedule under subparagraph (B) utilizing the factors under subparagraph (C).

''(F) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under subparagraph (E) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 803. DRUG SUPPLY QUALITY AND SAFETY.

Paragraph (a) of section 501 (21 U.S.C. 351) is amended by adding at the end the following: ''For purposes of subparagraph (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. 804. 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. 805. 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, in consultation with the Secretary of Homeland Security, may cause the destruction, without the opportunity for export, of any drug refused admission that has reasonable probability of causing serious adverse health consequences or death, as determined by the Secretary of Health and Human Services, or that is valued at an amount that is $2,000 or less (or such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 498 of the Tariff Act of 1930 (19 U.S.C. 1498))''.

(b) NOTICE.—Section 801(a) (21 U.S.C. 381(a)), 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 for a hearing on the destruction of a drug under the previous sentence. For a drug with a value less than and or equal to $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 498 of the Tariff Act of 1930 (19 U.S.C. 1498)) the regulations under the previous sentence shall provide for prompt notice and an opportunity for a hearing for the owner or consignee before or after the destruction has occurred. For a drug with a value greater than $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 498 of the Tariff Act of 1930 (19 U.S.C. 1498)) that has reasonable probability of causing serious adverse health consequences or death as determined by the Secretary of Health and Human Services, the regulations under the seventh sentence of this subsection shall provide for notice and an opportunity for a hearing to the owner or consignee before the destruction occurs.''.

(c) RESTITUTION.—In the regulations described in the seventh sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)), the Secretary of Health and Human Services shall establish an administrative process whereby an owner or consignee of a drug destroyed without an opportunity for a hearing on destruction may obtain restitution for the value of the drug destroyed under the sixth sentence of such section upon demonstration that such drug was wrongfully destroyed.

(d) CONFORMING AMENDMENT.—The first sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting '', except as otherwise described in the sixth and seventh sentences of this subsection,'' after ''giving notice thereof''.

SEC. 806. 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) REGULATION.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations 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.

(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. 807. ENHANCED CRIMINAL PENALTY FOR COUNTERFEIT DRUGS.

(a) IN GENERAL.—Section 303(a) (21 U.S.C. 333(a)) is amended by adding at the end the following:

''(3) Notwithstanding paragraph (2), any person who engages in any conduct described in section 301(i)(2) knowing or having reason to know that the conduct concerns the rendering of a drug as a counterfeit drug, or who engages in conduct described in section 301(i)(3) knowing or having reason to know that the conduct will cause a drug to be a counterfeit drug or knowing or having reason to know that a drug held, sold, or dispensed is a counterfeit drug, shall be fined in accordance with title 18, United States Code, or imprisoned not more than 20 years, or both, except that if the use of the counterfeit drug by a consumer is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life.''.

(b) CONFORMING AMENDMENT.—Section 201(g)(2) (21 U.S.C. 321(g)(2)) is amended by adding at the end the following sentence: ''The term 'counterfeit drug' shall not include a drug or placebo intended for use in a clinical trial that is intentionally labeled or marked to maintain proper blinding of the study.''.

SEC. 808. UNIQUE FACILITY IDENTIFICATION NUMBER.

(a) DOMESTIC ESTABLISHMENTS.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)(1), by striking ''and all such establishments'' and inserting ''all such establishments, and the unique facility identifier of each such establishment''; and

(2) in subsection (c), by striking ''and such establishment'' and inserting ''such establishment, and the unique facility identifier of such establishment''.

(b) FOREIGN ESTABLISHMENTS.—Subparagraph (A) of section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by inserting ''the unique facility identifier of the establishment,'' after ''the name and place of business of the establishment,''.

(c) GUIDANCE.—Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

''(q) GUIDANCE ON SUBMISSION OF UNIQUE FACILITY IDENTIFIERS.—

''(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this subsection, the Secretary shall, by guidance, specify—

''(A) the unique facility identifier system to be used to meet the requirements of—

''(i) subsections (b)(1), (c), and (i)(1)(A) of this section; and

''(ii) section 801(s) (relating to registration of commercial importers); and

''(B) the form, manner, and timing of submissions of unique facility identifiers under the provisions specified in subparagraph (A).

''(2) CONSIDERATION.—In developing the guidance under paragraph (1), the Secretary shall take into account the utilization of existing unique identification schemes and compatibility with customs automated systems.''.

(d) IMPORTATION.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting ''or (5) for an article that is a drug, the appropriate unique facility identifiers under subsection (s) (relating to commercial importers) and section

510(i) (relating to foreign establishments), as specified by the Secretary, are not provided,'' before ''then such article shall be refused admission''.

SEC. 809. DOCUMENTATION FOR ADMISSIBILITY OF IMPORTS.

Section 801 (21 U.S.C. 381) is amended by adding at the end the following:

''(r) DOCUMENTATION.—

''(1) SUBMISSION.—The Secretary may require, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection as determined appropriate by the Secretary, the submission of documentation or other information for a drug that is imported or offered for import into the United States.

''(2) REFUSAL OF ADMISSION.—A drug imported or offered for import into the United States shall be refused admission unless all documentation and information the Secretary requires under this Act, the Public Health Service Act, or both, as appropriate, for such article is submitted.

''(3) REGULATIONS.—

''(A) DOCUMENTS AND INFORMATION.—The Secretary shall issue a regulation to specify the documentation or other information that is described in paragraph (1). Such information may include—

''(i) 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;

''(ii) facility information, such as proof of registration and the unique facility identifier; and

''(iii) indication of compliance with current good manufacturing practice, such as satisfactory testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations.

''(B) EXEMPTION.—The Secretary may, by regulation, exempt drugs imported for research purposes only and other types of drug imports from some or all of the requirements of this subsection.

''(4) EFFECTIVE DATE.—The final rule under paragraph (3)(A) shall take effect not less than 180 days after the Secretary promulgates such final rule.''.

SEC. 810. 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 809, 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) consistent with the guidance under section 510(q), 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) EXPEDITED CLEARANCE FOR CERTAIN IMPORTERS.—In promulgating good importer practice regulations under subparagraph (A), the Secretary 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.

''(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) 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) 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. 811. NOTIFICATION.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 810, 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; 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. 812. EXCHANGE OF INFORMATION.

Section 708 (21 U.S.C. 379) is amended—

(1) by striking ''The Secretary may provide'' and inserting the following:

''(a) CONTRACTORS.—The Secretary may provide''; and

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION.—Except pursuant to an order of a court of the United States, the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law, any information relating to drugs obtained from a Federal, State, or local government agency, or from a foreign government agency, if the agency has requested that the information be kept confidential. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

''(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

''(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified 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 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 the following circumstances:

''(A) Information concerning the inspection of a facility may be provided 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.

''(d) NO LIMITATION ON AUTHORITY.—This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.''.

SEC. 813. 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.''.

SEC. 814. 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 engages in an activity that results in a drug becoming adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and having a reasonable probability of causing serious adverse health consequences or death shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.''.

SEC. 815. 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.''.

Subtitle B—Medical Gas Safety

SEC. 821. 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. 822. 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 821 of this Act.

(3) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

SEC. 823. 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 821 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—Generating Antibiotic Incentives Now

SEC. 831. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505D (21 U.S.C. 355e) 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 determined to be a qualified infectious disease product under subsection (d), then the four- and five-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the three-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 seven year period described in section 527, as applicable, shall be extended by five 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 by the same sponsor or manufacturer of a qualified infectious disease product described in paragraph (1) (or a licensor, predecessor in interest, or other related entity) for—

''(A) a change (not including a modification to the active moiety of the qualified infectious disease product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

''(B) a modification to the active moiety of the qualified infectious disease product that does not result in a change in safety or effectiveness; or

''(3) a product that does not meet the definition of a qualified infectious disease product under subsection (f) based upon its approved uses.

''(d) DETERMINATION.—The manufacturer or sponsor of a drug may request that the Secretary designate a drug as a qualified infectious disease product at any time in the drug development process prior to the submission of an application under section 505(b) for the drug, but not later than 45 days before the submission of such application. The Secretary shall, not later than 30 days after the submission of such request, determine whether the drug is a qualified infectious disease product.

''(e) REGULATIONS.—The Secretary shall promulgate regulations for carrying out this section. The Secretary shall promulgate the initial regulations for carrying out this section not later than 12 months after the date of the enactment of this section.

''(f) DEFINITIONS.—In this section:

''(1) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use that treats or prevents an infection caused by a qualifying pathogen.

''(2) QUALIFYING PATHOGEN.—The term 'qualifying pathogen' means—

''(A) resistant gram-positive pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Staphylococcus aureus (VRSA), and vancomycin-resistant enterococcus (VRE);

''(B) multidrug resistant gram-negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

''(C) multi-drug resistant tuberculosis; or

''(D) any other infectious pathogen identified for purposes of this section by the Secretary.''.

(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. 832. STUDY ON INCENTIVES FOR QUALIFIED INFECTIOUS DISEASE BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—The Comptroller General of the United States shall—

(1) conduct a study on the need for incentives to encourage research on and development and marketing of qualified infectious disease biological products; and

(2) not later than 1 year after the date of the enactment of this Act, submit a report to the Congress on the results of such study, including any recommendations of the Comptroller General on appropriate incentives for addressing such need.

(b) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The term ''qualified infectious disease biological product'' means a biological product for human use that treats or prevents an infection caused by a qualifying pathogen.

(3) The term ''qualifying pathogen'' has the meaning given to such term in section 505E of the Federal Food, Drug, and Cosmetic Act, as added by section 831 of this Act.

SEC. 833. CLINICAL TRIALS.

(a) REVIEW AND REVISION OF GUIDELINES.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, and not later than 4 years thereafter, the Secretary shall—

(A) review the guidance of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revise such guidance to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of an antibiotic and antifungal drug 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, and appropriate delta values for noninferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary of Health and Human Services makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise affect the guidance of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be used to treat or prevent a qualifying pathogen may request that the Secretary provide written recommendations for nonclinical and clinical investigations which may be conducted with the drug before it may be approved for such use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(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) DEFINITIONS.—In this section:

(1) The term ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) The term ''qualified infectious disease product'' has the meaning given to such term in section 505E of the Federal Food, Drug, and Cosmetic Act, as added by section 831 of this Act.

(3) The term ''qualifying pathogen'' has the meaning given to such term in section 505E of the Federal Food, Drug, and Cosmetic Act, as added by section 831 of this Act.

(4) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

SEC. 834. REASSESSMENT OF QUALIFIED INFECTIOUS DISEASE PRODUCT INCENTIVES IN 5 YEARS.

Not later than five 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, 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 this program; and

(C) whether such products address the need for antibacterial and antifungal drugs to treat serious and life-threatening infections.

(2) Recommendations—

(A) based on the information in 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 831; 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.

SEC. 835. 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.

Subtitle D—Accelerated Approval

SEC. 841. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—The Congress finds as follows:

(A) The Food and Drug Administration (referred to in this subsection 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 the Congress that the FDA 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.—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 A 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) of this Act 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.—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) of this Act or section 351(a) of the Public Health Service Act upon making a determination that the product has an effect on—

''(A) a surrogate endpoint that is reasonably likely to predict clinical benefit; or

''(B) 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 or rarity of the disease or condition and the availability of alternative treatments. The evidence to support that an endpoint is reasonably likely to predict clinical benefit may include epidemiological, pathophysiologic, pharmacologic, therapeutic or other evidence developed using, for example, biomarkers, or other scientific methods or tools.

''(2) LIMITATION.—Approval of a product under this subsection may, as determined by the Secretary, be subject to the following requirements—

''(A) that the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect of the product on irreversible morbidity or mortality or other clinical benefit; and

''(B) that the sponsor submit copies of all promotional materials related to the product, at least 30 days prior to dissemination of the materials—

''(i) during the preapproval review period; and

''(ii) following approval, for a period that the Secretary determines to be appropriate.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved pursuant to this subsection 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 post-approval study of the product 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 there exist significant unmet medical needs.''.

SEC. 842. GUIDANCE; AMENDED REGULATIONS.

(a) INITIAL GUIDANCE.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (in this subtitle referred to as the ''Secretary'') shall issue draft guidance to implement the amendment made by section 841.

(b) FINAL GUIDANCE.—Not later than one year after the issuance of draft guidance under subsection (a), after an opportunity for public comment, the Secretary shall—

(1) issue final guidance to implement the amendment made by section 841; and

(2) 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 amendments made by section 841.

(c) CONSIDERATIONS.—In developing the guidance under subsections (a) and (b)(1) and the amendments under subsection (b)(2), the Secretary shall consider—

(1) issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act (as amended by section 841) for drugs designated for a rare disease or condition under section 526 of the Federal, Food, Drug, and Cosmetic Act; and

(2) 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.

(d) NO DELAY IN REVIEW OR APPROVAL.—The issuance (or non-issuance) of guidance or conforming regulations implementing the amendments made by section 841 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 section 841.

SEC. 843. INDEPENDENT REVIEW.

(a) IN GENERAL.—The Secretary may, in conjunction with other planned reviews of the new drug review process, 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 section 841, and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions.

(b) CONSULTATION.—Any evaluation under subsection (a) shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

Subtitle E—Critical Path Reauthorization

SEC. 851. 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 F—Miscellaneous

SEC. 861. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ''2012'' and inserting ''2017''.

SEC. 862. 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, 2013, ''45 months'';

(B) during the period beginning on October 1, 2013, and ending on September 30, 2014, ''42 months'';

(C) during the period beginning on October 1, 2014, and ending on September 30, 2015, ''39 months''; and

(D) 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. 863. 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)'' inserting ''subsection (b)(2) or (j) of the Act or 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''; and

(3) 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. 864. 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. 865. 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 appropriation 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) IN GENERAL.—The Secretary shall deem a rare pediatric disease product application incomplete if such application does not contain a description of the plan of the sponsor of such application to market the product in the United States.

''(2) 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.

''(3) 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 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) REPORT.—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 on 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).''.

SEC. 866. 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''), acting through the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') and in coordination with other Federal agencies, as appropriate, shall review current Federal initiatives and identify gaps and opportunities with respect to ensuring the safe use of prescription drugs with the potential for abuse.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue a report to Congress on the findings of the review under subsection (a). Such report shall include 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 producing standardized data on adverse events, patient safety, and patient outcomes; and

(3) how best to develop provider and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON TAMPER-DETERRENT PRODUCTS.—Not later than 6 months after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall promulgate guidance on the development of tamper-deterrent drug products.

SEC. 867. 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. 868. 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 811(b), 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.—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—

''(1) such consultation will—

''(A) facilitate the Secretary's ability to complete the Secretary's review;

''(B) address outstanding deficiencies in the application; and

''(C) increase the likelihood of an approval decision in the current review cycle; or

''(2) the sponsor authorized such consultation.''.

SEC. 869. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 841, is further amended—

(1) by redesignating subsection (d) as subsection (e);

(2) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(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 non-clinical 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.'';

(4) in subsection (e)(1), as so redesignated, by striking ''applicable to accelerated approval'' and inserting ''applicable to breakthrough therapies, accelerated approval,''; and

(5) by adding at the end the following:

''(f) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually 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, with respect to this section for the previous fiscal year—

''(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

''(2) the number of products designated as a breakthrough therapy; and

''(3) for each product designated as a breakthrough therapy, a summary of the actions taken under subsection (a)(3).''.

(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 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) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) 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. 870. 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.''.

TITLE IX—DRUG SHORTAGES

SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

(a) IN GENERAL.—Section 506C (21 U.S.C. 356c) is amended to read as follows:

''SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug subject to section 503(b)(1)—

''(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; and

''(2) that is not a radio pharmaceutical drug product, a product derived from human plasma protein and their recombinant analogs, or any other product as designated by the Secretary,

shall notify the Secretary of a discontinuance of 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 manufacturer's supply of the drug, and the reason for such discontinuance or interruption, in accordance with subsection (b).

''(b) TIMING.—A notice required by 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 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 506D.

''(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 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 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.''.

(b) REGULATIONS.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, after issuing a notice of proposed rule and holding a public hearing, shall promulgate final regulations that implement the amendment made by subsection (a).

(2) CONTENTS.—Such regulations shall, for purposes of section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c)—

(A) define the terms ''life-supporting'', ''life-sustaining'', and ''intended for use in the prevention or treatment of a debilitating disease or condition''; and

(B) define the term ''interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the manufacturer's supply of the drug'' to mean a change in production that is highly likely to lead to more than a negligible reduction in the supply of the drug and affects the ability of the manufacturer to meet demand for such drug, but not to include a change in production 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.

SEC. 902. DRUG SHORTAGE LIST.

Title V (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following new section:

''SEC. 506D. 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.

''(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) 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. 903. 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 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 506D 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. 904. EXPEDITED REVIEW OF MAJOR MANUFACTURING CHANGES FOR POTENTIAL AND VERIFIED SHORTAGES OF DRUGS THAT ARE LIFE-SUPPORTING, LIFE-SUSTAINING, OR INTENDED FOR USE IN THE PREVENTION OF A DEBILITATING DISEASE OR CONDITION.

Subsection (c) of section 506A (21 U.S.C. 356a) is amended by adding at the end the following new paragraph:

''(3) CHANGES ADDRESSING A DRUG SHORTAGE.—

''(A) CERTIFICATION.—

''(i) DESCRIPTION.—A certification is described in this subparagraph if the manufacturer, having notified the Secretary of an interruption or discontinuance of a drug in accordance with Section 506C, certifies (in such certification) that the major manufacturing change for which approval is being sought may prevent or alleviate a discontinuance or interruption of such drug.

''(ii) BAD FAITH EXCEPTION.—Subparagraphs (B) and (C) do not apply in the case of a certification which the Secretary determines to be made in bad faith.

''(B) EXPEDITED REVIEW.—If a certification described in subparagraph (A) is submitted in connection with a supplemental application for a major manufacturing change, the Secretary shall—

''(i) expedite any technical review or inspection necessary for consideration of the supplemental application;

''(ii) provide any technical assistance necessary to facilitate approval of the supplemental application; and

''(iii) not later than 60 days after receipt of the certification, complete review of the supplemental application.''.

SEC. 905. 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 actual shortage over the preceding three 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) How have regulations, guidance documents, regulatory practices, and other actions of Federal departments and agencies (including the effectiveness of interagency and intraagency coordination, communication, strategic planning, and decision-making) affected drug shortages?

(5) How does hoarding affect drug shortages?

(6) How would incentives alleviate or prevent drug shortages?

(7) How are healthcare providers, including hospitals and physicians responding to drug shortages, to what extent are such providers able to adjust care effectively to compensate for such shortages, and what impediments exist that hinder provider ability to adjust to such shortages?

(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.—Note 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.

SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.

Not later than 18 months after the date of the enactment of this Act, and annually thereafter, the Secretary of Health and Human Services 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) 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;

(2) describes the Food and Drug Administration's efforts to expedite the review of new manufacturing sites, new suppliers, and specification changes to prevent or alleviate a drug shortage;

(3) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(4) 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;

(5) identifies the number of instances in which the Food and Drug Administration asked firms to increase production to prevent or alleviate a shortage;

(6) identifies the number of notifications submitted to the Secretary under section 506C of the Federal Food, Drug, and Cosmetic Act, as amended by section 901 of this Act, including the percentage of such notifications for a drug that is a sterile injectable;

(7) describes the Food and Drug Administration's implementation of section 506D of the Federal Food, Drug, and Cosmetic Act (relating to a drug shortage list), as added by section 902 of this Act, and identifies—

(A) the name of each drug on the list under such section 506D at any point during the period covered by the report;

(B) the name of each manufacturer of each such drug;

(C) the reason for the shortage of each such drug; and

(D) the anticipated or, if known, actual duration of the shortage of each such drug;

(8) identifies whether, and how, the Food and Drug Administration expedited the review of regulatory submissions to prevent or alleviate shortages, including how the Administration utilized the authority in section 506A(c)(3) of the Federal Food, Drug, and Cosmetic Act, as added by section 904 of this Act;

(9) identifies the number of certifications submitted under such section 506A(c)(3) and, for each such certification, whether the Food and Drug Administration completed expedited review within 60 days as required by subparagraph (B) of such section 506A(c)(3);

(10) describes the Secretary's public engagement on drug shortages with stakeholders, including physicians, pharmacists, patients, hospitals, drug manufacturers, and other health providers; and

(11) contains the Secretary's plan for addressing drug shortages in the upcoming year, including with respect to the issues described in paragraphs (1) through (10).

SEC. 907. 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 903 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 of Health and Human Services to be in shortage.

SEC. 908. HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE.

Chapter V (21 U.S.C. 351 et seq.), as amended by section 902 of this Act, is further amended by inserting after section 506D the following:

''SEC. 506E. 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 described in subsection (b); 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 of the Food and Drug Administration; 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 transfers 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 in which the health system is located.

''(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.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. UPTON) and the gentleman from New Jersey (Mr. PALLONE) 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 materials into the RECORD.

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

There was no objection.

Mr. UPTON. Mr. Speaker, I yield myself 2 minutes.

Mr. Speaker, I want to thank, first of all, Chairman PITTS, Dr. BURGESS, Mr. BARTON, Mr. WAXMAN, Mr. PALLONE, Mr. DINGELL, and other committee members on both sides of the aisle for their bipartisanship through this process. H.R. 5651 is a reflection of their hard work, dedication, and willingness to work together. And because of that outstanding work, we have a bill today that will help American patients and innovators, and it will support millions of jobs, believe it or not, millions of jobs in an important sector of our economy.

As I've said since the beginning of this Congress, we need to enact this user fee by the end of June, and I believe that we're on track to accomplish that goal.

And as we put this user-fee package together, I wanted to ensure that it fostered American innovation by improving the predictability, consistency, transparency, and efficiency of FDA regulation. Fostering innovation is essential in getting new treatments to patients and creating American jobs.

This bill will foster American innovation because it includes significant accountability and reform measures designed to hold the FDA responsible for its performance. The measures include independent assessments of FDA's drug-and-device review process. It also requires quarterly reporting from the device center so that we don't have to wait a year to find out their progress.

I commit today that our committee will continue its vigorous oversight of the FDA. For example, we're going to use the independent assessments to determine where the review process can be improved, and we will ensure FDA fixes the problems. Also, we'll use the quarterly data on device reviews and bring the FDA before our committee to explain how it's doing.

This bill will give us the information that we need to understand how the FDA is performing. It is up to us to ensure that we use that information to hold the FDA accountable for their performance.

Together, the committee members have produced a bill that will help American patients, while supporting innovation and job creators. I thank the committee for their participation.

I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Today marks a very exceptional day in this body, one that deserves great praise. The bill before us, H.R. 5651, the FDA Reform Act of 2012, is the product of bipartisanship, collaboration, and compromise that I'm very proud of. The bill is a result of more than a year of negotiations between industry, FDA, and Congress.

In the Energy and Commerce Committee, we held a number of hearings on the critical issues within the bill, and earlier this month it passed unanimously in both subcommittee and full committee. The bill is slightly modified from the bill reported by committee, as it now includes a bipartisan provision which results in the bill reducing the deficit by $370 million over the next 10 years.

The FDA Reform Act will ensure that Americans have access to safe and effective new medicines and medical devices by reauthorizing the user-fee programs for prescription drugs and medical devices. It will reduce drug costs for consumers by speeding the approval of lower-cost generic drugs with the establishment of new user-fee programs for generic drugs and for lower-cost versions of biotech drugs.

The bill will also reform and revitalize many FDA programs to improve its regulatory scheme to facilitate a more efficient and predictable review process.

Mr. Speaker, the bill also makes permanent two complementary programs, the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which both help to foster the development and safe use of prescription drugs for children.

In addition, a significant improvement was made to the FDA's ability to police an ever-growing global drug supply chain to improve patient safety, and these provisions will give the FDA critical tools it needs to keep our medicine safer.

It also includes important provisions to help prevent and mitigate drug shortages by requiring that drugmakers notify the FDA in advance of any expected disruption in the supply of certain critical drugs, and for the FDA to inform health care providers of the potential drug shortage.

I want to thank Chairman UPTON and Chairman PITTS, Ranking Member WAXMAN, Mr. DINGELL, and my other colleagues on the committee for their leadership and dedication to this important piece of legislation, a special thanks to the staffs, in particular my staff person, Tiffany Guarascio, who's to my right. But on both sides of the aisle, the staff worked hard, and they should be very proud of what we've accomplished.

Reauthorizing and revitalizing the FDA user-fee system is a critical investment to our Nation's public health.

Mr. Speaker, I urge all Members of the House to vote ''aye.''

I reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania (Mr. PITTS), chairman of the Health Subcommittee on the Energy and Commerce Committee.

Mr. PITTS. Mr. Speaker, the Food and Drug Administration Reform Act of 2012 is a product of nearly a year and a half of work in the Energy and Commerce Health Subcommittee. H.R. 5651 is the result of bipartisan negotiations. The bill passed out of the Health Subcommittee by a unanimous voice vote and passed out of the full committee 46–0.

I would especially like to thank Clay Alspach, Ryan Long, and Paul Edattel and the other staffers for their dedication and hard work in making this bill possible. I know they've put in a lot of hours; and because of that work, we have brought this bill to the floor in a timely manner.

The FDA Reform Act is critical to saving lives and sustaining a dynamic American industry. 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. This is a big job. The device and drug industries are dynamic and innovative. Companies spend tens of millions of dollars and years of work to develop products.

The review stage is a critical time for any company. Inconsistent reviews mean that the true cost of developing a new product is hidden, making it difficult to properly prepare.

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When we began considering this legislation last year, we heard from a number of individuals involved in the medical device industry 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 slow review process, the safety outcomes were comparable.

The FDA Reform Act contains critical reforms to the Medical Device User Fee Act which will hold the FDA accountable and keep the reviews on schedule. Under the fourth version of the Prescription Drug User Fee Act, the median time of approval was 9

months. With the reauthorization, we set the goal of reducing the review time to 8 months. Currently, generic drugs have an average approval time of 32 months. Included in this legislation is a new user-fee program that should be able to gradually reduce review times to 10 months for most products. A separate user-fee program for biosimilars has the goal of 10-month approval times for most products. Finally, we also include language to help patients, doctors, and hospitals to deal with drug shortages.

Mr. Speaker, I am proud of the work we have done here. I would like especially to thank full committee Chairman UPTON as well as Health Subcommittee Ranking Member FRANK PALLONE, full committee Ranking Member HENRY WAXMAN, and their staffs for patiently working with us on the FDA Reform Act.

This is legislation to help save lives and create jobs, which are two goals that we can all agree on. It is a bipartisan effort, and I urge all Members to support the legislation.

Mr. PALLONE. Mr. Speaker, I would like to yield 3 minutes to our chairman emeritus, Mr. DINGELL, who has worked so hard and who has been so much a part of this legislation.

Mr. DINGELL. I thank the gentleman from New Jersey.

Mr. Speaker, I rise in strong support of H.R. 5651, to reauthorize the prescription drug and medical device user-fee programs, to establish new user-fee programs for generic drugs and biosimilars, and also to give substantial new authorities to the Food and Drug Administration, with the support of the industry, to provide broad additional protections to American consumers.

H.R. 5651 is an excellent example of the great good that can be done when both parties come together in the spirit of bipartisanship, cooperation, and compromise, and when they work with consumers and the industry to achieve a bill supported by all.

This legislation will ensure the timely access to safe and effective drugs and medical devices, encourage the development of the innovative drug treatments for our children, and improve the Food and Drug Administration's current authority to deal with drug shortages. More importantly, this legislation will provide FDA with much-needed new authorities to secure the safety of our drug supply and to help prevent another incident like that unfortunate one involving heparin, in which over 80 people died from a blood thinner which was contaminated from where it came, in China, and which also sickened over 100 people of whom we know.

H.R. 5651's drug supply chain provisions will improve information FDA has about domestic and foreign drug manufacturers. It will, for the first time in history, provide FDA with information about importers and will enable FDA to control imported pharmaceuticals and devices. It will also allow FDA to detain or to destroy counterfeit or adulterated drugs, prohibit the entry of imported drugs that have been delayed or been denied inspection by FDA, and will encourage parity in the inspections of the domestic and foreign drug establishments. It will permit, for the first time, the real inspection of foreign producers, and it will treat all manufacturers alike.

These provisions mirror those in drug legislation which I authored earlier. The new authorities provided to FDA for our drug supply will enable the leveling of the playing field for our domestic drug manufacturers and will give American families the peace of mind that FDA can and will—and will have the authority to—respond to unsafe, misbranded, counterfeit, or contaminated drugs.

I want to thank my colleagues on the committee for the fine way this legislation was worked on, particularly Energy and Commerce Committee Chairman UPTON, Ranking Member WAXMAN, Subcommittee on Health Chairman PITTS, Ranking Member PALLONE, and their staffs—Clay Alspach, Ryan Long, Rachel Sher, Eric Flamm, Arun Patel, and Tiffany Guarascio, as well as Kimberlee Trzeciak of my staff—for their hard work and their commitment through this process to producing a bipartisan bill.

Mr. Speaker, I am pleased to be a coauthor of this important legislation. We have built upon the good work that FDA is already doing as well as the strong agreements negotiated by industry and FDA, and I urge the House to pass this bill.

I look forward to working with my colleagues in the Senate to swiftly pass legislation this summer that can be signed into law by the President.

Mr. UPTON. I yield myself 1½ minutes for the purpose of a colloquy, and I yield to the gentleman from Florida (Mr. BUCHANAN).

Mr. BUCHANAN. Mr. Chairman, I would like to thank you for working with me to advance my pill mill crackdown legislation and for your commitment to curbing prescription drug abuse. This crisis has created enormous pain and suffering on our families and communities, killing tens of thousands of Americans every year—tens of thousands.

I am pleased that the Senate FDA bill contains the central component of my bill to reschedule hydrocodone combination drugs—one of the most addictive and deadly drug mixtures. By reclassifying these drugs from a schedule III to a schedule II drug, we will be making them much more difficult to obtain and abuse. This provision has the support of the medical and the law enforcement communities as well.

I look forward to working with you, Mr. Chairman, to ensure that the final bill addresses this critical issue and contains the Buchanan pill mill provision.

Mr. UPTON. I appreciate your constant leadership on the national problem of prescription drug abuse. I appreciated your input during your phone call to me last week back in Michigan when the Senate passed this amendment. Our committee has focused on this issue, and you have been an outstanding partner with Congressman ED WHITFIELD and Congresswoman BONO MACK on this.

When used properly, we know that these medications provide needed therapies for those suffering from pain. However, the abuse of some of those products has devastated communities and destroyed families across the country. So, as we move forward on this bill in our discussions with the Senate, I hope that we can continue the partnership and be able to work this issue out.

At this point, Mr. Speaker, I ask unanimous consent that the balance of my time be controlled by the gentleman from Pennsylvania (Mr. PITTS).

The SPEAKER pro tempore. Without objection, the gentleman from Pennsylvania (Mr. PITTS) will control the remainder of the time.

There was no objection.

Mr. PALLONE. I yield 3 minutes to the gentlewoman from California (Mrs. CAPPS).

Mrs. CAPPS. I thank my colleague for yielding me time.

I rise today in strong support of the FDA Reform Act of 2012. I must say it is an honor to associate myself with the remarks of our chairman emeritus, Mr. DINGELL, who worked tirelessly over the years with regard to the Food and Drug Administration in making it a good institution that can only become better.

This bill represents the spirit of compromise—compromise across the aisle and also among the many stakeholders that work toward innovations to improve our health. It demonstrates that at a time when most of the country believes that we in Congress can't work together at all or pass a piece of legislation without a long and bitter fight, we can come together to improve health, protect the safety of the American people and, at the same time, to support good jobs and innovation in our health care industry.

I am especially pleased that two of my provisions have been included in this legislation. For example, the SAFE Devices Act will improve the postmarket surveillance of medical devices and the implementation of the unique device identifier program. This is an essential provision that will let us know that our devices work, and it will allow us to identify potential problems early on, protecting patients and identifying issues when they are easier and less costly to address. Additionally, the bill includes the simplification of FDA's de novo process—an important step to helping both medical devices manufacturers and patients.

I thank Chairmen UPTON and PITTS and Ranking Members PALLONE and WAXMAN for their leadership on this bill. I also thank the numerous advocates, the many patients and other

stakeholders who came together and contributed to this bill so that it would come to fruition today.

Of course, there is more work in front of us that remains to be done, but this bill before us is an important step in ensuring that our drug and device pipelines continue to produce needed cures and treatments in order to keep us all healthy, which is why I urge my colleagues to support it.

□ 1650

Mr. PITTS. Mr. Speaker, I yield 2 minutes to a gentleman who showed great leadership in the development of this legislation, in the negotiations, and has been a very integral part, the vice-chair of the Health Subcommittee, the gentleman from Texas, Dr. BURGESS.

Mr. BURGESS. I thank the gentleman for yielding.

Mr. Speaker, this is not a perfect bill, but it's a good bill, and it's a solid bill. It is worthy of the support of everyone on this floor. This bill reauthorizes the FDA's user-fee programs for prescription drugs and medical devices and, in fact, authorizes two new programs for generic devices and what are known as biosimilars. Together, all of these products provide powerful tools to prevent and alleviate human suffering.

The Food and Drug Administration must have the infrastructure and the resources to ensure patient safety and to approve new products in a straightforward and predictable fashion. Delayed reviews increase costs, hurt innovation, cost jobs, and deny patients potentially lifesaving products. These agreements present the tremendous opportunity to ensure that we have a strong and efficient FDA, and the committee responded appropriately and seized that opportunity. This bill will help the FDA build on what's working, address what isn't, and provide resources to meet future goals.

With the ranking member on the subcommittee, Mr. PALLONE, we crafted new guidelines for how the Food and Drug Administration recruits, approaches, and accesses relative scientific and medical expertise. I'm also pleased that we require the Food and Drug Administration to now notify Congress before issuing guidance regarding the regulation of laboratory-developed tests. We still need to strengthen and improve the oversight of laboratory-developed tests instead of promoting duplicative regulation that delays access to lifesaving diagnostics, but it's a good first step. Additionally, the bill takes good first steps to address critical drug shortages. No physician wants to tell a patient they can't receive the care that they need because the product is unavailable.

The process was respectful and resulted from hundreds of hours of negotiation. Certainly, Chairman PITTS and Ranking Members WAXMAN and PALLONE and Chairman Emeritus DINGELL and their staffs should be given tremendous credit, along with Ryan Long and Clay Alspach for the work they did on the majority staff, and my personal staff, J.P. Paluskiewicz, who put in long hours to get this product to the floor.

This vote is about patients. We need to get it right for them, and I think we've come awfully close to getting it right.

Mr. PALLONE. Mr. Speaker, I want to make a special thanks to another staff person for the committee, Rachel Sher, who is on my right here, as well. Thank you, Rachel.

I would now like to yield 3 minutes to the gentleman from Massachusetts (Mr. MARKEY).

Mr. MARKEY. I thank Chairman UPTON and Chairman PITTS and I thank Ranking Member PALLONE and Ranking Member WAXMAN for their work in bringing to the floor a bipartisan bill that provides FDA additional resources to bring new drugs and medical devices to market. But today's bill is also a huge missed opportunity. It would be a disservice to patient safety to ignore the bill's major shortfall.

Many Americans would be surprised to learn that 90 percent of medical devices are not required to undergo clinical testing in human beings prior to being sold. Under current law, the FDA is required to clear certain medical devices as long as they demonstrate their similarity to an earlier product, even if the new device is modeled after a similar defective device that caused serious injury or even death. Today's bill offered an important opportunity to address this device-safety loophole, but it doesn't. The loophole remains in place, and patients are still, and will remain, at grave risk.

Four years ago, Jaye Nevarez, a 50-year-old mother of three, was a healthy truck driver who earned a decent living, played in a band, and paid her bills on time. Then her doctor implanted a bladder mesh, a device that traces its origin back to a previous product that was recalled for causing serious injury and in some cases death. Jaye now lives in constant pain. She was forced to quit her job. She can't walk without a cane. She lost her insurance and faces a growing mountain of medical debt. The bank recently began foreclosure proceedings on her home where she lives with her 79-year-old mother.

Jaye isn't the first to be harmed by this loophole. If we fail to fix it, she won't be the last. There will be tens of thousands of others who fall into this loophole who will suffer serious injury.

I introduced the SOUND Devices Act providing FDA the ability to protect the public from these unsafe devices, but this was not included in the bill. The bill we are voting on today is critically important, however. It includes the EXPERRT Act, a bill that I authored to improve communication between FDA and experts in rare diseases. It includes bipartisan provisions that I'm proud to have worked with other Members to promote, especially in pediatric-device development.

This bill must not be the last word on medical-device safety. I hope that my colleagues will join with me to close this loophole so that we can keep the American public safe from harmful medical practices.

Mr. PITTS. Mr. Speaker, at this time I am happy to yield 1½ minutes to the subcommittee chairman of O&I, the gentleman from Florida (Mr. STEARNS).

Mr. STEARNS. Mr. Speaker, the authorization of the FDA user fees will simply provide stability at FDA's new product review as companies submit new and innovative devices and drugs for their approval.

I'm especially proud that in this bill I had a piece of legislation called the Faster Access to Specialized Treatments—FAST—Act, which is H.R. 4132. It was included in the FDA Reform Act. This act modernizes the FDA accelerated approval pathways to reflect the 20 years of science developed since accelerated approval was first established in 1992. So think of that: since 1992, with this bill that I've included in our FDA bill, it will accelerate approval through the FDA. It will simply allow new drugs to get to market faster for people who are 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. This act will save lives.

I would like to enter, Mr. Speaker, this letter of support for FAST signed by over 150 rare-disease groups into the RECORD.

I'm also glad that the FDA Reform Act includes the Expanding and Promoting Expertise in Review of Rare Treatments Act, EXPERRT Act, H.R. 4156. This will help FDA consult with medical experts when evaluating drugs dealing with rare disease such as cystic fibrosis. As the cofounder of the Cystic Fibrosis Caucus, I'm glad we're giving this tool to the FDA.

Mr. Speaker, I support passage of the FDA Reform Act.

MARCH 23, 2012.

Hon. CLIFF STEARNS,
U.S. House of Representatives, Washington, DC.
Hon. EDOLPHUS TOWNS,
U.S. House of Representatives, Washington, DC.

DEAR CONGRESSMEN STEARNS & TOWNS: On behalf of patients, physicians, and other members of the health advocacy community we are writing to express our support for H.R. 4132, the Faster Access to Specialized Treatments (FAST) Act. This legislation will modernize and expand the FDA's Accelerated Approval pathway to encompass a broader range of diseases and leverage 21st century drug development tools and strategies. This reform will speed the approval of much-needed therapies and cures to patients who are facing serious and life-threatening conditions, including Alzheimer's disease, autoimmune diseases, multiple sclerosis, Parkinson's disease, neuromuscular disease and hundreds of rare diseases that remain untreated.

We commend you for championing legislation that maintains the FDA's high standard for approval while at the same time ensuring the Agency can help facilitate the development of new and novel therapies to patients

in a more timely manner. In many cases our patients have no available treatment for their diseases, or they are using a therapy that is older and may not work as effectively and safely. This is not acceptable. We believe that this legislation will ensure patients receive the best, modern treatment as soon as possible and we applaud your efforts on their behalf.

Thank you for your leadership on this important bill and we look forward to working with you as it moves forward.

Sincerely,

Abigail Alliance for Better Access to Developmental Drugs; Advocacy for Patients with Chronic Illness, Inc.; Affiliated American CSA Foundation; Alliance for Aging Research; Alliance for Patient Access; American Autoimmune Related Diseases Association; American Brain Tumor Association; American Childhood Cancer Organization; American College of Medical Genetics; American Institute for Medical and Biological Engineering; American Society of Clinical Psychopharmacology; Batten Disease Support and Research Association; Break Through Cancer Coalition; Californians for Cures; Celiac Disease Center at Columbia University; Celiac Sprue Association; Charcot-Marie-Tooth Association (CMTA); Children's Cardiomyopathy Foundation, Inc.; Chinese American Association of Greater Chicago; Coalition Duchenne; Coalition for Pulmonary Fibrosis; Colon Cancer Alliance; Cooleys Anemia Foundation; Crohn's and Colitis Foundation of America; Cryoglobulinemia Vasculitis Organization; CureDuchenne; CurePSP; Digestive Disease National Coalition; Erik Metzler Foundation; EveryLife Foundation for Rare Diseases; Fabry Support & Information Group; Georgia PKU Connect; GIST Support International; Hadley Hope Fund; Hannah's Hope Fund; Hayden's Batten Disease Foundation Inc.; HealthHIV; Hope4Bridget Foundation; ICE Epilepsy Alliance; I Have IIH; In Need of Diagnosis, Inc. (INOD); Inspire; International Cancer Advocacy Network (ICAN); Jacob's Cure, Inc.; Jain Foundation Inc.; Jonah's Just Begun-Foundation to Cure Sanfilippo Inc.; LAM Treatment Alliance; LGS Foundation; Liddy Shriver Sarcoma Initiative; Little Miss Hannah Foundation; Lung Cancer Alliance; Lupus Foundation of America; Lymphangiomatosis & Gorham's Disease Alliance (LGDA); Lymphatic Malformation Institute (LMI); Macular Degeneration Support, Inc.; Madisons Foundation; Midwest Asian Health Association (MAHA); MLD Foundation; Mpdsupport.org—Myeloproliferative Disease Support; Muscular Dystrophy Association; National Family Caregivers Association; National MPS Society; National MS Society; National Niemann-Pick Disease Foundation, Inc.; National PKU Alliance; National Tay-Sachs & Allied Diseases Association; National Venture Capital Association; NBIA Disorders Association; New Jersey Association for Biomedical Research; NKH International Family Network; Noah's Hope—Batten Disease Fund; Oxalosis and Hyperoxaluria Foundation; Pachyonychia Congenita Project; Parkinson's Action Network; Parry-Romberg Syndrome Resource, Inc.; Partnership for Cures; Polycystic Kidney Disease Foundation; RARE Project; Russell-Silver Syndrome Support; Scleroderma Research Foundation; Sickle Cell Disease Association of America, Inc.; Society for Women's Health Research; Solving Kids' Cancer; Student Society for Stem Cell Research; Sudden Arrhythmia Death Syndromes (SADS) Foundation; Taylor's Tale; The Association for Frontotemporal Degeneration (AFTD); The Children's Medical Research Foundation, Inc.; The Erythromelalgia Association; The Focus Foundation; The Manton Center for Orphan Disease Research, Children's Hospital Boston; The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA); The Stop ALD Foundation; Tuberous Sclerosis Alliance; Veterans Health Council; VHL Family Alliance; Vietnam Veterans of America; ZERO—The Project to End Prostate Cancer.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from North Carolina (Mr. BUTTERFIELD).

Mr. BUTTERFIELD. I thank the gentleman for yielding, and I thank him for his leadership on our committee.

Mr. Speaker, I rise today in support of H.R. 5651, the Food and Drug Administration Reform Act, and want to simply highlight section 865, the Rare Pediatric Disease Priority Review Voucher Incentive program. I'm so pleased this section was included in the base text of the bill. I want to thank my colleagues on the committee and my good friend Congressman Mike McCaul of Texas for joining with me to see to its inclusion. Actually, we joined together in seeing to its inclusion. Also, let me give a strong thank you to Nancy Goodman with Kids vs. Cancer, who was a strong advocate on this issue.

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 FDA review of more profitable drugs in return for developing treatments for rare pediatric disease.

Since 1980, the FDA has approved only one new drug for treatment of childhood cancer while having approved 50 new cancer-fighting drugs for adults. Children living with life-threatening conditions need access to newly developed drugs that can treat these rare diseases.

□ 1700

Whether a disease is rare or common, the need for effective care and potential cures is the same. Therefore, I strongly urge its inclusion in the final bill that will go to the President for his signature.

Mr. Speaker, on a slightly different note, I would also like to discuss another issue of equal importance. My colleagues and I have worked closely with the Pharmaceutical Distribution Security Alliance to craft a consensus proposal that has the support of manufacturers, distributors, wholesalers, and both the community and chain pharmacists in dealing with traceability of prescription medication.

The proposal, known as RxTEC, would establish a national standard to address the serious issue of drug traceability and pedigree. I commend PDSA for their commitment to consumer and patient safety by working so diligently with both Chambers on this very important issue, ultimately securing placeholder language in the Senate FDA reform bill.

I am very supportive of this proposal, as RxTEC increases patient access to safe medicines, improves security of the pharmaceutical distribution chain, and lowers costs and regulatory burdens. Given the seriousness of this issue, and to avoid additional injuries and potential deaths from counterfeit drugs, I urge the FDA and all parties involved in these talks to find common ground so that we can include final supply chain integrity language into the final draft similar to section 865.

I ask my colleagues on the committee to also voice their support for inclusion.

Mr. PITTS. Mr. Speaker, I yield 2 minutes to the gentleman from Pennsylvania (Mr. MURPHY), a member of the Health Subcommittee, really the author of the sections on generic drug user fees and biosimilars in the bill.

Mr. MURPHY of Pennsylvania. I thank the chairman.

This year a typical senior will spend 15 percent of their household income on health care, including $620 plus on prescriptions.

But that sum would be much higher if there were no FDA-approved generic pharmaceuticals. Without generics, that same senior might pay $1,000 for medicine, and Medicare would spend some $67 billion more.

We must always assure that any medication, brand name or generic, is of the highest quality. But currently the Food and Drug Administration cannot assure that medicines coming in from overseas factories such as those in China are pure.

This bill includes my legislation, the Generic Drug and Biosimilar User Fee Act, to authorize for the first time an FDA program that will expedite approval of generics and clear a backlog of over 2,800 generic applications. Currently, the FDA is supposed to make a decision on the application within 16 months.

But the agency is taking twice that time because it lacks resources for conducting reviews and inspecting factories. U.S. factories are inspected perhaps once every 2 years, and more often if the FDA decides; foreign factories perhaps 7 to 9 years. That means millions of dosages of drugs coming in from overseas without any inspection.

Recall what happened when heparin ended up killing perhaps 100 to 200 people and causing other complications for many people. Ninety percent of pharmaceutical ingredients are made in foreign factories, but we cannot remain

dependent on drugs from other countries that are below U.S. standards.

People of all ages deserve peace of mind, and we all want to have the highest trust for all medicines, either brand name or generic. This bill will restore and support that trust for American consumers.

Mr. PALLONE. Mr. Speaker, I am not expecting any more speakers, and I reserve the balance of my time.

Mr. PITTS. Mr. Speaker, I yield 2 minutes to the gentleman from Georgia (Mr. GINGREY), another valued member of the Health Subcommittee, the author of the GAIN Act, the section dealing with antibiotics, and a valued participant in all these negotiations.

Mr. GINGREY of Georgia. I thank subcommittee Chairman PITTS, Chairman UPTON, subcommittee Ranking Member PALLONE. The bill that we are passing today in the House of Representatives, H.R. 5651, is an opportunity to come to the well in support of something that we have done in a bipartisan way. I really relish that fairly rare opportunity. Mr. Speaker, once again we are showing the American people that we can, when we have a need, a need and good ideas. Months and months and months went into working on this bill, staffs on both side. I commend them all and, of course, Ranking Member WAXMAN as well.

Let me just say this. Other Members are talking about the many aspects of the bill, talking about the user-fee aspect of prescription drugs, generic drugs, biologic, biosimilars, the drug safety chain aspect, addressing this problem of shortage of drugs. Emeritus Member DINGELL is a big part of that aspect of the bill.

Let me just say one thing about something that I had a lot of input into, and I am very proud of, and that is a specific drug, antibiotics, where we have a tremendous shortage. That inclusion of my bill, the GAIN Act, Generating Antibiotic Incentives Now, in this bill, I think, is hugely important. We have a lack of antibiotics in this country. We need to incentivize manufacturers to come forward with new and better antibiotics.

Mr. Speaker, I want to just mention very briefly anecdotally, in my district, the 11th District of Georgia, northwest Georgia, a young college student fell recently in a stream, the little Tallapoosa River, deeply gashed her leg. Bacteria got in that leg, which normally 99 out of a 100 times, Mr. Speaker, would cause no problems whatsoever.

In this instance, I guess maybe because of the depth of the wound and the amount of the trauma to the tissue, it resulted in something called necrotizing fasciitis. This young student, 24 years old, has been struggling for months in an Augusta hospital to recover from these injuries. She is on the way to recovery, thank God, but not without significant long-term disabilities. That's why things like the GAIN aspect of the bill is so important so that we can get new and better antibiotics to the market.

I support this bill tremendously in a bipartisan way.

Mr. PITTS. Mr. Speaker, I yield 2 minutes to the gentleman from Ohio (Mr. LATOURETTE).

Mr. LATOURETTE. I thank the gentleman very much for yielding.

I commend the Energy and Commerce Committee for producing a good piece of legislation. I also want to applaud the efforts to enhance the safety of America's pharmaceutical supply chain. While we are fortunate in America to not yet have a widespread problem, counterfeit drugs pose a serious health risk to all consumers.

The current patchwork of State requirements and licensing, however, makes supply chain compliance and safety inconsistent and challenging, which potentially jeopardizes the safety and welfare of millions of Americans. Unless a uniform Federal policy covering all pharmaceutical supply chain stakeholders is enacted, the U.S. will fail to provide the visibility and leverage technology that will provide a superior cost-effective consumer protection.

Third party logistic providers, or 3PLs, are playing a growing and important role in making sure that safe medicines reach their destinations. The term ''third party logistics provider'' refers to an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer.

Currently, Federal law does not recognize the role of a 3PL. Only one State today offers a license for 3PLs. Other States require a 3PL to apply for a wholesale distributor license, even though 3PLs don't buy or sell drugs.

The varying patchwork of inconsistent State requirements does not provide for optimum law enforcement, and there is an added cost without a safety benefit. 3PLs need to be defined in Federal legislation and properly licensed. Including a 3PL definition in Federal language is a strong first step towards the development of uniform Federal standards and 3PL licenses.

I want to thank my colleagues on the Energy and Commerce Committee in advance for a successful and constructive conference process, and I am confident that we can enhance the supply chain safety in a reasonable and cost-effective manner.

Mr. PALLONE. Mr. Speaker, I just want to say in closing that I think it's a great example with this bill of what we can do, not only in the Energy and Commerce Committee but in general in this House, on a bipartisan basis when everyone works together for a common goal.

□ 1710

This is actually a very important piece of legislation. It's important for the pharmaceutical industry. It's important in terms of job creation. It's important in terms of innovation and also bringing low-cost drugs to the American people. Without the type of bipartisan cooperation we had, we would not have been able to get here with this time schedule, which is truly amazing. So I want to thank everyone. I would like to say that I hope that we can do similar good work in the remainder of this Congress, and I would urge my colleagues to vote ''aye.''

I yield back the balance of my time.

Mr. PITTS. Mr. Speaker, in conclusion, I want to again commend leadership on both sides of the aisle: Ranking Member Emeritus Mr. DINGELL and Ranking Member Mr. PALLONE and Mr. WAXMAN and Chairman UPTON and staff of both sides. They have done a terrific job and spent countless hours. I especially want to mention Clay Alspach and Ryan Long on our side, as well as our personal staff. They have been absolutely terrific. Because of this, this legislation is going to save many lives. It's going to help the United States continue to be the world leader in the pharmaceutical and medical device industries and mean a lot to our economy as well.

I urge all Members to support this very important legislation, and I yield back the balance of my time.

Mr. BILBRAY. Mr. Speaker, I want to indicate my strong support of H.R. 5651, the Food and Drug Administration Reform Act of 2012, which we are addressing on the House floor today. This bipartisan legislation is not only good for the health of the American public; it is also a key component to restoring the health of our economy.

Nowhere will the impacts of this legislation be felt more than in Southern California and the San Diego region. According to BIOCOM, Southern California's life sciences cluster employs just over 97,000 in five sectors: biopharmaceuticals, industrial biotechnology and biofuels, life sciences trade, medical devices and diagnostics, and research and lab services. Medical devices and diagnostics is the region's largest life sciences sector, employing 33,871, followed by research and lab services with 31,878 jobs. These two sectors account for 68 percent of the total employment in the cluster, with over 65,000 jobs in the region. These innovative companies are on the forefront for discoveries from everything from Cancer therapies to the latest medical device that will prolong life.

The Food and Drug Administration Reform Act of 2012 will provide timely and necessary improvements to the user fee programs for drugs, medical devices, generics and biologics. Through this legislation, FDA will now be committed to meeting their performance goals for the review of life saving drugs—thus expediting these products to patients who need them, create an independent review entity to hold FDA accountable for the approval and clearance process for devices, as well as the creation of a new user fee program for generic drug and biologics approval all the while ensuring the safety of U.S. patients.

H.R. 5651 contains many provisions that will improve the lives of American patients and promote the competitiveness of the U.S. life science enterprise. However, there are two

provisions in this legislation that I am most proud of including. Included in the final House draft were two pieces of bipartisan legislation that I sponsored and worked with my colleagues on both sides of the aisle to get included. They are:

H.R. 3203, the Novel Device Regulatory Relief Act, coauthored with Representative LOIS CAPPS (D-Santa Barbara) improves the FDA's third party review and inspection of medical devices by making the process more efficient, transparent, and beneficial to the life science industry seeking approval.

H.R. 5334, the Breakthroughs Therapy Act, coauthored with Representative DIANA DEGETTE (D–Denver) expedites the review of breakthrough drugs for patients with serious or life-threatening disease or a condition where preliminary clinical evidence shows an improvement over existing therapies.

As we move forward in reconciling our legislation with the Senate it is my hope that we can address another national crisis that was not included in the House bill—the need for a reliable track and trace system for pharmaceutical products. For years, Congress has attempted to craft legislation that would secure the distribution chain for pharmaceuticals. Either due to lack of consensus from industry and patient participants or poor timing, this was never accomplished. This lack of action has resulted in a patchwork of State laws which create opportunities for bad actors to shop for States with the lowest safety requirements in order to introduce unsafe products into the legitimate supply chain. This patchwork also creates regulatory uncertainty in the supply chain, which adds increased costs and burden to the health care system.

But this year is different. For the first time, we have seen industry stakeholders put aside differences and come to a consensus on a language that is supported by me and my friend Mr. MATHESON that will create a national pedigree system which will replace a patchwork of State laws that are currently in place. While not a perfect solution, this legislation is a first step in creating a secure supply chain system that will protect the U.S. public from counterfeit drugs while preventing unwanted regulatory burden on American businesses. It is my goal to work with my colleagues to include track and trace language in the final legislation which will secure the drug supply chain and address the concerns of the large pharmaceutical distributors, secondary pharmaceutical distributors, local pharmacists, third party logistical providers and the large scale pharmacies.

In closing, I wish to thank Full Committee Chairman FRED UPTON and Health Subcommittee Chairman JOE PITTS for their commitment to this issue. Without their guidance and hard work, this legislation would never have seen the light of day. I look forward to casting my vote in support of H.R. 5651 and urge my colleagues to do the same.

Mrs. EMERSON. Mr. Speaker, I want to express my support for the reauthorization of the Food and Drug Administration (FDA) under consideration today. The FDA provides essential safeguards for patients in America and around the world, while making possible new treatments and therapies for diseases and conditions which affect millions. This bill supports greater speed of generic medications to market and assures much needed drugs to treat cancer will get to the patients who need them.

However, one provision (Section 805) in this legislation causes me special concern. The section includes the new authority for the Secretary of Health and Human Services to consult with the Department of Homeland Security to cause the destruction of any drug ''that has reasonable probability of causing serious adverse health consequences or death . . . or that is valued at an amount that is $2,000 or less.'' This section poses a serious concern to hundreds of thousands of Americans who receive their drugs by mail from licensed and regulated pharmacies in Canada and other foreign countries. For these patients, these American consumers, there is often only one choice beyond a Canadian pharmacy, and that is to not purchase the medicines they need at all.

Patients expecting receipt of legitimate prescriptions, written by their doctor and filled by a licensed pharmacy in Canada, could have their shipment of medication destroyed without receiving any notification either before or after the Federal Government takes that action. A bus full of senior citizens which crosses the border into Canada to visit a pharmacy where they can fill their prescriptions for one-third the price of the same medications in the United States could have their pill bottles seized at the border, their meager budget for their monthly health care expenses already exhausted. This is not good policy, nor is it what Americans expect from a free market.

This language threatens a critical, cost-effective supply of medications and pharmaceuticals. These drugs are exactly the same as their counterparts sold in America. I urge further discussion of this critical issue in conference and a full examination of the consequences of passing this provision into law.

Mr. WAXMAN. Mr. Speaker, today, the House considers a bill that represents a significant bipartisan achievement. Our work to find a common approach to legislation to support and strengthen the FDA is truly remarkable. It has been a pleasure to work with Mr. UPTON, Mr. PITTS, Mr. PALLONE, Mr. DINGELL, and other members of the Committee to achieve this result.

When we began this process, there were wildly divergent views on the various issues contained in this bill. But we worked together and found ways to address those issues in a way that protects both innovation and patients.

This legislation contains several provisions that are critical to the functioning of major parts of FDA. Our reauthorization of FDA's drug and medical device user fee programs will provide resources to enable the efficient review of applications and give patients access to therapies at the earliest possible time. We are also reauthorizing two pediatric programs which foster the development and safe use of prescription drugs in children.

This year we will be establishing two new programs to help speed FDA's 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 as a result of this legislation.

The bill also includes provisions to modernize FDA's authorities with respect to the drug supply chain. FDA has been trying to keep pace with our increasingly globalized drug supply chain using an outdated statute. This legislation will give FDA critical new tools to police this dramatically different marketplace.

We also have included some important provisions that will go a long way toward addressing drug shortages, which have unfortunately now become an all-too-frequent occurrence.

When we began this process, I had concerns about many of the Republican proposals relating to medical devices. But we worked together to address those concerns and to assure that nothing in this bill will take us backwards in terms of patient safety.

Our bipartisan work has truly paid off.

I support this bill, but I also think we can continue to improve it in the area of antibiotics. I agree that we need to look at ways to incentivize the development of new antibiotics. But we would more effectively address this need if we narrowed the provisions of the GAIN Act to target only drugs that treat serious and life-threatening infections. Additionally, mandating that steps be taken to preserve the effectiveness of antibiotics would strengthen the bill, in my view.

I want to thank my colleagues on both sides of the aisle, and their staffs, for the hard work they have put into making this a strong, bipartisan bill. I particularly want to thank Mr. PALLONE's and Mr. DINGELL's staff members Tiffany Guarascio and Kim Trzeciak as well as Mr. UPTON's and Mr. PITTS' staff, Ryan Long and Clay Alspach. And, finally, my own staff, Karen Nelson, Rachel Sher, Eric Flamm, and Arun Patel.

I expect the same level of bipartisan cooperation will continue as we work together with our colleagues in the Senate to get this to the President before the 4th of July recess.

Ms. KAPTUR. Mr. Speaker, I reluctantly rise today in support of H.R. 5651, the Food and Drug Administration Reform Act of 2012.

First, I would like to commend Chairman UPTON and Ranking Member WAXMAN for putting together a bipartisan bill. Bipartisan bills are a rarity in this Congress and I hope we can use the goodwill gained in this bill to come together on additional measures, such as those that create jobs and promote economic growth.

While this bill has support from both sides of the aisle, from my perspective, it does not go far enough.

The Food and Drug Administration (FDA) is tasked with ensuring the safety of $2 trillion in products produced by industry. The FDA's approval of a company's products all but guarantees profits for that company.

Companies that benefit from the FDA's approval should significantly contribute to the FDA's budget to reduce the burden on taxpayers who are already paying for tax cuts for millionaires and billionaires and two unpaid wars. In FY 12, user fees comprised a mere 35 percent of the FDA's budget.

The FDA is facing many challenges. Approximately half of medical devices used in the United States come from abroad. Nearly 40 percent of the drugs Americans take are made overseas and about 80 percent of the active pharmaceutical ingredients are imported. Several years ago, contaminated heparin from China caused a number of deaths and illnesses in my Congressional District.

Additional resources are needed to properly investigate, inspect, and police foreign products like heparin to ensure American consumers are fully protected. Industry should be contributing more.

Despite my reservations, this bill is a step in the right direction. It reauthorizes user fees for prescription drug and medical devices at levels that should provide the FDA with sufficient resources to give patients access to therapies at the earliest possible time.

In addition, this legislation authorizes a new user fee for generic drug reviews. In the last decade, the use of generic drugs saved the U.S. health care system more than $931 billion. Consequently, I'm glad to see the underlying bill provides resources to improve review times to ensure safe generic drugs come into the market as quickly as possible.

Finally, the bill addresses some of my concerns regarding foreign products. I strongly support the provisions that require drug importers to register with the FDA, requiring sufficient information from importers to allow the FDA to implement a risk-based approach to import screening and barring the entry of imported drugs if deemed to have been delayed, limited or denied a full safety inspection.

I also strongly support the section of the bill that provides extraterritorial Federal jurisdiction to enable United States law enforcement to hold those accountable who violate our safety laws, such as those who are responsible for the heparin-related deaths in my Congressional District.

Mr. TOWNS. Mr. Speaker, I rise today in support of H.R. 5651, The FDA Reform Act of 2012. I would like to thank my colleagues for working with me and my staff on this important piece of legislation. As we move forward in the legislative process I would like to state the importance of maintaining the provision in the accelerated approval section that requests guidance from the FDA on how to implement reforms to the drug approval process enacted by Congress. During our discussion in subcommittee I submitted letters in support of this language from NORD, BIO, and fifty other patient groups. I hope that we maintain this guidance language as we continue to move through the legislative process.

I have only a few remaining concerns that I hope we can work through together before the bill is signed into law. One issue is regarding our drug supply chain security and the second is regarding medical device technologies which potentiate drugs.

For many years, creating a national standard on drug traceability, or pedigree, has eluded Congress. Realizing that the U.S. pharmaceutical supply chain has many safeguards in place and companies spend significant amounts of money to ensure the integrity of their products—criminals, thieves and other bad actors will stop at nothing to make profit off of the high value prescription drugs that are manufactured and sent throughout the distribution chain down to our pharmacies, and ultimately to patients and consumers. I support efforts to create consensus language on this issue that has the backing of stakeholders—from manufacturers, to distributors, wholesalers on down to pharmacists—all involved in various aspects of the U.S. supply chain.

We know that the other chamber was able to include ''placeholder'' language in its version of the FDA bill to ensure that conversations can continue to play out between FDA, supply chain stakeholders and Congressional stakeholders to come to a final consensus over the course of the coming weeks. Given the seriousness of this issue—to avoid additional injuries and potential deaths from counterfeit and adulterated product, and to avoid a patchwork of individual state laws to address an issue which clearly requires a federal solution—I would urge the FDA and all parties involved in these talks to find common ground so that we can include final supply chain integrity language into the final FDA user fee bill that is agreed upon between the two chambers. I would ask my colleagues on the committee to also support this request and signal their support as well.

My final concern is regarding medical device technologies. The Centers for Disease Control and Prevention (CDC) estimates that more than 70% of bacterial and fungal pathogens resist at least one of the drugs typically used to eradicate them. The CDC estimates that these infections are responsible for over 90,000 deaths annually and cost the U.S. an excess of $4 billion. These life-threatening infections also prolong hospital stays and create substantial additional costs in the fighting of these infections.

With such knowledge, the importance of innovative treatments such as patented laser technology that combat resistant organisms such as MRSA is pivotal. One section of this bill addresses the critical need to improve the pipeline of medical drugs identified as qualified infectious disease products (QIDPs). It has been brought to my attention that new peer-reviewed and patented laser technology is emerging that has the potential to eradicate drug resistant bacteria and fungus by potentiation of existing generic antimicrobial drugs while preserving human tissue. The standard definition of ''potentiation'' is when one drug enhances a second drug so that the combined effect is greater than the sum of the effects of each one alone.

With these innovative technologies, we can improve post-surgical and inpatient outcomes. Furthermore, these technologies have shown the potential to successfully treat over 2.7 million patients annually suffering from diabetic ulcers and lower limb and amputations. I hope the FDA will consider medical device technology which potentiate drugs as well QIDPs which have already been identified in this legislation in taking steps toward eradicating bacterial and fungal infections.

Mr. Speaker, this legislation has been the model of bipartisanship. I hope that we can continue our important work together to have these critical provisions affecting patients included in the final bill before it is signed into law.

Ms. DELAURO. Mr. Speaker, while I have serious reservations, I rise in support of the Food and Drug Administration Reform Act of 2012 that we are considering under suspension of the rules today.

As we all know, this bill is critical to patients, consumers, and industry across the country. It will ensure that Americans continue to have access to safe, affordable, and effective medications and medical devices.

And there are several positive things in this legislation. For example, it will help to prevent drug shortages by requiring that companies notify the FDA if certain drugs are expected to experience manufacturing interruptions or discontinuances. Between 2005 and 2010, the number of reported drug shortages nearly tripled—so we must act, and the provisions in this bill are a step forward in addressing this issue.

The bill also permanently reauthorizes pediatric drug programs, including those originally created because of the Best Pharmaceuticals for Children's Act. It requires the electronic submission of new drug applications and issuance of regulations supporting a unique device identification system. It authorizes new efforts to prevent prescription drug abuse.

Unlike the Senate bill passed last week, this bill includes a clause that may result in the destruction of drugs valuing less than $2,000 entering this country before notifying the individual receiving the package—simply put, some Americans may order medications that never arrive, placing their health at risk as they wait for their affordable medication. We should move to the Senate position on this issue.

Unfortunately, this bill also represents a missed opportunity. We should be going much further to ensure that medications and medical devices are safe and effective, and to improve consumer and patient protections. For example, the bill does not strengthen the premarket review of medical devices, improve the agency's ability to appropriately reclassify medical devices, or even authorize an independent review of the drug approval process. It authorizes changes to the agency's conflict of interest policy for Advisory Committees, but does not strengthen them. And it does not reform the medical device clearance process.

The bill we consider today should not be an end point. American consumers need access to products that are safe and effective, and numerous independent organizations have found the current system lacking. Just last year, the Institute of Medicine found that the 510(k) clearance process is not ''a reliable premarket screen of the safety and effectiveness'' of some devices. In sum, we should pass this bill, but we must also do more to strengthen the pre-market and post-market oversight of drugs and devices.

Mrs. CHRISTENSEN. Mr. Speaker, there are so many reasons that I rise in strong support of this bipartisen legislation. Not only will it modernize the FDA review process of new and generic prescription drugs, biosimilars and medical devices, and ensure that Americans have reliable access to new, safe and innovative medicines and devices, as well as to affordable generic drugs, but it also promotes greater equity and safety in the development and use of prescription drugs for children—a level of importance that cannot be stressed enough.

I strongly support this legislation because it prioritizes and protects the health and welfare of consumers, while also being fair and just to the prescription drug and medical device industries. And, this legislation includes incentives for the development of new antibiotics to treat both life-threatening infections as well as those that if not treated, snowball into life-threatening situations.

Finally, I rise in strong support of this legislation because it will take significant steps forward to address our nation's ever-growing challenge with drug shortages. And so, Mr. Speaker, I urge my colleagues to join me with their strong support of this legislation so that we may achieve what we have long hoped to accomplish: reforming and strengthening many of the Food and Drug Administration's key programs which—together—will ensure that Americans have greater and more timely access to safe, affordable therapies and medical devices to treat and manage their conditions, and improve their overall health, quality of life and thus life opportunities.

Ms. MCCOLLUM. Mr. Speaker, I rise today in strong support of the Food and Drug Administration Reform Act of 2012 (H.R. 5651), which will strengthen Minnesota's health care system and economy.

The Food and Drug Administration Reform Act reauthorizes the FDA's drug and medical device user fee programs at a critical time. If these user fees are not reauthorized before the end of June, the FDA will not have the funding it needs to ensure life-saving drugs and medical devices are available to patients in a timely fashion. This bill also accelerates approval of treatments to address rare diseases, reauthorizes two successful pediatric programs, and helps to prevent drug shortages that are affecting families across the country. Overall, the reforms in H.R. 5651 bring the FDA into the 21st century by making the agency more responsive to changes in the U.S. health care system and better equipped to oversee a globalized market for medical products. This legislation will deliver safer treatments, faster innovation and better care for millions of American patients and families.

This legislation is especially important for America's medical device sector. The approval process for medical devices at the FDA slowed by as much as 60 percent since 2005, according to the General Accountability Office. While longer approval times do not contribute to patient safety, they have delayed or even denied life-saving treatments to patients and undermined the international competitiveness of the U.S. medical device industry. There is general agreement that the broken approval process for medical devices is doing real harm to patients and workers. This is especially concerning for Minnesota because our state is a hub of medical device innovation; the sector employs thousands of highly-skilled workers in our state. H.R. 5651 reforms and reauthorizes the medical device user fee program through fiscal year 2017, providing years of stability and increased regulatory certainty for companies that range from local small business startups to global Fortune 500 enterprises. Moreover, the bill will foster innovation in the sector by speeding market access for new and improved medical devices without compromising patient safety.

The Food and Drug Administration Reform Act is a rare bipartisan success story. This legislation comes to the House floor after months of close bipartisan collaboration. The Senate approved a bill very similar to H.R. 5651 by a vote of 96 to 1. The House Energy and Commerce Committee voted 46 to 0 to move H.R. 5651 to the floor. Both Democratic and Republican members of Congress understand that a high-quality health care system requires a strong and effective FDA. Today's bill is a major step forward for the FDA and a demonstration of legislative compromise for the good of the American people.

I urge all my colleagues to support H.R. 5651.

Mr. CHANDLER. Mr. Speaker, I rise today to address the significant bipartisan effort to reauthorize FDA user fee legislation. This reauthorization provides an opportunity to update the relevant FDA laws to reflect changes and challenges in the important area of prescription drugs and medical devices.

One critical area that Congress must continue to focus on is the safety and security of the pharmaceutical supply chain. Counterfeit drugs are a growing problem and put patient safety and health at risk. Patients who rely on certain medications should not have to live in fear they are not receiving the treatment they need because their medicine has been compromised.

This is unacceptable, and we must work to find a national solution to this growing problem of counterfeit drugs. Because so much of the pharmaceutical supply chain relies on interstate commerce, I believe our federal government must ensure that properly licensed entities are involved in our national pharmaceutical supply chain, particularly third-party logistics providers (3PLs).

The way prescription drugs are moved from the manufacturer to the consumer has changed over the past several years with the emerging role of 3PLs. These providers are not in the business of manufacturing, buying, selling, or dispensing prescription drugs; they provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, wholesaler, or dispenser. We cannot realistically expect to have a thorough and comprehensive national supply chain track-and-trace system without providing for a clear and accurate definition of third party logistics providers. Our federal laws need to reflect this new reality.

I applaud the Chairman and Ranking Member of the Energy & Commerce Committee for their leadership and diligent work on this bill, and I encourage them to ensure that the final product from the House-Senate conference implements a uniform federal serialization policy covering all pharmaceutical supply chain participants.

Mr. PASCRELL. Mr. Speaker, I stand today to support H.R. 5651—Food and Drug Administration Reform Act of 2012, which reauthorizes the Federal Drug Administration's (FDA) prescription drug and medical device user fee programs through 2017. This legislation will provide the FDA the ability to collect user fees from drug and medical device companies to help fund its reviews of their products. These user fee programs provide the FDA the resources to enable the efficient review of applications and give patients access to therapies at the earliest possible time, and most importantly, help prevent drug shortages that threaten public health.

I am supportive of the legislation because it will authorize a new user fee program for generic drugs, resulting in decreased review times, and it authorizes user fee program for biosimilars, thus ensuring parity. Additionally, the legislation reauthorizes and makes permanent two complementary pediatric drug programs, which foster the development and safe use of prescription drugs for children.

Further, the legislation will assist in the modernization of the FDA's global drug supply chain authority, resulting in improved safety of our prescription drugs The legislation will also provide new incentives for the development of antibiotics to address the public health threat of antibiotic resistance. Finally, the bill includes important provisions to help prevent and mitigate drug shortages, which have unfortunately now become an all-too-frequent occurrence.

Ultimately, the legislation will ensure that Americans have access to crucial medicines and medical devices, improves access to new and innovative medicines and devices, helps prevent and mitigate drug shortages and reduces drug costs for consumers by speeding the approval of lower-cost generic drugs.

Mr. PAULSEN. Mr. Speaker, I rise today in strong support of H.R. 5651, the Food and Drug Administration Reform Act.

The United States has led the global medical device industry for decades. This leadership has brought hundreds of thousands of high-paying jobs to our country and life-saving, life-improving devices to our nation's patients. U.S. medical device-related employment totals over 2 million jobs, and these are good, rewarding jobs.

This legislation will streamline and modernize the medical device approval process to make it more transparent, more consistent, and more predictable. This much needed reform will help companies bring their products to market quicker and cheaper, ultimately increasing patient access to life improving and life saving technologies.

I would like to highlight one portion of the bill that was taken from my legislation, the FDA REFORM Act. This provision would expand and clarify the FDA's ability to use accredited third party reviewers for low risk devices.

This will free up valuable resources and allow the FDA to function more effectively while still focusing on protecting patient safety.

I want to thank Chairman UPTON and his staff for their continued support and effort on this matter. I urge adoption of this crucial legislation that will help bring new products to market.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, H.R. 5651, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. PITTS. 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.

FEDERAL COMMUNICATIONS COMMISSION CONSOLIDATED REPORTING ACT OF 2012

Mr. SCALISE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3310) to amend the Communications Act of 1934 to consolidate the reporting obligations of the Federal Communications Commission in order to improve congressional oversight and reduce reporting burdens, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3310

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 ''Federal Communications Commission Consolidated Reporting Act of 2012''.

SEC. 2. COMMUNICATIONS MARKETPLACE REPORT.

Title I of the Communications Act of 1934 (47 U.S.C. 151 et seq.) is amended by adding at the end the following:

"SEC. 14. COMMUNICATIONS MARKETPLACE REPORT.

''(a) IN GENERAL.—In the last quarter of every even-numbered year, the Commission shall publish on its website and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a report on the state of the communications marketplace.

''(b) CONTENTS.—Each report required by subsection (a) shall—

''(1) assess the state of competition in the communications marketplace, including competition to deliver voice, video, audio, and data services among providers of telecommunications, providers of commercial mobile service (as defined in section 332), multichannel video programming distributors (as defined in section 602), broadcast stations, providers of satellite communications, Internet service providers, and other providers of communications services;

''(2) assess the state of deployment of communications capabilities, including advanced telecommunications capability (as defined in section 706 of the Telecommunications Act of 1996 (47 U.S.C. 1302)), regardless of the technology used for such deployment, including whether advanced telecommunications capability is being deployed to all Americans in a reasonable and timely fashion;

''(3) assess whether laws, regulations, or regulatory practices (whether those of the Federal Government, States, political subdivisions of States, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)), or foreign governments) pose a barrier to competitive entry into the communications marketplace or to the competitive expansion of existing providers of communications services;

''(4) describe the agenda of the Commission for the next 2-year period for addressing the challenges and opportunities in the communications marketplace that were identified through the assessments under paragraphs (1) through (3); and

''(5) describe the actions that the Commission has taken in pursuit of the agenda described pursuant to paragraph (4) in the previous report submitted under this section.

''(c) SPECIAL REQUIREMENTS.—

''(1) ASSESSING COMPETITION.—In assessing the state of competition under subsection (b)(1), the Commission shall consider all forms of competition, including the effect of intermodal competition, facilities-based competition, and competition from new and emergent communications services, including the provision of content and communications using the Internet.

''(2) ASSESSING DEPLOYMENT.—In assessing the state of deployment under subsection (b)(2), the Commission shall compile a list of geographical areas that are not served by any provider of advanced telecommunications capability.

''(3) INTERNATIONAL COMPARISONS AND DEMOGRAPHIC INFORMATION.—The Commission may use readily available data to draw appropriate comparisons between the United States communications marketplace and the international communications marketplace and to correlate its assessments with demographic information.

''(4) CONSIDERING SMALL BUSINESSES.—In assessing the state of competition under subsection (b)(1) and regulatory barriers under subsection (b)(3), the Commission shall consider market entry barriers for entrepreneurs and other small businesses in the communications marketplace in accordance with the national policy under section 257(b).''.

SEC. 3. CONSOLIDATION OF REDUNDANT REPORTS; CONFORMING AMENDMENTS.

(a) ORBIT ACT REPORT.—Section 646 of the Communications Satellite Act of 1962 (47 U.S.C. 765e; 114 Stat. 57) is repealed.

(b) SATELLITE COMPETITION REPORT.—Section 4 of Public Law 109–34 (47 U.S.C. 703) is repealed.

(c) INTERNATIONAL BROADBAND DATA REPORT.—Section 103 of the Broadband Data Improvement Act (47 U.S.C. 1303) is amended—

(1) by striking subsection (b); and

(2) by redesignating subsections (c) through (e) as subsections (b) through (d), respectively.

(d) STATUS OF COMPETITION IN THE MARKET FOR THE DELIVERY OF VIDEO PROGRAMMING REPORT.—Section 628 of the Communications Act of 1934 (47 U.S.C. 548) is amended—

(1) by striking subsection (g);

(2) by redesignating subsection (j) as subsection (g); and

(3) by transferring subsection (g) (as redesignated) so that it appears after subsection (f).

(e) REPORT ON CABLE INDUSTRY PRICES.—

(1) IN GENERAL.—Section 623 of the Communications Act of 1934 (47 U.S.C. 543) is amended—

(A) by striking subsection (k); and

(B) by redesignating subsections (l) through (n) as subsections (k) through (m), respectively.

(2) CONFORMING AMENDMENT.—Section 613(a)(3) of the Communications Act of 1934 (47 U.S.C. 533(a)(3)) is amended by striking ''623(l)'' and inserting ''623(k)''.

(f) TRIENNIAL REPORT IDENTIFYING AND ELIMINATING MARKET ENTRY BARRIERS FOR ENTREPRENEURS AND OTHER SMALL BUSINESSES.—Section 257 of the Communications Act of 1934 (47 U.S.C. 257) is amended by striking subsection (c).

(g) SECTION 706 REPORT.—Section 706 of the Telecommunications Act of 1996 (47 U.S.C. 1302) is amended—

(1) in subsection (b)—

(A) in the last sentence, by striking ''If the Commission's determination is negative, it'' and inserting ''If the Commission determines in its report under section 14 of the Communications Act of 1934 that advanced telecommunications capability is not being deployed to all Americans in a reasonable and timely fashion, the Commission''; and

(B) by striking the first and second sentences;

(2) by striking subsection (c);

(3) in subsection (d), by striking ''this subsection'' and inserting ''this section''; and

(4) by redesignating subsection (d) as subsection (c).

(h) STATE OF COMPETITIVE MARKET CONDITIONS WITH RESPECT TO COMMERCIAL MOBILE RADIO SERVICES.—Section 332(c)(1)(C) of the Communications Act of 1934 (47 U.S.C. 332(c)(1)(C)) is amended by striking the first and second sentences.

(i) PREVIOUSLY ELIMINATED ANNUAL REPORT.—

(1) IN GENERAL.—Section 4 of the Communications Act of 1934 (47 U.S.C. 154) is amended—

(A) by striking subsection (k); and

(B) by redesignating subsections (l) through (o) as subsections (k) through (n), respectively.

(2) CONFORMING AMENDMENTS.—The Communications Act of 1934 is amended—

(A) in section 9(i), by striking ''In the Commission's annual report, the Commission shall prepare an analysis of its progress in developing such systems and'' and inserting ''The Commission''; and

(B) in section 309(j)(8)(B), by striking the last sentence.

(j) ADDITIONAL OUTDATED REPORTS.—The Communications Act of 1934 is further amended—

(1) in section 4—

(A) in subsection (b)(2)(B)(ii), by striking ''and shall furnish notice of such action'' and all that follows through ''subject of the waiver''; and

(B) in subsection (g), by striking paragraph (2);

(2) in section 215—

(A) by striking subsection (b); and

(B) by redesignating subsection (c) as subsection (b);

(3) in section 227(e), by striking paragraph (4);

(4) in section 309(j)—

(A) by striking paragraph (12); and

(B) in paragraph (15)(C), by striking clause (iv);

(5) in section 331(b), by striking the last sentence;

(6) in section 336(e), by amending paragraph (4) to read as follows:

''(4) REPORT.—The Commission shall annually advise the Congress on the amounts collected pursuant to the program required by this subsection.'';

(7) in section 339(c), by striking paragraph (1);

(8) in section 396—

(A) by striking subsection (i);

(B) in subsection (k)—

(i) in paragraph (1), by striking subparagraph (F); and

(ii) in paragraph (3)(B)(iii), by striking subclause (V);

(C) in subsection (l)(1)(B), by striking ''shall be included'' and all that follows through ''The audit report''; and

(D) by striking subsection (m);

(9) in section 398(b)(4), by striking the third sentence;

(10) in section 624A(b)(1)—

(A) by striking ''REPORT; REGULATIONS'' and inserting ''REGULATIONS'';

(B) by striking ''Within 1 year after'' and all that follows through ''on means of assuring'' and inserting ''The Commission shall issue such regulations as are necessary to assure''; and

(C) by striking ''Within 180 days after'' and all that follows through ''to assure such compatibility.''; and

(11) in section 713, by striking subsection (a).

SEC. 4. EFFECT ON AUTHORITY.

Nothing in this Act or the amendments made by this Act shall be construed to expand or contract the authority of the Federal Communications Commission.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Louisiana (Mr. SCALISE) and the gentlewoman from California (Ms. MATSUI) each will control 20 minutes.

The Chair recognizes the gentleman from Louisiana.

GENERAL LEAVE

Mr. SCALISE. 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 into the RECORD.

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

There was no objection.

Mr. SCALISE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, we're bringing forward H.R. 3310, the FCC Consolidated Reporting Act. If you look throughout

the many different requirements that the FCC has, and the number of reports—this is just a small stack of the reports that FCC has been required to bring to Congress just in the last 2 years. Many of these reports not only place tremendous burden on the industry groups that have to provide this data, but many times, because of the way that they're structured, by the time the report is issued, the data is outdated and really doesn't look at any broad spectrum issues. They're mostly specific to an industry and a specific area of an industry instead of looking at the entire marketplace.

So what we're doing with the FCC Consolidated Reporting Act is actually bringing forward a measure that reduces the size of government and actually reins in the heavy hand of government and takes eight different annual reports and consolidates them into one consolidated biannual report. And so you're taking eight reports that in many cases are outdated by the time they're released; and, in some cases the FCC, even though they're required to produce this data annually, because the reports are so burdensome on industry and on the FCC, they're not even able to produce these reports annually. In many cases, we've had reports that are due annually that haven't been submitted to us since 2009. So we're actually making a much more commonsense approach to this reporting system.

In addition to that, we're actually repealing some of the requirements that are still on the books—laws that Congress has passed over the last few decades that are not even required anymore by FCC or other agencies yet are still on the law books. And so we're cleaning up a lot of those.

One of those I'll give as an example is we're still requiring a competitiveness report to be produced with the wireline telegraph industry. I don't know anybody since Samuel Morse invented that technology in the 1800s that is still using that technology on a broad scale. But surely Congress doesn't need to still have on the books a requirement that we have a report submitted by the FCC on competitiveness in the wire-line telegraph industry.

So this bill is a bipartisan approach to remove so many unnecessary requirements on our job creators who have to have compliance departments to comply with all these requests from the FCC; and, in many cases, they're getting these requests, and they know that when they submit this data the reports that they're submitting the data for aren't even going to be produced annually. And when those reports come out, they're going to be outdated, yet you still have to have massive compliance departments to go and gather all this information.

I think it makes much more sense for us to tell our job creators that, instead of having these massive compliance departments to do unnecessary work, that dollar would be much better spent going out and creating jobs and building out those wireless networks that people all across this country so desperately need.

Mr. Speaker, I reserve the balance of my time.

Ms. MATSUI. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 3310, the Federal Communications Commission Consolidated Reporting Act of 2012. This bill consolidates various technology-specific competition reports the Federal Communications Commission is required to make to Congress into a new, single communications marketplace report that will be submitted to Congress every 2 years.

The FCC is required to assess the state of competition, deployment, as well as regulatory barriers to market entry and competition in the communications marketplace, taking into special consideration Internet-based competition. I support efforts to streamline the FCC's reporting requirements, and I am pleased the committee majority, led by Communications and Technology Subcommittee Chairman WALDEN, worked with Democrats to improve the legislation throughout the markup process. These improvements include the adoption of an amendment offered by Ranking Member ESHOO that would ensure the FCC continues to have the ability to consider all forms of competition in producing the communications marketplace report.

H.R. 3310 seeks to reduce the reporting burdens Congress had previously imposed on the FCC while encouraging the agency to analyze competition in the communications marketplace in a much more comprehensive way.

Under Chairman Genachowski's leadership, the FCC has accomplished numerous reforms aimed at improving agency process. The FCC has improved the number of notices of proposed rulemakings that contain the full text of proposed rules from 38 percent to 85 percent. Additionally, the FCC has reduced average time between Commission vote and release of full text of the decision from 14 calendar days to 3 calendar days. In addition, the FCC voluntarily complied with President Obama's Executive order in conducting retrospective analysis of the Commission's existing rules. During the process, the FCC has eliminated over 200 obsolete regulations, including the Commission's elimination of 25 data collections as part of the Data Innovation Initiative.

Looking ahead, the FCC has a major task in implementing the public safety and spectrum provisions of the Middle Class Tax Relief and Job Creation Act. Specifically, the Commission will be undertaking arguably the most complex spectrum auction in history through an incentive auction of the broadcast spectrum. Congress must work closely with the FCC to ensure the auction's success.

As a cochair of the bipartisan Federal Spectrum Working Group, I'm hopeful that we'll have the opportunity to work closely with the FCC and the NTIA and other relevant agencies in identifying underutilized Federal and commercial spectrum for repurposing.

Mr. Speaker, our Nation continues to face a spectrum scrunch, particularly as more and more Americans opt for advanced technology and mobile devices and applications. We must ensure that we meet future demand.

Finally, I want to applaud the FCC's recent efforts ensuring that all Americans have access to the communication tools they need to be competitive in the 21st century economy.

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Today, one-third of Americans have not adopted broadband, and these numbers are particularly high among lower-income Americans, seniors, rural Americans, residents of tribal lands, and people with disabilities.

The commission recently approved responsible reforms to parts of the Universal Service Fund, including the creation of pilot programs to promote broadband adoption. These pilot projects will help make broadband more affordable for lower-income Americans and address other challenges to broadband adoption, including digital literacy and the cost of devices.

I commend the FCC for these efforts, and I look forward to working with the commission when these pilot projects are announced.

I reserve the balance of my time.

Mr. SCALISE. Mr. Speaker, I am honored to yield 2 minutes to the gentlewoman from Tennessee (Mrs. BLACKBURN), a member of the committee and subcommittee.

Mrs. BLACKBURN. Mr. Speaker, I thank the gentleman, and I do rise to support the Federal Communications Commission Consolidated Reporting Act. It's a commonsense piece of legislation, much like Mr. WALDEN's process reform bill for the FCC that was passed in this House in March on a bipartisan vote.

The FCC Consolidated Reporting Act, as Mr. SCALISE said, will streamline eight annual and triennial FCC reports into one single biennial communications marketplace report. The effect is to ease some of the reporting obligations while providing the FCC a better platform to analyze the converged nature of today's competitive communications marketplace.

It's important to get the reporting in check because the FCC has control over one-sixth of our Nation's economy. This legislation would simply bring back some efficiency and transparency to an agency that is clearly lacking in both categories. We need to redirect the FCC away from its antiquated approach to regulatory policymaking. A streamed and consolidated reporting system that better reflects today's competitive marketplace is necessary to help in this process, especially for those who understand that

we need wholesale change and deregulation at the Nation's leading communications governing agency.

I support the legislation to simplify the FCC's reporting measures. I encourage my colleagues to support the legislation.

Ms. MATSUI. I reserve the balance of my time.

Mr. SCALISE. Mr. Speaker, at this time I would like to yield 3 minutes to the gentleman from Oregon (Mr. WALDEN), the chairman of the Telecommunications Subcommittee.

Mr. WALDEN. Mr. Speaker, I want to thank Mr. SCALISE for his leadership on this issue, and I want to thank Ms. MATSUI for hers as well, and for the work that we are all doing on the subcommittee to improve the processes and procedures at the FCC, bring about efficiencies and accountability, and look for Federal spectrum that might be freed up to help grow jobs and spur innovation in America.

This particular piece of law, as we move it forward, H.R. 3310, gets about trying to reduce some waste. It really starts with Congress because this is all stuff that is in statute that we have to change. Believe it or not, the Communications Act still requires the Federal Communications Commission to assess the state of telegraph—telegraph—competition. This is not just unhelpful; it's a waste of taxpayer funds. The American public expects and deserves an efficient Federal Government that keeps pace with changes in the market, and this bill helps get us there.

Rationalizing the industry reports the FCC issues not only reduces some of the FCC'S administrative burdens but also helps make sure that the agency, the public, and stakeholders have a realistic picture of the marketplace upon which to make their policy judgments.

The communications and technology sector is very competitive. It's very innovative. It's creating jobs, and it's one of the most open sectors of our economy. From fiber optics to 4G wireless service, from the smartphone to the tablet to the connected TV, this sector has been creating new services, new devices, and the high-quality jobs that come with high-tech innovation and investment.

Despite even a lackluster economy, wireline, wireless, and cable providers invested $66 billion of private capital in broadband infrastructure in 2011. The U.S. is leading in cutting-edge wireless technologies. Industry convergence has led to a boom in competition; voice, video, audio, and data providers are competing across different platforms. And the market is simply moving faster than the law. Despite the convergence of the industry, the FCC is still required by law to evaluate stove-piped industry segments each year. For example, they have to write two reports each year on the satellite industry and two reports on the cable industry, and yet it is one market and there should just be one report covering both.

The FCC Consolidated Reporting Act consolidates eight separate congressionally mandated reports on the communications industry into a single comprehensive report with a focus on competition among technology platforms, deploying communications to unserved communities, eliminating regulatory barriers, and empowering small businesses.

The marketplace report is synched to the congressional calendar. That'll improve our oversight abilities, and it'll help reduce costs. The bill also eliminates 12 additional outdated reports from the Communications Act, including reports repealed more than a decade ago. The bill is bipartisan, and it's supported by CTIA, NAB, NCTA, USTelecom, and the U.S. Chamber of Commerce, and I urge my colleagues to join in this bipartisan piece of work out of your Subcommittee on Communications and Technology and pass it into law.

Ms. MATSUI. I reserve the balance of my time.

Mr. SCALISE. Mr. Speaker, I would like to yield 2 minutes to the gentleman from Georgia (Mr. GINGREY).

Mr. GINGREY of Georgia. Mr. Speaker, I thank the gentleman.

I rise today in strong support of H.R. 3310, the FCC Consolidating Reporting Act of 2012. I commend the author of this legislation and fellow member of the Communications and Technology Subcommittee, STEVE SCALISE of Louisiana, for his work on this issue. And I also applaud the work of subcommittee chairman GREG WALDEN, who ensured that we moved this legislation through regular order.

H.R. 3310 consolidates eight congressionally mandated studies into a single report with a focus on intermodal competition, deploying communications to underserved and unserved communities, eliminating regulatory barriers, and empowering small businesses. This legislation will also make the FCC more efficient by eliminating a number of duplicative, repealed, or outdated reports that are still listed in statute. For example, in the 21st century, it is simply not necessary for the FCC to provide the report on competition between wire telephone and wire telegraph providers. Think Morse code.

Mr. Speaker, H.R. 3310 passed the full Energy and Commerce Committee by a voice vote on March 6, 2012. It will alleviate the unnecessary and antiquated reporting standards and replace them with an analysis of the 21st century marketplace and its demands on the telecommunications industry. This legislation represents solid policy. I urge my colleagues, support H.R. 3310.

Ms. MATSUI. I reserve the balance of my time.

Mr. SCALISE. Mr. Speaker, I yield 2 minutes to the gentleman from Florida (Mr. STEARNS), the chairman of the Oversight Subcommittee.

Mr. STEARNS. Mr. Speaker, I thank my colleague.

Mr. Speaker, I rise in strong support of this bill. It streamlines, as mentioned, eight separate congressionally mandated reports into one, a single comprehensive report.

As chairman of the Energy and Commerce Subcommittee on Oversight and Investigation, as Mr. SCALISE mentioned, I, along with Chairman WALDEN, have looked into the backlog and workload of the FCC. In a report we released in November, we found that annual reports to Congress, such as the Satellite Competition Report and Video Programming Report, have not been completed in years. This is just disconcerting, particularly since the Telecom Act of 1996 was designed with a deregulatory slant—requiring the FCC to conduct these competition reports to determine whether regulation was indeed necessary. How can the FCC appropriately make these decisions and regulate an industry it has not comprehensively analyzed in more than 4 years? This bill is aimed at reducing some reporting burdens on the FCC to ensure that these annual reports are just that—they are simply reported annually.

At the same time, this bill encourages the agency in today's age of convergence to analyze competition in the marketplace as a whole, rather than based on archaic technology-specific silos. We no longer need to consider the Internet, satellite, and cable industries in a vacuum, as they compete head to head in most markets across this country.

□ 1730

In 1992, when we passed the Cable Act, cable occupied about 96 percent of the market. The FCC's most recent data cable now only occupies about a third of this market, competing with FIOS, satellite, Netflix, and the Internet. The report that looks at the marketplace as a whole will inform both the FCC and Congress more sufficiently, and it's a long time due. Therefore, I hope my colleagues will join me in supporting this important legislation, and I appreciate its authors.

Ms. MATSUI. Mr. Speaker, in closing, H.R. 3310 is a step forward to further ensuring transparency by requiring consolidation of various telecommunication reports by the FCC.

As broadband continues to play a critical role in our economy, it is important that we fully understand any and all barriers to Internet services while continuing to allow the Internet economy to grow and innovate.

Again, I want to thank my colleagues on the Energy and Commerce Committee for working in a bipartisan manner on this bill. I urge my colleagues to support this legislation, and I yield back the balance of my time.

Mr. SCALISE. Mr. Speaker, I want to thank the gentlelady from California for the bipartisan work that she's done on this legislation. Especially, I want to thank Chairman UPTON and Chairman WALDEN for allowing us to bring

this bipartisan legislation forward that takes a commonsense approach to so many reports and requirements that are placed on industry and the FCC, frankly, that require a whole lot of work to produce reports that are outdated before they're even filed. The job of government and regulators should not be just to make companies go and do busy work, to file reports just for the sake of building up reams and reams of papers that nobody can read and nobody can really do anything with because the data is not useful.

So what we're doing with this legislation is taking eight reports—eight reports that all look at very specific sector areas, but don't really tell a picture of what's happening in the industry—and we consolidate those into one report rather than annual, a biannual, and reducing a lot of requirements on business that just have to have these compliance departments because when they're asked by the FCC to provide data, they've got to go provide it, even though they know this data is not going to be used, and in some cases the data is not going to be useful in the context of the report that's going to be filed.

In addition to that, we often hear about all of the laws that are passed in Congress. People say why don't you go and repeal laws that have been sitting on the books for decades that serve no purpose. So we actually do that too with this bill. We go and repeal 12 different reports that are no longer used. As the example has been given a number of times, the telegraph report that is still a law that's on the books, we repeal that as well.

So it's a commonsense approach that tells the people that are out there building this infrastructure, building these wireless networks that so many people, millions and millions of people, in our country use every single day to improve their lives, their quality of life—and frankly the effectiveness of the job creators and our small businesses out there—and it says you don't need to have massive compliance departments to comply with things that nobody reads. You can actually go out and use those resources to create more jobs, to build out that network so that we can do even more innovative things with the technology we have today and that we'll have in the future.

With that, I urge all of my colleagues to support H.R. 3310, and I yield back the balance of my time.

Mr. UPTON. Mr. Speaker, Americans have demanded a more efficient government that eliminates outdated and unnecessary bureaucracy; a government that takes a hard look at the market before deciding to regulate it—in short, a government that works. The FCC Consolidated Reporting Act accomplishes those goals, all at no cost to the taxpayer.

Today, the FCC is required to write eight separate reports on discrete components of the communications marketplace. Eight separate reports multiplies the number of hours the FCC spends writing reports, multiplies the number of employees working on such reports, and multiplies the number of times industry has to respond to information requests from the Commission.

The FCC Consolidated Reporting Act takes a smarter approach. It consolidates these eight reports into a single, comprehensive report on the state of the communications marketplace, and eliminates twelve other reports from the Communications Act.

I want to thank Communications and Technology Subcommittee Chairman GREG WALDEN and Representative STEVE SCALISE for working on this important legislation. I support it, and I urge my colleagues to support it as well.

Mrs. CHRISTENSEN. Mr. Speaker, although, H.R. 3310 is intended to streamline the Federal Communication Commission's reporting requirements. There are concerns that FCC's statutory authority on data collection could be affected and certain pertinent reporting requirements could be eliminated.

H.R. 3310 would consolidate eight separate reports of the FCC into a single comprehensive report in order to reduce the reporting burdens on the FCC while encouraging the agency to analyze competition in the marketplace as a whole. I believe that this bill is not only unnecessary but harmful to the process especially since under Chairman Genachowski many reforms have been made to address the issues the Republicans have indicated they want to fix.

While the FCC has sufficient existing authority to collect data for statutorily required reports, the language contained in Sec. 4 could be construed as denying the Commission its ordinary data collection authority with respect to certain provisions of the bill.

While I support the general intent of the bill to streamline FCC reporting requirements, I did not support it at committee level in its present form and no significant changes were made to improve the bill before it was brought to the House floor.

I urge my colleagues not support this bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Louisiana (Mr. SCALISE) that the House suspend the rules and pass the bill, H.R. 3310, 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.

SERVICEMEMBER FAMILY PROTECTION ACT

Mr. STEARNS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4201) to amend the Servicemembers Civil Relief Act to provide for the protection of child custody arrangements for parents who are members of the Armed Forces.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4201

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 ''Servicemember Family Protection Act''.

SEC. 2. PROTECTION OF CHILD CUSTODY ARRANGEMENTS FOR PARENTS WHO ARE MEMBERS OF THE ARMED FORCES.

(a) CHILD CUSTODY PROTECTION.—Title II of the Servicemembers Civil Relief Act (50 U.S.C. App. 521 et seq.) is amended by adding at the end the following new section:

''SEC. 208. CHILD CUSTODY PROTECTION.

''(a) RESTRICTION ON TEMPORARY CUSTODY ORDER.—If a court renders a temporary order for custodial responsibility for a child based solely on a deployment or anticipated deployment of a parent who is a servicemember, then the court shall require that upon the return of the servicemember from deployment, the custody order that was in effect immediately preceding the temporary order shall be reinstated, unless the court finds that such a reinstatement is not in the best interest of the child, except that any such finding shall be subject to subsection (b).

''(b) EXCLUSION OF MILITARY SERVICE FROM DETERMINATION OF CHILD'S BEST INTEREST.—If a motion or a petition is filed seeking a permanent order to modify the custody of the child of a servicemember, no court may consider the absence of the servicemember by reason of deployment, or the possibility of deployment, in determining the best interest of the child.

''(c) NO FEDERAL RIGHT OF ACTION.—Nothing in this section shall create a Federal right of action.

''(d) PREEMPTION.—In any case where State law applicable to a child custody proceeding involving a temporary order as contemplated in this section provides a higher standard of protection to the rights of the parent who is a deploying servicemember than the rights provided under this section with respect to such temporary order, the appropriate court shall apply the higher State standard.

''(e) DEPLOYMENT DEFINED.—In this section, the term 'deployment' means the movement or mobilization of a servicemember for a period of longer than 60 days and not longer than 18 months pursuant to temporary or permanent official orders—

''(1) that are designated as unaccompanied;

''(2) for which dependent travel is not authorized; or

''(3) that otherwise do not permit the movement of family members to that location.''.

(b) CLERICAL AMENDMENT.—The table of contents in section 1(b) of such Act is amended by adding at the end of the items relating to title II the following new item:

''208. Child custody protection.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida (Mr. STEARNS) and the gentlewoman from Florida (Ms. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Florida.

GENERAL LEAVE

Mr. STEARNS. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days in which to revise and extend their remarks and include any extraneous material on H.R. 4201.

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

There was no objection.

Mr. STEARNS. Mr. Speaker, I yield myself such time as I may consume.

I rise today in strong support of the Servicemember Family Protection Act, H.R. 4201, a bill introduced by my good friend from Ohio (Mr. TURNER).

Mr. Speaker, as our Nation's servicemembers continue to endure long deployments overseas, the Servicemembers Civil Relief Act is there to protect their interests at home. At its core, SCRA ensures that servicemembers have certain protections in the event that military service impedes their ability to meet certain financial and legal obligations.

Although the current SCRA covers everything from mortgages to cell phone contracts, it simply fails to protect one uniform framework for protecting servicemembers' rights under child custody actions by State courts. This bill would protect these rights by amending the SCRA to require that if a court gives temporary custody of a servicemember's child to someone else because of the servicemember's deployment, the servicemember has the opportunity to have the previous custody order reinstated upon their return. This would occur unless the court determines that such a move would not be in the best interest of a child. The bill would also prohibit courts from considering the absence or potential absence of a servicemember from being considered as part of the court's determination of the child's best interest. Finally, my colleagues, the bill ensures that if higher protections than that provided by the bill, H.R. 4201, exist under any State law, then the higher standard should be applied.

Mr. Speaker, in previous Congresses, Members have received anecdotal evidence of servicemembers having to make the difficult decision of choosing between their military career and the legal custody of their children because of rulings made by courts that took their military service into account when assigning custody of the child. Mr. Speaker, I believe that our servicemembers who stand guard in constant defense of our liberties should never have to make this choice. That is why this bill's revisions to SCRA are so critically important to unit morale and our Nation as a whole.

So I want to again thank Mr. TURNER from Ohio for introducing this legislation. I also want to thank Chairman JEFF MILLER and Ranking Member Mr. FILNER for their support.

Mr. Speaker, I reserve the balance of my time.

Ms. BROWN of Florida. Mr. Speaker and Members of the House, I rise today as the House of Representatives returns from Memorial Day events around the country to honor our Nation's servicemen and their families.

On behalf of a grateful Nation, I want to thank our servicemen and -women for their sacrifices in defense of the freedoms we all hold so dear. As President Obama has said, it is important to follow these words with deeds, that we must do what we can for the veterans of past, present, and future conflicts.

I am pleased to have been a Member of Congress in 2009 when a Democratic President, Democratic House, and Democratic Senate passed the largest budget in the history of the Department of Veterans Affairs. In addition, we made sure that the VA was not subject to the whims of government shutdown, and the subject of the health care budget of the VA to advanced appropriations, removing the worry for our veterans that their health care would be available.

I am looking forward to the ceremony to be held at the end of June to honor the Montford Point Marines. It is necessary to honor all of America's war heroes' service and sacrifice, and in particular those who served at Montford Point, the marines who were the last group to integrate who are about to be officially recognized as a rich legacy of our Marine Corps. They answered our Nation's call at a time when our society was deeply divided along racial lines.

As our servicemembers continue to deploy, we need to ensure that we're doing everything we need to do to help the families. One item that has often been overlooked is the care of our servicemembers' children when they are deployed. H.R. 4201 would amend the Servicemembers Civil Relief Act to help protect the child custody rights of servicemembers being deployed overseas. This bill would protect a servicemember's custodial rights by requiring that temporary custody orders based solely on the servicemember's deployment will be exactly that—temporary—and that when the servicemember returns, the custody order in effect before deployment will be reinstated.

This bill provides important safeguards and peace of mind to our servicemembers facing overseas deployment and puts the interests of children first. This bill was passed by the House last Congress, and we should do it again.

Mr. Speaker, I reserve the balance of my time.

Mr. STEARNS. Mr. Speaker, I yield such time as he may consume to the gentleman from Ohio (Mr. TURNER).

□ 1740

Mr. TURNER of Ohio. Mr. Speaker, unbelievably, across this country in family law courts, in States, our servicemembers stand before family law court judges who take custody away from our servicemembers upon their return from either, previously, Iraq or, now, Afghanistan based solely on the fact that they were away from their children serving their country.

Mr. Speaker, we should not have one arm of the government ordering our servicemembers to deploy and another arm of our government taking their children away from them based upon the fact that they were away servicing their country. One servicemember, Eva Slusher, who has been a champion of this issue, has said that she did not understand when she got back, by law, they had to give her her job back but, by law, no one had to return to her her child.

Servicemembers risk their lives in support of the contingency operations that keep our Nation safe. State courts should not be allowed to use a servicemember's previous deployments or the possibility of future deployments when making child custody determinations. State courts should not be allowed to use a servicemember's previous deployments or the possibility when making these child custody determinations.

Our bill would amend the Servicemembers Civil Relief Act to protect servicemembers against this injustice by providing a uniform national standard. The lack of uniform laws creates uncertainty that adversely affects readiness and morale.

State laws differ on the question of whether deployment or the potential for future deployment can be used as a criterion for these courts, and many States have no laws at all. The difference in State laws provides an opportunity for ex-spouses to venue shop to find a State that will alter custody agreements. Many servicemember custody battles involve up to three States: the State of the original custody order, the State where the child is residing, and the State where the servicemember is stationed.

This bill creates a protective floor to ensure that all military parents can feel confident that their service to our country will not be used against them in our courts.

In supporting this legislation, Secretary Gates stated: ''I am convinced that the benefits outweigh the concerns and, thus, we should work with Congress to pursue an acceptable legislative formulation.''

The language of this bill has passed the House on seven separate occasions, and the bill has strong bipartisan support. I have a letter to Leon Panetta that is signed by every member of the House Armed Services Committee that I will enter into the RECORD.

Our men and women in uniform sacrifice a great deal to serve our country. We owe it to them to provide uniform legal standards regarding child custody. Our servicemen and -women should never be in the position of having to choose between their country and their family; or while they're on service, they should not have to worry what might happen to them when they return.

HOUSE OF REPRESENTATIVES,
Washington, DC, March 29, 2012.

Mr. LEON PANETTA,
Secretary of Defense,
Washington, DC.

DEAR SECRETARY PANETTA: We appreciate your interest stated during the February 15, 2012 House Armed Services Committee (HASC) hearing in protecting child custody rights for our men and women in uniform.

As you know, legislative language addressing this issue has already passed the House of Representatives on six separate occasions. It has passed five times as part of the National Defense Authorization Act, every year from 2008 through 2012. Additionally, in 2008 this language passed the House as a standalone bill (H.R. 6048) by voice vote. Sixty members from both sides of the aisle signed

on to H.R. 6048 as co-sponsors. Most recently, the bill was included in the Managers Package in the FY12 House NDAA and was supported by the Department of Defense (DoD).

Enclosed are letters of support that both Secretary Gates and Secretary Stanley provided for this legislation last year. Also enclosed is the 2010 HASC letter to Secretary Gates. As we move forward with the current legislative session, we look forward to the same level of support from the DoD in addressing this important issue and ensuring that our men and women in uniform have their parental rights protected.

Sincerely,

MICHAEL R. TURNER,
Member of Congress.
ROBERT ANDREWS,
Member of Congress.

HASC SIGNATURES

Michael Turner, Rob Andrews, Howard P. ''Buck'' McKeon, Chairman, Adam Smith, Ranking Member, Mac Thornberry, Vice Chairman, Roscoe G. Bartlett, Walter B. Jones, W. Todd Akin, J. Randy Forbes, Jeff Miller, Joe Wilson, Frank A. LoBiondo, John Kline, Mike Rogers, Trent Franks, Bill Shuster, K. Michael Conaway, Doug Lamborn, Rob Wittman, Duncan Hunter, John C. Fleming, Mike Coffman, Thomas J. Rooney, Todd Russell Platts, Scott Rigell, Chris Gibson, Vicky Hartzler, Joe Heck, Bobby Schilling, Jon Runyan, Austin Scott.

Tim Griffin, Steve Palazzo, Allen West, Martha Roby, Mo Brooks, Todd Young, Silvestre Reyes, Loretta Sanchez, Mike McIntyre, Robert A. Brady, Susan A. Davis, James R. Langevin, Rick Larsen, Jim Cooper, Madeleine Z. Bordallo, Joe Courtney, David Loebsack, Niki Tsongas, Chellie Pingree, Larry Kissell, Martin Heinrich, William L. Owens, John Garamendi, Mark Critz, Tim Ryan, C.A. Dutch Ruppersberger, Hank Johnson, Betty Sutton, Colleen Hanabusa, Kathleen C. Hochul, Jackie Speier.

Ms. BROWN of Florida. Mr. Speaker, how much time remains?

The SPEAKER pro tempore. The gentlewoman has 17½ minutes remaining.

Ms. BROWN of Florida. Mr. Speaker, I yield as much time as he may consume to the gentleman from New Jersey (Mr. ANDREWS).

(Mr. ANDREWS asked and was given permission to revise and extend his remarks.)

Mr. ANDREWS. Mr. Speaker, I would like to thank my friend from Florida for yielding and for putting deeds ahead of words when it comes serving our veterans, as I know the full committee does as well. This is an issue on which there is no Republican, Democrat, no liberal, conservative divide. There's unanimity we should put our deeds first and our words second. I commend my friend from Florida for being an exemplar of that principle.

No member of our armed services should ever be told that a custody decision involving their children depends solely on the fact that they have been deployed or will be deployed. Never should that happen.

Now, in the past, there's been arguments, frankly, from the other body against this provision on the argument that we must choose between the best interest of the child and the sovereign parental rights of our servicemembers. This is a false and inaccurate choice.

This bill starts from the premise that the best interest of the child is the paramount value. It in no way disrupts or subverts any State law in that respect, but it adds to that provision a provision that must be added by Federal law, because there must be a uniform standard since it's the Federal Government that is deciding who will be deployed and when. So, supplemental to the guiding principle of the best interest of the child is a principle in this bill that says that deployment cannot be the sole reason for a decision to deprive a man or woman of custody of his or her child.

Now, it strikes me that this is a complex legal issue. I will confess to that. But morally, this is a distinct, clear, and open issue. We all support the best interest of the child. But I think that we all support, and I think in a few minutes we're going to have a vote that demonstrates that we all support, the principle that the sovereignty of parenthood should not be forfeited by taking the oath of office to serve one's country in uniform. This should never happen.

So, again, here is what this means. It means that no child would ever be placed in a situation that's not in his or her best interest in the decision of the decisionmaker, of the judge or the Court. None of us wants that. But it also means that any State or any judge that says the sole reason that we are depriving a man or woman of custody of his or her son or daughter is because they volunteered to serve their country and followed an order to be deployed or are about to follow an order to be deployed.

This is morally clear. It is legally correct, and I hope it will be unanimously supported by the ladies and gentlemen of the House.

Mr. STEARNS. Mr. Speaker, I continue to reserve the balance of my time.

Ms. BROWN of Florida. I don't have any other speakers, so I yield back the balance of my time.

Mr. STEARNS. Mr. Speaker, I'll close using such time as I may consume to say:

This is a very important bill. Mr. TURNER just touched on something that I think I want to bring up again. This, the language in this bill, has passed the House on seven separate occasions, six times as part of the House National Defense Authorization Act in FY 2008, 2009, 2010, 2011, 2012, and 2013, and once, my colleagues, as a standalone bill by voice vote in 2008. And all the while, this bill has had strong bipartisan support.

Mr. Speaker, if I can, I urge the United States Senate that, upon passage today, our colleagues over there simply take up this bill and the 10 other bills that the Veterans' Committee has passed through our committee and the House and pass those also.

With that, I yield back the balance of my time.

Ms. JACKSON LEE of Texas. Mr. Speaker, I rise today in support of H.R. 4201, ''Servicemember Family Protection Act.'' This legislation amends the Servicemember Civil Relief Act and provides protection for servicemembers who lose temporary custodial responsibility for a child from court due to deployment or anticipated deployment. Upon return from deployment, the court must reinstate the custody order that was in effect preceding the deployment provided that the reinstatement is in the child's best interest.

H.R. 4201 would prevent previous and future deployment from being considered in the determination of a child's best interest in a motion seeking a permanent order to modify custody. In addition, it also creates a uniform nationwide standard for dealing with servicemembers and deployment.

Just as our service men and women are stationed around the world fighting for our rights and freedom, we must protect their rights here at home.

According to a report from USA Today, military divorces reached an all time high in 2011. When children are involved, these divorce proceedings face even greater complications.

It is unfair to say the least, to use a servicemember's previous service to this country and possible future service against them in child custody battles.

Not only does this create division in family households, it also creates negative feelings towards military service in the minds of the dedicated men and women who protect our freedom.

Past problems in these court cases have centered on a lack of uniformity of the law. Many states even lack laws concerning deployment as a criterion by courts. In previous cases this has caused servicemembers to fight custody suits in up to three states: the state where the suit began, the state where the child is residing and the state where the servicemember is stationed. Dealing with child custody battles is difficult even in civilian life. With the additional stress many in our military face, sometimes it can become unbearable. The Department of Defense and Service has even observed a connection between child custody battles and military suicides.

There must be justice and uniformity when deciding child custody disputes for our servicemembers. I urge my colleagues to join me in supporting H.R. 3140 ''Mass Transit Intelligence Prioritization Act.''

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida (Mr. STEARNS) that the House suspend the rules and pass the bill, H.R. 4201.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. STEARNS. 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.

SECURE BORDER ACT OF 2011

Mr. KING of New York. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1299) to achieve operational control of and improve security at the international land borders of the

United States, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1299

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 ''Secure Border Act of 2011''.

SEC. 2. STRATEGY TO ACHIEVE OPERATIONAL CONTROL OF THE BORDER.

(a) STRATEGY TO SECURE THE BORDER BETWEEN THE PORTS OF ENTRY.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security shall submit to the appropriate congressional committees a comprehensive strategy for gaining, within five years, operational control of the international borders between the ports of entry of the United States. The strategy shall include an analysis of the following:

(1) Staffing requirements for all border security functions.

(2) Investment in infrastructure, including pedestrian fencing, vehicle barriers, and roads.

(3) The use of unmanned aerial vehicles, camera technology, sensors, and other innovative technology as the Secretary may determine.

(4) Cooperative agreements with international, State, local, tribal, and other Federal law enforcement agencies that have jurisdiction on the northern border and southern border.

(5) Other means designed to detect, respond to, and interdict unlawful cross-border activity and to reduce the level of violence.

(6) A schedule for implementing security measures, including a prioritization for future investments.

(7) A comprehensive technology plan for major surveillance and detection technology programs, including a justification and rationale for technology choices and deployment locations.

(8) The recommendations made in the December 2010 Government Accountability Office report entitled ''Enhanced DHS Oversight and Assessment of Interagency Coordination is Needed for the Northern Border''.

(b) SECURING THE BORDER AT PORTS OF ENTRY.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security shall develop metrics to measure the effectiveness of security at ports of entry, which shall consider, at minimum, the following:

(1) The number of infractions related to personnel and cargo committed by major violators who are apprehended by U.S. Customs and Border Protection at such ports of entry.

(2) The estimated number of such infractions committed by major violators who are not so apprehended.

(3) The required number of U.S. Customs and Border Protection Officers, Agricultural Specialists, and Canine Enforcement Officers necessary to achieve operational control at such ports of entry.

(4) Infrastructure improvements required to achieve operational control at such ports of entry, including the installation of nonintrusive detection equipment, radiation portal monitors, biometrics, and other sensors and technology that the Secretary determines necessary.

(5) The deployment of resources based on the overall commercial and passenger traffic, cargo volume, and threat environment at such ports of entry.

(6) The recommendations made in the December 2010 Government Accountability Office report entitled ''Enhanced DHS Oversight and Assessment of Interagency Coordination is Needed for the Northern Border''.

(c) EVALUATION BY DEPARTMENT OF ENERGY NATIONAL LABORATORY.—The Secretary of Homeland Security shall request the head of an appropriate Department of Energy National Laboratory with prior expertise in border security to evaluate the measurement system required under subsection (b) to ensure its suitability and statistical validity for analyzing progress for the interdiction of illegal crossing and contraband at ports of entry.

(d) CONSIDERATION OF ALTERNATIVE BORDER SECURITY STANDARDS.—If in developing the strategic plan required under subsection (a) the Secretary of Homeland Security makes a determination to measure security between border ports of entry by a standard other than operational control, the Secretary shall request the head of an appropriate Department of Energy National Laboratory with prior expertise in border security to evaluate such alternative standard to ensure the suitability and statistical validity of such standard with respect to measuring the progress for the interdiction of illegal crossings and contraband that pass between such ports of entry.

(e) REPORTS.—Not later than 60 days after the date of the enactment of this Act and annually thereafter, the Secretary of Homeland Security shall submit the appropriate congressional committee a report on the following:

(1) A resource allocation model for current and future year staffing requirements that includes optimal staffing levels at all land, air, and sea ports of entry and an explanation of U.S. Customs and Border Protection methodology for aligning staffing levels and workload to threats and vulnerabilities across all mission areas.

(2) Detailed information on the level of manpower data available at all land, air, and sea ports of entry, including the number of canine and agricultural officers assigned to each such port of entry.

(f) DEFINITIONS.—In this Act:

(1) APPROPRIATE CONGRESSIONAL COMMITTEE.—The term ''appropriate congressional committee'' means the Committee on Homeland Security of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate.

(2) MAJOR VIOLATOR.—The term ''major violator'' means a person or entity that is or has engaged in serious criminal activities at any land, air, or sea port of entry, including possession of narcotics, smuggling of prohibited products, human smuggling, weapons possession, use of fraudulent United States documents, and other offenses serious enough to result in arrest.

(3) OPERATIONAL CONTROL.—The term ''operational control'' has the meaning given such term in section 2(b) of the Secure Fence Act of 2006 (8 U.S.C. 1701 note; Public Law 109–367).

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New York (Mr. KING) and the gentleman from Mississippi (Mr. THOMPSON) each will control 20 minutes.

The Chair recognizes the gentleman from New York.

GENERAL LEAVE

Mr. KING of New York. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days within which to revise and extend their remarks and include any extraneous material on the bill under consideration.

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

There was no objection.

Mr. KING of New York. Mr. Speaker, I yield myself such time as I may consume.

I would just suggest to the ranking member, since we are running short on time, I'm going to abbreviate my remarks. I know that your eloquence is unbounded, but I will try to restrict myself.

Mr. Speaker, H.R. 1299, the Border Security Act of 2011, requires the Secretary of Homeland Security to develop a strategy to gain operational control of the border within 5 years.

I want to commend Congresswoman MILLER, who's the chair of the Subcommittee on Border and Maritime Security, for her leadership on this issue.

Border security is an integral element of homeland security. We must secure our borders. Since 2004, Congress has allocated billions of dollars to secure the border through investments in personnel, technology, and infrastructure; however, our borders remain vulnerable.

We know from the documents made public after the Abbottabad raid on Osama bin Laden's compound that al Qaeda continues to examine crossing the border to gain access to the U.S. It is critical that the Department produce a comprehensive strategy to gain operational control over the border.

This legislation is commonsense legislation. It has bipartisan support. I urge my colleagues to support it.

I reserve the balance of my time.

Mr. Speaker, H.R. 1299, The Border Security Act of 2011, requires the Secretary of Homeland Security to develop a strategy to gain operational control of the border within 5 years.

I would like to thank Congresswoman MILLER, Chair of the Subcommittee on Border and Maritime Security, for her leadership on this issue.

Border security is an integral element of Homeland Security. We must secure our borders to prevent drug smugglers, terrorists, and others who pose a threat to the Homeland from entering the Country.

Since 2004, Congress has allocated billions of dollars to secure the border through investments in personnel, technology, and infrastructure. Through such investments, the size of the U.S. Border Patrol has doubled to more than 21,000 agents; almost 700 miles of vehicle and pedestrian fencing have been built; and significant investments have been made in camera detection technology. Without question, these investments have significantly increased security at the border.

However, our borders remain vulnerable and attractive for illegal aliens, criminals, and drug smugglers. We know from documents made public after the Abbottabad raid on Osama bin Laden's compound that al Qaeda continues to examine crossing the border to gain access to the United States.

It is critical that the Department of Homeland Security produce a comprehensive strategy to gain operational control over the border. As we move forward, Customs and Border Protection should explain what technology is being acquired, where it is being placed, and how those choices will fit into a comprehensive strategy to secure the border.

I am concerned that DHS has determined that they will no longer share operational control numbers with Congress as they have always done in past years in the annual budget submission. This legislation will ensure that these figures continue to be shared with Congress and that a National Laboratory will evaluate any new metrics developed by CBP.

We cannot continue to make ad hoc investments in border security; rather, border security funds should only be allocated as part of a larger strategic plan that gets us closer to a legitimately secure border both at and between the ports of entry.

This is a common sense bill, and I urge my colleagues to support it.

□ 1750

Mr. THOMPSON of Mississippi. Mr. Speaker, I rise in support of H.R. 1299, the Secure Border Act of 2011, and I yield myself such time as I may consume.

This bill would require the Secretary of Homeland Security to submit to Congress a comprehensive strategy for gaining operational control of our borders within the next 5 years. This bill defines operational control as the prevention of all unlawful entries into the United States, including entries by terrorists, other unlawful aliens, instruments of terrorism, narcotics, and other contraband.

While this is a laudable goal, it is also extraordinarily ambitious, and the bill authorizes no additional resources to achieving this goal. I am pleased, however, that the bill would require the Secretary to submit to Congress a resource allocation model for Customs and Border Protection staffing requirements at all land, air, and seaports of entry. This is important information that our committee has repeatedly requested from CBP on a bipartisan basis but has not yet received.

With that, Mr. Speaker, I reserve the balance of my time.

Mr. KING of New York. Mr. Speaker, I yield such time as she may consume to the distinguished chair of the subcommittee, the gentlelady from Michigan (Mrs. MILLER).

Mrs. MILLER of Michigan. I thank the gentleman for yielding.

Mr. Speaker, among the enumerated powers of the Constitution, providing for the common defense is, in my mind, the most important responsibility of the Congress. A key part of the common defense, of course, is ensuring that we secure the Nation's borders.

H.R. 1299, the Secure Border Act, moves the Nation closer to a more secure border by requiring the Department of Homeland Security to develop a plan to gain operational control of the border within 5 years. As part of that plan, the Department must account for staffing requirements, investments and infrastructure, and the justification and rationale for technology choices and deployment locations.

Since 9/11, this Nation has spent billions of dollars to increase security along our borders. We've doubled the size of the Border Patrol; built 700 miles of fence; and have invested in technology, such as UAVs and a wide array of surveillance equipment, for use along the border. Most of these investments have been worthwhile. Yet, instead of spending money in an ad hoc fashion, the Department of Homeland Security needs to develop a comprehensive and coherent plan to achieve control of the border while taking into account personnel, technology, and infrastructure needs. The need for a comprehensive strategy is apparent as previous border security efforts succeeded in shifting smuggling and illicit activities from urban areas of the Southwest border to more rural and remote areas, such as Arizona. However, this balloon effect has only succeeded in shifting the problem.

How we determine or measure what a secure border looks like has been the subject of a lot of debate, but the fact remains that the Congress and the American people should have a verifiable way to determine if we are making progress along the border. For years, we've relied on operational control as sort of a proxy for border security, and it has become a de facto term, but at the last count, only 44 percent of the Southwest border was under operational control, and less than 2 percent of the northern border was adequately secured.

In 2010, the Department of Homeland Security stopped reporting the numbers of miles of border under operational control, and as yet has really not supplied an alternative measure of border security to replace the discarded operational control measure. Just a few weeks ago, the Border Patrol released its new 2012 strategic plan, which makes no mention of operational control.

It is clear, Mr. Speaker, that the Department believes operational control is probably not the right measure to describe security at the border, and is working on something called the ''border condition index,'' which is supposed to be a holistic measure to inform our border security efforts. I think we are all open to a new, more robust standard if it supplements operational control and better describes what is happening with security at our border.

To this point, I don't think we can automatically assume that this new measure stacks up against operational control. With an issue this important, we just can't change the rules if we don't like the results. So, if the Secretary of the Department of Homeland Security decides to use a measure other than operational control, this bill would require that any other measure of border security would be vetted by a national laboratory with prior expertise in border security. I think that boils down to ''trust but verify.''

Security along the border is more often than not described in terms of fences, Border Patrol agents, UAVs, and camera towers. However, that is only one side of the story. We also need to increase security at our ports of entry—the conduit to much of the commerce and cargo that sustains our way of life. This bill requires the Secretary to develop a measure which gauges our progress at the points of entry so that, when combined with operational control or its successor, we have a very full picture of our border security.

Mr. Speaker, the men and women of the United States Border Patrol and the U.S. Customs and Border Protection have a very difficult job. I know that we all want to thank them for the very hard work that they do in some very demanding conditions to help secure our Nation. Certainly, it is our hope that the requirement for a comprehensive strategy will inform the Congress of the resources needs of the Department of Homeland Security, will give the men and women on the border the tools that they need, and will move us toward a more secure border both at and between the ports of entry.

I certainly would encourage all of my colleagues to support this bipartisan legislation.

Mr. THOMPSON of Mississippi. Mr. Speaker, I have no more speakers if the gentleman from New York is prepared to close.

Mr. KING of New York. Ranking Member, I have one further speaker.

Mr. Speaker, I yield 3 minutes to the gentleman from Texas (Mr. POE).

Mr. POE of Texas. Thank you for yielding the time, and I appreciate Mrs. MILLER for offering this legislation.

Having been a resident in Texas, a border State with Mexico, I see firsthand the situation on the border. We hear everything politically from ''the border is safe'' to ''it's a war zone,'' or somewhere in the middle. We actually do have a border security problem. Here are just a couple of statistics to show you how the border is so porous:

In our Federal penitentiaries, there is a group of people called ''criminal aliens.'' These are people who are illegally in the country and commit a felony in the United States. Twenty-five percent of the people in our Federal penitentiaries are criminal illegal aliens—illegally in the country, convicted and sent to our Federal penitentiaries. I regularly go and visit with our border sheriffs, and I ask them periodically, How many people in your jails are foreign nationals? The latest statistic that 17 border sheriffs in Texas gave me was: 34.5 percent of the people in our jails are foreign nationals.

So, yes, that crime comes into the United States is just one aspect of the lack of border security. But there is more.

I recently met with some ranchers down on the Southwest border. The owner of this ranch on the border comes out to meet me, and he is wearing a bulletproof vest. Yes, he has to wear a bulletproof vest on his own land because the drug cartels come through his land, and it's dangerous, which is just one more example of the porous border that we have.

And most recently, to show that the border is porous and that what happens in Mexico doesn't stay in Mexico, a couple of weeks ago, there was a family in our church back in Texas who had this problem: Their cousins in Mexico had been kidnapped by the Zeta drug

cartels and held for ransom. The family here in the United States, in Texas, paid the ransom to get the two cousins back. The drug cartels, the Zetas, they murdered them anyway.

So we have the problem of kidnappings taking place; we have the problem of extortion; and we have the problem of cross-border crime—but it is all because of the fact that the border needs to be more secure than it is. A plan is a good idea. A plan to actually address all of these issues of a porous border is something that's long overdue, but I'm glad to see that we're moving in that direction—to have a plan so that we know exactly what will take place and how we will protect our borders.

After all, the job of the Federal Government is to protect the national security.

Mr. THOMPSON of Mississippi. In closing, I thank the lead sponsor of this bill, the gentlewoman from Michigan, Representative MILLER, for her leadership on border and maritime issues and for her willingness to work on a bipartisan basis in areas of shared concern. I support the bill.

With that, I yield back the balance of my time.

Mr. KING of New York. Mr. Speaker, devising a comprehensive plan to secure our Nation's borders is the first step on the road to a more secure homeland. This bipartisan bill is a good start, and I ask my colleagues to support its passage.

I yield back the balance of my time.

Mr. GINGREY of Georgia. Mr. Speaker, I rise today as a proud cosponsor of H.R. 1299, the Secure Border Act of 2011, authored by my good friend, CANDICE MILLER, and urge my colleagues to support it.

This bill requires the Department of Homeland Security to develop a comprehensive strategy for gaining control of our borders at all ports of entry. In developing that strategy, an analysis of current security effectiveness will help define the needs and requirements of an implementable border security blueprint.

Mr. Speaker, the reason this is necessary is because illegal immigration is one of the biggest crises facing our nation and securing our borders is of paramount importance.

The Government Accountability Office recently reported that less than half of our southwest border is under operational control. At the same time, only 32 percent of our northern border operates at an ''acceptable'' security level.

Mr. Speaker, keeping our nation safe is the federal government's chief responsibility, and that's why it is so important that we pass this legislation.

I ask my colleagues to join me in supporting this bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, H.R. 1299, 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.

APPLICABILITY OF THE UNIFORMED SERVICES EMPLOYMENT AND REEMPLOYMENT RIGHTS ACT TO THE TRANSPORTATION SECURITY ADMINISTRATION

Mr. KING of New York. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3670) to require the Transportation Security Administration to comply with the Uniformed Services Employment and Reemployment Rights Act.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3670

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. APPLICABILITY OF THE UNIFORMED SERVICES EMPLOYMENT AND REEMPLOYMENT RIGHTS ACT TO THE TRANSPORTATION SECURITY ADMINISTRATION.

(a) IN GENERAL.—Section 111(d) of the Aviation and Transportation Security Act (49 U.S.C. 44935 note; Public Law 107–71) is amended—

(1) by striking ''Notwithstanding'' and inserting the following:

''(1) GENERAL AUTHORITY.—Except as provided in paragraph (2), and notwithstanding''; and

(2) by adding at the end the following:

''(2) UNIFORMED SERVICES EMPLOYMENT AND REEMPLOYMENT RIGHTS ACT.—In carrying out the functions authorized under paragraph (1), the Under Secretary shall be subject to the provisions set forth in chapter 43 of title 38, United States Code.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date that is 270 days after the date of the enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New York (Mr. KING) and the gentleman from Mississippi (Mr. THOMPSON) each will control 20 minutes.

The Chair recognizes the gentleman from New York.

□ 1800

GENERAL LEAVE

Mr. KING of New York. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days within which to revise and extend their remarks and include any extraneous material on the bill under consideration.

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

There was no objection.

Mr. KING of New York. Mr. Speaker, I yield myself such time as I may consume.

I will say again to the ranking member that this is a very vital bill. In the interest of time, because we still have this and three other pieces of legislation to pass in the next half hour, I will limit my remarks other than to say that the gentleman from Minnesota deserves tremendous credit for this bill.

H.R. 3670 is absolutely vital. It's necessary. It would guarantee that TSA employees who are called to active duty would keep their jobs when they come home and would further ensure that existing protections could not be in any way changed by potentially conflicting rules or regulations.

I also want to commend the gentleman from Florida (Mr. BILIRAKIS), who was the original cosponsor of this bill.

And, again, I just want to say with reference to my friend from Minnesota, he has dedicated a life of service to his country in the military, and he's continuing that outstanding service here in the United States Congress.

With that, I reserve the balance of my time.

Mr. Speaker, I rise in support of H.R. 3670, sponsored by the gentleman from Minnesota, Mr. WALZ.

This bipartisan bill addresses a fundamental gap in the protection of veterans' employment rights, which could easily be remedied.

I want to take this opportunity to recognize the efforts of my good friend from Florida, Congressman BILIRAKIS, Chairman of the Emergency Preparedness, Response and Communications Subcommittee, for his work on this issue and for being an original cosponsor of the bill.

Veterans make up roughly 20 percent of TSA's workforce. This bill simply requires TSA to comply with the Uniformed Services Employment and Reemployment Rights Act, or USERRA. This would guarantee that TSA employees who are called to active duty could keep their jobs when they come home.

In recent testimony submitted for the record to the Committee on Veterans' Affairs, TSA stated that its current practice already conforms to the requirements of H.R. 3670. This bill would simply ensure existing protections could not be changed later on by potentially conflicting rules or regulations.

This is a common sense bill and I urge all of my colleagues to support it.

Mr. THOMPSON of Mississippi. Mr. Speaker, I rise in strong support of H.R. 3670 and yield myself such time as I may consume.

Mr. Speaker, Memorial Day is a time not only to honor members of our armed services who gave their lives in defense of our liberty, but also to convey our support for veterans and servicemembers. With the commemoration of Memorial Day earlier this week, it is fitting that we're considering H.R. 3670 today.

H.R. 3670, by conferring job protections for servicemembers, conveys our commitment to help reservists and other members of the uniformed services return to civilian life. Specifically, the bill would ensure that the protections afforded under the Uniformed Services Employment and Reemployment Rights Act apply to Transportation Security Administration employees and applicants, just as they do everywhere in the public and private sector.

Mr. Speaker, I would also like to acknowledge TSA's leadership in hiring veterans. Currently, veterans make up over 23 percent of TSA's workforce. I would encourage my colleagues and the

general public to keep that number in mind when they encounter a TSA worker at an airport checkpoint. There is a one in four chance that the person conducting the screening is a veteran and deserves the respect and appreciation commensurate with that title.

With that, Mr. Speaker, I reserve the balance of my time.

Mr. KING of New York. I yield 3 minutes to the gentleman from Florida (Mr. STEARNS).

Mr. STEARNS. Mr. Speaker, I thank Chairman KING for the time. I also rise today in strong support of H.R. 3670, a bill introduced by my good friend, Mr. WALZ from Minnesota.

This bill extends reemployment protections to employees of the Transportation Security Administration by making them subject to the Uniformed Services Employment and Reemployment Rights Act, or USERRA.

USERRA is a law that protects the reemployment rights of servicemembers so they are able to keep their jobs, benefits, and seniority in their civilian jobs after serving on active duty.

When TSA was created soon after 9/11, it was given a USERRA exemption to allow the agency to hire new employees without delay for airport screenings. There is no evidence that applying USERRA to TSA will impede TSA's mission of protecting our Nation's air travel system. In fact, bringing TSA under USERRA will strengthen their ability to recruit and retain highly qualified veterans.

Mr. Speaker, I would note that in testimony submitted for the record on H.R. 3670, TSA stated that its current practice already conforms to the requirements that H.R. 3670 would put into statute. Therefore, enactment of H.R. 3670 would ensure existing protections could not be weakened by a change in administration rules or regulations.

I want to thank my good friend Mr. WALZ for introducing this legislation. I also thank Chairman JEFF MILLER of Florida and Ranking Member FILNER of California for their support, and I thank Mr. KING.

Mr. THOMPSON of Mississippi. Mr. Speaker, I yield such time as he may consume to the original sponsor of the legislation under consideration, the gentleman from Minnesota (Mr. WALZ).

Mr. WALZ of Minnesota. Mr. Speaker, I thank the gentleman and the chairman for bringing this bill to the floor. More importantly, I thank you both for your unwavering defense of this Nation in smart policy and an unwavering commitment to make sure we get it right.

I, like my colleagues and millions of other Americans, spent Monday at Memorial Day observances. That's the date we give thanks to those brave patriots who gave the supreme sacrifice so we could all live in freedom. But as the gentleman from Mississippi also said, it's also a time to think of the responsibility we have for those who have served and have come back.

Our responsibility to our veterans is our Nation's highest moral responsibility. After years of war, we have millions of returning veterans who deserve our respect and support. This piece of legislation helps us keep a promise to those brave warriors. As you heard from my colleagues, the Uniformed Services Employment and Reemployment Rights Act was passed by this Congress—a smart piece of legislation—in 1994. It simply says if you serve this Nation in uniform, you will not be disadvantaged in your civilian-sector job; you will have prompt reemployment when that service is done; and you will not be discriminated against because of current or past military service. It's keeping that commitment that if you put your life on the line, you put your health on the line, you shouldn't have to sacrifice your career progression against your peers just because you were willing to serve this Nation.

That piece of legislation was very clear also that the Federal Government should be a model employer. Also as the gentleman from Mississippi stated, TSA has a very important job of securing this Nation. They have done a wonderful job of hiring veterans. The issue at hand here is asking TSA to abide by the same rules as countless other agencies have. There is not a police force, a firefighting force, a school, or a private employer that hasn't sent a guardsman or a reservist off to do duty. They've had to change schedules and bring them back. In many small towns in my district, when you get a call up from the National Guard unit, most of the police department is gone with them. They've figured out how to do this, and they've done it by abiding by USERRA when they came back home and welcomed them back. It's absolutely unconscionable that TSA wouldn't.

As the gentleman from Florida (Mr. STEARNS) noted, they say they're already complying with most of the regulations. They've had time to adjust to this. We need to make sure at a time of high unemployment against our veterans, that we of all people—the Federal Government—throws up no barriers in front of them, but welcomes them back, replaces them in their jobs, and moves them forward. That's not only morally the right thing to do; that's the right thing to do for national defense. These are our best and brightest willing to put their lives on the line. I want them at the front lines at our airports and ports and other places, and we should get them back into it.

I want to thank these two gentlemen for their unwavering work and also the chairman of the VA, Mr. MILLER, and Mr. FILNER. As was stated earlier, I thank an absolute champion of veterans rights, Mr. BILIRAKIS, who is the original cosponsor of this.

Mr. KING of New York. I reserve the balance of my time.

Mr. THOMPSON of Mississippi. Mr. Speaker, I yield 2 minutes to the gentlelady from Florida (Ms. BROWN).

Ms. BROWN of Florida. Thank you, Chairman KING and Ranking Member THOMPSON, for bringing this bill to the floor as we return from Memorial Day events with our constituents.

When the TSA was formed in the wake of 9/11, the worst terrorist attack in the history of the United States, Congress was attempting to consolidate many of the Nation's security duties that were spread out over all of the Departments. We were dedicated to the proposition that this event should never be repeated. Our response was quick that our civilian transportation system should never be used for attack ever again.

Out of the need for better airport security, the Transportation Security Administration was born. However, at the time, Republicans did not want to give the same rights to those Members of the Federal workforce as other Federal employees enjoy. One of those rights was USERRA, the Uniform Services Employment and Reemployment Rights Act.

Under USERRA, individuals retain certain rights when that person needs to be absent from his or her civilian employment to serve in this country's uniformed services.

This bill would require the TSA to comply with USERRA when dealing with air transportation passengers and property screeners.

I support this legislation as a good first step toward giving the same rights available to all Federal employees.

And let me just take this moment to thank TSA for their hard work and dedication in keeping us safe. Sometimes I know it is inconvenient to the traveling public, but remember that they're there to protect us and they would not be there if 9/11 had not occurred. Thank you for your service.

Mr. KING of New York. Mr. Speaker, I advise my colleague that I am prepared to close as I have no further speakers.

Mr. THOMPSON of Mississippi. Mr. Speaker, I yield 2 minutes to the gentlelady from Texas (Ms. JACKSON LEE).

□ 1810

Ms. JACKSON LEE of Texas. Mr. Chairman, I thank you for yielding, and I thank the chairman of the full committee and the ranking member.

As a ranking member of the Transportation Security Subcommittee, it's my privilege to rise to support H.R. 3670.

Let me thank the author of the bill, the gentleman from Minnesota, for his leadership—he is always speaking eloquently but fighting for our veterans, and we thank you very much both for your service and your leadership—and also to thank the gentlelady from Florida for her kind and astute remarks regarding the importance of TSA.

In the last 24 hours, there was a breach of security in San Diego when an individual went through a secured door and boarded a plane. The immediate response of some of the commentators was: What was TSA doing? I

think the only comment is: They were doing their job.

And that breach obviously occurred before any entering into the secured area, but it tells us how important TSA really is and being on the front line of securing this Nation and being part of the team that has allowed us to not have a tragic incident on our soil since 9/11.

It is important to have the TSA comply with the Uniformed Services Employment and Reemployment Rights Act. The Uniformed Services Employment and Reemployment Rights Act, USERRA, ensures that our valued citizens who have served in the Armed Forces, Reserves, National Guard, or other uniformed services are not disadvantaged in their civilian careers because of their service. They deserve this protection.

Under current law, the TSA is not required to comply with certain provisions of Federal labor laws, including USERRA. This is not right. Currently the TSA, which has more than 50,000 employees, is not required to hold positions and promotions for employees who are called away for military service. Ten thousand veterans serve on the TSA's workforce. That is one-fifth, or 20 percent, of their entire workforce.

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

Mr. THOMPSON of Mississippi. I yield the gentlewoman an additional 30 seconds.

Ms. JACKSON LEE of Texas. The head of my airport, Bush Intercontinental Airport, Colonel Testa, is retired military. The law specifies certain rank for individuals who serve in the uniformed services, including those in the Reserves or the National Guard who are called to duty. I join with my colleagues to support this legislation to ensure that TSA complies with USERRA.

Just 2 days ago we celebrated Memorial Day, and I would offer to say that we must continue to support our veterans but also mourn those who are lost, but in their name, it's important to support this legislation.

Mr. Speaker, I rise today to debate H.R. 3670, ''To require the Transportation Security Administration to comply with the Uniformed Services Employment and Reemployment Rights Act.'' The Uniformed Services Employment and Reemployment Rights Act (USERRA) ensures that our valued citizens who serve or have served in the Armed Forces, Reserves, National Guard or other ''uniformed services'' are not disadvantaged in their civilian careers because of their service.

Under current law, the Transportation Security Administration (TSA) is not required to comply with certain provisions of federal labor laws, including USERRA. This is not right.

Currently the TSA, which has more than 50,000 employees, is not required to hold positions and promotions for employees who are called away for military service. 10,000 veterans serve on the TSA's workforce. That is ⅕ or 20 percent of their entire workforce.

The law specifies certain rights for individuals who serve in the uniformed services, including those in the reserves or the National Guard who are called to active duty.

In particular, USERRA prohibits employers from discriminating on the basis of military service or obligation and protects covered individuals' rights to be reemployed upon returning from duty.

H.R. 3670 requires the TSA to comply with USERRA. According to TSA, the agency's existing policies regarding individuals who leave TSA to undertake uniformed service are already consistent with USERRA. We want to make absolutely sure that our veterans, servicemen, and future soldiers are protected by the laws that govern our great Nation. We have to ensure that they are taken care of. They are courageous enough to defend, and sometimes give their lives for the United States. We should do what we can to honor their bravery.

The Congressional Budget Office (CBO) estimates that H.R. 3670 would not significantly affect the TSA's costs nor would enacting the bill affect direct spending or revenues.

I strongly support our troops and the brave men and women who have served in our armed forces. After their honorable service they should not have to face obstacles in finding civilian employment due to their service.

We must do everything in our power to ensure Members of our Armed Services are discriminated against based upon past, present, or future military service. They have sacrificed for their country and when they return to their civilian life that sacrifice should be honored not viewed as a negative. The federal government should be a ''model employer'' under USERRA, which is why H.R. 3670 is such a vital piece of legislation. Again, I urge you to honor the sacrifice of our troops.

Mr. THOMPSON of Mississippi. Mr. Chairman, I am prepared to close.

Mr. Speaker, H.R. 3670 enjoys bipartisan support of both the Committee on Veterans' Affairs and the Committee on Homeland Security and deserves the support of the full House today.

I yield back the balance of my time.

Mr. KING of New York. It's only because of the late hour—we have three more pieces of vital legislation to pass in the next 15 or 20 minutes—that I am not speaking at length on this issue because it is so vital. I thank the gentleman from Minnesota for it.

I urge Members to support the bill, and I yield back the balance of my time.

Ms. RICHARDSON. Mr. Speaker, I rise in support of H.R. 3670, to require the Transportation Security Administration, TSA, to comply with the Uniformed Services Employment and Reemployment Rights Act.

The Uniformed Services Employment and Reemployment Rights Act, USERRA, is intended to ensure that persons who serve or have served in the Armed Forces, Reserves, National Guard or other uniformed services: (1) are not disadvantaged in their civilian careers because of their service, (2) are promptly reemployed in their civilian jobs upon their return from duty, and (3) are not discriminated against in employment based on past, present, or future military service.

Soon after the attacks of 9/11, TSA was given USERRA exemption to allow the agency to hire new employees without delay for airport screenings. USERRA protects service members so they are able to keep their job, benefits, and seniority in their civilian job if they are called up to Active Duty. TSA has voluntarily adopted some USERRA provisions for their employees, but TSA no longer requires special hiring authorities that it required when newly created. With more than 10,000 veterans among the agency's employees, counting for 20 percent of the Transportation Security Officer workforce, TSA, like any other federal agency, should be required to comply with the same USERRA rules as other Federal agencies and private employers.

With the month of May and National Military Appreciation Month concluding, we must continue to appreciate and support our service members by supporting this legislation. Our veterans and servicemembers do not choose our conflicts and we cannot allow employers to punish them for their unrelenting dedication to our nation's freedom.

Mr. Speaker, requiring the Transportation Security Administration to comply with the Uniformed Services Employment and Reemployment Rights Act is the right thing to. That is why I strongly support H.R. 3670 and I urge my colleagues to support our servicemembers and veterans by supporting H.R. 3670.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, H.R. 3670.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

WMD INTELLIGENCE AND INFORMATION SHARING ACT OF 2012

Mr. KING of New York. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2764) to amend the Homeland Security Act of 2002 to establish weapons of mass destruction intelligence and information sharing functions of the Office of Intelligence and Analysis of the Department of Homeland Security and to require dissemination of information analyzed by the Department to entities with responsibilities relating to homeland security, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2764

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 ''WMD Intelligence and Information Sharing Act of 2012''.

SEC. 2. WEAPONS OF MASS DESTRUCTION INTELLIGENCE AND INFORMATION SHARING.

(a) IN GENERAL.—Subtitle A of title II of the Homeland Security Act of 2002 (6 U.S.C. 121 et seq.) is amended by adding at the end the following:

''SEC. 210G. WEAPONS OF MASS DESTRUCTION INTELLIGENCE AND INFORMATION SHARING.

''(a) IN GENERAL.—The Office of Intelligence and Analysis of the Department of Homeland Security shall—

''(1) support homeland security-focused intelligence analysis of terrorist actors, their claims,

and their plans to conduct attacks involving chemical, biological, radiological, and nuclear materials against the Nation;

''(2) support homeland security-focused intelligence analysis of global biological threats, including global infectious disease, public health, food, agricultural, and veterinary issues, through activities such as engagement of international partners;

''(3) support homeland security-focused risk analysis and risk assessments of the homeland security hazards described in paragraphs (1) and (2) by providing relevant quantitative and nonquantitative threat information;

''(4) leverage existing and emerging homeland security intelligence capabilities and structures to enhance prevention, protection, response, and recovery efforts with respect to a chemical, biological, radiological, or nuclear attack;

''(5) share information and provide tailored analytical support on these threats to State, local, and tribal authorities as well as other national biosecurity and biodefense stakeholders; and

''(6) perform other responsibilities, as assigned by the Secretary.

''(b) COORDINATION.—Where appropriate, the Office of Intelligence and Analysis shall coordinate with other relevant Department components, others in the Intelligence Community, including the National Counter Proliferation Center, and other Federal, State, local, and tribal authorities, including officials from high-threat areas, and enable such entities to provide recommendations on optimal information sharing mechanisms, including expeditious sharing of classified information, and on how they can provide information to the Department.

''(c) REPORT.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of this section and annually thereafter, the Secretary shall report to the appropriate congressional committees on—

''(A) the intelligence and information sharing activities under subsection (a) and of all relevant entities within the Department to counter the threat from weapons of mass destruction; and

''(B) the Department's activities in accordance with relevant intelligence strategies.

''(2) ASSESSMENT OF IMPLEMENTATION.—The report shall include—

''(A) a description of methods established to assess progress of the Office of Intelligence and Analysis in implementing this section; and

''(B) such assessment.

''(d) DEFINITIONS.—In this section:

''(1) The term 'appropriate congressional committees' means the Committee on Homeland Security of the House of Representatives and any committee of the House of Representatives or the Senate having legislative jurisdiction under the rules of the House of Representatives or Senate, respectively, over the matter concerned.

''(2) The term 'Intelligence Community' has the meaning given that term in section 3(4) of the National Security Act of 1947 (50 U.S.C. 401a(4)).

''(3) The term 'national biosecurity and biodefense stakeholders' means officials from the Federal, State, local, and tribal authorities and individuals from the private sector who are involved in efforts to prevent, protect against, respond to, and recover from a biological attack or other phenomena that may have serious health consequences for the United States, including wide-scale fatalities or infectious disease outbreaks.''.

(b) CLERICAL AMENDMENT.—The table of contents in section 1(b) of such Act is amended by adding at the end of the items relating to such subtitle the following:

''Sec. 210G. Weapons of mass destruction intelligence and information sharing.''.

SEC. 3. DISSEMINATION OF INFORMATION ANALYZED BY THE DEPARTMENT TO STATE, LOCAL, TRIBAL, AND PRIVATE ENTITIES WITH RESPONSIBILITIES RELATING TO HOMELAND SECURITY.

Section 201(d)(8) of the Homeland Security Act of 2002 (6 U.S.C. 121(d)(8)) is amended by striking ''and to agencies of State'' and all that follows and inserting ''to State, local, tribal, and private entities with such responsibilities, and, as appropriate, to the public, in order to assist in preventing, deterring, or responding to acts of terrorism against the United States.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New York (Mr. KING) and the gentleman from Mississippi (Mr. THOMPSON) each will control 20 minutes.

The Chair recognizes the gentleman from New York.

GENERAL LEAVE

Mr. KING of New York. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days within which to revise and extend their remarks and include any extraneous material on the bill under consideration.

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

There was no objection.

Mr. KING of New York. I want to commend Mr. MEEHAN, who is the chairman of the Subcommittee on Counterterrorism and Intelligence, for his work on this matter.

This basically ensures that the intelligence and analyses of chemical, biological, radiological, and nuclear threats are a priority to the Department of Homeland Security.

Again, because of the time constraints, I urge support for the measure, and I reserve the balance of my time.

Mr. Speaker, H.R. 2764 amends the Homeland Security Act of 2002 to ensure that intelligence and analyses of chemical, biological, radiological, and nuclear threats are a priority for the Department of Homeland Security.

I would like to thank Representative MEEHAN, the Chairman of the Subcommittee on Counterterrorism and Intelligence, for his work on this matter.

This measure requires the DHS Office of Intelligence and Analysis (1) to support homeland security-focused intelligence analysis of threats involving chemical, biological, radiological, and nuclear materials and global health hazards such as biothreats to food and agriculture; (2) to provide relevant threat information to partners; (3) to utilize existing homeland security intelligence capabilities to enhance prevention, protection, response, and recovery efforts with respect to a chemical, biological, radiological or nuclear attack; and (4) to support and share information of these threats with state, local, and tribal authorities.

I urge support for this measure.

CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 11, 2012.

Hon. PETER T. KING,
Chairman, Committee on Homeland Security, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2764, the WMD Intelligence and Information Sharing Act of 2011.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz, who can be reached at 226–2860.

Sincerely,

DOUGLAS W. ELMENDORF,
Director.

Enclosure.

H.R. 2764—WMD Intelligence and Information Sharing Act of 2011

CBO estimates that implementing H.R. 2764 would have no significant cost to the federal government. Enacting the legislation would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 2764 would direct the Department of Homeland Security (DHS), through the Office of Intelligence and Analysis (OIA), to undertake various activities to combat the threat of weapons of mass destruction. Those efforts would include assessments and analyses of threats and the sharing of such reports with federal, state, local, and tribal authorities as well as other stakeholders. The requirements of H.R. 2764 are similar to the ongoing activities of OIA and other offices within the department therefore, CBO estimates that implementing the bill would not significantly affect spending by DHS.

Because CBO does not provide estimates for classified programs, this estimate addresses only the budgetary effects of unclassified activities. It is possible there could be costs to classified programs, but CBO does not provide such estimates.

H.R. 2764 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Mark Grabowicz. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

Mr. THOMPSON of Mississippi. I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 2764, the WMD Intelligence and Information Sharing Act of 2011.

Mr. Speaker, this bill would strengthen information sharing at all levels of government with regard to chemical, biological, radiological, and nuclear terrorist threats.

In the decade since the attacks on September 11, 2001, concern about an attack on U.S. soil with weapons of mass destruction or dirty bombs have come in sharper focus, specifically concerns that terrorists and other rogue actors may want to access loose nuclear materials from the former Soviet Union or even weaponized biological agents that originated from stockpiles of now-toppled authoritarian regimes have grown.

This bill also requires DHS to coordinate with other components in the intelligence community and other Federal, State, local, and tribal authorities to provide recommendations on information sharing.

I would note for the record, Mr. Speaker, that the committee approved, on a bipartisan basis, the Pascrell WMD bill earlier this month.

I look forward to seeing this measure, which was endorsed by a bipartisan commission, considered on the House floor in the very near future.

I reserve the balance of my time.

Mr. KING of New York. Mr. Speaker, I yield such time as he may consume to the gentleman from Pennsylvania, Representative MEEHAN, who is chair of the Subcommittee on Counterterrorism and Intelligence.

Mr. MEEHAN. Thank you, Mr. Chairman. I thank you for yielding and I thank you for your kind words, and I thank the ranking member for his kind words in support of this important amendment.

I urge support for H.R. 2764, which provides, as has been explained, important guidance for the weapons of mass destruction and intelligence sharing functions of the Department of Homeland Security.

Now, this work has been built on a framework of important work, the roots of which were set with former Senators Bob Graham and Jim Talent, who were charged by a previous Congress just 2 years ago with establishing the Weapons of Mass Destruction Weapons Commission. They found that unless decisive action was taken, it was their prediction that a WMD attack would occur somewhere in the world by 2013.

I recently returned from the Middle East, and one of the striking takeaways from that trip was the amount of chemical weapons which are currently stockpiled in Syria. Similar concerns have been expressed about missing Libyan chemical weapons stockpiles. And obviously the great fear of all is that these weapons will get into the hands of al Qaeda terrorists or others during times of great instability.

We can't also forget the world's top State sponsor of terrorism, Iran, which has explicitly stated that it would use nuclear weapons to ''wipe Israel off the map.''

Al Qaeda has reportedly made efforts to acquire what we call chemical, biological, radiological, and nuclear materials, or CBRN, to make weapons of mass destruction in the past. Osama bin Laden's death should not create an atmosphere of complacency. In fact, with multiple affiliate networks around the world targeting the U.S. homeland and interests, it is important that we remain as vigilant as ever. Al Qaeda is now led by Ayman al-Zawahiri, bin Laden's longtime second in command, and the possibility of a WMD terrorist attack cannot be overstated.

The congressionally established WMD Commission has been relentless in its efforts to ensure that actions are being taken to meet what they describe as a very real threat. Congress must do its part to ensure that the Nation is meeting its WMD detection and prevention responsibilities in a meaningful and risk-based way.

□ 1820

CBRN materials can be quite difficult to detect and to prevent, and the danger they pose is unimaginable. This bill will ensure sustained DHS commitment and facilitate the partnership across the intelligence community, other government partners, and with the public.

I urge support for this bipartisan bill.

Mr. THOMPSON of Mississippi. Mr. Speaker, I urge passage of H.R. 2764. Enactment of this measure will strengthen the partnership between the Department of Homeland Security and our Nation's first preventers against one of the most vexing homeland security threats: weapons of mass destruction.

Mr. Speaker, I yield back the balance of my time.

Mr. KING of New York. Mr. Speaker, Representative MEEHAN has spent a great deal of time studying various threats to the homeland, including al Qaeda in the Arabian Peninsula, the Pakistani Taliban, Hezbollah, and Boko Haram. He fully understands the threat to the U.S. homeland and why this legislation is so vital.

I urge Members to support H.R. 2764, and I yield back the balance of my time.

Ms. JACKSON LEE of Texas. Mr. Speaker, I rise today in support of H.R. 2764, ''WMD Intelligence and Information Sharing Act of 2011.'' This legislation amends the Homeland Security Act of 2002 would direct the Department of Homeland Security (DHS), through the Office of Intelligence and Analysis (OIA), to undertake various activities to combat the threat of weapons of mass destruction. Those efforts would include assessments and analyses of threats and the sharing of such reports with federal, state, local, and tribal authorities.

While our intelligence community is strong and sophisticated, it is made even more powerful through the sharing of information between federal, state, and local officials as well as across bureaus.

We are all working towards a common goal—to keep the US and its citizens safe. In order to ensure we are working with all of our available resources and information, we must continue to advance regulations that allow for the sharing of information between our officials. This also includes ensuring that local law enforcement officers across the nation are trained to identify any potential threats and contact the correct authorities.

A partnership between DHS analysts and local law enforcement can enhance situational awareness with respect to the threat of terrorism to the millions of Americans who rely on mass transit systems, including the threat of an attack involving a weapon of mass destruction.

Mass transit systems across the world have continually been a target for terrorist threats, namely the 2004 terrorist attack on a packed commuter train in Madrid, Spain that killed 191 people. There was also the suicide bombing attack in London that left 50 dead in 2005.

While we have so far been fortunate to have not had any incidents of terrorism in our mass transit systems, we know of the threat planned by al-Qaeda to commemorate the both anniversary of 9/11 by attacking US mass transit systems. Thankfully, a Naval SEALS raid on Osama bin Laden's compound discovered and thwarted this plot.

Past incidents that were looked over by federal authorizes have been resolved by local enforcement officers. It is imperative that they continue to assist the efforts of the DHS and that the DHS is open and accessible to these officers via the communication of appropriate information.

SHORT OVERVIEW OF BILL

H.R. 2764, ''WMD Intelligence and Information Sharing Act of 2011.''—amends the Homeland Security Act of 2002 and would require the Department of Homeland Security (DHS) to:

(1) support homeland security-focused intelligence analysis of terrorist actors, their claims, and their plans to conduct attacks involving chemical, biological, radiological, and nuclear materials against the nation and of global infectious disease, public health, food, agricultural, and veterinary issues;

(2) support homeland security-focused risk analysis and risk assessments of such homeland security hazards by providing relevant quantitative and non-quantitative threat information;

(3) leverage homeland security intelligence capabilities and structures to enhance prevention, protection, response, and recovery efforts with respect to a chemical, biological, radiological, or nuclear attack; and

(4) share information and provide tailored analytical support on these threats to state, local, and tribal authorities as well as other national biosecurity and biodefense stakeholders.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, H.R. 2764, 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.

JAIME ZAPATA BORDER ENFORCEMENT SECURITY TASK FORCE ACT

Mr. KING of New York. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 915) to establish a Border Enforcement Security Task Force program to enhance border security by fostering coordinated efforts among Federal, State, and local border and law enforcement officials to protect United States border cities and communities from trans-national crime, including violence associated with drug trafficking, arms smuggling, illegal alien trafficking and smuggling, violence, and kidnapping along and across the international borders of the United States, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 915

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 ''Jaime Zapata Border Enforcement Security Task Force Act''.

SEC. 2. FINDINGS AND DECLARATION OF PURPOSES.

Congress finds the following:

(1) The Department of Homeland Security's (DHS) overriding mission is to lead a unified national effort to protect the United States. United States Immigration and Customs Enforcement (ICE) is the largest investigative agency within DHS and is charged with enforcing a wide array of laws, including laws related to securing the border and combating criminal smuggling.

(2) Mexico's northern border with the United States has experienced a dramatic surge in border crime and violence in recent years due to intense competition between Mexican drug cartels and criminal smuggling organizations that employ predatory tactics to realize their profits.

(3) Law enforcement agencies at the United States northern border face similar challenges from transnational smuggling organizations.

(4) In response, DHS has partnered with Federal, State, local, tribal, and foreign law enforcement counterparts to create the Border Enforcement Security Task Force (BEST) initiative as a comprehensive approach to addressing border security threats. These multi-agency teams are designed to increase information-sharing and collaboration among the participating law enforcement agencies.

(5) BEST teams incorporate personnel from ICE, United States Customs and Border Protection (CBP), the Drug Enforcement Administration (DEA), the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATFE), the Federal Bureau of Investigation (FBI), the United States Coast Guard (USCG), and the U.S. Attorney's Office (USAO), along with other key Federal, State and local law enforcement agencies.

(6) Foreign law enforcement agencies include Mexico's Secretaria de Seguridad Publica (SSP), the Canada Border Services Agency (CBSA), the Ontario Provincial Police (OPP), and the Royal Canadian Mounted Police (RCMP).

SEC. 3. BORDER ENFORCEMENT SECURITY TASK FORCE.

(a) ESTABLISHMENT.—There is established in United States Immigration and Customs Enforcement (ICE) a program known as a Border Enforcement Security Task Force (referred to as ''BEST'').

(b) PURPOSE.—The purpose of the BEST program is to establish units to enhance border security by addressing and reducing border security threats and violence by—

(1) facilitating collaboration among Federal, State, local, tribal, and foreign law enforcement agencies to execute coordinated activities in furtherance of border security, and homeland security; and

(2) enhancing information-sharing, including the dissemination of homeland security information among such agencies.

(c) COMPOSITION AND DESIGNATION.—

(1) COMPOSITION.—BEST units may be comprised of personnel from—

(A) United States Immigration and Customs Enforcement;

(B) United States Customs and Border Protection;

(C) the United States Coast Guard;

(D) other Federal agencies, as appropriate;

(E) appropriate State law enforcement agencies;

(F) foreign law enforcement agencies, as appropriate;

(G) local law enforcement agencies from affected border cities and communities; and

(H) appropriate tribal law enforcement agencies.

(2) DESIGNATION.—The Secretary of Homeland Security, acting through the Assistant Secretary for ICE, is authorized to establish BEST units in jurisdictions where such units can contribute to the BEST program's missions, as appropriate. Prior to establishing a BEST unit, the Assistant Secretary shall consider the following factors:

(A) Whether the area where the BEST unit would be established is significantly impacted by cross-border threats.

(B) The availability of Federal, State, local, tribal, and foreign law enforcement resources to participate in the BEST unit.

(C) The extent to which border security threats are having a significant harmful impact in the jurisdiction in which the BEST unit is to be established, and other jurisdictions of the country.

(D) Whether or not an Integrated Border Enforcement Team already exists in the area where the BEST unit would be established.

(d) OPERATION.—After making a designation under subsection (c)(2), and in order to provide Federal assistance to the area so designated, the Secretary of Homeland Security may—

(1) obligate such sums as are appropriated for the BEST program;

(2) direct the assignment of Federal personnel to the BEST program, subject to the approval of the head of the department or agency that employs such personnel; and

(3) take other actions to assist State, local, tribal, and foreign jurisdictions to participate in the BEST program.

(e) REPORT.—Not later than 180 days after the date of the establishment of the BEST program under subsection (a) and annually thereafter, the Secretary of Homeland Security shall submit to Congress a report on the effectiveness of the BEST program in enhancing border security and reducing the drug trafficking, arms smuggling, illegal alien trafficking and smuggling, violence, and kidnapping along and across the international borders of the United States as measured by crime statistics, including violent deaths, incidents of violence, and drug-related arrests.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Secretary of Homeland Security $10,000,000 for each of fiscal years 2012 through 2016 to—

(1) establish and operate the BEST program, including to provide for operational, administrative, and technological costs to Federal, State, local, tribal and foreign law enforcement agencies participating in the BEST program; and

(2) investigate, apprehend, and prosecute individuals engaged in drug trafficking, arms smuggling, illegal alien trafficking and smuggling, violence, and kidnapping along and across the international borders of the United States.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New York (Mr. KING) and the gentleman from Mississippi (Mr. THOMPSON) each will control 20 minutes.

The Chair recognizes the gentleman from New York.

GENERAL LEAVE

Mr. KING of New York. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days within which to revise and extend their remarks and include any extraneous material on the bill under consideration.

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

There was no objection.

Mr. KING of New York. Mr. Speaker, I yield myself such time as I may consume.

There is probably no bill that is more meaningful to Members of Congress, particularly the gentleman from Texas, my good friend, Mr. CUELLAR, than the Jaime Zapata Border Enforcement Security Task Force Act. This would authorize for the first time a task force, led by Immigrations and Customs Enforcement, known as Border Enforcement Security Task Force, or BEST teams. It is named after ICE Agent Jaime Zapata, who was killed in the line of duty while serving on a BEST team in Mexico in February 2011.

I want to thank the sponsors of the legislation, Mr. CUELLAR, the ranking member of the Border and Maritime Subcommittee, and Mr. MCCAUL of Texas, the chairman of the Oversight, Investigations, and Management Subcommittee, for their dedicated work on this bipartisan bill.

I reserve the balance of my time.

Mr. Speaker, H.R. 915, the Jamie Zapata Border Enforcement Security Task Force Act, would authorize for the first time a task force led by Immigration and Customs Enforcement (ICE), known as Border Enforcement Security Task Forces, or BEST Teams.

This legislation is named after the Immigration and Customs Enforcement agent, Jamie Zapata, who was killed in the line of duty while serving on a BEST team in Mexico in February 2011.

I would like to thank the sponsors of this legislation, Mr. CUELLAR of Texas, the Ranking Member of the Border and Maritime Subcommittee, and Mr. MCCAUL of Texas, the Chairman of the Oversight, Investigations, and Management Subcommittee, for their dedicated work on this bipartisan bill.

The Department of Homeland Security's overriding mission is to lead a unified national effort to protect the United States. ICE is the largest investigative agency within DHS and is charged with enforcing a wide array of laws, including laws related to securing the border and combating criminal smuggling.

BEST teams incorporate personnel from ICE, Customs and Border Protection, DEA, ATF, FBI, U.S. Coast Guard, as well as other Federal, state, local and foreign law enforcement agencies.

These task forces focus on the identification, prioritization, and investigation of emerging and existing border security threats including transnational crime, violence associated with drug trafficking, arms smuggling, illegal alien trafficking, and kidnapping along the international borders of the United States.

Since the inception of the BEST program, BEST teams have made over 8,000 criminal arrests and 5,000 administrative arrests resulting in 4,570 indictments and 3,936 convictions. BEST teams have also seized over 69,000 pounds of cocaine, 752,000 pounds of marijuana, 3,800 pounds of methamphetamines, 3,000 vehicles, 13,000 weapons, and approximately $97 million in U.S. currency and monetary instruments.

In addition, the bill includes language to address a potential duplication identified by the Government Accountability Office in its March 2011 report to ensure that BEST units do not overlap with other Integrated Law Enforcement task forces along the Northern Border.

I urge my colleagues to support this bipartisan legislation.

Mr. THOMPSON of Mississippi. Mr. Speaker, I yield myself such time as I may consume.

I rise in strong support of H.R. 915, the Jaime Zapata Border Enforcement Security Task Force Act. H.R. 915 would, for the first time, statutorily authorize an important border security program, the BEST program.

Under BEST, ICE partners with Federal, State, local, and foreign law enforcement counterparts to establish targeted, cross-agency teams to identify, disrupt, and dismantle criminal

organizations posing significant threats to the border security. Currently, the BEST programs has 31 teams located at our Nation's northern and southern borders, as well as at seaports and places as varied as Tucson, Arizona; Detroit, Michigan; the New York Seaport; and Mexico City, Mexico.

To date, BEST units have initiated more than 6,800 cases, resulting in criminal and administrative arrests and the seizure of significant quantities of narcotics, weapons, ammunition, and currency.

Mr. Speaker, I yield such time as he may consume to the original sponsor of the legislation under consideration, the ranking member of the Subcommittee on Border and Maritime Security, the gentleman from Texas (Mr. CUELLAR).

Mr. CUELLAR. I want to thank the ranking member for yielding this time to me.

I'm pleased that the House is considering H.R. 915, the Jaime Zapata Border Enforcement Security Task Force, or BEST Act, a bipartisan bill by myself and Congressman MICHAEL MCCAUL from Texas. I would like to thank my friend, Chairman KING; my good friend, Ranking Member THOMPSON; and also Subcommittee Chairwoman MILLER for their support of this bill, as this bill was unanimously reported out of the House Homeland Security Committee.

As many of you know, the Immigration and Customs Enforcement, or ICE, Homeland Security Investigations, in partnership with U.S. Customs and Border Protection, as well as other Federal, State, local, and foreign law enforcement counterparts created the BEST initiative—in fact, my hometown of Laredo is the first one—which is a comprehensive approach to identifying, disrupting, and dismantling criminal organizations posing significant threats to border and maritime security.

H.R. 915 would codify the BEST program by authorizing the Secretary of Homeland Security, acting through the director of ICE, to establish the BEST units to make sure that everybody works together and coordinates and communicates together to make sure that we fight crime.

This bill authorizes $10 million per year for the program. And this bill, as the chairman said a few minutes ago, is named in the memory of Jaime Zapata, a Homeland Security Investigations special agent and BEST unit member who was killed in the line of duty in Mexico in February of 2011. We are grateful for Special Agent Zapata's service to our Nation and for the exemplary work of his colleagues in support of homeland security.

Currently, the BEST units are comprised of 750 members, representing over 100 law enforcement agencies working together. These BEST units are building an impressive record of success. And I'm asking now that we all support this particular bill.

Again, I want to thank the chairman, the ranking member of the subcommittee, my friend MICHAEL MCCAUL, and urge all Members to support this important bipartisan bill.

Mr. THOMPSON of Mississippi. Mr. Speaker, I yield 1 minute to the gentlelady from Texas (Ms. JACKSON LEE).

Ms. JACKSON LEE of Texas. Coming from Texas, I want to thank the gentleman from Texas, the ranking member of the subcommittee, for this legislation.

I rise in support of H.R. 915. We have heard that there has been a constant intrusion of activity over the border, specifically dealing with drug cartels. We recognize that it is important to utilize the combination of resources, and fusion centers represent an excellent logistical use of that, as they have been in our urban centers. Let me support and salute the utilization of fusion centers because it is extremely important that we provide a safe and secure border in the United States and on border States.

Mr. KING of New York. I have no further requests for time.

Mr. THOMPSON of Mississippi. Mr. Speaker, I ask support of H.R. 915. It's a good bill. I urge its adoption, and I yield back the balance of my time.

Mr. KING of New York. Mr. Speaker, I want to thank the gentleman from Laredo, Mr. CUELLAR, for introducing this bill and for his outstanding work on the committee, and also my good friend, Mr. MCCAUL, for their cosponsorship of the legislation.

I urge my colleagues to support the bill, and I yield back the balance of my time.

Mr. MCCAUL. Mr. Speaker, as an original cosponsor of the Jaime Zapata Border Enforcement Security Task Force Act, I rise today in favor of this important legislation. H.R. 915 strengthens our homeland security by codifying the authority to create Border Enforcement Security Task Force, BEST teams and giving the program the resources it needs.

It is an unfortunate fact of life that for generations our border communities have been subjected to crime and violence at the hands of criminals, smugglers and drug cartels. Now with the terrible rise of violence that has occurred in Mexico over the past few years, this threat has never been greater. In response to these realities, the Department of Homeland Security created the Border Enforcement Security Task Force initiative as an innovative approach to combating the increasing threat of transnational crime.

BEST operates by bringing together all of the federal, state and local law enforcement agencies that share the responsibility of securing our borders. Under the auspices of U.S. Immigration and Customs Enforcement (ICE), the BEST program enables the unique capabilities and resources of each participating agency to combine into a synergistic response to border crime and violence. BEST has also expanded to include our seaports and other non-border ports of entry as well. This has allowed the BEST program to evolve into a truly comprehensive security countermeasure against transnational crime and terrorist attack.

It is also altogether fitting and proper that this bill be named after ICE Special Agent Jaime J. Zapata. On February 15, 2011, Special Agent Zapata gave his life in support of the ideals that are engendered in the BEST program. This legislation will stand as a testament to his selfless sacrifice and steadfast devotion to his duty as an American law enforcement officer.

As chairman of the Homeland Security Subcommittee for Oversight, Investigations and Management, it is clear to me that the BEST program has made our border communities and our Nation safer and more secure. I urge my colleagues to pass this legislation so that we may continue its success in protecting our Nation.

Ms. RICHARDSON. Mr. Speaker, I rise in support of H.R. 915, the Jaime Zapata Border Enforcement Security Task Force Act, which establishes a Border Enforcement Security Task Force program to enhance cooperation amongst border security forces.

This legislation is named in honor of Immigration and Customs Enforcement (ICE) agent Jaime Zapata, who was killed in the line of the duty while serving on a Border Enforcement Security Task Force (BEST) team in Mexico. BEST teams incorporate personnel from ICE, Customs and Border Protection (CBP), the Drug Enforcement Administration (DEA), the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATFE), the Federal Bureau of Investigation (FBI), the United States Coast Guard (USCG), and the U.S. Attorney's Office (USAO), along with other key Federal, State and local law enforcement agencies.

H.R. 915 establishes a BEST program to enhance border security by fostering coordinated efforts among Federal, State, and local border and law enforcement officials to protect United States border cities and communities from transnational crime, including violence associated with drug trafficking, arms smuggling, illegal alien trafficking and smuggling, violence, and kidnapping along and across the international borders of the United States.

Securing our borders from those who would harm Americans is my highest priority as a Member of Congress. As a member of the Homeland Security Committee I am committed to working with my colleagues and the Administration to keep our borders secure from all those who threaten our freedom and liberty. As the Ranking Member on the Subcommittee on Emergency Preparedness, Response, and Communications of the Committee on Homeland Security, I have sponsored and co-sponsored legislation that improves our Nation's ability to secure the Nation's borders. I support H.R. 915 because it is a positive step in the right direction and I strongly urge my colleagues to do so as well.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, H.R. 915, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. THOMPSON of Mississippi. 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.

MASS TRANSIT INTELLIGENCE PRIORITIZATION ACT

Mr. KING of New York. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3140) to amend the Homeland Security Act of 2002 to direct the Secretary of Homeland Security to prioritize the assignment of officers and analysts to certain State and urban area fusion centers to enhance the security of mass transit systems.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3140

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 ''Mass Transit Intelligence Prioritization Act''.

SEC. 2. MASS TRANSIT INTELLIGENCE PRIORITIZATION.

Section 210A of the Homeland Security Act of 2002 (6 U.S.C. 124h) is amended—

(1) by redesignating subsections (f) through (k) as subsections (e) through (l), respectively;

(2) in subsection (l), as so redesignated, by striking ''subsection (i)'' and inserting ''subsection (j)''; and

(3) by inserting after subsection (e) the following new subsection (f):

''(f) MASS TRANSIT INTELLIGENCE PRIORITIZATION.—

''(1) IN GENERAL.—The Secretary shall make it a priority to assign officers and intelligence analysts under this section from the Department, including the Transportation Security Administration, to participating State and urban area fusion centers located in high-risk jurisdictions with mass transit systems in order to enhance the security of such mass transit systems by assisting Federal, State, local, and tribal law enforcement authorities in identifying, investigating, and otherwise interdicting persons, weapons, and contraband that pose a threat to homeland security.

''(2) MASS TRANSIT INTELLIGENCE PRODUCTS.—When performing the responsibilities described in subsection (d), officers and intelligence analysts assigned to participating State and urban area fusion centers under this section shall have, as a primary responsibility, the creation of mass transit intelligence products that—

''(A) assist State, local, and tribal law enforcement agencies in deploying their resources most efficiently to help detect and interdict terrorists, weapons of mass destruction, and contraband at mass transit systems of the United States;

''(B) promote more consistent and timely dissemination of mass transit security-relevant information among jurisdictions with mass transit systems; and

''(C) enhance the Department's situational awareness with respect to the threat of acts of terrorism at or involving mass transit systems of the United States.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New York (Mr. KING) and the gentleman from Mississippi (Mr. THOMPSON) each will control 20 minutes.

The Chair recognizes the gentleman from New York.

□ 1830

GENERAL LEAVE

Mr. KING of New York. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days within which to revise and extend their remarks and include any extraneous material on the bill under consideration.

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

There was no objection.

Mr. KING of New York. Mr. Speaker, I yield myself such time as I may consume.

Only due to the shortness of time, I will keep my remarks brief. This bill amends the Homeland Security Act of 2002 and directs the DHS Secretary to make it a priority to assign officers and intelligence analysts to participate in State and urban area fusion centers located in high-risk jurisdictions with mass transit systems.

I would like to thank Congresswoman SPEIER and Chairman MEEHAN for their dedicated work in this area.

I reserve the balance of my time.

This bill amends the Homeland Security Act of 2002 to direct the Secretary of Homeland Security to make it a priority to assign DHS officers and intelligence analysts to participate in state and urban area fusion centers located in high-risk jurisdictions with mass transit systems.

I would like to thank Congresswoman SPEIER and Chairman MEEHAN for their dedicated work in this area.

These officers and analysts will enhance the security of mass transit systems by assisting law enforcement authorities in identifying, investigating, and otherwise interdicting persons, weapons, and contraband that pose a threat to homeland security.

The primary responsibility of these officers and analysts will be to create mass transit intelligence products that assist law enforcement agencies in deploying their resources more efficiently, promote more consistent and timely dissemination of mass transit security-related information among jurisdictions with mass transit systems, and improve DHS' situational awareness in regard to the threat of terrorist acts at or involving U.S. mass transit.

It has been noted in documents uncovered from his Abbottabad compound, that Osama bin Laden expressed a continued interested in striking mass transit systems in the United States—railroads in particular.

That raid is a stark reminder that—after 9/11, the Christmas Day plot, Najibullah Zazi, Bryant Neal Vinas, and others—al Qaeda is still focused on striking our transportation systems. I urge support for this bipartisan measure.

Mr. THOMPSON of Mississippi. Mr. Speaker, I rise in support of H.R. 3140, the Mass Transit Intelligence Prioritization Act, and I yield myself such time as I may consume.

Mr. Speaker, as ranking member on the Committee on Homeland Security, I have observed that mass transit systems over the years have consistently been a target for terrorist groups, including al Qaeda. H.R. 3140, the Mass Transit Intelligence Prioritization Act, requires the Secretary of Homeland Security to prioritize the assignment of mass transit intelligence analysts, including from TSA, to State and local fusion centers with major mass transit systems in their jurisdictions.

In short, this is a commonsense bill that would enhance security for the mass transit systems of our Nation by improving the sharing of information, and I urge my colleagues' support of it.

With that, Mr. Speaker, I reserve the balance of my time.

Mr. KING of New York. Mr. Speaker, I reserve the balance of my time.

Mr. THOMPSON of Mississippi. Mr. Speaker, I yield such time as she may consume to the original sponsor of the legislation under consideration and a former member of the Committee on Homeland Security, the gentlewoman from California (Ms. SPEIER).

Ms. SPEIER. Mr. Speaker, I thank the ranking member for yielding and the chairman for his leadership as well.

As has been mentioned, this bill is important in our efforts to make sure that mass transit is under the umbrella for the sharing of information. Let us not forget that in 2004 al Qaeda detonated multiple explosives during rush hour on a packed commuter train in Madrid, Spain, killing 191 people. A little more than a year later in London, a terrorist cell linked to al Qaeda carried out four suicide bombings, three of them on the London Underground, killing more than 50. To date, the United States has not experienced the death and destruction associated with dirty bombs or a mass transit attack. But that doesn't mean we haven't had close calls. In fact, in September of 2009, Najibullah Zazi was arrested in New York City for allegedly plotting to blow up New York City subways.

In October 2010, the FBI arrested a man who was plotting a large-scale attack here in Washington, D.C. on the Metro system. Last year he was sentenced to 23 years in Federal prison.

Most recently, we learned through documents taken from the compound of Osama bin Laden following the successful Navy SEAL raid that al Qaeda was plotting to attack U.S. mass transit systems to commemorate the 10th anniversary of 9/11.

Millions of Americans travel each day on mass transit to work, but these systems, such as subways, have relatively few security measures. This bill will change that. It will make sure that fusion centers bring together Federal, State, and local law enforcement and emergency management agencies to share information and protect communities. The bill further requires that officers assigned to these fusion centers create mass transit intelligence products. One of the key lessons of 9/11 is information-sharing is key to terrorism prevention.

I urge my colleagues to support this measure. The CBO has determined that this bill would have no significant impact on the budget. I also would like to pay special respect to the chair of the Counterterrorism and Intelligence Subcommittee, the gentleman from Pennsylvania, who I enjoyed working with immensely

Mr. THOMPSON of Mississippi. I have no other speakers, and I'm prepared to close.

Mr. Speaker, H.R. 3140, as introduced by our former committee colleague, Ms. SPEIER, is a needed, commonsense piece of legislation with a history of bipartisan support. I urge my colleagues to support this measure and the security of our mass transit systems.

With that, I yield back the balance of my time.

Mr. KING of New York. Mr. Speaker, I come from a region which has almost 6 million daily passengers on subway and commuter lines. This legislation is absolutely vital, I urge its adoption, and I yield back the balance of my time.

Ms. RICHARDSON. Mr. Speaker, today I rise in support of H.R. 3140, the Mass Transit Intelligence Prioritization Act. Since the catastrophic events of September 11th, 2001 the United States has gone to every possible length to prevent another terrorist attack.

Unfortunately, our enemies cannot be deterred through logic and reason. No matter how secure we make our borders they will always be developing new ways to threaten our citizens. For this reason it is vital that America continues to improve its security and intelligence capabilities.

Since 9/11 mass transit attacks against the West have been on the rise. In 2004 a terrorist cell of Al Qaeda detonated multiple explosives on packed trains in Madrid, Spain, killing 191 people. Only a year later London was attacked by another cell linked to Al Qaeda. Four suicide bombers, all of whom were on public transportation killed more than fifty people. The Mumbai attacks followed, which killed over 200 people during evening rush hour on the local train network.

Mr. Speaker, if there is one lesson to take away from all of these horrific events, it is that America is still frighteningly vulnerable to a mass transit attack. Terrorists continue to develop methods to get around our security systems and inflict as much damage as possible.

As a member of the House Committee on Homeland Security it is my duty to ensure everything possible is being done to prevent another attack on U.S. soil. In my own district in California there are multiple systems that could be prone to attack, but across the country there are systems that have little protection.

The Metropolitan Transportation Authority is North America's largest public transportation system. It serves a population of 14.6 million people in the 5,000-square-mile area fanning out from New York City through Long Island, southeastern New York State, and Connecticut. Each weekday an average of 8,487,642 use this system. If this system is targeted, they have little security or defense and millions of people could be at risk.

The Mass Transit Intelligence Prioritization Act aims to direct the Secretary of Homeland Security to prioritize intelligence officers and analysts, including those from the Transportation Security Administration to high-risk jurisdictions with mass transit systems. The bill also requires the officers assigned to these areas to develop mass transit intelligence products as a primary responsibility.

This bill offers a way to promote the timely sharing of information between Federal, State and local partners, with the ultimate goal of preventing any attack against an American mass transit system.

Mr. Speaker, I fully support H.R. 3140 and the added security it brings to American citizens, and all those using our public transportation systems.

Ms. JACKSON LEE of Texas. Mr. Speaker, I rise today in support of H.R. 3140, ''Mass Transit Intelligence Prioritization Act.'' This legislation would amend the Homeland Security Act of 2002. It calls for the Secretary of Homeland Security (DHS) to make it a priority to assign DHS officers and intelligence analysts, including from the Transportation Security Administration (TSA), to participating state and urban area fusion centers located in high-risk jurisdictions with mass transit systems to enhance the security of these systems. These officers would help local enforcement authorities identify and investigate any threats to homeland security.

The DHS officers and analysts will also be responsible for creating mass transit intelligence products that will: (1) assist law enforcement agencies in deploying their resources most efficiently to help detect and interdict terrorists, weapons of mass destruction, and contraband at U.S. mass transit systems; (2) promote more consistent and timely dissemination of mass transit security-relevant information among jurisdictions with such systems; and (3) enhance DHS's situational awareness with respect to the threat of terrorist acts at or involving U.S. mass transit systems.

As a Ranking Member on the Subcommittee for Transportation, ensuring the safety and security of the nation's public transportation system is one of my top priorities.

Mass transit systems across the world have continually been a target for terrorist threats, namely the 2004 terrorist attack on a packed commuter train in Madrid, Spain that killed 191 people. There was also the suicide bombing attack in London that left 50 dead in 2005.

While we have so far been fortunate to have not had any incidents of terrorism in our mass transit systems, we know of the threat planned by al-Qaeda to commemorate the 10th anniversary of 9/11 by attacking US mass transit systems. Thankfully, a Naval SEALS raid on Osama bin Laden's compound discovered and thwarted this plot.

Rising gas prices have caused metro transportation systems to be used now more than ever, creating an additional urgency to keep citizens safe on the daily commute.

According to the American Public Transportation Association (APTA), Americans made 10.4 billion trips on public transportation in 2011. This is the second highest annual ridership since 1957. Houston's Metropolitan Transit Authority of Harris County accounted for 5.2 percent of that gain and has seen six consecutive months of increased ridership. In Houston, we understand the importance of a secured public transportation system.

Our metro transit system is closely partnered with the US Department of Homeland Security. It is equipped with surveillance capabilities and our officers are trained in counterterrorism measures as well as in the latest law enforcement techniques. In addition officers regularly check bus and rail lines and perform sweeps through the Transit Center as well as through the Park & Ride lots and bus stops.

As the city grows and new metro employees are hired, it is my goal that the Houston public transportation system maintains its high level of security and a strong relationship with Homeland Security. I desire this same level of security for all of the public transportation systems in the US.

I urge my colleagues to join me in supporting H.R. 3140 ''Mass Transit Intelligence Prioritization Act.''

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, H.R. 3140.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 5743, INTELLIGENCE AUTHORIZATION ACT FOR FISCAL YEAR 2013; PROVIDING FOR CONSIDERATION OF H.R. 5854, MILITARY CONSTRUCTION AND VETERANS AFFAIRS AND RELATED AGENCIES APPROPRIATIONS ACT, 2013; PROVIDING FOR CONSIDERATION OF H.R. 5855, DEPARTMENT OF HOMELAND SECURITY APPROPRIATIONS ACT, 2013; AND PROVIDING FOR CONSIDERATION OF H.R. 5325, ENERGY AND WATER DEVELOPMENT AND RELATED AGENCIES APPROPRIATIONS ACT, 2013

Mr. NUGENT, from the Committee on Rules, submitted a privileged report (Rept. No. 112–504) on the resolution (H. Res. 667) providing for consideration of the bill (H.R. 5743) to authorize appropriations for fiscal year 2013 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes; providing for consideration of the bill (H.R. 5854) making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2013, and for other purposes; providing for consideration of the bill (H.R. 5855) making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2013, and for other purposes; and providing for consideration of the bill (H.R. 5325) making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2013, and for other purposes, which was referred to the House Calendar and ordered to be printed.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on motions to suspend the rules previously postponed.

Votes will be taken in the following order:

H.R. 5651, by the yeas and nays;
H.R. 4201, by the yeas and nays;
H.R. 915, by the yeas and nays.

The first electronic vote will be conducted as a 15-minute vote. Remaining electronic votes will be conducted as 5-minute votes.

FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 5651) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes, as amended, on which the yeas and nays were ordered.

The Clerk read the title of the 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, as amended.

The vote was taken by electronic device, and there were—yeas 387, nays 5, not voting 39, as follows:

[Roll No. 294]

YEAS—387

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

NAYS—5

Amash
Hinchey
Labrador
McClintock
Paul

NOT VOTING—39

Bachmann
Brady (TX)
Burton (IN)
Costa
Doyle
Filner
Fortenberry
Frank (MA)
Guinta
Gutierrez
Hahn
Heinrich
Hinojosa
Hirono
Johnson, Sam
Jordan
Landry
Langevin
Lewis (CA)
Luján
Mack
Maloney
Marchant
McCarthy (CA)
Meeks
Neugebauer
Palazzo
Pascrell
Roby
Rohrabacher
Rothman (NJ)
Rush
Sires
Slaughter
Smith (WA)
Towns
Turner (NY)
Velázquez
Young (FL)

□ 1859

Mr. HARRIS changed his vote from ''nay'' to ''yea.''

So (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Mr. FILNER. Mr. Speaker, on rollcall 294, I was away from the Capitol due to prior commitments to my constituents. Had I been present, I would have voted "yea."

SERVICEMEMBER FAMILY PROTECTION ACT

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 4201) to amend the Servicemembers Civil Relief Act to provide for the protection of child custody arrangements for parents who are members of the Armed Forces, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida (Mr. STEARNS) that the House suspend the rules and pass the bill.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 390, nays 2, not voting 39, as follows:

[Roll No. 295]

YEAS—390

Ackerman
Adams
Aderholt
Akin
Alexander
Altmire
Amodei
Andrews
Austria
Baca
Bachus
Baldwin
Barletta
Barrow
Bartlett
Barton (TX)
Bass (CA)
Bass (NH)
Becerra
Benishek
Berg
Berkley
Berman
Biggert
Bilbray
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Black
Blackburn
Blumenauer
Bonamici
Bonner
Bono Mack
Boren
Boswell
Boustany
Brady (PA)
Braley (IA)
Brooks
Broun (GA)
Brown (FL)
Buchanan
Bucshon
Buerkle
Burgess
Butterfield
Calvert
Camp
Campbell
Canseco
Cantor
Capito
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Carter
Cassidy
Castor (FL)
Chabot
Chaffetz
Chandler
Chu
Cicilline
Clarke (MI)
Clarke (NY)
Clay
Cleaver
Clyburn
Coble
Coffman (CO)
Cohen
Cole
Conaway
Connolly (VA)
Conyers
Cooper
Costello
Courtney
Cravaack
Crawford
Crenshaw
Critz
Crowley
Cuellar
Culberson
Cummings
Davis (CA)
Davis (IL)
Davis (KY)
DeFazio
DeGette
DeLauro
Denham
Dent
DesJarlais
Deutch
Diaz-Balart
Dicks
Dingell
Doggett
Dold
Donnelly (IN)
Dreier
Duffy
Duncan (SC)
Duncan (TN)
Edwards
Ellison
Ellmers
Emerson
Engel
Eshoo
Farenthold
Farr
Fattah
Fincher
Fitzpatrick
Flake
Fleischmann
Fleming
Flores
Forbes
Foxx
Frank (MA)
Franks (AZ)
Frelinghuysen
Fudge
Gallegly
Garamendi
Gardner
Garrett
Gerlach
Gibbs
Gibson
Gingrey (GA)
Gohmert
Gonzalez
Goodlatte
Gosar
Gowdy
Granger
Graves (GA)
Graves (MO)
Green, Al
Green, Gene
Griffin (AR)
Griffith (VA)
Grijalva

Grimm
Guthrie
Hall
Hanabusa
Hanna
Harper
Harris
Hartzler
Hastings (FL)
Hastings (WA)
Hayworth
Heck
Hensarling
Herger
Herrera Beutler
Higgins
Himes
Hinchey
Hochul
Holden
Holt
Honda
Hoyer
Huelskamp
Huizenga (MI)
Hultgren
Hunter
Hurt
Israel
Issa
Jackson (IL)
Jackson Lee (TX)
Jenkins
Johnson (GA)
Johnson (IL)
Johnson (OH)
Johnson, E. B.
Jones
Kaptur
Keating
Kelly
Kildee
Kind
King (IA)
King (NY)
Kingston
Kinzinger (IL)
Kissell
Kline
Kucinich
Labrador
Lamborn
Lance
Lankford
Larsen (WA)
Larson (CT)
Latham
LaTourette
Latta
Lee (CA)
Levin
Lewis (GA)
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Long
Lowey
Lucas
Luetkemeyer
Luján
Lummis
Lungren, Daniel E.
Lynch
Manzullo
Marino
Markey
Matheson
Matsui
McCarthy (NY)
McCaul
McClintock
McCollum
McCotter
McDermott
McGovern
McHenry
McIntyre
McKeon
McKinley
McMorris Rodgers
McNerney
Meehan
Mica
Michaud
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Moore
Moran
Mulvaney
Murphy (CT)
Murphy (PA)
Myrick
Nadler
Napolitano
Neal
Noem
Nugent
Nunes
Nunnelee
Olson
Olver
Owens
Pallone
Pastor (AZ)
Paulsen
Pearce
Pelosi
Pence
Perlmutter
Peters
Peterson
Petri
Pingree (ME)
Pitts
Platts
Poe (TX)
Polis
Pompeo
Posey
Price (GA)
Price (NC)
Quayle
Quigley
Rahall
Rangel
Reed
Rehberg
Reichert
Renacci
Reyes
Ribble
Richardson
Richmond
Rigell
Rivera
Roe (TN)
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rokita
Rooney
Ros-Lehtinen
Roskam
Ross (AR)
Ross (FL)
Roybal-Allard
Royce
Runyan
Ruppersberger
Ryan (OH)
Ryan (WI)
Sanchez, Loretta
Sarbanes
Scalise
Schakowsky
Schiff
Schilling
Schmidt
Schock
Schrader
Schwartz
Schweikert
Scott (SC)
Scott (VA)
Scott, Austin
Scott, David
Sensenbrenner
Serrano
Sessions
Sewell
Sherman
Shimkus
Shuler
Shuster
Simpson
Smith (NE)
Smith (TX)
Southerland
Speier
Stark
Stearns
Stivers
Stutzman
Sullivan
Sutton
Terry
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tiberi
Tierney
Tipton
Tonko
Tsongas
Turner (OH)
Upton
Van Hollen
Visclosky
Walberg
Walden
Walsh (IL)
Walz (MN)
Wasserman Schultz
Waters
Watt
Waxman
Webster
Welch
West
Westmoreland
Whitfield
Wilson (FL)
Wilson (SC)
Wittman
Wolf
Womack
Woodall
Woolsey
Yarmuth
Yoder
Young (AK)
Young (IN)

NAYS—2

Amash
Paul

NOT VOTING—39

Bachmann
Brady (TX)
Burton (IN)
Costa
Doyle
Filner
Fortenberry
Guinta
Gutierrez
Hahn
Heinrich
Hinojosa
Hirono
Johnson, Sam
Jordan
Landry
Langevin
Lewis (CA)
Mack
Maloney
Marchant
McCarthy (CA)
Meeks
Neugebauer
Palazzo
Pascrell
Roby
Rohrabacher
Rothman (NJ)
Rush
Sánchez, Linda T.
Sires
Slaughter
Smith (NJ)
Smith (WA)
Towns
Turner (NY)
Velázquez
Young (FL)

□ 1906

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Mr. FILNER. Mr. Speaker, on rollcall 295, I was away from the Capitol due to prior commitments to my constituents. Had I been present, I would have voted "yea."

PERSONAL EXPLANATION

Mr. LANGEVIN. Mr. Speaker, on rollcall vote Nos. 294 and 295, I was unavoidably detained. Had I been present, I would have voted "yea" on both votes.

JAIME ZAPATA BORDER ENFORCEMENT SECURITY TASK FORCE ACT

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 915) to establish a Border Enforcement Security Task Force program to enhance border security by fostering coordinated efforts among Federal, State, and local border and law enforcement officials to protect United States border cities and communities from trans-national crime, including violence associated with drug trafficking, arms smuggling, illegal alien trafficking and smuggling, violence, and kidnapping along and across the international borders of the United States, and for other purposes, as amended, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, as amended.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 391, nays 2, not voting 38, as follows:

[Roll No. 296]

YEAS—391

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

Walden	Webster	Wolf
Walsh (IL)	Welch	Womack
Walz (MN)	West	Woodall
Wasserman Schultz	Westmoreland	Woolsey
Waters	Whitfield	Yarmuth
Watt	Wilson (FL)	Yoder
Waxman	Wilson (SC)	Young (AK)
	Wittman	Young (IN)

NAYS—2

Amash	Paul

NOT VOTING—38

Bachmann	Hirono	Pascrell
Benishek	Johnson, Sam	Roby
Brady (TX)	Jordan	Rohrabacher
Burton (IN)	Landry	Rothman (NJ)
Costa	Lewis (CA)	Rush
Doyle	Mack	Sires
Filner	Maloney	Slaughter
Fortenberry	Marchant	Smith (WA)
Guinta	McCarthy (CA)	Towns
Gutierrez	Meeks	Turner (NY)
Hahn	Moore	Velázquez
Heinrich	Neugebauer	Young (FL)
Hinojosa	Palazzo	

□ 1914

So (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Mr. FILNER. Mr. Speaker, on rollcall 296, I was away from the Capitol due to prior commitments to my constituents. Had I been present, I would have voted "yea."

PERSONAL EXPLANATION

Mrs. BACHMANN. Mr. Speaker, during the evening of Wednesday, 30 May 2012, I missed House votes due to an illness in my family. If I had been present, here is how I would have voted:

H.R. 5651—Food and Drug Administration Reform Act of 2012, as amended, "yea."

H.R. 4201—The Servicemember Family Protection Act, "yea."

H.R. 915—Jaime Zapata Border Security Task Force, "yea."

PERSONAL EXPLANATION

Ms. SLAUGHTER. Mr. Speaker, I was unavoidably detained and missed rollcall vote Nos. 294, 295 and 296. Had I been present, I would have voted "yea" on rollcall vote Nos. 294, 295 and 296.

PERSONAL EXPLANATION

Mr. PASCRELL. Mr. Speaker, I want to state for the record that on May 30, 2012, I missed the three rollcall votes of the day. Had I been present I would have voted "yea" on rollcall No. 294, H.R. 5651, The Food and Drug Administration Reform Act of 2012; "yea" on H.R. 4201, The Servicemember Family Protection; "yea" on H.R. 915, The Jaime Zapata Border Security Task Force Act.

REMOVAL OF NAME OF MEMBER AS COSPONSOR OF H.R. 1513

Mr. GINGREY of Georgia. Mr. Speaker, I ask unanimous consent to have my name removed from H.R. 1513.

The SPEAKER pro tempore (Mr. TIPTON). Is there objection to the request of the gentleman from Georgia?

There was no objection.

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

Mr. BROUN of Georgia. 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:

Mr. Broun of Georgia 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 provisions that limit funding out of the Highway Trust Fund (including the Mass Transit Account) for Federal-aid highway and transit programs to amounts that do not exceed the following levels:

(1) $37,900,000,000 for fiscal year 2012.

(2) $37,500,000,000 for fiscal year 2013.

□ 1920

NATIONAL FLOOD INSURANCE PROGRAM EXTENSION ACT

Mrs. BIGGERT. Mr. Speaker, I move to suspend the rules and concur in the Senate amendment to the bill (H.R. 5740) to extend the National Flood Insurance Program, and for other purposes.

The Clerk read the title of the bill.

The text of the Senate amendment is as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. EXTENSION OF THE NATIONAL FLOOD INSURANCE PROGRAM.

(a) PROGRAM EXTENSION.—Section 1319 of the National Flood Insurance Act of 1968 (42 U.S.C. 4026) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''July 31, 2012''.

(b) FINANCING.—Section 1309(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a)) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''July 31, 2012''.

SEC. 2. EXCLUSION OF VACATION HOMES AND SECOND HOMES FROM RECEIVING SUBSIDIZED PREMIUM RATES.

(a) IN GENERAL.—Section 1307(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4014(a)(2)) is amended by inserting before ''; and'' the following: '', except that the Administrator shall not estimate rates under this paragraph for any residential property which is not the primary residence of an individual''.

(b) PHASE-OUT OF SUBSIDIZED PREMIUM RATES.—Section 1308(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4015(e)) is amended—

(1) by striking ''under this title for any properties within any single'' and inserting the following: ''under this title for—

''(1) any properties within any single''; and

(2) by striking the period at the end and inserting the following: ''; and

''(2) any residential properties which are not the primary residence of an individual, as described in section 1307(a)(2), shall be increased by 25 percent each year, until the average risk premium rate for such properties is equal to the average of the risk premium rates for properties described under paragraph (1).''.

(c) EFFECTIVE DATE.—The first increase in chargeable risk premium rates for residential properties which are not the primary residence of an individual under section 1308(e)(2) of the National Flood Insurance Act of 1968, as added by this Act, shall take effect on July 1, 2012, and the chargeable risk premium rates for such properties shall be increased by 25 percent each year thereafter, as provided in such section 1308(e)(2).

SEC. 3. COMPLIANCE WITH PAYGO.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from Illinois (Mrs. BIGGERT) and the gentleman from Georgia (Mr. DAVID SCOTT) each will control 20 minutes.

The Chair recognizes the gentlewoman from Illinois.

GENERAL LEAVE

Mrs. BIGGERT. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to add extraneous material on this bill.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Illinois?

There was no objection.

Mrs. BIGGERT. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of the Senate amendment to H.R. 5740, the National Flood Insurance Program Extension Act. As my colleagues know, the NFIP is set to expire on May 31. This program provides vital flood insurance coverage to homeowners in flood-prone communities.

Just 2 weeks ago, we passed a 30-day extension, H.R. 5740, to spare property owners and the housing market from another lapse in the NFIP. That bill was approved by this Chamber on May 17 by a vote of 402–18.

The Senate has since amended our legislation, extending the authorization for an additional 30 days, for a total of 60 days, or until July 31. The Senate amendment also eliminates subsidized rates for second and vacation homes. According to an unofficial Congressional Budget Office staff estimate, this provision will generate approximately $2 billion to $2.5 billion over 10 years.

Although not identical, the Senate's reform provision mirrors section 5 of H.R. 1309, the 5-year flood reform bill that we in the House passed with overwhelming bipartisan support last July. And if any technical changes are needed, they can be addressed in any long-term reform measure that we consider in the coming weeks.

On that note, I am pleased to report that, as part of reaching an agreement on this extension, Senate leaders have offered their public and private assurances that they will vote this June on the long-term flood insurance reform. This agreement is a major breakthrough for those of us who have been

pushing for the Senate passage of the long-term bill since the House completed its work nearly 11 months ago. The Senate Banking Committee has already approved a bipartisan NFIP proposal, and I remain confident that the House and Senate can reconcile any differences that remain between our respective visions for reform.

Mr. Speaker, the NFIP is over $17 billion in debt to taxpayers, and since 2008 Congress has enacted 16 stopgap measures to keep the program running. Today's bill can and should be the last short-term extension, because this program is too important to let lapse and too in debt to continue without reform. Today's bill not only prevents a lapse, it brings us closer to a responsible long-term solution. And the sooner we accomplish this goal, the sooner taxpayers can stop bearing the full expense and risk of an outdated flood program.

With that, I would urge my colleagues to support the Senate amendment to H.R. 5740, and I reserve the balance of my time.

Mr. DAVID SCOTT of Georgia. Mr. Speaker, again, it is certainly a pleasure always to work with the gentlewoman from Illinois on this issue.

We brought this issue up awhile back, and we were very successful in getting a 5-year extension, the way this should be dealt with. The Senate, unfortunately, chose not to immediately pursue that, so we came back 2 weeks ago and asked for a 30-day extension, to our good graces and the good grace of the Senate. They doubled that and came back with a 60-day extension, but yet we still need the 5-year extension, so we hope that this is a sign of us moving in the right direction. We are very pleased that the Senate is moving with the House in the right direction on this very important plan, and this is an important plan.

We are now just 2 days from the start of the hurricane season and, as a matter of fact, as I was here before 2 weeks ago, I said we needed to make sure we prepared for the storm before the hurricane is raging and that we were just a couple of weeks away from the start of the hurricane season. But we had an early arrival. We had Beryl come in. So you see how pressing and how urgent this is.

This piece of legislation is perhaps the most important piece of legislation that we can pass right now of major benefit for the American people. They will be able to go to sleep tonight to know that at least for the next 2 months this National Flood Insurance Program will be in place. And this will be a great sigh of relief, but that still leaves the heavy lifting to do. We have got the 5-year program and we have got to do that.

I do want to say thank you and my hat is off to Senator REID and Senator COBURN, who came to an agreement. I think it's a good agreement. It's an agreement that we certainly accept here, too. And what we understand happened in the Senate was that the Senate amendment, which was offered in the Senate Banking Committee by Senator TIM JOHNSON, was to make sure that those homes that are second homes or vacation homes would not receive subsidized rates, and we think that's fair. That's a part of what's in our 5-year plan as well, so that is very much appreciated there.

As we look forward now, all we have to do now is pass this out now and move forward in good faith with the Senate to let's move with dispatch and get the 5-year plan. Now, the reason we need the 5-year plan is because of the continuity, of the dependability, so that people will know well in advance exactly that we have this program in place.

If I may, and with just my short time here, in case some of the people do not know why this 5-year plan is so important, I do want to state exactly what it does.

First of all, it does, in fact, extend the flood insurance program for 5 years.

It will also delay, for 5 years, the mandatory purchase requirement resulting from new flood maps.

The bill certainly requires annual notification to homeowners who are living in flood zones about the risks to their community. As I noted last week, a couple of weeks ago, many people move into areas, and they don't even know that they are in a flood zone, so it's very important that we will notify people. Our bill, this 5-year program, lets people know every single year because you have people moving in, you have people moving out. Every year there will be a notification as to whether or not they are in a flood zone.

The other important part about this is we have noticed, particularly in my own home State of Georgia where we had such a devastating flood in the year 2009, it was the worst flood we had there since we started taking records of that. As I mentioned, we lost lives. Seven individuals lost their lives in one county in my district. The application of flood maps all across this country, in every corner of this country, our flood maps are outdated.

Well, this bill will make sure that they are dated—so that many of our constituency who are at the risk of flood damage are at that risk without any knowledge—by making the flood maps current, by making sure that information is imparted to individuals who move in and out of communities every year that they are in a flood zone.

Most importantly, most importantly in these tough economic times, under our 5-year plan, individuals will be able to purchase their flood insurance in installments instead of one lump sum. This has caused many people not to be able to be have the flood insurance, because prior to this bill, this 5-year plan, as of right now, to get flood insurance, you have to do it as a lump sum. That's why this 5-year plan is important, and it's important for the Senate to move so that we can get this done right away.

But this is good news for the American people. We do have 2 months, as the hurricane season starts, and I think we have a good agreement here and good energy to move forward, the House and the Senate together, and put the 5-year plan in place.

I reserve the balance of my time.

□ 1930

Mrs. BIGGERT. Mr. Speaker, I yield 3 minutes to the gentleman from Ohio (Mr. STIVERS), a valued member of the Financial Services Committee.

Mr. STIVERS. Mr. Speaker, I would like to thank the gentlelady from Illinois for yielding me time. I'd like to thank her as chairwoman of the Subcommittee on Insurance and Housing for the Financial Services Committee for her incredible bipartisan effort that she led on this bill, along with Members of the other side, including the gentlelady from California and the gentleman from Georgia. It's been a true bipartisan effort. Obviously, that's reflected in the 402–18 vote coming out of this Chamber in May.

I'm happy that the Senate has finally reached an agreement to move forward with the multiyear extension of the National Flood Insurance Program because if we don't have a multiyear extension, what could happen is it could really cause problems in our housing market. I think the gentleman from Georgia has really talked about the importance of continuity and why that's really important for people that live in a flood plain to be able to know they can sell their house and also know that somebody can buy a home that happens to be in a flood plain.

I think it is important that we have accurate flood maps. This bill will ensure that we have much more accurate flood maps that have three dimensions on them, and that will result in better knowledge of where the flood plains are and where the risk is.

This bill will help stop the taxpayer-funded bailouts. As you know, the National Flood Insurance Program owes $17 billion to the taxpayers. We've got to make sure that it is sustainable into the future.

I think some of the Senate changes are good. The amendment by Senator COBURN that makes sure that we don't subsidize second and third homes that happen to be vacation homes makes a lot of sense. It steps up the premiums 25 percent a year for multiple years until they become actuarially sound. We need to ultimately move the whole program to an actuarially sound basis. That's why I'm concerned about some of the other provisions in the amended Senate language that removed the GAO study regarding privatization and allowing a chance to look at the flood insurance program's ability to pay claims over the long term.

I think it is important that we know the viability of the flood insurance program. But overall, I think having Senate amendments and a Senate agreement is a major step forward. I'm excited about continuing to work together to move this program forward and reauthorize it, hopefully, for a 5-year term. But this step to agree to Senate amendments to extend the time for a total of 60 days to get us past July so that hopefully the Senate will have time in June to bring this up, I think allows us the time we need to make that happen.

I do think if anybody in this body cares about our housing market or cares about stopping taxpayer-funded bailouts or wants to make sure that we have accurate flood maps, they should vote to agree to these amendments, and I hope all my colleagues will do so.

Mr. DAVID SCOTT of Georgia. I only have myself to close.

Mrs. BIGGERT. I have no further requests for time.

Mr. DAVID SCOTT of Georgia. Again, let me thank the gentlelady from Illinois (Mrs. BIGGERT) for her outstanding leadership on this. It's been a joy to work with her. The American people are certainly appreciative of her efforts in leading this fight. I also want to thank Ms. MAXINE WATERS, who is our subcommittee ranking member; and I also want to extend congratulations to Senator HARRY REID and Senator TOM COBURN.

I also want to just say a word for the bipartisan relationships that have developed on this bill. This is how we move bills forward. This is how we've got to move the country forward, and this is what the American people are looking to us to do. This is not a Democratic or a Republican Congress. It is a Congress of the American people. And the progress of this flood insurance bill is indicative of that fact.

With that, I yield back the balance of my time.

Mrs. BIGGERT. I yield myself the balance of my time.

Mr. Speaker, as I mentioned earlier, this bill is the 17th short-term extension of the National Flood Insurance Program. Our colleagues in the Senate have assured us that in June they will take up the version of a long-term NFIP reauthorization and reform bill, so I am confident that this will be our last short-term extension.

H.R. 5740, with the Senate amendment, extends the program for an additional 2 months in order to protect homeowners, communities in flood-prone areas, and the housing market. Including at least one reform provision in H.R. 5740—to eliminate subsidized rates for second and vacation homes—reduces some of the NFIP's risk to taxpayers.

H.R. 5740 also buys the House and Senate 2 more months to finalize a larger bill to reauthorize the 5 years and reform the National Flood Insurance Program.

Eleven months ago, over 400 Members of the House from both sides of the aisle voted for H.R. 1309 to reform this program. Actually, the reform bill passed out of the Financial Services Committee 54–0. So this is a real bipartisan effort. The House also has approved the same 5-year NFIP reauthorization and reform bill as part of the Middle Class Tax Relief and Job Creation Act of 2012 in December, and as part of the Reconciliation Act that was passed a couple of weeks ago.

Again, earlier this month over 400 Members of the House voted for the first version of H.R. 5740 to ensure that NFIP doesn't lapse. NFIP is over $17 billion in debt to taxpayers and it cannot continue without reforms, but shouldn't lapse, particularly at the start of the hurricane season, which begins this week on June 1.

With that, I urge my colleagues to again support H.R. 5740.

Finally, I would really like to thank Ms. WATERS for cosponsoring this bill as the lead cosponsor and Mr. SCOTT from Georgia for managing time for the other side and all other Members on both sides of the aisle. We've had a really great turnout for the NFIP reform effort.

Mr. DAVID SCOTT of Georgia. Will the gentlelady yield?

Mrs. BIGGERT. I yield to the gentleman.

Mr. DAVID SCOTT of Georgia. I misspoke when I referred to Ms. WATERS as the ranking member of the Housing Subcommittee. That honor goes to the Congressman from Illinois (Mr. GUTIERREZ). So I just wanted to correct that. Ms. WATERS was the former chairman of the Housing Subcommittee. All of us worked together in such a way, but I did want to correct that as Mr. GUTIERREZ as the ranking member

Mrs. BIGGERT. I thank the gentleman. Both of the Members have been great in working with this. I know that Ms. WATERS has been the ranking member for the committee in the past and has always worked on the flood insurance.

I yield back the balance of my time.

Mrs. MILLER of Michigan. Mr. Speaker, I once again rise in strong opposition to the reauthorization of the National Flood Insurance Program.

With all the challenges our nation faces I have a simple question for everyone . . . why in the world is the federal government in the flood insurance business?

The federal government is a bad insurance company. This program which began issuing policies in the 1970's is now almost $19 billion in debt with no hope to ever repay that debt because it is not run with sound actuarial standards.

I opposed this bill a few weeks ago when it passed this House and while the Senate made improvements by taking away subsidized rates from second homes, which is a start, but it still provides others with subsidies while charging premium rates to others, like many in my district with little risk of ever flooding, to provide that subsidy to others in more flood prone areas.

I believe strongly that this is a practice best left to the private sectors or individual states. It is long past time to get the federal government out of the flood insurance business and I continue to oppose this bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Illinois (Mrs. BIGGERT) that the House suspend the rules and concur in the Senate amendment to the bill, H.R. 5740.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the Senate amendment was concurred in.

A motion to reconsider was laid on the table.

EXPORT PROMOTION REFORM ACT

Mr. MANZULLO. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4041) to amend the Export Enhancement Act of 1988 to further enhance the promotion of exports of United States goods and services, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4041

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 ''Export Promotion Reform Act''.

SEC. 2. IMPROVED COORDINATION EXPORT PROMOTION ACTIVITIES OF FEDERAL AGENCIES.

Section 2312 of the Export Enhancement Act of 1988 (relating to the Trade Promotion Coordinating Committee; 15 U.S.C. 4727) is amended—

(1) in subsection (b)—

(A) in paragraph (5), by striking ''and'' after the semicolon;

(B) by redesignating paragraph (6) as paragraph (7); and

(C) by inserting after paragraph (5) the following:

''(6) in making the assessments under paragraph (5), review the proposed annual budget of each agency described in paragraph (5), under procedures established by the Committee for such review, before the agency submits that budget to the Office of Management and Budget and the President for inclusion in the budget of the United States submitted to Congress under section 1105(a) of title 31, United States Code; and'';

(2) in subsection (c)—

(A) by redesignating paragraphs (3) through (6) as paragraphs (4) through (7), respectively; and

(B) by inserting after paragraph (2) the following:

''(3) in conducting the review and developing the plan under paragraph (2), take into account recommendations from a representative number of United States exporters, in particular small businesses and medium-sized businesses, and representatives of United States workers;''; and

(3) by adding at the end the following:

''(g) EXECUTIVE ORDER AND REGULATIONS.—The President shall issue an executive order and such regulations as are necessary to provide the chairperson of the TPCC with the authority to ensure that the TPCC carries out each of its duties under subsection (b) and develops and implements the strategic plan under subsection (c).

''(h) DEFINITION.—In this section, the term 'small business' means a small business concern as defined under section 3 of the Small Business Act (15 U.S.C. 632).''.

SEC. 3. EFFECTIVE DEPLOYMENT OF U.S. COMMERCIAL SERVICE RESOURCES.

Section 2301(c)(4) of the Export Enhancement Act of 1988 (relating to the United States and Foreign Commercial Service; 15 U.S.C. 4721(c)(4)) is amended—

(1) by redesignating subparagraphs (B) through (F) as subparagraphs (C) through (G), respectively; and

(2) by striking ''(4) FOREIGN OFFICES.—(A) The Secretary may'' and inserting the following:

''(4) FOREIGN OFFICES.—(A)(i) In consultation with the Trade Promotion Coordinating Committee, the Secretary shall conduct a global assessment of overseas markets to determine those with the greatest potential for increasing United States exports, and to deploy the Commercial Service personnel and other resources on the basis of the global assessment.

''(ii) The assessment conducted under clause (i) shall take into account recommendations from a representative number of United States exporters, in particular small- and medium-sized businesses, and representatives of United States workers.

''(iii) Not later than 6 months after the date of enactment of the Export Promotion Reform Act, the Secretary shall submit to Congress results of the global assessment conducted under clause (i) and a plan for deployment of Commercial Service personnel and other resources on the basis of the global assessment.

''(iv) The Secretary shall conduct an assessment and deployment described in clause (i) not less than once in every 5-year period.

''(B) The Secretary may''.

SEC. 4. STRENGTHENED U.S. COMMERCIAL DIPLOMACY IN SUPPORT OF U.S. EXPORTS.

(a) DEVELOPMENT OF PLAN.—Section 207(c) of the Foreign Service Act of 1980 (22 U.S.C. 3927(c)) is amended by inserting before the period at the end the following: '', including through the development of a plan, drafted in consultation with the Trade Promotion Coordinating Committee, for effective diplomacy to remove or reduce obstacles to exports of United States goods and services''.

(b) ASSESSMENTS AND PROMOTIONS.—Section 603(b) of the Foreign Service Act of 1980 (22 U.S.C. 4003(b)) is amended, in the second sentence, by inserting after ''expertise'' the following: ''and (with respect to members of the Service with responsibilities relating to economic affairs) of the effectiveness of efforts to promote the export of United States goods and services in accordance with a commercial diplomacy plan developed pursuant to section 207(c),''.

(c) INSPECTOR GENERAL.—Section 209(b) of the Foreign Service Act of 1980 (22 U.S.C. 3929(b)) is amended—

(1) in paragraph (4), by striking ''and'' at the end;

(2) by redesignating paragraph (5) as paragraph (6); and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) the effectiveness of commercial diplomacy relating to the promotion of exports of United States goods and services; and''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Illinois (Mr. MANZULLO) and the gentleman from California (Mr. BERMAN) each will control 20 minutes.

The Chair recognizes the gentleman from Illinois.

□ 1940

GENERAL LEAVE

Mr. MANZULLO. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend and to submit extraneous materials for the RECORD.

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

There was no objection.

Mr. MANZULLO. Mr. Speaker I yield myself such time as I may consume.

Mr. Speaker, this bill has been many years in the making and is the result of several hearings, including one I held as chairman of the House Small Business Committee back in 2006. This is simply a good-government bill that costs nothing.

I recognize that market forces play a predominant role in international trade. However, export promotion programs can play a useful role in helping small and medium-sized enterprises find new markets and customers overseas. Several small companies in northern Illinois expanded their operations and hired new workers after U.S. Commercial Service identified new exporting opportunities.

Also, according to the National District Export Council, every $1 spent on export promotion has resulted in $135 in exports. However, many of our trade-promotion programs are not fully integrated. This has been confirmed in various Government Accountability Office, GAO, and Inspector General reports measuring the effectiveness of the Trade Promotion Coordinating Committee, which is known as the TPCC. Congressional intent behind the legislation this committee passed in 1992 has not been fulfilled.

Our trading partners are well organized and effectively market their businesses overseas. I recall on one of my trips to China some years ago, the CEO of a very large Chinese manufacturing company told me he often sees Europeans and Japanese as trade-promotion officials, but he had yet to see Americans doing the same thing. And he asked me the question: Where are the Americans?

According to the National District Export Council, while the U.S. spends about 21 cents per $1,000 of total exports on trade-promotion programs and services, Japan spends 30 cents, France spends 43 cents, and Great Britain spends 75 cents. With small businesses offering the best prospect to boost export growth, we should make every effort that gets the greatest return for any taxpayer money spent on export promotion.

In 2006 and in 2008, I introduced legislation that would reform the TPCC and move its responsibilities into the executive office of the President. I was pleased in 2010 when the President announced the formation of the Export Cabinet and adopted many of the reform ideas contained in my legislation, such as instituting measurable benchmarks for achieving goals set forth in the annual National Export Strategy report.

However, there is one key reform missing from the President's proposal: having an integrated trade budget. Currently, each trade-promotion agency submits its own budget to the Office of Management and Budget and the President on its own without a separate review as to whether or not each request fits within the overall trade agenda for the U.S. Government.

The TPCC needs budget-review authority in order to be fully effective. In 2010, I was proud to join with our former colleague, Representative Gabby Giffords, in introducing legislation to remedy this problem. While the bill did not pass in the previous Congress, I am proud to join with my good friend, Representative HOWARD BERMAN, in continuing Ms. Giffords' legacy and support the Export Promotion Reform Act.

While the President issued a subsequent memorandum last February that would give the Export Cabinet and the TPCC the ability to make recommendations to the Office of Management and Budget for more effective use of trade-promotion funds, this bill is needed to codify and clarify this role to guarantee that the TPCC will be able to influence decisions on the President's budget request prior to its submission to Congress.

Process and good-government reforms oftentimes do not get the attention they deserve. However, this bill recognizes their importance. I urge my colleagues to support this bill because it will ultimately benefit small and medium-sized exporters.

I reserve the balance of my time.

Mr. BERMAN. Mr. Speaker, I rise in strong support of H.R. 4041, and I yield myself such time as I may consume.

Mr. Speaker, the Export Promotion Reform Act is a bipartisan, noncontroversial bill that will help increase the export of American goods and services, and in the process create new, high-quality jobs. I want to thank the gentleman from Illinois (Mr. MANZULLO) for working with me on this legislation. He has been one of the strongest voices for export promotion and export control reform in this Chamber, and he's been a great partner to have on this legislation. I also want to thank my chairman of the Foreign Affairs Committee, ILEANA ROS-LEHTINEN, and her staff for helping to move this through the legislative process to this point.

H.R. 4041 would implement recommendations by the GAO, the Government Accountability Office, to make more effective use of our export-promotion programs. According to the Congressional Budget Office, the bill doesn't authorize any new programs, nor does it add any new spending or impose any new mandates.

The bill has been endorsed by a number of prominent business organizations, including the U.S. Chamber of Commerce, the National Association of Manufacturers, and the Business Roundtable.

The Export Promotion Reform Act would make sound, practical improvements that would benefit many of the

Nation's 293,000 exporting firms, more than 97 percent of which are small and medium-sized businesses, while exercising fiscal prudence on behalf of the American taxpayer.

American firms have renewed opportunities for growth and increased employment through increased sales overseas. However, the competition in world trade is fierce, and our export-promotion programs often don't measure up to those of our competitors. GAO has told us repeatedly that these programs would be more effective with improved coordination. To that end, H.R. 4041 would eliminate duplicative activities and improve service delivery to exporters; require a global plan to identify and target the best growth markets for U.S. goods and services; and require our ambassadors to develop country-by-country commercial diplomacy plans aimed at increasing U.S. exports, while making the effectiveness of their commercial diplomacy efforts part of their annual performance review.

Mr. Speaker, the U.S. Department of Commerce estimates that every $1 billion of U.S. exports supports approximately 5,800 jobs here at home. With 95 percent of the world's consumers living overseas, expanding U.S. exports in world markets is one of the best ways for American business to grow and create jobs.

I urge all of my colleagues to support this legislation, and I yield back the balance of my time.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 19, 2012.

Hon. ILEANA ROS-LEHTINEN,
Chairman, Committee on Foreign Affairs, House of Representatives, Washington, DC.

DEAR MADAM CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4041, the Export Promotion Reform Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sunita D'Monte.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 4041—Export Promotion Reform Act

H.R. 4041 would require the Secretary of Commerce to assess overseas markets, at least once every five years, to determine which markets present the greatest opportunities to increase United States exports. The Secretary would be required to relocate personnel that promote U.S. trade opportunities based on the outcome of the assessment. The bill also would require Chiefs of Missions in foreign countries to use those assessments in promoting United States exports.

Based on information from the Department of State and the International Trade Administration, the agencies that would administer the bill's provisions, CBO estimates that implementing H.R. 4041 would have discretionary costs of less than $500,000 a year, totaling about $1 million over the 2012–2017 period, assuming the availability of appropriated funds.

Enacting H.R. 4041 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 4041 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

On January 17, 2012, CBO transmitted a cost estimate for H.R. 2987, the American Export Promotion and Job Creation Act, as introduced on September 21, 2011. The language in that bill is similar to that in H.R. 4041 and the estimated costs for the two bills are identical.

The CBO staff contact for this estimate is Sunita D'Monte. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA,
Washington, DC., April 18, 2012.

Hon. HOWARD BERMAN,
House of Representatives,
Washington, DC.
Hon. DONALD MANZULLO,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVES BERMAN AND MANZULLO: The U.S. Chamber of Commerce, the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector, and region, supports H.R. 4041, the ''Export Promotion Reform Act,'' which would boost exports of goods and services by improving the coordination of U.S. export promotion programs.

International trade plays a central role in creating American jobs and boosting economic growth at home. More than 38 million American jobs already depend on trade, and more than 97% of the 275,000 U.S. companies that export are small and medium-sized enterprises (SMEs). However, this figure represents just one of every 100 U.S. SMEs, underscoring how difficult it is for smaller firms to enter export markets. At virtually no cost, this bill would ensure that the federal government's limited export promotion resources are used efficiently to offer these smaller companies the help they need to break into the international marketplace.

The Government Accountability Office (GAO) has determined that the 17 federal agencies with export promotion programs could be made more effective through better coordination, elimination of duplicative activities, and better allocation of resources. In particular, GAO found that strengthening the interagency Trade Promotion Coordinating Committee would improve the effectiveness of U.S. export promotion programs. GAO also found that effective export promotion programs can provide significant benefits to SMEs in the competitive global economy.

H.R. 4041 would put many of the GAO recommendations into effect. It would require the Secretary of Commerce to assess overseas markets at least once every five years to determine which markets present the greatest opportunities for U.S. exporters. The bill also would require U.S. ambassadors abroad to use those assessments as U.S. embassies promote U.S. exports of goods and services.

The Chamber supports H.R. 4041, which would help more U.S. companies tap export markets and create American jobs, and applauds you for your leadership on this important issue. The Chamber looks forward to working with you on this important legislation.

Sincerely,

R. BRUCE JOSTEN.

NATIONAL ASSOCIATION OF
MANUFACTURERS,
Washington, DC., April 10, 2012.

Hon. HOWARD BERMAN,
House of Representatives, Washington, DC.
Hon. DONALD MANZULLO
House of Representatives, Washington, DC.

DEAR REPRESENTATIVES BERMAN AND MANZULLO: The National Association of Manufacturers (NAM) very much appreciates the opportunity to support legislation that will streamline U.S. export promotion activities. We believe that The Export Promotion Reform Act (H.R. 4041) will help increase the export of domestically made goods.

The NAM is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. The ability of U.S. companies to export has always been a critical issue for the NAM, and exports are increasingly important to the U.S. economy and to the success of American manufacturing.

Foreign markets, particularly in emerging economies, are growing faster than the mature U.S. domestic market. That means in order to obtain the jobs growth we all want, manufacturers need to turn increasingly to export markets. Unfortunately, the United States is falling behind. We are still the world's largest manufacturer, but we lack the export orientation of our major competitors and have been losing share in world markets. In fact, the United States exports less than half as much of its manufacturing output as the global average. And in comparing the United States with the 15 major manufacturing economies, we rank 13th in the proportion of our manufacturing output that is exported.

Increasing U.S. exports contributes directly to jobs for American workers. Global trade flows are recovering, and there are increasing opportunities for sales overseas. However, the more than 90 percent of exporters that are small or medium-sized firms need more effective export promotion assistance in order to compete with the support that foreign firms received from their governments. H.R. 4041 can help here.

According to the GAO, 17 federal agencies have export promotion programs. With improved coordination, these agencies can eliminate duplicative activities and utilize their resources more efficiently. The NAM believes that strengthening the interagency Trade Promotion Coordinating Committee (TPCC), led by the Secretary of Commerce, will improve federal export promotion programs and help the global competitiveness of manufacturers in the United States.

H.R. 4041 will strengthen the TPCC by requiring it to assess current export promotion programs, outline necessary improvement, and coordinate the implementation of export promotion activities by other agencies. The Export Promotion Reform Act will also improve export promotion and provide much-needed practical help to manufacturers and manufacturing workers by providing for the redeployment of U.S. Commercial Service resources. This will help exporters find more customers and better understand foreign Customs rules and regulations.

The NAM hopes to see The Export Promotion Reform Act move quickly toward becoming law, and want to express our strong support for its passage as we all work toward the goal of doubling U.S. exports.

Sincerely,

FRANK VARGO.

BUSINESS ROUNDTABLE,
Washington, DC, April 17, 2012.

Hon. HOWARD BERMAN,
House of Representatives, Rayburn House Office Building, Washington, DC.

Hon. DONALD MANZULLO,
House of Representatives, Rayburn House Office Building, Washington, DC.

DEAR REPRESENTATIVES BERMAN AND MANZULLO: Business Roundtable supports your bipartisan legislation, H.R. 4041—the Export Promotion Reform Act, which will help expand U.S. exports and thereby support U.S. economic growth and jobs.

In its recent report, Taking Action for America: A CEO Plan for Jobs and Economic Growth, Business Roundtable put forward a comprehensive plan to revitalize U.S. economic growth and job creation. The plan recognizes that expanding international trade and investment is one of several critical areas for action. The facts demonstrate clearly that international trade is an important engine for U.S. economic growth and job creation:

Over the last two decades, 24 million new trade-related jobs for American workers were created.

In 2008, more than 38 million jobs in America—more than one in five—depended on international trade—exports and imports.

In 2009, more than 275,000 U.S. companies exported merchandise to customers abroad.

Exports support higher-paying jobs. Positions in the manufacturing sector linked to the export of goods pay on average 18 percent more than other jobs.

H.R. 4041 will put in place policies and reforms needed to make U.S. export promotion programs more efficient and effective and help U.S. exporters compete for sales around the world against our foreign competitors. I understand that H.R. 4041 will accomplish these important objectives at existing funding levels.

If given the tools, American companies and exporters can increase their share of world trade. H.R. 4041 will give them more of the tools they need to expand U.S. exports.

Sincerely,

JOHN ENGLER.

COALITION FOR EMPLOYMENT THROUGH EXPORTS, INC.,
Washington, DC, April 2, 2012.

Hon. JOHN A. BOEHNER,
Speaker of the House of Representatives, Office of the Speaker, Capitol Building, Washington, DC.

DEAR SPEAKER BOEHNER: On behalf of its members, the Coalition for Employment through Exports (CEE) writes in support of H.R. 4041, The Export Promotion Reform Act. CEE is comprised of the largest exporters and manufacturers in the country and thus understands the importance of exports to the creation of American jobs and improving the economy. However, with countries all over the world focused on exporting their way out of the economic downturn, it is essential that U.S. companies—large and small—have the necessary tools and support to compete in the global marketplace. H.R. 4041 helps sharpen the focus of U.S. export promotion efforts with special emphasis on small and medium size firms; CEE hopes the House will take up action on this Bill over the next few weeks.

We are especially pleased with the provisions focused on finding export opportunities, granting the Trade Promotion Coordinating Committee (TPCC) more authority, and seeking the advice of SME exporters. The last item is especially critical as it recognizes the unique needs small businesses have when exporting. It is very difficult for small companies to locate customers, verify the stability of the foreign company and line up financing; this bill will enable export promotion efforts to better target the needs of these exporters. If enacted, CEE believes H.R. 4041 would help mitigate the complications faced by the job-creating American small business.

CEE urges the Congress to act quickly on this critical bill.

Sincerely,

JOHN HARDY, Jr.

NATIONAL FOREIGN TRADE COUNCIL, INC.,
Washington, DC, March 19, 2012.

Hon. JOHN A. BOEHNER,
Speaker of the House of Representatives, Office of the Speaker, Capitol Building, Washington, DC.

DEAR MR. SPEAKER: The National Foreign Trade Council, a business organization advocating for an open, rule-based global trading system and representing over 250 member companies, would like to express our support for H.R. 4041, The Export Promotion Reform Act. We hope this bill will be considered on the House floor soon.

We believe that the Export Promotion Reform Act would increase the exports of American goods and services, thereby creating more American jobs and spurring more economic growth. It is estimated that one in three manufacturing jobs depends on exports, and, according to the Department of Agriculture, one in three acres on U.S. farmland is planted for consumers abroad. If America is to continue reaching consumers all across the globe, we must actively pursue legislation that promotes American exports.

The Export Promotion Reform Act amends the Export Enhancement Act of 1988 requiring the Commerce department to assess global markets to identify opportunities for increases in U.S exports. Such actions are critical to addressing America's growing trade deficit. Between 2003 and 2009, the U.S. fell from first to third place behind China and Germany in dollar value of exports. Addressing the prospect of new and untapped markets is crucial if American firms are to increase sales and to continue the trend of job growth.

Additionally, by enhancing interagency coordination through strengthening the Trade Promotion Coordinating Committee and by setting directives for ambassadors to develop country-by-country commercial diplomacy, the bill provides a clear and cohesive plan for government agencies to communicate with businesses on U.S. trade promotion.

Finally, the bill addresses the fact that more than 97% of U.S. export companies are small and medium-sized enterprises (SME's) and account for nearly a third of U.S. merchandise exports. By directing the Commerce Department to seek recommendations for U.S. exporters, specifically SMEs, the bill upholds a standard that all companies should have an opportunity to access new markets.

The NFTC urges your full support of H.R. 4041, the Export Promotion Reform Act.

Sincerely,

WILLIAM A. REINSCH,
President.

Mr. MANZULLO. Mr. Speaker, I yield back the balance of my time.

Mr. MCDERMOTT. Mr. Speaker, I rise in support of the Berman/Manzullo bill to reform how we promote exports. This is a great down payment on a whole host of reforms we can make to how the government works with U.S. businesses to create jobs by exporting our goods and services.

We have enormous business opportunities in overseas markets, and we have overwhelming data and analysis that shows that other countries have been doing a better job at promoting their exports and that we can easily do much better.

Today's bill will focus our export promotions activities and reduce obstacles to exporting without spending any more money.

As you may know, Mr. REICHERT and I also have a bill with a couple of additional export promotion provisions that also have no cost and are uncontroversial.

Because of a quirk in the tax code we are getting inaccurate data on services exports that could be up to one-third wrong. We need to fix it. We also need to have a better annual report and plan from the TPCC on how the government's overall export work is matching up with the needs of U.S. businesses.

I'd ask the members for their support in continuing to push on this bill, to get it through the Senate, and on other measures too, like what Mr. REICHERT and I have put together—costless improvements we can make to improve exports and create jobs.

Ms. RICHARDSON. Mr. Speaker, I rise in support of H.R. 4041, the Export Promotion Reform Act, which will revise the duties of the Trade Promotion Coordinating Committee (TPCC) to improve the research conducted for export promotion efforts. If enacted, this bill will increase the effectiveness of the steps that are taken by the TPCC to boost international trade. I support the bill because expanding America's share of the export market is critical if we are to compete and win in the global economy of the 21st century and provide jobs that will sustain a middle-class standard of living for our people.

Mr. Speaker, this bill will require the government to take into account the recommendations of small- and medium-sized businesses when developing federal trade promotion efforts. This requirement will enable policymakers to better understand the environment in which they are attempting to promote trade.

A more focused understanding of the current economic environment can help the government create more effective export expansion initiatives. By creating targeted initiatives, the Federal Government can help the U.S. economy by expanding economic opportunity for local business to increase foreign sales, thereby creating more good-paying jobs, and economic growth.

This bill also requires the Secretary of Commerce to conduct global assessments of overseas markets to determine which markets have the greatest export potential, and deploy resources accordingly. This will assist U.S. businesses in identifying profitable market opportunities abroad, making it easier for them to begin exporting goods and services. Additionally, the deployed personnel and other resources will help to limit barriers to entry of foreign markets by U.S. businesses.

I support this bill also because of the strong positive impact that an increase in exports will have on the constituents of the 37th Congressional District of California, which I am privileged to represent. The Ports of Los Angeles and Long Beach are major economic engines in the Southern California economy, currently providing nearly $14.5 billion a year in trade-related wages, and more than $47 billion in direct and indirect business sales.

An increase in international exports will boost these figures and create jobs. Additionally, an increase in exports will, provide more opportunities for local businesses to thrive by expanding into foreign markets.

For these reasons, I urge my colleagues to join me in support of H.R. 4041.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Illinois (Mr. MANZULLO) that the House suspend the rules and pass the bill, H.R. 4041, 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.

JEWISH AMERICAN HERITAGE MONTH

The SPEAKER pro tempore. Under the Speaker's announced policy of January 5, 2011, the gentlewoman from Florida (Ms. WASSERMAN SCHULTZ) is recognized for 60 minutes as the designee of the minority leader.

GENERAL LEAVE

Ms. WASSERMAN SCHULTZ. I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks on the topic of this Special Order.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Florida?

There was no objection.

Ms. WASSERMAN SCHULTZ. Mr. Speaker, I rise today to honor May as Jewish American Heritage Month. I'm so pleased to be joined by my colleagues tonight as we honor our Nation's Jewish community through Jewish American Heritage Month.

□ 1950

As the first Jewish woman to represent the State of Florida in the United States Congress, I am so proud to be a strong voice on many issues crucial to our community, from tolerance and understanding to tikkun olam—repairing the world.

In 2005, members of the Jewish community in south Florida approached me with the idea to designate a month to honor the contributions that American Jews have made to our Nation. As a result, I was the proud sponsor of Jewish American Heritage Month, which the House and Senate unanimously passed in 2006 and has been proclaimed by both President Bush and President Obama annually since then.

This year, in 2012, is the Seventh Annual Jewish American Heritage Month. JAHM promotes awareness of the contributions American Jews have made to the fabric of American life from technology and literature to entertainment, politics, and medicine.

As we are all well aware, the foundation of our country is built upon the strengths of our unique cultures and backgrounds. The American Jewish experience is the story of the immigrant, the labor movement, the battle for civil rights, and so much more. Jews in America have blazed trails from the battlefield to the Supreme Court, from the sports field and symphony hall to the pages of our Nation's history books and our Nation's Capital.

From the time of the Colonies until today, Jewish communities have played a significant role in American history and telling the American story. That's why communities across the country have come together to celebrate Jewish American Heritage Month during the month of May.

Seven years ago, this idea gained momentum as 250 of my colleagues joined me as original cosponsors of a resolution urging the President to issue a proclamation for this important month. Senator Arlen Specter led the effort in the Senate, and together the House and Senate unanimously passed resolutions supporting the creation of Jewish American Heritage Month.

Now, each year, the month of May introduces Jewish culture to the entire country in order to raise awareness and dispel harmful prejudices. Unfortunately, Mr. Speaker, we have seen a precipitous rise in intolerance and anti-Semitism, not just in this country but across the globe. It is my hope that by providing the framework for the discussion of Jewish culture and contributions to our Nation we will be able to reduce the ignorance that ultimately leads to anti-Semitism.

Over the last number of years, I have talked about the impact and the contributions of the Jewish community to our country over more than 350 years of Jewish life in America. It has always struck me that Jews in America are less than 2 percent of the American population, and so as much, many of our colleagues—most Americans—never actually spend much time around the Jewish community. So our traditions are unfamiliar, our culture and our religion—of which we are both—are not something that most folks encounter every day. That is the reason that we honor communities like the Jewish community with a cultural awareness month so that we can raise that awareness and make sure that people who don't usually have an opportunity to get the kinds of information that these months provide can really reach out to one another and learn more so that we can be the melting pot and also the salad bowl that is always debated about the United States of America.

Over the last 7 years, we have seen JAHM grow from an inspired idea to a national reality. We've had a group of committed organizations and museums around the country that have worked to get JAHM into the classroom, on the airwaves, and into the halls of our government, as today's activities demonstrate.

Just before votes this evening, President Obama hosted the Third Annual Jewish American Heritage Month reception at the White House, welcoming leaders from the Jewish community into the Nation's House.

The President told the story—not a really wonderful note in our Nation's history—of General Ulysses Grant who, at the time of the Civil War, had actually issued an order, Mr. Speaker, to expel Jews from their homes in the war zone during the Civil War. President Obama went on to also talk about how President Lincoln issued an order rescinding that order. The Library of Congress brought out from its archives all of the documents related to General Grant's order and President Lincoln's order to make sure that we could protect the rights of individuals and make sure that our commitment as a Nation to religious tolerance and freedom was preserved from then through history.

Tonight, I'm so pleased to be joined by my colleagues to commemorate the American Jewish experience. From sports games, to concerts, to lectures and films, JAHM is truly an interdisciplinary and multimedia experience, and we want to see these efforts continue to grow. However, it's vital that this idea takes hold not only for Jewish organizations, because, after all, we're already familiar with the contributions of Jewish life in America. We want to make sure that this month is an opportunity to grow that knowledge and reach out to communities across the country.

It's our responsibility to continue this education. If we as a Nation are to prepare our children for the challenges that lie ahead, then teaching diversity and celebrating it is a fundamental part of that promise. Together, we can help achieve this goal of understanding with the celebration of Jewish American Heritage Month.

The lessons of Judaism inspire us to do great things, from our commitment to service, to our political advocacy, to our cultural contributions to this Nation. Together, we can and should celebrate our community's history and values so that not only the Jewish people, but all Americans may go from strength to strength.

Now I'm delighted to recognize one of my colleagues who has been an incredible leader for the United States of America, for the people of her district in New York, and someone that I am proud to say has been a mentor throughout my time here in the U.S. House of Representatives, Congresswoman NITA LOWEY from the great State of New York. By the way, let me add, Mr. Speaker, that Congresswoman LOWEY is the ranking member on the Foreign Operations Subcommittee of the Appropriations Committee.

Mrs. LOWEY. Let me thank my outstanding colleague from the State of Florida, Congresswoman WASSERMAN SCHULTZ. I personally want to express my appreciation for the work you have done to make this day a reality so that we can all acknowledge Jewish American Heritage Month. It's because of you that this day is noted, and it's because of you that we have gathered at the White House for a really inspirational speech from President Obama. So as a Jewish American, I want to express my appreciation to you.

I know that it may not be coincidental that this was a special time in

your life this past week. I think it's appropriate that we talk about your family and your personal commitment to your Jewish heritage. During this month—last week, I believe—your daughter celebrated her bat mitzvah or bene mitzvah. This is such an amazing, amazing time in your life when your daughter or your son reaches that point where they have studied, they have learned what it is to be a Jewish American here in the United States of America. I am sure that your family was just overflowing with joy. And I just want to say mazel tov to you. That means good luck and congratulations.

So today I not only rise, Mr. Speaker, to express my appreciation to Congresswoman DEBBIE WASSERMAN SCHULTZ for making this Jewish American Heritage Month an annual tradition, but to express my appreciation to you for organizing this event tonight.

I rise to mark the contributions of Jewish Americans to the rich culture and history of our Nation during this Jewish American Heritage Month.

Jewish tradition embraces the concept of Tikkun Olam, repairing the world. Indeed, our actions in Congress are aimed at that concept—helping to improve our society and create equity for all Americans through quality health care, education, and economic opportunity, regardless of their ethnic, cultural, or socioeconomic background. What I am very proud of is that our commitment to justice reaches beyond our borders.

□ 2000

The history of the Jewish people reminds us of our unique responsibility in the international community to stand up for what is right, speak out against hatred and injustice, and ensure that the lessons of the Holocaust are not lost to history. We have a responsibility, and we must defend those unjustly persecuted, no matter where they are, and we must stand by our ally, Israel, in the face of continued threats.

I hope you will join me in celebrating the rich history of Jewish Americans and in looking forward to an even more vibrant and just future for all people.

Thank you.

Ms. WASSERMAN SCHULTZ. Thank you so much, Congresswoman LOWEY. Thank you for your leadership and your commitment as a Jewish American woman, and for blazing a trail. And thank you for acknowledging my daughter and son's bar and bat mitzvah.

Mrs. LOWEY. Oh, it's the twins?

Ms. WASSERMAN SCHULTZ. It was the twins, yes, both of them, and it was a pretty incredible weekend. It was really amazing to, coincidentally, have the B'nai Mitzvah service and ceremony during Jewish American Heritage Month. Their birthday is May 15, and we had a wonderful celebration last weekend.

Thank you so much. And thank you for being an incredible example. As a Jewish mother who is raising Jewish daughters, thank you for being an incredible example for them.

Mrs. LOWEY. Well, as a Jewish mother and a Jewish grandmother, I am very proud of my three children and my 8 grandchildren. And I just want to say, again, that you are really a role model for all women, not just Jewish women, a strong woman with integrity, who is committed to her Judaism, her family, and yet you understand so well that we have an obligation beyond ourselves, as we lift people up and hope that all people, in the United States of America and around the world, have the opportunity to raise children and have a good life, and can have a future.

So I want to thank you because you are a role model that just does it all. In fact, it's amazing to me that you've done it all. So congratulations. Thank you again for marking this important month for all of us.

Ms. WASSERMAN SCHULTZ. Thank you for joining us. Thank you so much.

It is now my privilege—boy, it's hard to say enough good things about an incredible woman, a fighter, someone who has been a champion for the values that I know I was raised to believe in around my family dinner table growing up, the epitome of Tikkun olam.

Mr. Speaker, let me—we're going to use some Yiddish phrases here and Hebrew expressions tonight that some may not understand. But the foundation of the Jewish community, and our commitments to service and our commitment to fighting injustice, is based in the notion of Tikkun olam, which means repairing the world. And so often, we have mountains in front of us that seem so tough to climb, and repairing the world can seem like an insurmountable obstacle. But working together to address a little bit of injustice, just a small bite at a time, but banding together to do it, is something that the Jewish community has stood for for many years.

And there is no finer example of someone—I have to tell you that JAN SCHAKOWSKY, as a representative from Illinois, and as someone who had a reputation that I became aware of long before I actually had the privilege of serving in this institution, was someone I wanted to be like when I grew up because she has been the absolute epitome of what I know I was taught to believe in around my family table, which was that we should stand up for people who have no voice, fight for the civil rights and civil liberties that are instilled as Jewish values. And I'm so thrilled that you joined us here tonight, Congresswoman JAN SCHAKOWSKY from the great State of Illinois.

Ms. SCHAKOWSKY. Thank you so much, DEBBIE WASSERMAN SCHULTZ, for your leadership role in making Jewish American Heritage Month a reality. Really, this was your idea, and you mobilized the Members of the House in a bipartisan way to make this happen, and we're so appreciative.

I think Jews and non-Jews alike realize that it's important that we honor the culture and the heritage of the Jewish community. Throughout American history, Jewish Americans have helped shape American culture and society. For over 350 years, Jewish Americans have made untold contributions to our country, through science, art, medicine, education, sports, technology, entertainment, and government. Jewish Americans have served in the military and in government, have helped build and grow our economy, and have served their communities as teachers, nurses, organizers, and in countless other critical roles.

American Jews played a critical role in creating and sustaining a homeland for all Jews around the world—the State of Israel, our beloved State of Israel, first, as a refuge for those who survived the Holocaust, continuing to be a place where all Jews are welcome, and today, an enduring and essential ally of the United States of America.

As a first-generation Jewish American, I have personally witnessed the struggles and successes of Jewish immigrants who came to this Nation in order to create a better life for themselves, their families, and future generations, the reasons that all immigrants seek out the United States. Like other important immigrant communities, the Jewish experience in the United States represents the promise, the opportunity, and the freedom of America.

I think today about my grandparents, Sam and Mary Cosnow, who settled in Chicago with three of their four children. The fourth was born in the United States. My mother was not. They came from Russia. They left a place that they knew they would never return to, left a place where there were pogroms, where it was dangerous for the Jews, and came to Chicago, Illinois.

And every Sunday we would go to my grandparents House in Humboldt Park, and I would rush out to what is now the garage, but then was the barn, where Teddy, the horse, was there. And I would say hello first to Teddy, I think, even before my grandparents.

Teddy would pull the cart that my grandfather, a peddler, would—every weekday he would get up at the crack of dawn and take Teddy and the wagon to the vegetable and fruit market several miles away and load up the cart and carry bags of potatoes up several flights of stairs in the alleys of Humboldt Park to his customers.

My grandmother stayed home. She made the clothes for her children and was a homemaker. And they put all of their children through college. That was the American Dream.

My grandfather, as a peddler—now, college tuition wasn't what it is today and it was easier to do that, but two teachers, one lawyer, one business college student, all of those children of Sam Cosnow, the peddler, could make it in America. That is the American

Dream. It's the immigrant dream. It's the dream of hardworking people who believed that if you are willing to get up at the crack of dawn and carry potatoes up the back porch that you could do it here. That's the America we dream for everyone and for our children and their children; that they can have a good life if they are willing to work hard.

An estimated 250,000 Jews live in Chigago today. Chicago's vibrant Jewish community has been home to countless prominent figures, from sports to the arts to politics. Saul Alinksy, the father of community organizing, came from a Russian Jewish immigrant family. Nobel Prize-winning author Saul Bellow grew up in Chicago, a Jewish—from Humboldt Park, as my grandparents and my parents lived. And his work strongly reflects both his Jewish roots and the city of Chicago.

Actors Jeremy Piven and Mandy Patinkin were both raised in Jewish households in Chicago. And Benny Goodman, the clarinetist known as the ''King of Swing,'' called Chicago home.

□ 2010

Sidney Yates, my predecessor, served in the House for nearly 50 years, passionately working for environmental protection and government funding for the arts. Also, two current members of the Chicago Bears NFL team, Gabe Carimi and Adam Podlesh, are Jewish Americans.

So, Mr. Speaker, Jewish American Heritage Month is an opportunity to recognize the contributions of Jewish Americans to our community, to our country, to our culture. For 350 years, Jewish Americans have made extraordinary contributions to American life and culture; and in Chicago and throughout the country, American Jews continue to be leaders in their communities.

All of those Jews in America today owe a thank-you to Congresswoman WASSERMAN SCHULTZ for creating the Jewish American Heritage Month of May, so I thank you.

Ms. WASSERMAN SCHULTZ. Thank you, Congresswoman.

Let me also thank you for your leadership as a ranking member of the Subcommittee on Commerce, Manufacturing and Trade for the Energy and Commerce Committee; and your leadership in the area of health care has been incredibly important for America.

I think it's interesting. First of all, you taught me something that I didn't know tonight. I did not know that there are two Jewish players on the Chicago Bears. One of your staffers was joking with my staffer today, saying that there are actually more Jews on the Chicago Bears than there are in the Illinois delegation, which is really kind of ironic, actually. Thank you so much for being here.

Now it is my privilege to introduce and acknowledge a friend and colleague from the neighboring district of mine, someone who is a relatively new Member, who had some big shoes to fill but who has done so capably. He serves as a member of the House Committee on the Judiciary and on the House Committee on Foreign Affairs, and he was a State senator in the State of Florida. I am fortunate that I don't need his bio as a cheat sheet because I know him so well. He is our colleague from the great State of Florida, Congressman TED DEUTCH.

Mr. DEUTCH. Thank you very much to my dear friend Congresswoman WASSERMAN SCHULTZ, and thank you for your committed work in making sure that not only this Special Order hour takes place tonight but for your work in ensuring that Jewish American Heritage Month has become a reality. You are to be commended for that, and I think we are all the better for it. I appreciate it, and I appreciate the opportunity to be here tonight.

Mr. Speaker, I rise to celebrate the seventh annual Jewish American Heritage Month, which is an opportunity for our Nation to recognize the many contributions of Jewish Americans throughout our history. America's Jewish community has helped shape our country since its inception. Jewish Americans have courageously served in our Armed Forces in every major conflict of our Nation's history. They've also helped drive America as a powerhouse of economic innovation, contributing key advances in everything from science and medicine to the law and the arts.

Today, as we mark this year's Jewish American Heritage Month here in Congress, I would like to highlight our community's tremendous contributions to American social policy. Jewish Americans have a long history of shaping our political priorities as a Nation. I am proud to be part of a community that has led efforts to protect the most vulnerable, to ensure fairness in our justice system, to promote economic opportunity, and to safeguard the religious freedoms and liberties of all Americans.

We need look no further than Social Security, a program that helps keep 50 million Americans economically secure each year. Serving on the committee that helped establish Social Security was Wilbur Cohen, a man who was eventually appointed by President Kennedy as an Assistant Secretary for Legislation of Health, Education, and Welfare. As a member of President Johnson's Cabinet, Wilbur Cohen's influence over issues that impact America's seniors continue to grow, and many today regard him as the man who built Medicare.

Jewish Americans also took an active role in our Nation's struggle for civil rights. In the 1950s and 1960s, Jewish Americans were passionately engaged in the struggle for civil rights:

Rabbi Stephen Wise, the great American Jewish leader, was one of the founders of the NAACP. He made the case that civil rights were not only a Jewish issue but that civil rights were a quintessential Jewish issue. He understood and believed firmly that the Jewish community and that the Nation—America—were stronger when prejudice was defeated and when equal rights were extended to all;

Rabbi Abraham Joshua Heschel marched with Martin Luther King, Jr., in Selma. In reflecting upon that march, Rabbi Heschel said, When I marched in Selma, my legs were praying. It was his understanding, his commitment, to what he viewed as essentially the holy work of lifting up all Americans and of ensuring equal rights for all;

Several prominent Jewish activists, including Michael Schwerner and Andrew Goodman lost their lives, along with African American activist James Chaney, while fighting for the right to vote alongside organizers in the South;

And perhaps there is no greater indication of Jewish Americans' involvement in the struggle for civil rights than the fact that both the Civil Rights Act of 1964 and the Voting Rights Act of 1965—two landmark pieces of civil rights legislation—were both drafted as legislation at the Religious Action Center of Reform Judaism.

As a Jewish American, I am honored to be part of a community that throughout our Nation's history has helped make America a more fair and a more just Nation—a Nation where opportunity extends to all, where everyone can be lifted up by being given the chance to succeed. It is a commitment to ensuring that seniors live lives of dignity and where the poor receive the support that they need when times are most difficult. Finally, it is the respect for every American—the dignity of every American—that is recognized and fought for still to this day by so many in the Jewish community.

I am so grateful to my friend Congresswoman WASSERMAN SCHULTZ for helping to ensure that we have the opportunity to share these thoughts here on the floor of the U.S. House of Representatives this evening. I am grateful for that opportunity. I thank you for it.

Ms. WASSERMAN SCHULTZ. Thank you so much for your commitment and for your leadership. It is really a privilege to fight side by side with you on behalf of our constituents in south Florida and on behalf of the values that matter so deeply to our community.

For many years, actually, before you were elected to public office, I watched your commitment to the U.S.-Israel relationship and to a strong and vibrant Jewish State of Israel as an AIPAC activist and then as a State senator, now as a Member of Congress and as a colleague. I thank you so much for joining us here this evening.

It is now my privilege to recognize a newer colleague and a newer friend but someone whom I have seen develop as a leader and someone who has stepped up to represent her constituents in the

western part of our country, which I'm sure is a completely different Jewish experience than the east coast experience. Congresswoman SUZANNE BONAMICI is a new Member who was elected in a special election not even a year ago—actually, just a few short months ago. She has stepped up and represents the Portland area in Oregon. More importantly, she is a member of Congregation Beth Israel, and I am pleased to recognize her here tonight.

Ms. BONAMICI. Thank you so much for yielding me this time, Congresswoman WASSERMAN SCHULTZ, and for your leadership in Jewish American Heritage Month. It is great to join you and our other colleagues here this evening.

Mr. Speaker, I would like to recognize the contributions that so many Jewish Americans have made to our communities, to our States, to our country. There are many Jewish Americans who could be recognized here this evening and who deserve to be recognized for their contributions here this evening in honor of Jewish American Heritage Month.

I rise to pay tribute to a great Jewish American, an Oregonian, Mr. Harold Schnitzer. Born in 1923, Harold Schnitzer was the fifth of seven children of Russian immigrants.

□ 2020

He was born to Rose and Sam Schnitzer, who took a junk business and turned it into a steel empire.

As a boy, Harold earned 25 cents a week for polishing metal at his father's scrap yard. He told his teachers at Lincoln High School in Portland that his future was in steel. By the age of 16, he came back here to the East and he was studying at the Massachusetts Institute of Technology, from which he graduated in 1944. He served in World War II. He dealt scrap metal during his time in the Army, and he was expected to take over the family business, but something happened. He didn't want to compete with his brothers. So he left to start his own real estate company, Harsch Investment Properties.

Throughout his life, Harold, along with his wife Arlene Schnitzer, generously supported education, health care, and cultural and Jewish institutions and organizations not only in Portland, but throughout the State of Oregon. Harold Schnitzer lost his life last year in 2011 at the age of 87. There is no question that he embodied tikkun olam. He made the world a better place.

I want to thank you for this opportunity, Congresswoman WASSERMAN SCHULTZ, to pay tribute to a great Jewish American, but also to say thank you again for making Jewish American Heritage Month a reality so that others can learn about the contributions of Jewish Americans around this great country.

Thank you again for this opportunity.

Ms. WASSERMAN SCHULTZ. Thank you so much, and thank you for your service on the House committee on the Budget. We serve on that committee together, and you have represented your constituents well. I appreciate you honoring the contributions of Jewish Americans across this country here tonight.

Now it is my privilege to bring to the rostrum—for lack of a better term—a friend and colleague who represents the southern region of California in San Diego, who has been an incredible leader on the Armed Services Committee, and who has definitely in her own right been a Jewish leader and as a Jewish woman someone who has taken a leadership role in the area of armed services, not only not traditional for women, but one that we have a story to tell about Jewish involvement throughout our American military history. And I'm going to share a little bit about that later, but thank you so much.

Congresswoman SUSAN DAVIS.

Mrs. DAVIS of California. Thank you.

And I want to thank my colleague DEBBIE WASSERMAN SCHULTZ for having us together to talk about Jewish American Heritage Month this evening. It's important for us to do that.

Whenever we think of perfecting our union—the President spoke about this a little bit today as he hosted a number of individuals in the Jewish community and people from around the country. The thing that I always think about is tikkun olam, because it is part of our tradition to repair the world.

Many Jewish people came to the United States having left a community in which they weren't able to make contributions, and I think that's partly why in bringing some talents and some skills—and, yes, in many cases they weren't skills that were honed very well when they first came to this country, but they developed those. And in developing those skills and making a contribution and becoming treasures for each of their communities, they clearly made a great deal of effort to repair the world. They continue to do that in so many ways.

There is another tradition that we have. It's called tzedakah. It's about caring for others. It's about giving to others. It's about engaging people in that effort. It's about going down to soup kitchens from time to time. It's about bringing homeless people into your synagogue or into your temple during the winter. It's about engaging all the time because we know that that's important to do. That caring of tzedakah goes back to so many of the traditions that we all share. It's about the golden rule. It's about taking care of one another. It's about treating people the way that we want to be treated. That's very much a part of our heritage.

I'm going to share a little story today, and it's a story that I think my colleague is going to be laughing a little bit about because it's not something that I would ordinarily do. But I had a chance to read a little bit about a very special Jewish woman. Her name was Thelma Tiby Eisen, and she was born in 1922 and lives today. I tell this story because she was very famous as a professional athlete in America. Probably people who don't know about Jewish women in athletics or in baseball wouldn't know of her, but those who do would know that name.

I bring that up because my colleague brought me into the first and only bipartisan women's softball team here in the Capitol. I have to share my story because I never played team sports in my life. In fact, I probably picked up a baseball maybe once to hit somebody, but I really don't remember doing that at all.

So when I was asked by my colleague to join with her in this team, which is supporting young survivors of breast cancer, I thought, Well, that's crazy for me to even do this because I can't make a contribution to this team. But I've done it because I've cared about the cause certainly of young survivors who have breast cancer and largely because there are a number of Jewish women who by virtue of their genes have a propensity to develop breast cancer.

Right around the time that I actually had agreed to be on this team—actually, this even goes back to walking in the 3-day march for breast cancer—I learned that my sister had breast cancer. Fortunately, she has been able to overcome that. But it was something that I knew and I had to take account of in my own life, as well. But I wanted to share this story because I enjoyed reading about Thelma Tiby Eisen. I'm going to share that.

One of the most versatile and talented professional athletes in America was Gertrude Tiby Eisen. She was born in Los Angeles in 1922, and she was a star of the All-American Girls Professional Baseball League, the only professional women's league in baseball history. The women's hardball league lasted from 1943 until 1954, and she was one of at least four Jewish women in that professional league. As its only Jewish superstar and a pioneer in American women's sports, she was an outstanding athlete in her native Los Angeles. She started playing semipro softball at age 14. When the league was formed in 1943, she won a spot on the Milwaukee team, which was moved the next year to Grand Rapids, Michigan. Her best season was in 1946, when she led the league in triples. She stole 128 bases and made the all-star team.

The part of the story that I particularly like was that Eisen's family was very ambivalent about the career choice that this ''nice Jewish girl'' had made, although she ultimately won all of their respect.

''We played a big charity game in Chicago for a Jewish hospital,'' Eisen recalled in an interview with historian David Spaner. ''My name and picture were in every Jewish newspaper. My uncle, who had said, 'You shouldn't be

playing baseball—you'll get a bad reputation, a bad name,' was in the stands bursting with pride that I was there.''

When she retired from professional baseball in 1952, she settled in the Pacific Palisades area and became a star for the Orange Lionette Softball Team, leading them to a world championship in 1993. She helped establish the women's exhibit at the Baseball Hall of Fame in Cooperstown, New York, and she wanted to have all this recorded to keep the baseball league in the limelight:

''It gets pushed into the background,'' she said, ''just as women have been pushed into the background forever. If they knew more about our league, perhaps in the future some women will say, 'Hey, maybe we can do it again.' ''

Well, that's probably how all of us feel here in our bipartisan effort in women's softball. We're going to play this game on June 20. We're going to play against all of our women colleagues in the media: TV, radio, and print.

□ 2030

We certainly hope that we're going to bring back a victory here.

If I may, Mr. Speaker, I wanted to just highlight a few people, really my contemporaries in San Diego, who have made such a contribution because they're well known in our community and certainly when we think of Jewish American Heritage Month, we can't help but think of these individuals who today are continuing to make a contribution. Two of them have passed on.

One, of course, is Jonas Salk that we all know very well. The Salk Institute of San Diego continues to educate our scientists for our country and really for the world, globally. I've had an opportunity to meet with a number of young scientists there from time to time, and their enthusiasm and their desire to really cure diseases in our country are just always inspiring, and I think of them often when I think of the Salk Institute.

The other person who I wanted to highlight very briefly is a gentleman named Sol Price. Sol Price was the founder of Price Club, he and his family. Whenever you think of ingenuity, innovation, entrepreneurs, he was great, great at this. He also founded an organization that I had an opportunity to be the executive director of in its early years, the Aaron Price Fellows Program, educating a very, very diverse group of young people to repair the world, to find in civic life as a student and then as they go on as adults, to find a way to really make a contribution to their community. It's a wonderful program and the young people come here to Washington every year.

Finally, to just say, in regard to great contributors in our community and across, across the world today, Dr. Irwin and Joan Jacobs. Dr. Jacobs is the founder of Qualcomm along with Doctor Vitebi in San Diego, who have made such extraordinary, extraordinary contributions and continue to do that every day. It's a real honor to be in a community where their philanthropy is so well known.

Finally, we have a very active group of Jewish war veterans in San Diego, and I just wanted to thank Alan Milefsky, who has been the Veteran of the Year in San Diego and continues to reach out and make a great contribution and remind everybody of his extraordinary story as a Jewish war veteran.

Thank you very much to my colleague for bringing us together today, and it's been my honor to have an opportunity to speak about Jewish American Heritage Month.

Ms. WASSERMAN SCHULTZ. Thank you so much. Thank you, Congresswoman DAVIS. Thank you for your leadership and for sharing the stories of the important contributions that Jews in the San Diego community in America have made through the fabric of American history.

It's now my pleasure and my privilege to ask my colleague from the great State of Connecticut, CHRIS MURPHY, to share some things.

I had—this is a reunion of sorts. A number of years ago, when Mr. MURPHY and I, along with Mr. RYAN of Ohio and our former colleague, Congressman Meek from Florida, we used to spend a little time down here on the House floor, around this time of night or later in the 30-Something Working Group, and you may still actually be eligible to participate. I no longer would be.

Mr. MURPHY of Connecticut. Barely.

Ms. WASSERMAN SCHULTZ. Maybe I would be part of the ''something'' in 30-something.

I did have a chance to meet your fantastic Lieutenant Governor, Nancy Wyman, today at the Jewish American Heritage Month reception at the White House. She is obviously an incredible leader, an example of the political leadership that is part of the contributions that American Jews have made to American life.

Mr. MURPHY.

Mr. MURPHY of Connecticut. Thank you very much, Congresswoman WASSERMAN SCHULTZ. I don't think that we were ever allowed down on the House floor this early. It was normally close to the witching hour when I, Representative RYAN, you, and Representative Meek were down here, but it is wonderful to be back here.

I was really touched when you approached me earlier today to ask me to come and say a few words, because the Murphys are not a very well known Jewish American family. Yet in Connecticut we are so, so proud of the legacy that we have helped contribute to with respect to Jewish American heritage, and this is a great way to be part of this month's celebration.

You know, the list is long in Connecticut. You know, I think about somebody like Annie Fisher, who was one of the pioneers of special education in this country trying to segment out a different way to teach kids with learning disabilities. She was the first female principal, first female superintendent in Hartford, Connecticut.

I think about a young guy by the name of Kid Kaplan, who was from my district, from Meriden, Connecticut, was a featherweight champion of the world, one of the top 10 featherweights by most people's estimates. But I think maybe most about some of the political legacy that Jewish Americans from Connecticut have left this country.

I think a lot about Abraham Ribicoff. Abraham Ribicoff was everything in Connecticut. He was our Governor, he was our Senator, he was our Congressman. He faced, not so quietly, the prejudice that so many Jewish Americans faced as they entered into political life and commercial life throughout the last 100 years.

He talked openly when he first ran for Governor about walking into social halls and hearing prejudiced whispers throughout the room as he walked in. He also talked about taking that prejudice head on. He would walk up to the podium, and he would talk about the fact that he had lived the American Dream as the son of Polish immigrants, as a young guy who grew up working in zipper and buckle factories throughout the Hartford region, that he was living the American Dream, that if he could do it so could everybody else and their kids in that room.

He was probably best known for a moment at the podium of the Democratic National Convention in 1968 when Chicago police were outside treating protesters fairly roughly. He was the one member of the political elite to stand up on that podium and call them out for their tactics, and even with the mayor of that city sitting in the front row calling him some pretty unfriendly names. He kept his cool and is credited with essentially marginalizing that kind of violence, certainly with historical hindsight.

Maybe most important is that Abraham Ribicoff also saw his role as one of the leading American Jewish political figures in this country to help pave the way for others. He had a young intern, not long after he became U.S. Senator, named JOE LIEBERMAN. He hired, in the early 1970s, his administrative assistant, a young hot-shot lawyer named RICHARD BLUMENTHAL.

The two of them, both given their political sea legs by Abraham Ribicoff, are today proudly serving as Connecticut's two United States Senators, both part of our proud political tradition in Connecticut of Jewish American participation in American politics.

I am really thrilled to be down here with you to share my gratitude for what Jewish Americans in Connecticut have meant to our cultural life, to our educational life, to our sporting life and, yes, to our political life. Representative WASSERMAN SCHULTZ,

thank you for your leadership and thank you for allowing me and asking me to come down this evening.

Ms. WASSERMAN SCHULTZ. Thank you so much, Mr. MURPHY, and thank you for your leadership as a member on the Foreign Affairs Committee, as well, and your commitment and support to a strong U.S.-Israel relationship, also an important issue to those of us in the Jewish community and important to Americans, as Israel is our strongest ally and friend.

You are right, and the reason that I wanted you to come down tonight is because growing up as a nice Jewish girl on Long Island, I knew a few folks over your way in Connecticut, being a resident of the tri-State area, and knowing the rich tradition of political activism and involvement of Jewish leaders in Connecticut and your leadership. You know, we will call you an honorary Jew tonight—Murphyberg, or something like that. But thank you so much for your leadership on behalf of your constituents and your State, and thank you for joining me this evening to honor the contributions of American Jews to the fabric and the tapestry of American life.

Mr. Speaker, I am going to wrap up here in a few moments. I want to share a few other things to help tie a ribbon on the second-to-last day of Jewish American Heritage Month. We'll wrap up tomorrow.

□ 2040

I want to share a story of a Floridian, because oftentimes—certainly, recently—Florida would be well-known for our significant, sizable, and accomplished Jewish community, particularly in south Florida, where my district is. I like to say that I'm the person that represents paradise down our way in south Florida. But the paradise that we see today in south Florida was mostly swamp land many, many years ago. And so the pioneers that blazed the trail that allowed for the vibrant communities that we have in our State really were just that—they were pioneers.

I want to share a story of one of those pioneers. For example, Moses Elias Levy, who lived from 1782 to 1854, was one of the earliest and largest developers in the State of Florida. At his Pilgrimage Plantation, which was the first Jewish communitarian settlement in our country, Moses housed several Jewish German families while reintroducing sugarcane to our State. Thanks to his cultivation of the first sugarcane plantation in Alachua County, which also has the good fortune of being the home county to the University of Florida, my alma mater—go, Gators—Florida boasts a thriving sugar production market today, and that can be traced directly to Moses Elias Levy.

As a civil rights activist, though—that's the contribution that I want to highlight—as America's first Jewish abolitionist author, Levy exemplified not only the American entrepreneurial spirit, but the Jewish value that we've been talking about here this evening of tikkun olam—repairing the world.

He was an early and ardent advocate for public education for both boys and girls—and that also was not common back then. Education was typically more often left for boys, and girls were kind of lucky if they had someone in their lives that encouraged them to get an education and to continue it for any length of time.

So I'm proud to remember Moses Elias Levy's early contributions and dedication to education and gender equality. Interestingly enough, Levy County today is named after this gentleman, as well as David Yulee Levy, who was our first United States Senator in the State of Florida, and who was also an American Jew.

The other thing I want to mention, Mr. Speaker, is it is also not often that Americans are aware of Jewish contributions to our military history. And there is a way that people can get educated about American Jewish contributions to the military history throughout our history of involvement militarily by going and visiting the National Museum of American Jewish Military History, which is in our Nation's Capitol on Dupont Circle. I had an opportunity to host a Jewish American Heritage Month event month there a few years ago, and was really thrilled to learn about the contributions all the way back, Mr. Speaker, to the Revolutionary War.

Jews were not only a part of fighting the Revolutionary War and fighting for freedom in the United States, but also financing and making sure—Haym Solomon was an important figure in ensuring that the Minutemen had the resources under George Washington's leadership to ultimately be able to make sure that we have a country and that we are the beacon of freedom across the world that we are today. That was in no small measures thanks to the contributions of Jews who were pioneers here in America.

Lastly, Mr. Speaker, I want to share some of the really unique and wonderful events that have happened throughout Jewish American Heritage Month, and that we will continue to foster and thrive in and encourage both Jews and non-Jews to celebrate these rich traditions.

Earlier this month, right at the beginning, on May 2, there was a focus and program on ''Religion and Politics: When General Grant Expelled the Jews.'' It's so important. And Jewish community leaders and religious leaders talk so often about the importance of not forgetting about previous persecution so that we can make sure that history doesn't repeat it. Having an opportunity at the National Museum of American Jewish History in Philadelphia to hold that lecture so that we are familiar with that history was important.

There was also a program in Miami Beach, ''Coming to America: The Jewish Impact and the Jewish Response.'' We had some unique programming, ''The American Jewish Deli—A History,'' because food is so important to the Jewish way of life all over the world. That was held in New York City at the Park East Synagogue.

Two other important events to highlight were the Jewish American Heritage Month Film Festival, which was held right here in Washington, D.C., in the Martin Luther King, Jr., Memorial Library Auditorium. And lastly, the program held in Margate, New Jersey, by the Board of Jewish Education highlighting the contributions of Jewish women in America.

As a Jewish woman in America, I am really proud to have been a part of introducing this resolution ensuring that ultimately we were able to honor the contributions of American Jews to our history, but also to make sure that we can help all Americans make it a priority that we promote tolerance, that we reduce anti-Semitism, reduce bigotry, and hopefully, Mr. Speaker, reach out to non-Jews across this country and help them learn a little bit more about a culture that they may be unfamiliar with, about a tradition and a history that might be a little bit foreign to them, so that we can all come together as we're so committed to do in America as one people standing for freedom, standing for tolerance, and standing for justice.

I yield back the balance of my time.

CLEARING THE NAMES OF JOHN BROW AND BROOKS GRUBER

The SPEAKER pro tempore (Mr. STIVERS). Under the Speaker's announced policy of January 5, 2011, the gentleman from North Carolina (Mr. JONES) is recognized for 60 minutes as the designee of the majority leader.

Mr. JONES. Mr. Speaker, this is not the first time I've been on the floor of the House to speak about the V–22 Osprey crash that took place in Arizona in 2000—the crash that claimed the lives of 19 Marines. Mr. Speaker, the pilots of the Osprey, Major Brooks Gruber and Lieutenant Colonel John Brow, have been blamed for the accident by the media.

The reason I'm standing here 12 years later is that the Marine Corps has not supported the finding of their own accident investigation for 12 years. The fact is, the official report, known as the JAGMAN report, conducted by the United States Marine Corps, clearly states that the pilots were not at fault.

On page 77 of the JAGMAN it says:

''During this investigation, we found nothing that we would characterize as negligence, deliberate pilot error, or maintenance material failure.''

After 12 years, the JAGMAN, which has not been—nor do we want to try to change that report that I just read, Mr. Speaker, but we're asking the United States Marine Corps to make the change that is necessary because after the crash on April 8 of 2000, the United

States Marine Corps claimed in their own press release:

''The pilots' drive to accomplish the mission appears to be the fatal factor.''

Mr. Speaker, the Osprey, for those that might not be familiar, is the helicopter that goes from the helicopter mode into an airplane mode. At the time of this crash the V–22 was still an experimental plane. What needed to be asked by the Marine Corps was for Bell-Boeing to do more testing—and more testing would have probably meant that they would have understood an issue that's called vortex ring state, or VRS. It is well known in most helicopters, but in the Osprey that has the twin engines they did not know how the vortex ring state would impact one engine or the other engine. And that's what caused this tragic accident in April of 2000. Again, there were 19 marines killed and burned to death.

Mr. Speaker, in this 10-year journey that I have been on to clear the names of the two marine pilots—and the picture on my immediate left is Colonel John Brow. His lovely wife, Trish, and their two children, Matthew and Michael, live in California, Maryland.

□ 2050

The other young marine beside Colonel Brow's photograph is the copilot whose name is Major Brooks Gruber. Major Gruber's wife, Connie, lives in my district. She's the one who brought this to my attention.

In these 10 years, in addition to the JAGMAN report I just quoted that says that these pilots were not at fault, I have reached out to so many people that it's unbelievable, including the former Assistant Secretary of Defense Phil Coyle, and I would like to read his comment:

Major Gruber should not be blamed for an accident caused by loss of lift due to the aircraft entering vortex ring state, phenomena which no one in the Marine Corps adequately understood in relation to the Osprey at the time of the accident. Not only did the Marine Corps not understand Osprey performance under VRS, the root cause of the accident, but neither the contractor nor the Marine Corps had not tested the aircraft at near VRS conditions—something which, following the accident, it later took the Marine Corps years to accomplish. Surely, Major Gruber cannot be blamed for something that the Marine Corps itself did not grasp until years after his death.

Mr. Speaker, I further quote Phil Coyle:

Considering that it was ignorance on the part of the Marine Corps that caused the April 2000 accident, the Marine Corps should make it clear to Gruber's family—with no if, ands or buts, that Gruber was not responsible for the accident. I don't suppose the Marine Corps ever apologizes, but considering that the accident was their fault, and not major Gruber's, an apology to the family would be in order also.

Mr. Speaker, I don't really like reading that because I have such great respect for the Marine Corps, but I must say today on the floor that I am very disappointed in the Marine Corps; because before I finish in just a few minutes you will understand why I am disappointed because the two wives have asked for something very simple, and I will explain that before I close.

Another one of the experts who has joined us, former adviser to the Secretary of Defense, Rex Rivolo, stated:

The failure of the manufacturer, Bell-Boeing, and the Navy to characterize the slow speed, high rate of descent handling qualities of the V–22 through flight testing, to describe them for the aircrew in the NATOPS, and to provide an adequate warning system were the causes of the mishap, not aircrew error.

With the passing of 10 years, and the future of the aircraft now secure, I sincerely hope that the names of Lieutenant Colonel Brow and Major Gruber can now be exonerated and cleared for posterity. I strongly support any and all measures to this end, and request this letter be included in any official record regarding the causes of the MV–22 mishap at Marana, Arizona, on April 8 or any resolution attempting to clear the names of Lieutenant Colonel John Brow and Major Brooks Gruber.

Mr. Speaker, so many people in this 10-year effort have joined, it's just unbelievable. I have just read from two of those individuals who are well known to the defense industry.

Another person who was in the air in the third Osprey, Lieutenant Colonel James Shafer, a dear friend of Brow and Gruber's who was in the air with them that night in a separate plane, agrees with me and has gone above and beyond in his quest to clear his friends' names. I want to thank Lieutenant Colonel James Shafer for stepping out. He's a great marine. He loves the Marine Corps, but he know that these two gentlemen should never be seen as being at fault.

I've gotten to know the two attorneys who defended the families. Jim Furman in Texas was the attorney for the John Brow and Brooks Gruber families. In New York, the attorney was Brian Alexander. He and his associate defended the 17 marines and their families who were killed in the back of the plane. Both these attorneys, Mr. Speaker, have written to the Commandant of the Marine Corps and made it perfectly clear that the lawsuits are all settled and nothing—should the Marine Corps decide to give the two wives what I'm going to describe in just a few minutes, a letter stating clearly that their husbands, Colonel John Brow and Major Brooks Gruber, should not be seen at fault. They have stated in writing and I have copies, Mr. Speaker, that there will be no lawsuits. The lawsuits are over.

This is what Connie Gruber wrote me back in 2002. I want to read part of this for the record:

I contact you in hopes that leaders of integrity, free of bias, would have both the intelligence and the courage it takes to decide the facts for themselves. If you do that, you will agree the human factor/pilot error findings should not stand as it is in the military history. Again, I respectfully ask for your support. Please do not simply pass this matter along to General Jones without offering the support my husband and his comrades deserve. Please remember, these 19 marines can no longer speak for themselves. I certainly am not afraid to speak for them, and I believe somebody has to. Even though it is easier put to rest and forgotten, please join me in doing the right thing by taking the time to address this important issue.

Over the years I have received some help from the United States Marine Corps, but the Commandant is the person now, Mr. Speaker, that could give the wives what they are looking for, and that is just a simple letter I'm going to read for the record. That is:

On July 27, 2000, the United States Marine Corps issued a press release about the April 8, 2000, MV–22 Osprey crash that killed 19 marines near Marana, Arizona. In that press release, the Marine Corps cited human factors as the cause of the accident. Furthermore, the release included a statement saying ''the pilots' drive to accomplish that mission appears to have been the fatal factor.'' Since that press release, there has been a mistaken perception in the news media and written history that cause of the accident was pilot error. That perception dishonors the pilots who died that night, Lieutenant Colonel John Brow and Major Brooks Gruber. I would like to set the record straight on this matter. The July 27, 2000 press release unfairly placed the blame for the accident at the pilots' feet. It is morally wrong to place the blame for that accident on John Brow and Brooks Gruber. The mishap was not a result of pilot error, but was the result of a perfect storm of circumstances. Any accident is a result of a multitude of factors. The primary causal factors of this accident were:

One, insufficient developmental research and flight testing;

Two, no knowledge of the possible sudden onset of an asymmetrical flight condition and loss of control during vertex ring state;

Three, inadequate MV–22 NATOPS VRS discussion, warnings, and procedures;

Four, no VRS avoidance training.

With no knowledge, training, or warning concerning the possible consequences of VRS, John Brow and Brooks Gruber were essentially on their own in uncharted territory. The official investigation into this mishap explicitly states, ''During this investigation, we found nothing that we would characterize as negligence, deliberate pilot error, or maintenance/material failure.'' I wholeheartedly agree with the investigation. Any publication that is contrary to the official Marine Corps investigation and reflects the mishap was a result of pilot error should be corrected and recanted. Lieutenant Colonel John Brow and Major Brooks Gruber were aviation pioneers in the truest sense. The ultimate sacrifice made by all 19 marines aboard the aircraft that night led to a critical advancement in MV–22 safety and capability and overall readiness of the United States Marine Corps. It is because of their sacrifice that the MV–22 is successfully carrying marines in and out of combat today.

□ 2100

Mr. Speaker, the letter I just read has been approved by the marines who wrote the investigation, Colonel Mike Morgan, Colonel Ron Radich and Major Phil Stackhouse, and has been approved by the widows, Connie Gruber down in Jacksonville, and her daughter Brooks, and Trish Brow in California, Maryland, and her two sons, Michael and Matthew. The letter does not go against any word in the investigation. The commandant should send these letters to the two wives.

Mr. Speaker, I have said to the commandant a few months ago: Sir, if you

would call a press conference at marine headquarters in Washington, D.C. and you would invite the families of John Brow and Brooks Gruber, you would present the two wives, Connie and Trish, on your stationery, exactly, Mr. Speaker, what I just read, this would bring a tragedy to a close.

I'm going to continue to beat this drum, Mr. Speaker, for as long as I can because the dead cannot speak for themselves. If we the living do not speak for the dead and tell the truth, how can you ever correct a mistake if we don't take this upon ourselves?

Mr. Speaker, the last point before I close, I want to read this. This is from the attorneys Brian Alexander and Francis Young. These two attorneys went to an administrative judge, and the lawyers for Bell-Boeing were there, and they made this point on April 8, 2000:

There was no emergency procedure or recovery technique for asymmetric VRS. The pilot manual lacked adequate content, accuracy and clarity. Because of incomplete development testing there was insufficient explanatory or emphatic test to warn pilots of the hazards of operating in this area. The pilot manual was plagued with inaccuracies that degraded flight operations and contained performance charts provided by the developers which did not reflect actual conditions.

Mr. Speaker, Bell-Boeing, after the lawsuit, had an experimental pilot named Tom McDonald who spent 700 hours in the air trying to figure out how you respond to vortex ring state. He figured it out. He won the Kincheloe Award, which is only given to one experimental pilot in this country per year, because he solved the problem of vortex ring state—VRS—what pilots are supposed to do when they hit that VRS state.

Mr. Speaker, I hope that the commandant of the Marine Corps, who I have great respect for, will do what is right for John Brow, Brooks Gruber, and actually the 17 marines in the back of the plane that crashed and issue the letter that I just read for the record to the two wives, do it in a public setting, bring the press in and say that the Marine Corps does not forget its dead.

It is so simple, Mr. Speaker, that you will never believe how many people have said to me in this 10-year journey: Why doesn't the Marine Corps do it? I can't explain it. The lawsuits are over. The plane is safe. The V–22 is safe. Nobody's trying to take it out of the program. But for the families of John Brow and Brooks Gruber, this is the right thing to do. In my humble opinion, the Marine Corps is so well respected and thought of in this Nation that they would be even revered more if they would say to Colonel John Brow, to Major Brooks Gruber and their families, you did your job, you did it to the best of your ability. We regret that you were not prepared, but it was not your fault that you were not prepared. It was a rush to get this thing completed by Bell-Boeing and the United States Marine Corps.

With that, Mr. Speaker, I want to thank the staff for staying later tonight. I knew that I could convey my heart in about 25 minutes.

Mr. Speaker, I will continue to be on the floor from time to time with the photographs of these two young marine officers. I wish I had the 17 that were in the back of the plane, but I don't.

With that, Mr. Speaker, as I always do when I think about our troops over in Afghanistan and Iraq, I close by asking God to please bless the families of our men and women in uniform. I ask God to please bless those who have given a child dying for freedom in Afghanistan and Iraq. And I'm going to ask God tonight to please bless this effort to clear the names of John Brow and Brooks Gruber. I'm going to ask God to please bless the House and Senate, that we will do what is right in the eyes of God for his people in America. I ask God to please bless Mr. Obama, that he will do what is right in the eyes of God for the American people. And three times I will ask God, please, God, please, God, please continue to bless America.

With that, Mr. Speaker, I yield back the balance of my time.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. BURTON of Indiana (at the request of Mr. CANTOR) for today and the balance of the week on account of family health problems.

Mr. FORTENBERRY (at the request of Mr. CANTOR) for today and the balance of the week on account of official business.

Mr. YOUNG of Florida (at the request of Mr. CANTOR) for today on account of a death in the family.

Mr. HEINRICH (at the request of Ms. PELOSI) for today.

Ms. VELÁZQUEZ (at the request of Ms. PELOSI) for today on account of family illness.

ENROLLED BILL SIGNED

Karen L. Haas, Clerk of the House, reported and found truly enrolled a bill of the House of the following title, which was thereupon signed by the Speaker:

H.R. 5740. An act to extend the National Flood Insurance Program, and for other purposes.

BILLS PRESENTED TO THE PRESIDENT

Karen L. Haas, Clerk of the House, reported that on May 18, 2012, she presented to the President of the United States, for his approval, the following bills:

H.R. 4045. To modify the Department of Defense Program Guidance relating to the award of Post-Deployment/Mobilization Respite Absence administrative absence days to members of the reserve components to exempt any member whose qualified mobilization commenced before October 1, 2011, and continued on or after that date, from the changes to the program guidance that took effect on that date.

H.R. 4967. To prevent the termination of the temporary office of bankruptcy judges in certain judicial districts.

ADJOURNMENT

Mr. JONES. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 9 o'clock and 6 minutes p.m.), under its previous order, the House adjourned until tomorrow, Thursday, May 31, 2012, at 10 a.m. for morning-hour debate.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

6174. A letter from the Chief Counsel, Department of Homeland Security, transmitting the Department's final rule — Supension of Community Eligibility [Docket No: FEMA-2012-0003] [Internal Agency Docket No. FEMA-8223] received April 11, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Financial Services.

6175. A letter from the Chief Counsel, Department of Homeland Security, transmitting the Department's final rule — Final Flood Elevation Determinations [Docket ID: FEMA-2012-0003] received April 11, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Financial Services.

6176. A letter from the Program Manager, Department of Health and Human Services, transmitting the Department's final rule — World Trade Center Health Program Requirements for the Addition of New WTC-Related Health Conditions (RIN: 0920-AA45) received April 25, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6177. A letter from the Director, Regulatory Management Divison, Environmental Protection Agency, transmitting the Agency's final rule — Significant New Use Rules on Certain Chemical Substances [EPA-HQ-OPPT-2011-0577; FRL-9343-4] (RIN: 2070-AB27) received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6178. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Underground Storage Tank Program: Approved State Program for the State of Oregon [EPA-R10-UST-2011-0097; FRL-9615-4] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6179. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Significant New Use Rules on Certain Chemical Substances [EPA-HQ-OPPT-2012-0182; FRL-9345-4] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6180. A letter from the Director, Regulatory Management Agency, Environmental Protection Agency, transmitting the Agency's final rule — Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems [Docket No.: EPA-HQ-OW-2009-0090; FRL-9660-4] (RIN: 2040-AF10) received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6181. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Revisions to the Hawaii State Implementation Plan [EPA-R09-OAR-2012-0082; FRL-9634-1] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6182. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Revisions to the California State Implementation Plan, Antelope Valley Air Quality Management District and Eastern Kern and Santa Barbara County Air Pollution Control Districts [EPA-R09-OAR-2011-0643; FRL-9652-4] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6183. A letter from the Director, Regulatory Management Agency, Environmental Protection Agency, transmitting the Agency's final rule — Modification of Significant New Uses of Tris Carbamoyl Triazine; Technical Amendment [EPA-HQ-OPPT-2011-0118; FRL-9344-7] (RIN: 2070-AB27) received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6184. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Interim Final Determination to Stay and Defer Sanctions, San Joaquin Valley Unified Air Pollution Control District [EPA-R09-OAR-2012-0266; FRL-9665-5], pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6185. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Direct Final Approval of Hospital/Medical/Infectious Waste Incinerators State Plan for Designated Facilities and Pollutants: Indiana [EPA-R05-OAR-2012-0086; FRL-9663-2] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6186. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Approval and Promulgation of Implementation Plans; Arizona; Update to Stage II Gasoline Vapor Recovery Program; Change in the Definition of ''Gasoline'' to Exclude ''E85'' [EPA-R09-OAR-2010-0717; FRL-9661-3] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6187. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Approval and Promulgation of Implementation Plans: Georgia; Approval of Substitution for Transportation Control Measures [EPA-R04-OAR-2012-0136-201162; FRL-9662-8] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6188. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Approval and Promulgation of Implementation Plans and Designations of Areas for Air Quality Planning Purposes; Missouri and Illinois; St. Louis; Determination of Attainment by Applicable Attainment Date for the 1997 Ozone National Ambient Air Quality Standard (NAAQS) [EPA-R07-OAR-2012-0053; FRL-9666-2] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6189. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Approval and Promulgation of Air Quality Implementation Plans; Massachusetts Determination of Attainment of the One-hour Ozone Standard for the Springfield Area [EPA-R01-OAR-2012-0008; A-1-FRL-9664-8] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6190. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Approval and Promulgation of Air Quality Implementation Plans; Maryland; Removal of the 1980 Consent Order for the Maryland Slag Company [EPA-R03-OAR-2012-0271; FRL-9664-2] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6191. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Director Final Approval of Hospital/Medical/Infectious Waste Incinerators State Plan for Designated Facilities and Pollutants: Illinois [EPA-R05-OAR-2012-0087; FRL-9663-4] received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Energy and Commerce.

6192. A letter from the Attorney-Advisor, Department of Homeland Security, transmitting the Department's final rule — Special Local Regulation; Hebda Cup Rowing Regatta, Trenton Channel; Detroit River, Wyandotte, MI [Docket No.: USCG-2012-0340] (RIN: 1625-AA08) received May 14, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6193. A letter from the Attorney Advisor, Department of Homeland Security, transmitting the Department's final rule — Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA [Docket No.: USCG-2012-0280] received May 14, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6194. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Amendment of Class E Airspace; Hastings, NE [Docket No.: FAA-2011-0499; Airspace Docket No. 11-ACE-10] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6195. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Amendment of Restricted Areas R-5801 and R-5803; Chambersburg, PA [Docket No.: FAA-2012-0174; Airspace Docket No. 11-AEA-3] (RIN: 2120-AA66) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6196. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Amendment of Class E Airspace; Lamar, CO [Docket No.: FAA-2011-1262; Airspace Docket No. 11-ANM-25] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6197. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Establishment of Class E Airspace; Piseco, NY [Docket No.: FAA-2011-0726; Airspace Docket No. 11-AEA-18] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6198. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Establishment of Class E Airspace; Marion, AL [Docket No.: FAA-2011-0590; Airspace Docket No. 11-ASO-25] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6199. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Establishment of Class E Airspace; Bonye City, MI [Docket No.: FAA-2011-0828; Airspace Docket No. 11-AGL-16] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6200. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Amendment of Class E Airspace; Wilcox, AZ, and Revocation of Class E Airspace; Cochise, AZ [Docket No.: FAA-2011-1314; Airspace Docket No. 11-AWP-18] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6201. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Amendment of Class E Airspace; Springfield, CO [Docket No.: FAA-2011-1247; Airspace Docket No. 11-ANM-24] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6202. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Amendment of Class E Airspace; Tobe, CO [Docket No.: FAA-2011-1338; Airspace Docket No. 11-ANM-27] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6203. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Revocation of Class E Airspace; Southport, NC, and Establishment of Class E Airspace; Oak Island, NC [Docket No.: FAA-2011-1148; Airspace Docket No. 11-ASO-37] received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6204. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Agusta S.p.A. Helicopters [Docket No.: FAA-2011-0409; Directorate Identifier 2011-SW-055-AD; Amendment 39-17020; AD 2011-18-52] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6205. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters [Docket No.: FAA-2011-1115; Directorate Identifier 2010-SW-011-AD; Amendment 39-17017; AD 2012-08-01] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6206. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Turbomeca S.A. Turboshaft Engines [Docket No.: FAA-2009-0330; Directorate Identifier 2008-NE-43-AD; Amendment 39-17015; AD 2012-07-09] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6207. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; The Boeing Company Airplanes [Docket No.: FAA-2011-0644; Directorate Identifier 2010-NM-265-AD; Amendment 39-17026; AD 2012-08-09] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6208. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Learjet Inc. Airplanes [Docket No.: FAA-2011-1258; Directorate Identifier 2011-NM-184-AD; Amendment 39-17033; AD 2012-08-16] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6209. A letter from the Program Analyst, Department of Transportation, transmitting

the Department's final rule — Airworthiness Directives; Bombardier, Inc. Airplanes [Docket No.: FAA-2011-1223; Directorate Identifier 2011-NM-173-AD; Amendment 39-17027; AD 2012-08-10] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6210. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Learjet Inc. [Docket No.: FAA-2011-1069; Directorate Identifier 2011-NM-025-AD; Amendment 39-17025; AD 2012-08-08] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6211. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Airplanes [Docket No.: FAA-2011-1325; Directorate Identifier 2010-NM-250-AD; Amendment 39-17014; AD 2012-07-08] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6212. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Turbomeca S.A. Turboshaft Engines [Docket No.: FAA-2012-0010; Directorate Identifier 2012-NE-03-AD; Amendment 39-17035; AD 2012-08-18] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6213. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Airbus Airplanes [Docket No.: FAA-2012-0033; Directorate Identifier 2011-NM-086-AD; Amendment 39-17029; AD 2012-08-12] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6214. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; The Boeing Company Airplanes [Docket No.: FAA-2012-0110; Directorate Identifier 2011-NM-148-AD; Amendment 39-17034; AD 2012-08-17] (RIN: 2120-AA64) received May 15, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

6215. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures [EPA-HQ-OW-2010-0192; FRL-9664-6] (RIN: 2040-AF09) received April 24, 2012, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

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 reference to the proper calendar, as follows:

Mr. KING of New York: Committee on Homeland Security. H.R. 3857. A bill to amend the Implementing Recommendations of the 9/11 Commission Act of 2007 to require the Secretary of Homeland Security to include as an eligible use the sustainment of specialized operational teams used by local law enforcement under the Transit Security Grant Program, and for other purposes; with an amendment (Rept. 112–498). Referred to the Committee of the Whole House on the state of the Union.

Mr. KING of New York: Committee on Homeland Security. H.R. 4005. A bill to direct the Secretary of Homeland Security to conduct a study and report to Congress on gaps in port security in the United States and a plan to address them; with an amendment (Rept. 112–499). Referred to the Committee of the Whole House on the state of the Union.

Mr. HASTINGS of Washington: Committee on Natural Resources. H.R. 1237. A bill to provide for a land exchange with the Trinity Public Utilities District of Trinity County, California, involving the transfer of land to the Bureau of Land Management and the Six Rivers National Forest in exchange for National Forest System land in the Shasta-Trinity National Forest, and for other purposes (Rept. 112–500. Referred to the Committee of the Whole House on the state of the Union.

Mr. HASTINGS of Washington: Committee on Natural Resources. H.R. 1272. A bill to provide for the use and distribution of the funds awarded to the Minnesota Chippewa Tribe, et al, by the United States Court of Federal Claims in Docket Numbers 19 and 188, and for other purposes; with an amendment (Rept. 112–501). Referred to the Committee of the Whole House on the state of the Union.

Mr. HASTINGS of Washington: Committee on Natural Resources. S. 363. An act to authorize the Secretary of Commerce to convey property of the National Oceanic and Atmospheric Administration to the City of Pascagoula, Mississippi, and for other purposes (Rept. 112–502). Referred to the Committee of the Whole House on the state of the Union.

Mr. HASTINGS of Washington: Committee on Natural Resources. H.R. 460. A bill to authorize the Secretary of the Interior to facilitate the development of hydroelectric power on the Diamond Fork System of the Central Utah Project; with an amendment (Rept. 112–503 Pt. 1). Referred to the Committee of the Whole House on the state of the Union.

Mr. NUGENT: Committee on Rules. House Resolution 667. Resolution providing for consideration of the bill (H.R. 5743) to authorize appropriations for fiscal year 2013 for intelligence and intelligence-related activities of the United States Government, the community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes; providing for consideration of the bill (H.R. 5854) making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2013, and for other purposes; providing for consideration of the bill (H.R. 5855) making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2013, and for other purposes; and providing for consideration of the bill (H.R. 5325) making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2013, and for other purposes (Rept. 112–504). Referred to the House Calendar.

Mr. HASTINGS of Washington: Committee on Natural Resources. H.R. 1818. A bill to designate Mt. Andrea Lawrence, and for other purposes (Rept. 112–505). Referred to the House Calendar.

Mr. HASTINGS of Washington: Committee on Natural Resources. S. 925. An act to designate Mt. Andrea Lawrence (Rept. 112–506). Referred to the House Calendar.

Ms. ROS-LEHTINEN: Committee on Foreign Affairs. H.R. 1280. A bill to amend the Atomic Energy Act of 1954 to require congressional approval of agreements for peaceful nuclear cooperation with foreign countries, and for other purposes; with an amendment (Rept. 112–507 Pt. 1). Ordered to be printed.

Mr. ISSA: Committee on Oversight and Government Reform. H.R. 3289. A bill to amend title 5, United States Code, to provide clarification relating to disclosures of information protected from prohibited personnel practices; to require a statement in nondisclosure policies, forms, and agreements that such policies, forms, and agreements are in conformance with certain protections; to provide certain additional authorities to the Office of Special Counsel; and for other purposes; with amendments (Rept. 112–508 Pt. 1). Ordered to be printed.

DISCHARGE OF COMMITTEE

[The following action occurred on May 30, 2012]

Pursuant to clause 2 of rule XIII, the Committee on the Budget discharged from further consideration. H.R. 460 referred to the Committee of the Whole House on the state of the Union.

REPORTED BILL SEQUENTIALLY REFERRED

Under clause 2 of rule XII, bills and reports were delivered to the Clerk for printing, and bills referred as follows:

[The following action occurred on May 30, 2012]

Ms. ROS-LEHTINEN: Committee on Foreign Affairs. H.R. 1280. A bill to amend the Atomic Energy Act of 1954 to require congressional approval of agreements for peaceful nuclear cooperation with foreign countries, and for other purposes, with an amendment; referred to the Committee on Energy and Commerce for a period ending not later than October 1, 2012.

TIME LIMITATION OF REFERRED BILLS

Pursuant to clause 2 of rule XII, the following actions were taken by the Speaker:

[The following actions occurred on May 30, 2012]

H.R. 1280. Referral to the Committees on Rules and Energy and Commerce extended for a period ending not later than October 1, 2012.

H.R. 1838. Referral to the Committee on Agriculture extended for a period ending not later than July 16, 2012.

H.R. 3283. Referral to the Committee on Agriculture extended for a period ending not later than July 16, 2012.

H.R. 3289. Referral to the Committees on Intelligence (Permanent Select) and Homeland Security extended for a period ending not later than October 1, 2012.

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. HARPER (for himself and Mr. OWENS):

H.R. 5859. A bill to repeal an obsolete provision in title 49, United States Code, requiring motor vehicle insurance cost reporting; to the Committee on Energy and Commerce.

By Mr. FRANK of Massachusetts (for himself, Mr. WAXMAN, and Mr. PETERSON):

H.R. 5860. A bill to prohibit individuals from insuring against possible losses from

having to repay illegally-received compensation or from having to pay civil penalties, and for other purposes; to the Committee on Financial Services, and in addition to the Committee on Agriculture, 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. FILNER:

H.R. 5861. A bill to direct the Secretary of Veterans Affairs and the Secretary of Housing and Urban Development to establish a grant pilot program to provide housing to elderly homeless veterans; to the Committee on Financial Services, and in addition to the Committee on Veterans' Affairs, 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. COLE (for himself and Mr. BOREN):

H.R. 5862. A bill relating to members of the Quapaw Tribe of Oklahoma (O-Gah-Pah); to the Committee on Natural Resources.

By Mr. BURGESS:

H.R. 5863. A bill to clarify section 1702 of the Energy Policy Act of 2005 to include penalties for violations of title XVII of that Act; to the Committee on Energy and Commerce, and in addition to the Committee on Science, Space, and Technology, 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 Ms. SLAUGHTER (for herself, Mr. RANGEL, Mr. ROGERS of Michigan, Mr. KUCINICH, Ms. BORDALLO, Mr. HINCHEY, Mr. FARR, Mrs. MALONEY, Mr. KILDEE, and Mr. GRIJALVA):

H.R. 5864. A bill to establish an improved regulatory process for injurious wildlife to prevent the introduction and establishment in the United States of nonnative wildlife and wild animal pathogens and parasites that are likely to cause harm; to the Committee on Natural Resources, and in addition to the Committees on the Judiciary, Ways and Means, and 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. LIPINSKI (for himself and Mr. KINZINGER of Illinois):

H.R. 5865. A bill to promote the growth and competitiveness of American manufacturing; to the Committee on Energy and Commerce, 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. BRALEY of Iowa:

H.R. 5866. A bill to enhance Food and Drug Administration oversight of medical device recalls, to provide for the conditional clearance of certain medical devices, and for other purposes; to the Committee on Energy and Commerce.

By Mrs. CHRISTENSEN:

H.R. 5867. A bill to designate the facility of the United States Postal Service located at 4605 Tutu Park Mall in St. Thomas, United States Virgin Islands, as the ''Kenneth Leslie Hermon Post Office''; to the Committee on Oversight and Government Reform.

By Mr. LEWIS of Georgia:

H.R. 5868. A bill to provide children in foster care with school stability and equal access to educational opportunities; to the Committee on Education and the Workforce, and in addition to the Committee on Ways and Means, 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. RIVERA:

H.R. 5869. A bill to authorize the cancellation of removal and adjustment of status of certain aliens who are long-term United States residents and who entered the United States as children, and for other purposes; to the Committee on the Judiciary, and in addition to the Committees on Homeland Security, and Ways and Means, 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. SCHIFF:

H.R. 5870. A bill to revise the regulations regarding estimated cost of the assistance and localized impacts factors used by the Administrator of the Federal Emergency Management Agency, and for other purposes; to the Committee on Transportation and Infrastructure.

By Mrs. BONO MACK (for herself, Mr. UPTON, Mr. WAXMAN, Mr. WALDEN, and Ms. ESHOO):

H. Con. Res. 127. Concurrent resolution expressing the sense of Congress regarding actions to preserve and advance the multistakeholder governance model under which the Internet has thrived; to the Committee on Energy and Commerce.

By Ms. BROWN of Florida (for herself, Mr. BACHUS, Mr. BISHOP of Georgia, Mr. JONES, Mr. CRENSHAW, and Mr. WEST):

H. Con. Res. 128. Concurrent resolution authorizing the use of Emancipation Hall in the Capitol Visitor Center for an event to award the Congressional Gold Medal, collectively, to the Montford Point Marines; to the Committee on House Administration.

By Mr. COLE (for himself and Mr. BOREN):

H. Res. 668. A resolution to refer H.R. 5862, a bill making congressional reference to the United States Court of Federal Claims pursuant to sections 1492 and 2509 of title 28, United States Code, the Indian trust-related claims of the Quapaw Tribe of Oklahoma (O-Gah-Pah) as well as its individual members; to the Committee on the Judiciary.

By Mr. GINGREY of Georgia (for himself, Mr. POMPEO, Mrs. ELLMERS, and Mr. THOMPSON of Pennsylvania):

H. Res. 669. A resolution commending the Patriot Guard Riders for their mission to show sincere respect for fallen members of the Armed Forces by attending the funeral services of a fallen member as invited guests of the family of the member; to the Committee on Armed Services, and in addition to the Committee on Veterans' Affairs, 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 Ms. NORTON:

H. Res. 670. A resolution expressing support for designating August 22, 2012, as national ''Chuck Brown Day'' and honoring Chuck Brown's contributions to music and to the District of Columbia; to the Committee on Oversight and Government Reform.

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. HARPER:

H.R. 5859.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 18

By Mr. FRANK of Massachusetts:

H.R. 5860.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 3 (the Commerce Clause).

By Mr. FILNER:

H.R. 5861.

Congress has the power to enact this legislation pursuant to the following:

This bill is enacted pursuant to the power granted to Congress under Article I, Section 8, Clause 18 of the United States Constitution.

By Mr. COLE:

H.R. 5862.

Congress has the power to enact this legislation pursuant to the following:

This bill is enacted pursuant to Article I, Section 8 which allows Congress to regulate trade amongst the Indian Tribes.

This bill is enacted pursuant to treaties lawfully entered into and ratified pursuant to the power granted to Congress under Article II, Section 2, Clause 2.

This bill is enacted pursuant to Article III Section 2 which grants Congress power to regulate jurisdiction in courts inferior to the United States Supreme Court

By Mr. BURGESS:

H.R. 5863.

Congress has the power to enact this legislation pursuant to the following:

The attached language falls within Congress' delegated authority to legislate interstate commerce, found in Article I, Section 8, clause 3 of the U.S. Constitution. Further, Congress' authority to regulate the actions of government officials tasked to carry out duly-enacted legislation can be found in Article I, Section 8, clause 18, which authorizes Congress to ''make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers . . .''

By Ms. SLAUGHTER:

H.R. 5864.

Congress has the power to enact this legislation pursuant to the following:

Congress has the power to enact this legislation pursuant to the following: Clause 3 of Section 8 of Article I of the Constitution.

By Mr. LIPINSKI:

H.R. 5865.

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 regulate foreign and interstate commerce, as enumerated in Article 1, Section 8, Clause 3 of the United States Constitution.

By Mr. BRALEY of Iowa:

H.R. 5866.

Congress has the power to enact this legislation pursuant to the following:

This bill is enacted pursuant to the power granted to Congress under Article I, Section 8, Clause 18 of the United States Constitution.

By Mrs. CHRISTENSEN:

H.R. 5867.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 7 of the Constitution, which provides: ''The Congress shall have Power to establish Post Offices and post Roads.''

By Mr. LEWIS of Georgia:

H.R. 5868.

Congress has the power to enact this legislation pursuant to the following:

This bill is enacted pursuant to the power granted to Congress under Article I of the United States Constitution and its subsequent amendments, and further clarified and

interpreted by the Supreme Court of the United States.

By Mr. RIVERA:

H.R. 5869.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 4: Immigration Regulation

By Mr. SCHIFF:

H.R. 5870.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 18, the necessary and proper clause, which gives Congress the power to make all laws that are necessary and proper.

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions as follows:

H.R. 23: Mr. CRAVAACK.
H.R. 87: Mr. SAM JOHNSON of Texas.
H.R. 139: Mrs. DAVIS of California, Ms. BERKLEY, and Mr. MEEKS.
H.R. 157: Mr. WALDEN, Mr. WILSON of South Carolina, and Mr. GRIMM.
H.R. 191: Ms. KAPTUR.
H.R. 324: Mr. CLARKE of Michigan.
H.R. 345: Mr. RANGEL.
H.R. 436: Mr. BOREN.
H.R. 451: Mr. CRENSHAW, Mrs. NAPOLITANO, and Mr. ROSS of Florida.
H.R. 458: Ms. KAPTUR.
H.R. 459: Mr. PENCE, Mr. ROGERS of Kentucky, and Mr. TONKO.
H.R. 466: Ms. KAPTUR.
H.R. 530: Ms. NORTON.
H.R. 605: Mr. HECK.
H.R. 645: Mr. LOBIONDO.
H.R. 718: Ms. HIRONO and Mrs. BACHMANN.
H.R. 719: Mr. SCHILLING and Mr. ENGEL.
H.R. 805: Mr. MILLER of North Carolina.
H.R. 811: Mr. MICHAUD.
H.R. 812: Ms. KAPTUR.
H.R. 816: Mr. HARRIS and Mr. ROHRABACHER.
H.R. 860: Mr. PALAZZO and Mr. TURNER of New York.
H.R. 930: Mr. NADLER and Ms. LORETTA SANCHEZ of California.
H.R. 938: Mr. LANCE and Mr. MCKINLEY.
H.R. 941: Ms. MCCOLLUM.
H.R. 942: Mr. WILSON of South Carolina, Mr. HARPER, Mr. SCHILLING, Mr. WAXMAN, Mr. PETERS, and Ms. LINDA T. SÁNCHEZ of California.
H.R. 965: Mrs. CAPPS, Mr. FATTAH, and Mrs. DAVIS of California.
H.R. 997: Mr. ROGERS of Kentucky.
H.R. 1057: Ms. KAPTUR.
H.R. 1063: Mr. KILDEE and Mr. CLEAVER.
H.R. 1177: Mr. HINOJOSA.
H.R. 1195: Ms. BONAMICI.
H.R. 1206: Mrs. BACHMANN, Mr. BUCHANAN, and Mrs. NOEM.
H.R. 1244: Mr. OLSON.
H.R. 1285: Mr. RIGELL.
H.R. 1332: Mr. GRIMM and Mr. STIVERS.
H.R. 1340: Mr. REED.
H.R. 1366: Mr. CARNAHAN and Mr. GRIJALVA.
H.R. 1370: Mr. YOUNG of Florida, Mr. AUSTRIA, and Mrs. MYRICK.
H.R. 1394: Mr. COBLE, Mr. LEWIS of Georgia, Ms. BROWN of Florida, and Mrs. DAVIS of California.
H.R. 1416: Mr. NUNNELEE.
H.R. 1418: Mr. RANGEL and Mr. HANNA.
H.R. 1547: Mr. CONNOLLY of Virginia.
H.R. 1639: Mr. PENCE and Mr. YOUNG of Florida.
H.R. 1653: Mr. THOMPSON of Mississippi and Mr. BUCSHON.
H.R. 1681: Ms. FUDGE.
H.R. 1687: Mr. HIMES.
H.R. 1735: Mr. PETERS .
H.R. 1736: Mr. RENACCI.
H.R. 1792: Mr. CHANDLER.
H.R. 1860: Mr. SCALISE, Mr. DEUTCH and Mr. HOLDEN.
H.R. 1897: Mr. PETRI, Mr. GARY G. MILLER of California and Mr. CICILLINE.
H.R. 1936: Mr. BOREN.
H.R. 1956: Mr. WOLF, Mr. LATTA, Mr. WHITFIELD, Mr. ROYCE, Mr. HUIZENGA of Michigan, Mr. ROE of Tennessee, Mr. STIVERS and Mr. UPTON.
H.R. 1971: Mr. BOREN and Mr. BISHOP of New York.
H.R. 2051: Mr. WITTMAN.
H.R. 2082: Mr. BOUSTANY and Ms. JENKINS.
H.R. 2139: Mr. GENE GREEN of Texas, Mr. GRIMM, Mr. HOYER, Mr. ROYCE, Mr. NADLER, Mr. SCOTT of Virginia, Mr. CROWLEY and Ms. VELÁZQUEZ.
H.R. 2140: Mr. BECERRA.
H.R. 2194: Mrs. CAPPS.
H.R. 2245: Ms. KAPTUR and Mr. KEATING.
H.R. 2272: Ms. BONAMICI.
H.R. 2284: Mr. YOUNG of Alaska.
H.R. 2288: Mr. WITTMAN.
H.R. 2353: Mr. RICHMOND.
H.R. 2505: Mr. BACA.
H.R. 2541: Mr. GIBBS.
H.R. 2569: Mr. QUAYLE.
H.R. 2697: Mr. CHABOT.
H.R. 2705: Mr. ANDREWS.
H.R. 2721: Mrs. DAVIS of California, Ms. CLARKE of New York, Mr. LOEBSACK, Mr. WATT, Mr. PLATTS and Mr. CARSON of Indiana.
H.R. 2741: Mrs. CAPPS.
H.R. 2775: Mr. KILDEE, Mr. KUCINICH, Mr. CLAY and Mr. SERRANO.
H.R. 2827: Ms. HIRONO.
H.R. 2959: Mr. LANKFORD and Mr. LEWIS of Georgia.
H.R. 2989: Mr. PAULSEN and Mr. RANGEL.
H.R. 3023: Mr. QUIGLEY.
H.R. 3036: Mr. RICHMOND.
H.R. 3053: Mr. HOLT.
H.R. 3057: Mr. DOYLE and Ms. KAPTUR.
H.R. 3073: Mr. MCCAUL.
H.R. 3091: Mr. ROSS of Arkansas and Mr. ROE of Tennessee.
H.R. 3187: Mr. PETRI, Mr. BARROW, Mr. BLUMENAUER, Mr. GUINTA, Mr. GEORGE MILLER of California, Ms. DELAURO, Mr. DUFFY, Mr. MARINO, Mr. BISHOP of New York, Mr. WILSON of South Carolina, Mr. COSTA, Mr. COFFMAN of Colorado and Mr. PIERLUISI.
H.R. 3242: Mr. OLVER.
H.R. 3300: Mr. BRADY of Pennsylvania.
H.R. 3307: Mr. GIBSON.
H.R. 3352: Mr. RANGEL.
H.R. 3368: Ms. FUDGE.
H.R. 3395: Mr. CARNAHAN.
H.R. 3423: Mr. ROSS of Arkansas.
H.R. 3429: Mr. BONNER.
H.R. 3485: Mr. ENGEL, Mr. MURPHY of Connecticut, Ms. KAPTUR and Mr. Israel.
H.R. 3497: Mr. CRENSHAW, Mr. TIBERI, Mr. LUJÁN, Mr. WOLF, Mr. PALAZZO, Mr. SESSIONS, Mr. PASCRELL and Mr. FILNER.
H.R. 3528: Mr. RAHALL and Ms. FUDGE.
H.R. 3612: Mr. BACA.
H.R. 3613: Mr. NADLER.
H.R. 3618: Mr. POLIS, Mr. VAN HOLLEN, Mr. CLAY, Mr. BUTTERFIELD, Mr. HASTINGS of Florida and Mr. CARSON of Indiana.
H.R. 3619: Mr. MILLER of North Carolina, Ms. CLARKE of New York, Ms. SCHAKOWSKY, Mr. GEORGE MILLER of California, Ms. LEE of California, Ms. ROYBAL-ALLARD, Mr. HINOJOSA, Mr. WATT and Mr. NEAL.
H.R. 3624: Ms. NORTON.
H.R. 3627: Mr. WALDEN, Ms. ZOE LOFGREN of California, Mr. BOSWELL, Mr. BARROW, Mr. Quigley and Mr. BILBRAY.
H.R. 3643: Mr. REHBERG.
H.R. 3665: Mr. SCOTT of Virginia.
H.R. 3667: Mrs. NOEM and Mr. COSTELLO.
H.R. 3724: Mr. YODER.
H.R. 3769: Mr. BRADY of Texas.
H.R. 3770: Mr. KINZINGER of Illinois.
H.R. 3776: Mr. ANDREWS.
H.R. 3790: Mr. CONNOLLY of Virginia and Mr. PIERLUISI.
H.R. 3811: Mr. DANIEL E. LUNGREN of California.
H.R. 3848: Mr. SCALISE, Mr. SAM JOHNSON of Texas and Mr. PALAZZO.
H.R. 3863: Mr. CONYERS.
H.R. 3973: Mr. BERG.
H.R. 4054: Mr. CICILLINE.
H.R. 4057: Mr. SHERMAN, Mr. FILNER, and Mrs. MCCARTHY of New York.
H.R. 4066: Mr. ROHRABACHER.
H.R. 4077: Mr. REICHERT and Mr. TONKO.
H.R. 4091: Mr. DEUTCH.
H.R. 4115: Mr. GRIFFIN of Arkansas.
H.R. 4151: Mr. CRENSHAW.
H.R. 4155: Mr. GARY G. MILLER of California, Ms. BORDALLO, and Mr. CARTER.
H.R. 4169: Mr. MURPHY of Pennsylvania, Ms. KAPTUR, and Mr. VAN HOLLEN.
H.R. 4208: Mr. CICILLINE.
H.R. 4215: Mr. BOREN and Mr. BISHOP of New York.
H.R. 4221: Mr. MANZULLO.
H.R. 4227: Mr. KUCINICH and Mr. LANGEVIN.
H.R. 4231: Ms. SLAUGHTER and Ms. SCHAKOWSKY.
H.R. 4232: Mr. STIVERS.
H.R. 4243: Mr. COHEN.
H.R. 4249: Mr. RANGEL.
H.R. 4269: Mr. KINZINGER of Illinois.
H.R. 4277: Mr. CLAY.
H.R. 4287: Mr. MCDERMOTT, Mr. DAVIS of Illinois, Mr. LEVIN, Ms. MOORE, Ms. CLARKE of New York, Mr. KUCINICH, Mr. CLARKE of Michigan, Mr. BRADY of Pennsylvania, Ms. BERKLEY, Mr. BARTLETT, Mr. RYAN of Ohio, Ms. NORTON, Mr. LUJÁN, and Mr. JACKSON of Illinois.
H.R. 4318: Mr. ROTHMAN of New Jersey and Mr. FILNER.
H.R. 4345: Mr. POE of Texas, Mr. MATHESON, and Mr. COFFMAN of Colorado.
H.R. 4350: Mr. SIRES, Mr. MILLER of North Carolina, Mr. LOEBSACK, and Mr. TIERNEY.
H.R. 4367: Mr. WOMACK, Mr. GRAVES of Georgia, Ms. WATERS, Mr. LARSEN of Washington, Mr. ROONEY, Mr. GRAVES of Missouri, Mr. HINOJOSA, Mr. FILNER, Mr. CARSON of Indiana, Mr. HASTINGS of Washington, Mrs. MCCARTHY of New York, and Mr. GUTIERREZ.
H.R. 4402: Mr. TIPTON, Mr. COBLE, Mr. LABRADOR, Mr. FRANKS of Arizona, and Mr. YOUNG of Alaska.
H.R. 4406: Ms. SUTTON, Mr. KUCINICH, Ms. FUDGE, Mr. CLARKE of Michigan, and Mrs. MILLER of Michigan.
H.R. 4454: Mrs. BLACKBURN and Mr. STEARNS.
H.R. 4816: Mr. WAXMAN.
H.R. 4972: Ms. SCHAKOWSKY and Mr. FILNER.
H.R. 5050: Mr. BLUMENAUER and Mr. GENE GREEN of Texas.
H.R. 5186: Ms. SCHAKOWSKY.
H.R. 5187: Mr. CARNEY.
H.R. 5188: Mr. SABLAN.
H.R. 5638: Mr. SABLAN.
H.R. 5713: Mr. MILLER of North Carolina.
H.R. 5716: Mr. FARR.
H.R. 5741: Ms. HANABUSA, Ms. HIRONO, and Ms. NORTON.
H.R. 5749: Ms. CLARKE of New York.
H.R. 5826: Mr. LIPINSKI, Ms. WOOLSEY, and Mr. TONKO.
H.R. 5827: Mr. MILLER of North Carolina, Mr. LIPINSKI, Mr. COSTELLO, Mr. MCNERNEY, Ms. WOOLSEY, and Mr. TONKO.
H.R. 5842: Mrs. BLACK, Mrs. BLACKBURN, Mr. JONES, and Mr. PAUL.
H.R. 5850: Mr. CHABOT, Mr. MANZULLO, Ms. BUERKLE, Mr. HULTGREN, and Mrs. SCHMIDT.
H.R. 5851: Ms. DELAURO, Mr. LOEBSACK, and Ms. HIRONO.
H.R. 5858: Mrs. BLACK.
H.J. Res. 13: Ms. BORDALLO.

H.J. Res. 28: Mr. HINCHEY, Ms. SLAUGHTER, and Mr. MCGOVERN.

H.J. Res. 104: Mrs. ELLMERS and Mr. KISSELL.

H. Con. Res. 40: Mr. BACA.

H. Con. Res. 116: Mr. LEWIS of Georgia.

H. Res. 134: Mr. TURNER of New York and Mr. CHABOT.

H. Res. 177: Mr. MURPHY of Connecticut.

H. Res. 283: Mr. VAN HOLLEN.

H. Res. 583: Mr. REICHERT and Mr. HONDA.

H. Res. 616: Mr. KING of Iowa.

H. Res. 618: Mr. LEWIS of Georgia, Mr. SESSIONS, Mr. ISRAEL, Mr. ROONEY, Mr. HINCHEY, Mr. MARKEY, Mr. GRIMM, Mr. WILSON of South Carolina, Mr. HULTGREN, Mr. MCDERMOTT, Mr. THOMPSON of Pennsylvania, Ms. SPEIER, Mr. BLUMENAUER, Ms. CLARKE of New York, and Mr. COURTNEY.

H. Res. 662: Mr. WOODALL.

H. Res. 663: Mr. PETERS, Mr. HECK, Ms. BONAMICI, and Mrs. SCHMIDT.

DELETION OF SPONSORS FROM PUBLIC BILLS AND RESOLUTIONS

Under clause 7 of rule XII, sponsors were deleted from public bills and resolutions as follows:

H.R. 1513: Mr. GINGREY of Georgia.

AMENDMENTS

Under clause 8 of rule XVIII, proposed amendments were submitted as follows:

H.R. 5854

OFFERED BY: MR. BLUMENAUER

AMENDMENT NO. 1: Page 31, line 5, after the dollar amount, insert ''(reduced by $35,000,000) (increased by $35,000,000)''.

H.R. 5854

OFFERED BY: MR. BLUMENAUER

AMENDMENT NO. 2: Page 4, line 14, insert after the dollar amount the following: ''(reduced by $10,000,000) (increased by $10,000,000)''.

Page 4, line 23, insert after the dollar amount the following: ''(increased by $10,000,000)''.

H.R. 5854

OFFERED BY: MR. QUAYLE

AMENDMENT NO. 3: Page 66, after line 10, add the following new section:

SEC. 519. None of the funds made available by this Act may be used to implement, administer, or enforce the final rule published by the National Labor Relations Board in the Federal Register on August 30, 2011 (76 Fed. Reg. 54006).

H.R. 5854

OFFERED BY: MR. POE OF TEXAS

AMENDMENT NO. 4: At the end of the bill (before the short title), insert the following:

SEC. ____. None of the funds made available by this Act may be used for a director of a national cemetery who, on or after the date that is 180 days after the date of the enactment of this Act, is not a veteran.

H.R. 5854

OFFERED BY: MR. POE OF TEXAS

AMENDMENT NO. 5: At the end of the bill (before the short title), insert the following:

SEC. ____. None of the funds made available by this Act may be used to censor or otherwise limit the speech of a veterans service organization participating in the funeral or memorial service of a veteran.

H.R. 5854

OFFERED BY: MR. TERRY

AMENDMENT NO. 6: At the end of the bill (before the short title), insert the following:

SEC. ____. None of the funds made available by this Act may be used to deny or delay a waiver request regarding a hospital construction project of the Department of Veterans Affairs that requires an exemption from building requirements that were not included in the original bid for such hospital.

H.R. 5854

OFFERED BY: MR. TERRY

AMENDMENT NO. 7: Page 37, line 15, after the first dollar amount, insert ''(reduced by $1) (increased by $1)''.

H.R. 5854

OFFERED BY: MR. FRANKS OF ARIZONA

AMENDMENT NO. 8: Page 66, after line 10, add the following new section:

SEC. 519. None of the funds made available by this Act may be used to implement, administer, or enforce the prevailing wage requirements in subchapter IV of chapter 31 of title 40, United States Code (commonly referred to as the Davis-Bacon Act).