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ALLEGATIONS OF WASTE, FRAUD, AND

ABUSE IN PHARMACEUTICAL PRICING:

FINANCIAL IMPACTS ON FEDERAL HEALTH

PROGRAMS AND THE FEDERAL TAXPAYER

Friday, February 9, 2007

House of Representatives,

Committee on Oversight and

Government Reform,

Washington, D.C.

Committee Hearings

of the

U.S. HOUSE OF REPRESENTATIVES

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ALLEGATIONS OF WASTE, FRAUD, AND ABUSE IN PHARMACEUTICAL PRICING: FINANCIAL IMPACTS ON FEDERAL HEALTH PROGRAMS AND THE FEDERAL TAXPAYER

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The committee met, pursuant to call, at 10:02 a.m., in Room 2154, Rayburn House Office Building, Hon. Henry A. Waxman [chairman of the committee] presiding.

Present: Representatives Waxman, Cummings, Tierney, Yarmuth, McCollum, Cooper, Sarbanes, Welch, Davis of Virginia, Bilbray and Sali.

Staff Present: Phil Schiliro, Chief of Staff; Phil Barnett, Staff Director and Chief Counsel; Kristin Amerling, General Counsel; Karen Nelson, Health Policy Director, Karen

Lightfoot, Communications Director and Senior Policy Advisor; Sarah Despres, Senior Health Counsel; Brian Cohen, Senior Investigator and Policy Advisor; Steve Cha, Professional Staff Member; Earley Green, Chief Clerk; Teresa Coufal, Deputy Clerk; Davis Hake; Kerry Gutknecht; David Marin, minority Staff Director; Larry Halloran, Minority Deputy Staff Director; Jennifer Safavian, Minority Chief Counsel for Oversight and Investigations; Keith Ausbrook, Minority General Counsel; Anne Marie Turner, Minority Counsel; Susie Schulte, Minority Senior Professional Staff Member; Kristina Husar, Minority Professional Staff Member; John Cuaderes, Minority Senior Investigator and Policy Advisor; Patrick Lyden, Minority Parliamentarian and Member Services Coordinator; Benjamin Chance, Minority Clerk; Yasmin Szabados, Minority Intern; and Bill Womack, Minority Legislative Director.

Chairman WAXMAN. Meeting of the committee will please come to order.

Today we will complete our first set of hearings into the impact of waste, fraud and abuse on the taxpayer. In this hearing we will investigate allegations that some pharmaceutical companies are profiteering from public health programs at the expense of the American taxpayer and the most vulnerable in our society, poor and the elderly who rely on these programs for their health care.

We will hear testimony about patterns of waste, fraud and abuse in pharmaceutical pricing. The testimony will help us determine our priorities for future oversight in this area.

I care deeply about this issue. Throughout my career in Congress I have worked hard to expand and improve health care coverage for seniors, for persons with disabilities and for low-income families; and I have worked just as hard to make sure that the taxpayers gets their money's worth out of the Medicare, Medicaid and public health programs. That is why I am so concerned about these allegations involving the pharmaceutical industry. If even half of them are true, billions of Federal dollars that should be buying needed care are instead adding to drug company profits. That waste would be bad enough time any time, but in this area of tight budgets it is particularly tragic.

We will hear reports that the Federal Medicaid program, which provides health care to almost 50 million low-income beneficiaries, has been repeatedly overcharged for essential medications.

The Medicaid program is a huge purchaser, buying over $30 billion worth of drugs in 2005. Congress in 1990 recognized that such a large purchaser should get low prices and passed legislation requiring the drug manufacturers provide the Medicaid program with the same discounts they provide private purchasers such as large HMOs and hospital chains. But, according to whistle-blowers who have filed dozens of cases over the last decade, drug manufacturers have deliberately crafted business plans to avoid giving Medicaid the proper discounts.

Today, we will hear testimony from the Texas Attorney General's Office and the U.S. Department of Justice detailing some of the tactics used by pharmaceutical companies to avoid providing appropriate discounts to Medicaid.

The laws are here for waste, fraud and abuse in the Public Health Service's 340B program. Under this program, federally funded health clinics are supposed to have access to brand name and generic drugs at very low prices. These programs serve vulnerable populations, and they do it while facing severe budget shortages.

But a series of reports and audits by the GAO and by the

HHS Office of the Inspector General have found that these clinics are being overcharged for the drugs they need, costing them tens of millions of dollars annually; and I look forward from hearing from the HHS Inspector General and GAO about how to make these critical public health programs work better.

Finally, we will hear about the Medicare Part D program. This new program has been controversial from the start, passed in the dark of night, amid allegation that the votes were being bought and sold on the House floor and that the Bush administration hid the true costs of the new program. The proponents of the new Part D program argued that private pharmacy benefit managers and insurers that provide the benefits would be able to obtain the low prices from drug manufacturers, but the evidence seems to point in the opposite direction.

Analyses by my staff and others suggest that drug prices under these plans are higher than prices in other Federal programs, higher than prices in Canada, and even higher than prices available on Costco and drugstore.COM. Beneficiaries are justifiably puzzled as they see out-of-pocket costs increasing and drug prices skyrocketing at three to four times inflation rate. Meanwhile, drug companies are reporting massive increases in their profits.

Dr. Schondelmeyer and Dr. Anderson will provide us

insights into what is happening with the Part D drug prices.

This committee will have an aggressive oversight agenda when it comes to pharmaceutical manufacturers and other companies that engage in wasteful, fraudulent or abusive tactics that affect Federal health care programs.

We begin our oversight with this hearing and with a set of letters that I am sending today to the insurers and pharmacy benefit managers that are running the Medicaid Part D program, and I am asking these companies to provide us with information on the discounts that they have negotiated with drug manufacturers and the way in which these discounts are being passed on to seniors who are signed up for Medicaid Part D.

This information will be critical as our committee assesses whether high drug costs are increasing beneficiary costs and wasting taxpayers dollars in the Medicare drug program. The testimony we hear today will help us establish additional investigative priorities for the next 2 years, and I am looking forward to hearing from our witnesses today.

[Prepared statement of Mr. Waxman follows:]

******** INSERT 1-1 ********

Chairman WAXMAN. Before we call on our witnesses, I want to recognize, first of all, Mr. Davis, the ranking member of the committee, to make his opening statement. We will have opening statements not to exceed 2 minutes by other members who seek recognition, and members may instead submit their statements for the record, which will be held open for 7 days.

Mr. DAVIS OF VIRGINIA. Mr. Chairman, thank you very much.

I want to note for the record that I am unable to join you in the request for the information, because I think we are entitled to this information, but I think the manner in which you seek it is one which I am not ready to support at this point.

This information is required to be submitted to the Centers for Medicare and Medicaid Services. CMS is the repository of this information, so it seems to me it would be faster and easier if we got this information from CMS, rather than having to go to 12 different providers. It is sitting there.

I have to wonder whether this goal is to harass the private industry or to get the information. So we have a letter today going out to CMS for this same information, giving them 2 weeks; and we will see who gets there first.

I want to thank the chairman for holding today's hearing

to consider the potential for waste, fraud and abuse in three Federal health care programs. In the past, we shared a bipartisan zero tolerance approach to the misuse of vital health care dollars, and I look forward to continuing that important work on behalf of U.S. taxpayers.

In This oversight, fiscal vigilance also means better physical well-being for millions of Americans who use these Federal programs. As you will hear today, both the HHS Inspector General and the Department of Justice are actively prosecuting drug manufacturers who circumvent pricing and reporting requirements designed to make sure patients treated by Medicare, Medicaid and public health clinics get mandated discounts on prescription drugs.

In the complex world of pharmaceutical prescribing, packaging and pricing--as in the rest of the health care delivery system--costs shift between providers, payers and patients, and it can be difficult to trace.

But when payments shift unlawfully into someone's pockets, oversight systems have to be able to detect and recoup those losses. So I am particularly interested in hearing testimony from today's witnesses on the different forms of waste, fraud and abuse they find in these very different Federal health programs.

In the Medicaid and 340B systems, the Federal Government is directly involved in negotiating drug prices. Some of us

call that the "old way of doing things." We will hear today how those systems have been scammed.

On the other hand, the new Medicaid Part D prescription drug plan passed in 2003 I think by one vote--my vote--relies far more heavily--I think I am the only one in the room who supported it--been ascribed to by an overwhelming number of seniors. It is a program, I might add, that one million VA beneficiaries have voluntarily migrated from the VA system, where you have direct government negotiations, to Medicare Part D because of the options that it gives them trying to bring competition to the market place.

We rely far more heavily on competitive market forces to get the best price for our senior citizens. The health care delivery systems today really lack competition. It is a third-party payer system. One of the things we try to do with this type of program is try to bring direct competition in. And just to note if you take a look at health care today and the rising costs there is one area where health costs are going down, laser surgery for eyes. It not covered by insurance companies, and people pay directly for that service, and it has driven costs down, and it has driven technology up.

Those of us on this side believe competition is the best way to bring costs down, not some one-size-fits-all

government program. Because, as I said before, a million veterans have migrated from this system voluntarily to the Part D system.

Now the majority mistrusts that mechanism, alleging higher cost, greater potential for fraud because the Part D program lacks the best-price provision that Federal price negotiators might ~~get in that~~ use to get a better deal. We passed H.R. 4 to give the HHS Secretary that negotiating authority.

With that in mind, I hope this hearing is not an exercise in backward oversight, a conclusion in search of facts. There is no evidence that the Medicare prescription drug benefit is more costly or more prone to abuse than any other government-run-programs under discussion here today. In fact, the average monthly premium for the basic Medicare drug benefit is down more than 40 percent from the $37 per month originally projected. This year, the average monthly premium for the basic benefit is $22, a dollar less than the year before. Where else in health care is that happening?

A recent Congressional Budget Office analysis of H.R. 4 has concluded the bill would have very little effect on net Federal spending and would not result in drug prices any lower than those achieved by the current system; and, as I said before, the current system offers more options, more choices, which is why veterans are migrating from the current system that have particular needs.

I would ask unanimous consent, Mr. Chairman, to insert the January 10th, 2007, CBO analysis into the hearing record.

Chairman WAXMAN. Without objection, it will be entered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. DAVIS OF VIRGINIA. I think this is great news for American seniors, and it is a direct result of competition and choice. It is also probably why 80 percent of participating seniors are happy with the drug benefit. If the young Medicare Part D program is susceptible to unique forms of waste, fraud and abuse, we need to hear about it from these witnesses, and we need to address those vulnerabilities with deterrence and strong enforcement programs. I am sure there are scammers out there that will figure the new program, ways to get into that, too.

Let me just also note that there are three PBMs that have greater buying power than the Federal Government. So the Federal Government isn't the largest purchaser. We are the fourth largest purchaser in the marketplace, and for those who think that somehow--and many of the plans currently under Medicare Part D are utilizing that buying power to lower their costs.

But we shouldn't base our oversight on premature conclusions about the efficiency and the pricing mechanism that is serving 33 million citizens so well today.

I look forward to this hearing, Mr. Chairman. This is an important hearing, and I appreciate your calling it.

Chairman WAXMAN. Thank you, Mr. Davis.

Let me point out that we have written directly to the pharmaceutical manufacturers because the information we have

requested is quite sensitive and we would rather deal with them directly on the issues they may raise. Mr. Davis has contacted HHS, we both want this information, and we will work together once we get we get it.

Mr. DAVIS OF VIRGINIA. Absolutely. Absolutely.

Chairman WAXMAN. Thank you.

I want to now recognize Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman. Thank you for having this hearing.

In my district, besides having any number of people that are receiving prescription drug assistance through the Medicare Part D program and veterans program and the Federally funded community health clinics, they probably would not want to see Mr. Davis if he were claiming that he was the vote that passed the Medicare bill because, since the doughnut hole kicked in, most of them would like to find him and kick something else.

But the fact of the matter is I think it is denies logic to think that we are giving away some $57.5 million in subsidies to private entities and then claiming that we are saving the taxpayer money. So I am looking forward to this hearing. I think we have to get to the bottom if there is waste, fraud or abuse in any of these programs and anticipate what might rise in other programs so that we can stay on top of that and save individuals as much as we can.

It is vital and critical, as we know, for these people to be able to afford the prescription drugs. We should do in all that we can in that sense, and I am glad we are going to do it in a bipartisan manner and get that information. That will be important.

Again, I want to thank you, Mr. Waxman, for conducting this hearing.

Chairman WAXMAN. Turning to Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chairman.

Mr. Chairman, I wasn't going to make an opening statement, and I am sure that will make a lot of people happy. But I can't go a long time without pointing out that I appreciate the fact that the chairman and the ranking member have such a good working relationship. And I just--after that opening statement by the ranking member, I hope that the members on the other side of the aisle realize what a resource the ranking member is from a lot of point of views.

But perception of Republicans always coming from the business side of the spectrum is a misperception. The ranking member is somebody who has actually provided health care to the public, actually with a public agency, was the director of a public agency that served millions of people that actually got the job done.

Too often in Congress we have people that come from

different spectrums but very few of us have the practical knowledge and experience--of firsthand experience of providing this service to the public, and I think that Mr. Davis's experience is something that both sides of the aisle should draw on, and I am glad to see that the chairman works so closely with the ranking member on this issue.

And I may be prejudiced because, like it or not, I come from the same background. I was a county supervisor. I was an executive for the county that actually provided those programs that the Federal and State legislators always talk about but never really execute. And I hope that we are able to work across the aisle, draw upon the experience of everyone here, especially those of us that have worked with these types programs and have experienced the huge gap between the theoretical approach and the practical application. I think both sides can learn from that practical experience.

I want to commend the ranking member for continuing the good relationship with the chairman of this committee; and, hopefully, those who receive our services or should be receiving our Federal services will be able to benefit from this relationship.

I yield back, Mr. Chairman.

Mr. DAVIS OF VIRGINIA. I think we ought to be given 5 additional minutes, the way he is going.

Chairman WAXMAN. Well, thank you, Mr. Bilbray. I am constantly reminded of the enormous value that Mr. Davis brings to the deliberations of this committee. He is a consummate Member of Congress, and I am pleased to be able to have this opportunity to continue to be able to work with him.

Mr. DAVIS OF VIRGINIA. In your current capacity.

Chairman WAXMAN. Especially.

But I didn't know you actually provided the services directly.

Mr. DAVIS OF VIRGINIA. County government. I did. I didn't deliver any babies or anything.

Chairman WAXMAN. Thank you.

Mr. BILBRAY. There are some who claim he was providing the drug benefits.

Chairman WAXMAN. Who is next in seniority? Ms. McCollum.

Ms. MCCOLLUM. Thank you Mr. Chairman for holding this meeting on what I think we all know is a very important issue. There is not an American in this country who isn't affected by the pharmaceutical industry.

I would also like to thank all the witnesses for being here today, but in particular I would like to offer a warm welcome--because it is warmer here in Washington, D.C., than it is in Minnesota--to Dr. Stephen Schondelmeyer, professor

and head of the Department of Pharmaceutical Care and Health Systems at the College of Pharmacy at the University of Minnesota. Welcome. It must feel a lot warmer than the below zero we had back home.

For me and the people that I represent, we don't view health care in the United States as a privilege. In the wealthiest country in the world, for its citizens, health care should be a right. But the cost of health care and how we provide that is a critical issue and one that must be discussed here in Congress. We also heard the this loud and clear in the last election. People want health care addressed in this Nation.

By 2015, health care costs are expected to total around $4 trillion. That is 20 percent of the gross national product. We know that rising health care costs have a very strong affect on family budgets, employers and, yes, the Federal budget well. The costs are also responsible for the rising number of uninsured, currently 46 million Americans, and--can you believe it--there are 8 million children in this country without access to health care.

There are many important factors that drive up the health care costs, and today we are going to talk about the costs of prescription drugs. Prescription drugs are a vital part of health care and improving the quality of life for our families. However, the pharmaceutical companies need to know

that we must be treated in a fair manner both as citizens and as a government. As I say in my community, access to the quality of care is a first priority, not corporate profits.

In Minnesota alone, we have had to file lawsuits against pharmaceutical companies. One was found guilty of inflating the costs of chemotherapy drugs for the treatment of breast cancer, lung, testicular cancer and other cancers 12 to 20 times what it should have been.

Another form of fraud that is costing taxpayers money is the promotion of off labeling. I spoke with a person who had intimate knowledge on this, professionally working with the government and pharmaceutical companies; and he shared with me about the case where a doctor was paid hundreds of thousands of dollars by Jag Pharmaceutical to promote off-label use of a narcolepsy medication with a primary ingredient GHB, the date rape drug, the doctor prescribing this dangerous drug, which is in the same class as heroin, as a therapy for patients suffering from fatigue, chronic pain and other unapproved uses. The pharmaceutical company was also counseling doctors on how to ensure reimbursement for this unapproved treatment.

While these are two examples of fraud, Mr. Chairman, I know we are going to be hearing about what this government can do to protect its citizens and make access to pharmaceuticals more effective. But we have to keep in mind

that we are here to represent people, people who don't have health care, people who have often been victims of crimes due to off-labeling.

So I am here to hear more about this serious issue. This hearing is an important first step in moving forward to address the problem of access to pharmaceuticals in this country.

Thank you, Mr. Chair.

Chairman WAXMAN. Thank you for your opening statement.

Mr. Sali.

Mr. SALI. Thank you, Mr. Chairman.

We all know that no one on this committee is willing to accept the misuse of taxpayers' dollars, especially with respect to critically needed prescription drugs. Millions of Americans depend on prescription pharmaceuticals not only for good quality of life but for their very survival. When such drugs are deliberately priced out of people's reaches, it is an affront to the men and women who depend to prescription medications, and it has to be stopped.

Yet drug prices in many regards are going down almost across the board and primarily from competition. Wal-Mart, for example, now offers 331 generic prescription drugs for only $4 per month. That is what happens when market-based competition is allowed to operate.

According to the Centers for Medicaid and Medicare

Services, as a result of strong competition and informed beneficiary choice, the average Part D premium due to basic benefits is 42 percent lower than had been projected originally; and the cost of the average premium is also going down another dollar between 2006 and 2007, from $23 to $22.

Although we are looking at $113 billion in greater savings in the Medicare prescription drug program over the 10 years, from 2007 to 2016, it is also noteworthy that the President has proposed a far-reaching plan to curtail excessive costs in the Medicare program, including his proposal to introduce competitive bidding for clinical laboratory services.

It is my hope, Mr. Chairman, that we join those on this side of the aisle in giving these factors appropriate and careful consideration and regard in this hearing.

Additionally, prescription drugs, even when high-priced, can be much less expensive than such things as emergency care, hospital care, and other expensive therapies. This isn't to justify price gouging, but perspective is important, and we need to keep it in place as we consider this issue.

Let's also remember something said by Will Rogers many years ago, this country has come to feel the same when Congress is in session as when baby gets ahold of a hammer.

In the name of protecting people from waste, fraud and abuse let's not make the mistake of waving a hammer

indiscriminately. Let's make the taxpayers proud of our fair and thoughtful deliberation here today and throughout this upcoming session of Congress.

Thank you, Mr. Chairman. I yield back.

Chairman WAXMAN. Thank you for your statement.

Mr. Cooper.

Mr. COOPER. I thank the chairman for calling what is one of the most important hearings of the year both for the taxpayer and for anyone with a health problem. I represent part of the State of Tennessee and, according to a recent Blue Cross/Blue Shield study, our State once again ranks number one in America in terms of prescription drug prescriptions per citizen.

We also rank number one in America among all the States for drug spending per capita. It is some 17.3 prescriptions per person and a drug bill per person of over $1,100. And yet, for all of this therapy, we rank 47th in America in terms of our health status.

That is one aspect of the problem of what is going on in a State like Tennessee.

Another aspect is--as we will hear from these distinguished witnesses--the line of fines and, in some cases, criminal penalties since the year 2001 is extraordinary. It approaches and exceeds $4 billion. The recent Bristol-Myers Squibb settlement pushes it over Mr.

Moorman's limit of $3.9 billion. That is enough money to fund health care for virtually every poor child in America for a year.

But the finding that, Mr. Moorman, that really impressed me was, with 180 pending cases unresolved, the liability could be as much as $60 billion. That is almost double what we spend to defend America in homeland security every year, and this is one relatively small group of very prestigious companies.

Why is so much wrongdoing going on? That is the purpose of this hearing. And I would ask that unanimous consent of the Blue Cross study be included as well as the recent--Bristol-Myers Squibb settlement.

Chairman WAXMAN. Without objection, those documents will be added to the record.

[The information follows:]

******** INSERT 1-2 ********

Chairman WAXMAN. I think, Mr. Yarmuth, you are next.

Mr. YARMUTH. Thank you, Mr. Chairman. I also congratulate you on calling these hearings on a most important topic; and I would also like to say that I am also very interested in hearing Dr. Schondelmeyer who, while living in Minnesota now, was trained at the University of Kentucky. So welcome to you.

Mr. Chairman, I want to express my appreciation to you. We all owe a debt to the generations that came before us, the men and women who made this country great. But, instead of paying a debt, we are failing our seniors. It would be difficult to deny that. When Canada and Costco are offering better prices on prescription drugs than United States, that is an utter failure.

We will talk about many things probably during these hearings, why a certain Member of the Congress left after--for a $2 million PhRMA salary after guiding the passage of Medicare Part D. And we will talk about cases of fraud and the $115 million spent lobbying on Part D alone. And we will certainly discuss the fact that even the laws that the drug companies haven't written themselves they break, like the mandatory 15 percent discounts to Medicaid recipients. They simply refuse to comply, yet they go on unrestrained.

These aren't new facts. But what has changed is this:

We now have a Congress ready to do something about it, and today's hearing is the beginning of that change. We are here to find the answer to why the rule of law ceases to apply and our intended beneficiaries are suffering as a result.

But this I already know: Our present course cannot continue unchecked while Americans are in need, indeed are exploited and suffering. We have an obligation not only to our seniors but to American citizens whose tax dollars are funding a system to get the best possible deal on their behalf.

I am confident this new Congress will fulfill that responsibility. This hearing is a positive first step and I hope just the beginning of what we will do to contain costs and make sure taxpayers receive the best possible deal on pharmaceutical coverage.

I yield back the remainder of my time.

Chairman WAXMAN. Thank you, very much, Mr. Yarmuth.

Next, I want to call Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman. I appreciate your holding this hearing today on pharmaceutical pricing, particularly as it affects Medicare, Medicaid, the so-called 340B programs.

Mr. Chairman, I had the opportunity for almost two decades to work in the health care industry representing a lot of providers in Maryland and much of that was with

respect to issues of reimbursement. And I know that there is nothing--there is nothing more opaque than pharmaceutical pricing.

The background memo, Mr. Chairman, that you circulated relates correctly, for example, that the rebate amount for the Medicaid program is 15.1 percent of the average manufacturing price of the drug or, if it results in a lower net price than Medicaid, the difference between the average price and the, quote, best price at which the manufacturers sells.

The problem is that nobody really knows what the average manufacturer price is, and nobody really knows what the best price is. So there's a lot of manipulating that can go on.

Why does this matter? It matters because there are huge savings that we could realize if we could get a real fix on what the pricing is in this industry. And I, like many, see an increased role for the Medicaid program in health care reform as we go forward. So it is important to nail down what this pricing environment is.

Finally, Mr. Chairman, 2 weeks ago we gave the Secretary of Health and Human Services the right to negotiate lower drug prices on behalf of Medicare beneficiaries. The ability of the Secretary to do that effectively will depend again on us understanding clearly the way pharmaceutical pricing works.

So I look forward to the panel's testimony, and I thank you for the hearing.

Chairman WAXMAN. Thank you very much, Mr. Sarbanes.

Mr. Welch.

Mr. WELCH. Thank you, Mr. Chairman and Ranking Member, for calling this hearing.

The pharmaceutical industry does two things extremely well. The first is that they create drugs that extend life, alleviate suffering and, in some cases, cure disease; and for that they are to be applauded. The second thing they do extremely well is rip off consumers and taxpayers.

It is quite astonishing that the power of this industry was so successful that last year they actually got injected into law a provision that prohibited price negotiation. It is shocking. It is appalling. And, as my colleague from Maryland said, the House of Representatives just passed legislation to rescind what is a disgrace to the American public and the American taxpayers to which the pharmaceutical industry should apologize.

We in Vermont watched in dismay as the price of prescription drugs went out of sight, making it very difficult for people who need the life-saving, pain-relieving, life-extending promise of good prescription medication go beyond their ability to pay; and we acted, as did many other States, Mr. Chairman, by requiring price

negotiation with manufacturers, working with other States to create purchasing pools to lower the price, providing for prescription drug formularies, to allow price drug importation from Canada. These initiatives saved the Vermont taxpayer millions and millions of dollars literally; and, in many cases, we, as I said, work with other States.

Now, I believe that it is absolutely essential to the American taxpayer and the American consumer that we have fair pricing and fair policies with prescription drugs. The industry is important because it does do something that is essential to meeting the medical needs of our people. But they cannot hide behind the fact that they are providing an important service as the justification to use their market power and their political power to rip us off. It's got to end, and I believe that this hearing is going to help expose the abuse of that market power that this pharmaceutical industry has so that we can bring this back to balance and have fair profits and fair policies that are going to benefit the American consumer and the American taxpayer.

Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you very much, Mr. Welch.

The committee will now receive testimony from the witnesses before us today, and I want to introduce our first panel: Dr. Stephen Schondelmeyer, Professor at the University of Minnesota College of Pharmacy, previously from

Kentucky, I learned today; Dr. Gerard Anderson, Professor at the Johns Hopkins Bloomberg School of Public Health; and James W. Moorman, President and CEO of Taxpayers Against Fraud.

It is the policy of our committee to swear in all witnesses. You are not being singled out. All witnesses are sworn in. So I would like to ask you to rise and raise your right hand.

[witnesses.]

Chairman WAXMAN. The record will indicate that each of the witnesses answered in the affirmative.

STATEMENTS OF STEVEN SCHONDELMEYER, PHARMD, PH.D., PROFESSOR AND HEAD, DEPARTMENT OF PHARMACEUTICAL CARE AND HEALTH SYSTEMS, UNIVERSITY OF MINNESOTA COLLEGE OF PHARMACY; GERARD F. ANDERSON, PH.D., PROFESSOR, DEPARTMENT OF HEALTH POLICY AND MANAGEMENT DIRECTOR, CENTER FOR HOSPITAL FINANCE AND MANAGEMENT, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH; AND JAMES W. MOORMAN, PRESIDENT AND CEO, TAXPAYERS AGAINST FRAUD

Chairman WAXMAN. We are going to start with Dr. Schondelmeyer, if you would. All of your prepared statements will be in the record in its entirety, and we would like to

652 ask you if you would to try to keep it to around 5 minutes.

STATEMENT OF STEVEN SCHONDELMEYER

Mr. SCHONDELMEYER. Thank you, Mr. Chairman, and thank you, committee members, for including me on your panel today.

The pharmaceutical marketplace is a market that I have studied for about 30 years now and I find it extremely fascinating and dynamic.

First, let me apologize. Due to the relatively short nature of my timing and getting involved with this, I don't have a written statement now. But I will provide one shortly after the hearing to the committee at the committee's office.

I always like to step back and remind us, as many of the Members have, of the value and the role of pharmaceuticals. First, and quickly, half of all working adults, three-quarters of all elderly use one or more prescription medicines every week. If we look at any type of medicine, including over-the-counters and herbals and other supplemental types of medicines, three-fourths of working adults and nine out of ten elderly use a prescription or some type of medicine every week. So virtually everyone uses prescription medicines. There is a universal demand for prescription drugs.

Secondly, I often hear and see in many policy journals and academic journals and government reports a quote that

drugs are a small part of health care, and the number they quote is drugs are 11 percent of the health care dollar. That number is accurate. It comes from the Office of the Actuary, and the Office of the Actuary very carefully defines that to mean drugs in the outpatient prescription market.

Now, if you understand where I am headed, that isn't all drugs in society, but we use the number as if it was. And I have tried to dig behind and done some estimates of what drugs in all of our national health expenditure accounts really represent. They represent today closer to 18 or 19 percent of the health care dollar, and by the year 2014 or '15 we expect drugs to be more than 25 percent of the health care dollar.

Now, again, let's put that in perspective. If we look at drugs as a part of the total economy, today drugs are about 4 percent of our total economy. By 2014, '15, they will be about 5 percent of our total GDP. That is a much bigger factor than we give them credit for.

So let's first quit minimizing drugs as a small part of society. And I don't say that to say that is good or bad, but it is reality, and let's start using real numbers.

That brings me to my first recommendation.

I would recommend that you ask the Office of the Actuary to create a parallel estimate of drugs in all of society and in the total national health accounts and not just the

outpatient number that we keep using and fooling ourselves that drugs are a small part of health care. Because, without knowing the real total amount that is spent on drugs, we don't put it in a very appropriate policy perspective.

Secondly, they should subdivide that into how much is being paid for by government, Federal, State and other levels of government versus private sources. As best I can tell, drugs are really more than half of the--more than half of paid for by government today and not the private market.

I realize a statement was made earlier that the private market really manages more drugs. They may manage them, but Medicare is paying them to manage those. If we count the financing source for drugs, government is the largest payer for prescription drugs in the marketplace today, and we need to understand that number and understand what it means.

So let's put drugs in their right perspective, first of all.

There have been a number of major changes that have occurred to the pharmaceutical market place in just the last few years. The Medicare Part D program in many ways is very helpful. It helps a lot of seniors that didn't have drug coverage. But it also creates some issues.

Secondly, there have been shifts of the dual-eligibles from the Medicaid, the State-run programs, to the Federal program. And when you make that shift of dual-eligibles you

shift them out of the Medicaid program that had the drug rebates. The amount, as best I can tell from looking at the prices on the Web sites, from Medicare is being paid by Medicare for seniors that are dual-eligibles is 20 to 30 percent higher than it would have been if those patients remained under the current Medicaid rebate program.

Which brings into question why did we move patients to a system that costs us more as a government? And, no, that prices haven't gone down for most drugs to account for that, even in the private system. And certainly even if the premiums may have held even or gone down slightly, it isn't enough to account for 20 to 30 percent change in drug spending.

Another change that occurred is the Deficit Reduction Act of 2005 that made significant changes in pharmacy payment under Medicaid. That Act included redefining the average manufacturer price and some proposed rules that have recently come out with respect to that average manufacture price redefinition. Those rules I think do improve the definition of average manufacturer price from their perspective of a basis to calculate rebates that manufacturers owed to Medicaid.

What that act also tied the AMP to was how pharmacies at the retail level will be paid for their prescription drugs. And I think that the new definition of AMP actually is not

necessarily a substantial improvement in determining actual prices to retail pharmacies because pharmacies don't purchase direct from manufacturers. They purchase through wholesalers. They have other costs in the system. We are trying to use one number to do two things that are different, and we need to make adjustments in that.

I think we also have recognized in the private marketplace that the list price systems of average wholesale price and wholesale acquisition costs that we have used for 30 or more years I have seen as I grew up in this marketplace those list prices create problems and create overpayments in government programs, they create overpayments in private programs, and they need change. We need better transparency and/or regulation of both manufacturers in the drug price database systems that list those prices so it doesn't continue to create that type of fraud.

What do we need to do ahead? I think--several recommendations, including I think you must continue to monitor the ways that fraud and abuse can occur. We have fixed some of those with the new Medicare program with the Medicaid Deficit Reduction Act. But anytime you make changes the market is also very dynamic and innovative with respect to pricing, and they will find my new ways to create fraud and abuse, and you have to monitor for that.

You need to encourage--to create the GAO and the Office

of the Inspector General and GAO to be ever vigilant and to fund them adequately. You need to make price databases and transaction databases transparent and available to both government and private policy researchers and academic policy researchers so we can continue to develop new payments, not just find fraud. Just finding and fixing fraud doesn't mean you have developed an appropriate payment system. So we need to define appropriate positive incentives, performance-based pay for manufacturers and for pharmacists and for the pharmaceutical distribution system, not just for physicians, as we have done.

I will wrap up by saying the Medicare drug rebate program still needs some attention. I don't think--I have heard some propose eliminating the rebate program or converting it to just a fixed flat rebate, and that doesn't solve the problem. In fact, it would take away some very important tools. I think it is important you keep the tools of the best price, which is market based in that calculation, inflation adjuster is rarely talked about but one of the most important tools in the Medicaid rebate. You must keep that because it is market based and not just a government regulation per se, and you have to keep that in, I think.

And you need to keep in a provision like the State-negotiated supplemental rebates because, again, it allows the innovation of the States to develop different

approaches and different ways of creating things.

Chairman WAXMAN. Thank you very much, Mr. Schondelmeyer. We will get to some of these other points in the question and answer period.

[Prepared statement of Mr. Schondelmeyer follows:]

******** INSERT 1-3 ********

Chairman WAXMAN. Dr. Anderson.

STATEMENT OF GERARD F. ANDERSON

Mr. ANDERSON. Mr. Waxman and members of the committee, thank you for inviting me to testify this morning.

My analysis suggests three things: First of all, few government programs actually know the prices that they pay for drugs; two, different government programs are paying very different prices for exactly the same drugs; and, three, Part D plans are paying substantially higher drug prices than most other government programs.

In light of these findings, I have three recommendations for the committee to consider.

First of all, each government program should know the prices--the actual prices--that it pays for specific drugs. Second of all, drug prices should be compared across the government programs to determine which programs are paying the highest and which are paying the lowest prices for specific drugs. And, third, Congress should consider a more consolidated approach to purchasing drugs that would eliminate some of the disparities across these programs.

In my written testimony, I discussed several reasons why HRSA does not know the prices it is paying for 340B programs

and CMS does not understand the prices that Medicaid programs are paying for drugs. Given that some States pay five times more for drugs than other States, I think greater understanding of Medicaid prices by CMS is needed.

However, in my oral testimony I want to focus on the Medicare Part D program. Surprisingly, the Secretary of HHS, the CMS actuaries, CBO, CRS, GAO, et cetera, do not know the prices that the Part D plans are actually paying for drugs.

The raw data that is available is CMS headquarters simply has not been analyzed. It will be interesting for me to compare the data that Mr. Waxman and Mr. Davis has requested to see if they give you exactly the same numbers.

Chairman WAXMAN. Can you pull the mic a little closer?

Mr. ANDERSON. The Secretary of HHS should compare the lowest prices that any Part D plan is paying for the drugs to the prices that Medicaid or VA or Canada are paying for the same drug.

Mr. Davis, maybe the market is working. We should just know this.

Without actual data on the prices that Part D plans are paying, it is impossible to definitively say if the Part D plans are paying the highest rates. However, many organizations have tried to compare the rates that various government agencies pay, and the States have consistently found that the Part D plans are paying the highest rates.

For example, in 2005, CBO estimated the average price paid by the Medicaid program and the 340B programs were 51 percent of the average wholesale price and that VA was paying 42 percent of the average wholesale price. The same CBO report did not estimate the reduction Part D plans were receiving. Therefore, I had to turn to the CMS actuaries for additional data on Part D plans. In their 2006 report on the projected costs in the Part D program, the CMS actuaries assumed that Part D plans will pay 73 percent of the average wholesale price. First, it should be noted that the average price reduction obtained by Part D plans is 22 percent less than what Medicaid or the 340B programs have attained and 31 percent less than the VA.

So what does this mean for Medicare spending? The Medicare actuaries forecast that the Medicare program will spend $1 trillion on Medicare Part D over the next 10 years. And remember when they promised you how much it would cost originally they said $400 million. So it is now $1 trillion. The 22 percent reduction in price is associated with a 200 to $300 billion savings in the Medicare program over 10 years.

Second of all, the CMS actuaries do not project that the Part D plans obtained any further price reductions from two pharmaceutical companies. In fact, the CMS actuaries project Part D expenditures will increase an average of 10.3 percent

per year over the next 10 years; and this is much faster than the CMS actuaries project Part A or Part B to increase over this same time period.

So with the information on the relative prices the various government agencies are paying for drugs, Congress should examine three questions.

First, are the price variations across the government agencies for all drugs? Are they the same or do they vary by certain types of drugs? The theory and limited data suggest that government agencies are probably paying similar prices for generics and widely different prices for brand names.

Second of all, what explains the variation in price? The most likely explanation is that different government agencies use different approaches and some approaches are more effective than others.

And, third of all, should the government consolidate its approach for purchasing drugs? I really do have trouble understanding why certain government agencies should pay more for drugs than other government agencies.

For example, why should the Medicare program pay more for drugs than the VA for exactly the same drugs? Unless there is good reason why one government program should pay a lower price than another government program, I think the Congress should consider a common approach for the government to purchase drugs.

Thank you for the opportunity to testify this morning.

Chairman WAXMAN. Thank you very much, Dr. Anderson.

[Prepared statement of Mr. Anderson follows:]

******** INSERT 1-4 ********

Chairman WAXMAN. Mr. Moorman.

STATEMENT OF JAMES W. MOORMAN

Mr. MOORMAN. Thank you, Mr. Chairman.

The Federal Government is spending hundreds of billions of dollars to fund Medicare, Medicaid and other health care programs. It is essential that as much as possible be done to ensure that these funds are not lost to fraud but are spent on purchasing the health care services for the more than 90 million Americans these programs serve.

One particular area, fraud by pharmaceutical companies against Medicaid, is ripe for effective anti-fraud action. Whistleblower cases under the False Claims Act have brought three types of fraud into view that are costing Medicaid many billions of dollars: Medicaid best price fraud, average wholesale price fraud and off-label marketing fraud.

One of the biggest, if not the biggest, is best price fraud. There are several ways to cheat the best price rules which, in their simplest terms, require drug manufacturers to pay specific rebates on drugs sold to Medicaid or, alternatively, the best price given to other customers, whichever is lower.

Now one way to cheat is to simply not report the

discounts that would increase the amount of the rebates to Medicaid. Another way is to give unreported kickbacks to big customers. Sometimes these kickbacks are in the form of special fees for reported services, such as data fees, or they could involve the shipment of large quantity of, quote, free samples to the customer. A third form of cheating--sometimes called lick and stick--is to mislabel the drugs in the name of another entity with a distinct national drug code number that is not bound by the best price rules.

So far, there have been 16 settlements of cases involving these frauds that have recouped nearly $4 billion in civil damages and criminal penalties from drug manufacturers. There are more than 180 additional unresolved cases. The potential liability involved has not been reported, but, based on the cases settled to date and what is known about the unresolved cases out from under seal, it is likely to be in the $60 billion range.

There's a serious danger that the Justice Department will be unable to resolve most of these cases in a timely and satisfactory manner, despite the fact that the lawyers handling these cases work hard and are very good lawyers. The reason is the lack of resources in top-level leadership.

These cases are being resolved at the rate of less than three a year. Many cases are over a decade old. There is a serious inadequate number of lawyers assigned to the cases.

Only a few U.S. Attorneys Offices are seriously involved. Money allocated from the Health Care Fraud and Abuse Control account, sometimes called the HCFAC account, for health care fraud cases seems to have been withheld.

Indeed, the U.S. Attorneys appear to be getting only a third of the $30 million allocated to them for this purpose, and the civil division received receives only a varying fraction of a $14.5 million allocation.

Support from investigative agencies is spotty. The active support of the Attorney General and his deputy are not in evidence. The drug manufacturer defendants are aware of these deficiencies, and many of them appear to be trying to run out the clock on the Justice Department's attorneys.

These problems are particularly frustrating because the entire set of cases provide the government with an opportunity to close a multi-billion-dollar fraud gap. That would be the difference between fraudulent conduct that has occurred and fraudulent conduct held to account.

In order to grasp this opportunity, however, the Department of Justice must alter the status quo of how it is pursuing these cases. The top officers of the Department must take an active interest in the cases, adequate resources must be deployed and should be deployed quickly, HHS must provide more support, full support by investigative agencies is mandatory, the Civil Division's fraud section needs to be

augmented, more U.S. Attorneys Offices must participate in these cases in a significant way, and action must be taken to prevent these cases from languishing or allowing the clock to run out on them.

That completes my oral testimony, Mr. Chairman. I want to thank the committee for this opportunity to testify.

[Prepared statement of Mr. Moorman follows:]

******** INSERT 1-5 ********

Chairman WAXMAN. Thank you, all three of you, for your testimony.

We have two models in effect. Medicaid has paid for drugs by establishing limits. The government establishes limits, either the best price or a specified reduction in the price of drugs. That means the lowest price that is charged for the drug anywhere will be charged for the Medicaid program. And, Mr. Moorman, you outlined a lot of problems where there could be abuse by the drug manufacturers to avoid actually giving the discounts that the law requires of them to give.

Medicare, on the other hand, is a different model. Medicare is supposed to be an open market where consumers and the plans will be able to choose; and, in choosing from these different plans, that will give an incentive for the plans to hold down the price of drugs, a market, supposedly. Now, is there a potential for that market-based system to be one where there can be fraud and waste and abuse, as we have seen the attempts to use the Medicaid program as a way to make the taxpayers pay more money under those circumstances?

Dr. Schondelmeyer, why don't you start? What are the potentials? Is it harder or is it easier for abuse in the Medicare Part D program?

Mr. SCHONDELMEYER. Actually, there is certainly opportunity for fraud in both systems. It will take us

several years to know for sure if it is really more, but I would argue that the Medicare "let it go in the private marketplace," "everybody has a different way of doing things system" is sometimes harder to catch fraud in because there are many innovative and different types of fraud that can occur and at different levels. There is less data, less accountability, less information that can be monitored by either government officials or the private policy world to evaluate the impact.

I am not sure when we will see data like we get under Medicaid available for the prescription drug plan under Medicare. That may be 3, 4, 5 years before we get it as researchers. You may get it a little earlier as government. But just the delay in getting data in all these systems and reconciling it and aggregating it opens up the opportunity for fraud.

Chairman WAXMAN. Well, we do know that when we had the Medicaid program paying for those who were dual-eligible we paid a lot less than we are now paying for those same people who are under the Medicare Part D program. Dr. Anderson, you referred to that. How much more are we paying for those same people for their drugs than what we used to pay under the Medicaid program?

Mr. ANDERSON. It is hard to say exactly how much more we are paying, but our best estimate is about 20 percent

more. We base this on CBO reports, and we base this on filings that are at the SEC that are done by the drug companies themselves. They essentially tell us that, because of the Medicare program, they are having to pay out fewer rebates, they are getting higher prices for these dual-eligibles, and that is quite a sizable amount of money.

Chairman WAXMAN. Well, it is very peculiar, as you pointed out, that the government will pay for the same drug at one price for the veterans, at a different--probably higher--price for Medicaid--not necessarily, could be the same--but when it comes to Medicare we could be paying a lot more for that same drug. And, of course, if we look at the way the drug is marketed in other places, we are paying far more for our drugs in this country than people are paying for the very same drugs somewhere else. So it seems like there is no real price attached to the cost of a drug. It is just whatever the market will bear.

Is the Medicare Part D allowing the market to bear higher prices for the taxpayers to pay for those drugs?

Mr. ANDERSON. I think it definitely is, and I think the CMS actuaries are telling you that they are. When they originally did their cost estimates, the CBO told you it was $400 billion, the actuaries might have said $500 billion, but the 2006 trustees report says that in over the next 10 years it will be $1 trillion; and all of our estimates suggest that

they are paying substantially more under Medicare Part D than they are paying under any of the other government programs.

I think that is part of the reason why the new estimate is $1 trillion in 2006 and why, essentially, it is Part D is going to grow faster than Part A, and it is going to grow faster than part D, and it is going to grow faster than Medicaid spending. It is because we don't have good control over the spending in Medicare Part D.

Chairman WAXMAN. A lot of the Republican proposals, especially from, I think, the Bush administration, in health care is to have more transparency, on the theory people will shop around before they go to a hospital and check the prices, see what the doctors charge and make a choice between doctors based on their prices. That, of course, may work if you have time to do it. If you, however, are sick and you need health care, you are not going to be able to shop around.

But the whole premise of some of these high-deductible plans is that we want to give incentives for consumers to be able to shop around and choose the lowest price.

What kind of transparency do we have in the pharmaceutical area, and if we had greater transparency would that help the buyers of drugs, whether they be individuals, insurance companies or the government, to make sure we are not getting a higher bill?

Mr. ANDERSON. As an economist, I believe in markets. I think markets work in certain circumstances. But it appears that in the pharmaceutical industry they don't work very well and so we need to have greater price transparency. We need to know what at least the lowest price that any of the Part D plans are able to obtain and compare that to the price that the VA is paying for that same drug to know whether or not the market place is working.

We can all believe from economic theory that markets work, but we really need the data. As Ronald Reagan once said, trust but verify. You need to be able to verify that the marketplace is in fact working.

RPTS THOMAS

DCMN HERZFELD

[11 p.m.]

Chairman WAXMAN. If I were trying to make my decision as to which of the--in many cases of the 40-plus plans to choose from to cover my prescription drugs under Medicare, would I have any idea what any of those plans pay for the drug--for drugs that I use?

Mr. ANDERSON. You wouldn't have any idea and either do they know of what other plans. The other Part D plans don't know what the prices are. There is just no price transparency. That is precluded from it, and the CBO is precluded from getting that data from the Medicare Modernization Act of 2003.

Chairman WAXMAN. Mr. Moorman, maybe you can answer this, but maybe one of the other members of the panels can. So I am trying to decide between different plans under Medicare. I don't know what they are actually paying under each plan for the drugs I use. The only thing I can choose from are the--the amount that the plans want to charge me and different deductibles and premiums, and sometimes they cover my drug, and sometimes they may not.

How is that--does that market lend itself to more fraud because we don't know whether there are kickbacks going on with these plans? Does it lead to more fraud because they

don't know what they are paying for, the drugs themselves, and some of the other things that you have explored and the fraud cases?

Mr. MOORMAN. I think there are many opportunities for fraud in that system. For example, PBM that is managing the drugs could dispense a cheap generic drug, but charge the insurance policy a more expensive--for a more expensive drug that does the same thing.

And where you have the manufacturers, the PBMs and the insurance, you have many sort of ways in which you can hide things and charge the insurance policies far more money, which in the long run will cost the program more.

And the insurance companies themselves can play games with things like enrollment, and I predict you will see this in due course. For example, they could enroll someone in August, but report they enrolled him in May; or if he leaves their policy, they could keep him on their rolls to collect additional premiums for an additional 3 or 6 months. There are plenty of ways in a complicated system like that for the parties to inflate their charges to somebody else, and ultimately it is the program that pays this.

Chairman WAXMAN. Dr. Schondelmeyer, I want to ask you this: The drug companies tell us they have to keep their pricing secret because they have to maintain their competitive positions in the market, this proprietary

information, and therefore, it is their right to keep this secret. How do you respond to that argument by the drug companies?

Mr. SCHONDELMEYER. Well, I believe the markets work better with information, including price information, made transparent. If I am a consumer and want to get a better airfare to Washington, D.C., I go on line and look at different courses and look to see what the prices are.

I think in the pharmaceutical market, I think the market works different than a lot of other markets. So really the manufacturer-level and the retail-level prices aren't necessarily indicative of each other. The only transparency we have so far is purported retail prices by the prescription drug plans posted on their Web site. We have no way of verifying if that's the actual charge being charged to Medicare, and how much the manufacturer actually charged the prescription drug program or pharmacy, and how much rebate was paid, and what impact those rebates had. Rebates, really, in the private market, I'm not--I'm not talking about Medicaid, but in the private market have become an institutionalized form of kickback that in some cases result in prescription drug programs encouraging more use of higher-price drugs because they get more rebates that they convert into profits and don't necessarily always pass on in lower price or lower premiums. And we don't have any way of

tracking that because it's all hidden.

If we don't open up the black box, I think we are open to much more fraud.

Chairman WAXMAN. Is that fraud, or is that just a business practice?

Mr. SCHONDELMEYER. I think we are open to both; more fraud within it and higher prices due to inefficient business practices.

Chairman WAXMAN. Dr. Anderson.

Mr. ANDERSON. One of the things that I am particularly concerned about, if a Medicare beneficiary signs up with a plan based upon a set of prices, the Part D plan can then change those prices the next day, and you have made a decision based upon one set of prices, and then you are looking at a totally different set of prices a day or a week later when you develop it, particularly on this. I don't know if that is fraud, but I think it's a serious thing that Congress should take a look at.

Mr. SCHONDELMEYER. Classic bait and switch that sometimes is fraud.

Chairman WAXMAN. Mr. Davis.

Mr. DAVIS OF VIRGINIA. Thank you very much.

Mr. Chairman, I would like to enter into the record a letter from the Secretary of the Veterans Administration, Mr. R. James Nicholson, dated January 11th, to Speaker Pelosi.

In it he notes that it is important to recognize that the VA of the Medicare Part D program differ significantly with their constituencies, strategies, and structures.

The pharmaceutical manufacturers, well, VA's integrated health care system facilitates the provision of pharmaceutical care for prescriber to dispenser to veteran. The fully integrated structure, along with the use of VA's electronic health records, supports an effective formulary management process and must allow the VA to be able to provide the highest quality of health care to veterans and monitor their progress.

But I think the entire--

Chairman WAXMAN. Without objection, the letter will be made part of the record.

[The information follows:]

******** COMMITTEE INSERT ********

Chairman WAXMAN. Dr. Anderson, let me start with you. I want the same information Mr. Waxman does. It is a question of how you best get it, and we are going to get it and figure it out, and hopefully we can have a reasoned debate once we get that.

In your opinion, are the costs of Medicare Part D higher or lower than the cost estimate made when the act was passed?

Mr. ANDERSON. If I look at the 2006 trustees report right now, and I look for the 10-year period from 2006 to 2015, and I add up the numbers, it's 1--$1.013 trillion. And the--when you passed the legislation, there was the large debate over how much it would cost, and CBO said 400 billion, and the actuaries, I think, were really saying about 500 million. So that is twice as much or two and a half times as much.

Mr. DAVIS OF VIRGINIA. But the initial was for the first 10 years of the program. You are taking 10 years, and for the first 2-1/2 years the program wasn't in effect.

Mr. ANDERSON. Correct.

Mr. DAVIS OF VIRGINIA. You are taking basically a 7-year program and applying it to a 10-year program, and you've added beneficiaries because of the retiring baby boomers.

Mr. ANDERSON. There is some differences in years. I totally agree with that. But I still think the estimates are

substantially higher than they were when the CBO did its initial estimates.

Mr. DAVIS OF VIRGINIA. Have Medicare A and B, which incorporate government price control, succeeded in controlling health care costs?

Mr. ANDERSON. They haven't done a great job, but they are doing better than Part D is doing, according to actuaries.

Mr. DAVIS OF VIRGINIA. Have their costs grown in line with overall inflation?

Mr. ANDERSON. No.

Mr. DAVIS OF VIRGINIA. You say the CMS actuary, as we noted in openings, the average premium's going down, isn't it, next year, for Medicare Part D?

Mr. ANDERSON. I am looking at the 2006 trustees report and looking at total expenditures and seeing that they are growing on average 10.3 percent per year from 2006 to 2015. That is--for me is not evidence that the prices are going down.

Mr. DAVIS OF VIRGINIA. As you just--I think we just concluded you are looking at 10-year differentials where 3 years of the first year differential there wasn't any cost in it, and now you have retirement.

Let me move ahead. I have seen comparisons between the prices paid by VA for certain plans and prices paid by

Medicare plans. First, there was an article in USA Today that talks about drugs that are not available under the VA plan. In fact, they listed the top 20 drugs under Medicare Part D and the VA. Celebrex patients have to first fail on older achieving drugs to even be eligible. Lipitor isn't available at all, one of the most widely used drugs in the market. And Nexium is not available at all. Prevacid--I am not sure how you pronounce it--is not available at all. Xalatan is not available at all.

The theory of this plan was to allow people choices. If you don't need one drug, it is not contained in there. You don't have to buy a program that is chock full of drugs you don't need. And you can try to find one, and it's probably more complicated than anyone anticipated when it started, but overall you pick the plan that is best for you as opposed to kind of a one-size-fits-all formulation.

Now, VA prices cited in comparisons are actual wholesale prices; isn't that correct?

Mr. ANDERSON. Yes. In the CBO report, yes.

Mr. DAVIS OF VIRGINIA. The prices are cited for Medicare from the CMS plan finder Web site which--is that correct?

Mr. ANDERSON. That is not what I was using. I was using CMS actuarial numbers.

Mr. DAVIS OF VIRGINIA. But those are overall numbers.

Those are not available plan to plan.

Mr. ANDERSON. Unfortunately they are not.

Mr. DAVIS OF VIRGINIA. I think that is the key. What I am trying to analyze--that is what makes it so difficult to analyze. You may have one group in putting together a plan decide to give reductions here and raise it here to be able to attract a clientele, and it makes it very difficult. So of course you are going to pay more in one area than another. Grocery stores are competitive, but I go to Safeway and I pay one price for Diet Coke, and I pay another at Giant. That is the difficulty here of comparing apples to apples is why the government would be paying more under one plan than another.

Mr. ANDERSON. I understand that completely. What I am looking for in the Part D plan is the lowest price that any of the Part D plans are able to negotiate for each one of the individual drugs. So if the marketplace is working, it should work in getting low prices for Celebrex in one of the Part D plans.

Mr. DAVIS OF VIRGINIA. What you're saying, they should have the lowest price for everything in every plan, and that is not the way marketing is.

Mr. ANDERSON. I am looking for all of the Part D plans what is the lowest price that the marketplace can obtain and compare that to the VA price. I am not looking for all of

the Part D plans. I am just looking for the lowest price.

Mr. DAVIS OF VIRGINIA. I understand in putting in packaging, which is what you are doing in this kind of case, you are going to get variances, and that is good for the consumer in a sense. Not everybody is going to take the lowest price for everything and just stick it together. That is not how you get competitive and give people choices. You agree with that?

Mr. ANDERSON. Absolutely.

Mr. DAVIS OF VIRGINIA. It's difficult when we make sweeping changes to understand that the marketplace works different than everybody taking the lower cost, and you either believe it or you don't. You will find a greater suspicion of the marketplace with some members than with others. I don't always like the verdicts of the marketplace, but I respect the efficiencies that it brings and sometimes the unintended consequences.

We need to tamper in a way we don't understand. But what we are trying to find today is ways with the--particularly the new plans where we know people will find ways to find fraud and the like. It's a new plan. We don't know yet what that is going to be. And I think we all agree that we want to continue to market--I mean, to analyze what that will be, and I think all of you agree on that and continued scrutiny from GAO to find out what scams will come

forward, and they do in all of these areas. And Medicare Part D is so new, it is difficult to pinpoint; is that a fair comment?

Mr. ANDERSON. Yes.

Mr. DAVIS OF VIRGINIA. Dr. Schondelmeyer.

Mr. SCHONDELMEYER. I think we identify answers in places it might occur. We talked about the rebates, and it is not required that they may be passed on as lower prices to the consumer either in prescription price or in premium. It is not required. It may be used to increase or enhance the profits of the prescription drug plan, and they may--they have really a perverse incentive sometimes to increase the use of higher-priced drugs to the detriment of the consumer or us taxpayers. So I think the hidden rebates are a concern for fraud already.

Mr. DAVIS OF VIRGINIA. Let me ask you, I think you are a little more suspicious of the competitive pressures driving down costs, is that fair to say, on the Part D?

Mr. SCHONDELMEYER. I am suspicious partly because what we know is nobody really makes the ultimate price value decision in the Medicare price program. I have spent a lot of time doing focus groups and interviews, and we are conducting a survey right now of seniors who have might have these choices, and their primary driving factor is the premium alone, or the premium and the deductible and/or are

my two or three drugs that I am on right now on there; but when they change, find out they change to a different drug, it is not covered, or it's higher price, and the program changes over time, so it ends up costing them more.

Mr. DAVIS OF VIRGINIA. But you always find that. People are constantly making adjustments in the marketplace.

Mr. ANDERSON. It is not a very good, efficient system.

Mr. DAVIS OF VIRGINIA. Many argue the success of the competitive system demonstrated by the fact that the monthly premium has dropped from the estimated costs of $38 to $23 and now down to $22 at a time when everything else is going up. How do you explain that?

Mr. SCHONDELMEYER. Because the cost is coming in either adjustments in the program, higher deductibles, the amount they charge for copays, or the way they charge them in the system, the amount of rebates that they get from the manufacturers for pushing higher-priced drugs. All of those could explain lower premiums and higher costs of the system, even under the current program.

Mr. DAVIS OF VIRGINIA. I think if you take a look at the monthly and the copays and the monthlies and everything else, that they are actually much lower than the inflationary cost. Maybe it is first year. I also think that as a lot of seniors in first selection may be getting a program that doesn't quite suit them, they were pushed in because of

advertising, but over time, as they become better educated, hopefully that will drive prices down as well.

The plan competition, in my opinion, works for medical Part D the same way it works for Members of Congress, Congressional staff and the 8.3 other--million other Federal employees covered by FEHBP. Private plans, pharmacy benefit managers have significant experience driving things, and, you know, overall, I think we are going to need more data over the next 2 or 3 years, and we can continue to come back and look at this.

Mr. SCHONDELMEYER. I would point out that Members of Congress and employees don't chose their program, and their employers choose them, and they spend a lot of time and effort in analyzing--

Mr. DAVIS OF VIRGINIA. Actually, that's not correct. We choose our own plan.

Mr. SCHONDELMEYER. Within a small step that's been carefully designed by government.

Mr. DAVIS OF VIRGINIA. It's not two or three plans. It's literally dozens of plans that we have to select from. So it is a quite a few plans that they have, not one or two.

Chairman WAXMAN. Thank you, Mr. Davis.

Mr. Tierney.

Mr. TIERNEY. I was struck by the fact there are only a few Members of Congress in their eighties or nineties that

might have to deal with the confusing aspects of this.

Just to go back to one point, when the comment was made to individuals when they find the prescription drug was appointed to them changes the set-up for the plan, that they could just make an adjustment. That is not entirely accurate that they can make an adjustment on the spot. Don't they to have wait a certain period of time before they have the opportunity again?

Mr. SCHONDELMEYER. With the way the plan is structured, they are locked into that plan for a year, and they can't change to a different plan. And the next year they don't know the certainty that that drug will be there and will be covered for a year.

Mr. TIERNEY. I hear they are stuck for a period of time, and it's so confusing the first time, they're reluctant to change at all. You go through the process again.

Mr. ANDERSON. You are dealing with the most vulnerable people. They have a new illness, And now all of a sudden they are faced with a drug plan that isn't covering that particular new illness, or that doctor tells them that this drug used to work for you, it used to work, but it doesn't work anymore, and you need another drug, and that drug's not on your formula.

Mr. TIERNEY. Proponents of this Medicaid Part D, they have been prescribing lower than expected cost estimates and

drug plan previews of the program. They then contend that this provides evidence of drug plans and negotiating discounts. Is that actually true? Is that what is happening here, or is it primarily that there is lower enrollment?

Mr. SCHONDELMEYER. There is lower enrollment. There are slightly lower premiums, but as was pointed out by a Member earlier, you have to look at the whole package, and if you look at the whole package, as has been pointed out by Dr. Anderson, I don't believe the total cost is lower. It is higher than what was previously expected.

Mr. TIERNEY. In 2007, did the individual Medicare Part D premiums increase?

Mr. ANDERSON. In many cases they, in fact, did.

Mr. TIERNEY. How large?

Mr. ANDERSON. Some of them went from $1 a month to $10 a month. Some of them weren't that big of an increase, but many of them increased.

Mr. TIERNEY. So is it true that the drug prices are higher than the VA's in many instances?

Mr. ANDERSON. We don't know the data. If we knew the data, we could answer that definitively, but the best answer that we have with incomplete evidence that we are paying--the Part D plans are paying substantially--the Part B plans are paying substantially higher prices than VA.

Mr. TIERNEY. I don't know for the record that that was

introduced into the committee, but the subcommittee to veterans' affairs had hearings up in my State, and then the Secretary Mr. Principi testified very clearly that savings would be more substantial if the procurement process of Medicare Part D more closely resembled that of the Veterans Administration. So it depends on time there.

If we look at those findings that cost more than--the VA pays more than what it costs in Canada, more than it costs at Costco's, drugstore.com, is there any convincing evidence that you gentlemen can cite that the Medicare plans were able to obtain low prices from drug manufacturers?

Mr. SCHONDELMEYER. I don't see it in the prices that they post to Web sites for the most part. You can find two or three drugs that you can find to be the case. But I have had graduate students taking data off the Web sites every week since the first day of the program last year across 50 drugs, across every plan available in about 10 different markets across the country, and we don't see evidence of widespread price reductions.

Mr. TIERNEY. I want to close and get this in if we can. The President put out a budget last week. In it he contained a provision that I am finding difficult to understand. He proposes in fiscal year 2008 to eliminate the best price provision for Medicaid law. Good idea or bad idea?

Mr. SCHONDELMEYER. Bad idea because it is one of the few market-based functions in that program. The best price is set by the market, and it keeps the amount of rebates having a market base to it.

Mr. TIERNEY. Mr. Moorman?

Mr. MOORMAN. I agree.

Mr. TIERNEY. So there is no rationale for eliminating entirely and giving way to the pharmaceutical industry.

Mr. MOORMAN. A lot of them haven't been paying the best price, and this is the best way to wiggle out of it.

Chairman WAXMAN. Thank you, Mr. Tierney.

Mr. Bilbray.

Mr. BILBRAY. I have to admit I sort of feel I am in a time warp here. I left Congress in 2000, and I had sort of taken the attitude then--or the discussion that was going on when Mr. Waxman and I served on Energy and Commerce working on health issues, I would almost think that that is some kind of weird parallel universe. The Republicans are talking about quality and service, choice to the consumer and the related increased costs, and the Democratic Party is talking about savings, cutting, bringing it down to the minimum expense in trying to reduce that impact.

And so I am a bit taken aback by the discussion, but I think that the one thing comes clear to me. I represent an area with some of the highest concentration of veterans

anywhere in the world: San Diego. Just in our--so when you talk about the veterans, I know what my veterans say about their veteran program and this new program. And believe me, though I would probably have not voted for the Republican proposal a few years ago, if I go back now and tell my veterans that I was going to eliminate this choice that they have had and they are choosing, they would basically be running out with the hangman's knot to take care of them.

So I think, you know, when you look at California where the comparison--where you have like 34 access points for veterans, but this new program gives over 5,000 access points, I think there has got to be a consideration that things aren't as simple as they may look here.

But I agree with you that we need to look at the impact on those who have made a choice, the consumer who's decided that this is a menu with a price tag, and that price tag or that menu, the price on that menu, should have some life expectancy for the consumer, and I think that is a simple thing that we can work on.

What isn't simple is the fact that when you move the different market share and impact on a single industry from 50 or 34 access units to 5,000 just in one State, there is a bigger impact and less of a wiggle room economically for that industry than there was with a very small micropart of the deal. We are talking about really moving into a huge angle

here; I mean, a portion of it.

My question is there is--are we really keeping in our minds, too, while we do this there is the elephant in the backyard or closet that we are not talking about? Is there an industry anywhere in America that spends more percentagewise on research and development than the pharmaceutical, biomedical research--I mean, do we know if any of them--would anybody try to venture? Would we agree that this industry tries to do more?

Mr. ANDERSON. I can't answer that question, but I know of no other industry that rigs the government more.

Mr. BILBRAY. If you take oil and drilling and those kinds of things, then they actually do spend more money on R&D oil if you do not consider the issue that you brought up, government oversight and regulatory guidelines in the industry, because one of the major costs that are in R&D are not specifically R&D, but regulatory oversight, which is a major issue.

My concern when we do this is let's take care of consumers. Let's try to take care of the price, but let us always remember in the back that there is a huge genie out there that has been producing miracles that we take for granted now. And as we try to ramp this down, we have to consider if we are talking about long-term benefits to the consumer. Wouldn't you agree that we have to consider as we

do this the long-term impact on investment in research and development and the creation of new benefits, new drugs not just for the consumer, but for those of us in government that would have to pay the price of illnesses because we didn't have these breakthroughs? And you seem to be the most critical. Do you think we should ignore the R&D impact in the long run or make sure we keep those in while we are looking into the abuses?

Mr. MOORMAN. I am not a specialist in that, but I am interested in the taxpayers as I am the consumer, And I don't want him ripped off.

Mr. ANDERSON. I think if you look at the numbers, R&D represents 12 to 15 percent of their expenditures. It is not like it's 50 percent. And it is their lifeblood, and we certainly need to know it. The question is who should pay for it? Right now it is the United States that is paying for most of the R&D, and especially it is the Medicare senior that is paying for most of the R&D in the world by the pharmaceutical companies, and the question is is it appropriate for the Medicare senior to be paying--who has gaps in coverage--to be the one that is paying for most of the R&D in the world?

Mr. BILBRAY. Wouldn't you agree that the consumer, be it the government paying it or the consumer of the drug, always pays R&D for any product in the free enterprise

system?

Mr. ANDERSON. Sure. But essentially what we have got to have is make sure with these varying different prices that Part D plans are planning that the Part D plan's paying, that the VA is paying, that we have got to think about whether we want the Medicare senior to be the one who's paying for the pharmaceutical R&D in the world.

I'll say it again. The consumer is going to pay for it no matter what.

Mr. BILBRAY. Your point is there are American benefits going around the world. I hope we remember that when Congress starts talking about giving free drug benefits to the rest of the world and doesn't put our seniors first in line for those benefits because the political pressure isn't being put for those consumers that the rest of the world is getting.

I yield my time.

Chairman WAXMAN. The gentleman's time has expired.

Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chair.

I want to go back into this--the whole drug pricing, and I am wondering if you could tell me how the lack of transparency is complicating the oversight of these programs in a little more detail. Both of you doctors touched in your testimony on the transparency. I think people think there is

transparency, because if I log on to the sites to do a comparison with any of my seniors, I see the cost of the drug shows up under the plans. So people would think there is transparency, but that is not the transparency you gentlemen are talking about to reduce fraud.

Mr. SCHONDELMEYER. That is not the only one, but you need transparency at other levels and about other decisions. Logging on to the Web site can just tell me if I'm buying a specific drug to treat my heartburn, does that exact drug have different prices across different plans. And I can only make that choice once a year, and the plans change their formulary several times a year, so that may shift.

But what is really more important is if you all remember the Medicare Part B program pays for certain medications administered in a doctor's office, and under that program, the way the payment was set up, which isn't greatly different than what we have in the Medicare Part D program now, in some ways the drug companies were able to list much higher prices and then sell them at a huge rebated discount to the physicians. And the physicians were making huge margins, and they made more money by prescribing higher-priced drugs. And, yes, the market worked because physicians did prescribe more higher-priced drugs where they got more money.

But we changed that to the average sales price system instead of the mark-up off of AWP that we used to have under

Medicare Part B. In many ways, the Medicare Part D program allows rebates to be paid on a hidden basis from a drug company to the prescription drug plan, and it will affect the drugs they call their preferred drug, and so you may get prescribed a higher-priced drug than one that works just as well, just as safe, just as effectively, but isn't the preferred drug and costs less.

But that is not a choice you can make as a consumer when you log onto that Web site, and consumers don't have the knowledge often to know I could get this drug, and instead of this drug, it is a different drug, but it would work just as well. We usually don't know that.

So I would argue this market, because of its very structure and the complexity, doesn't work, of course, effectively at the consumer level. The physician doesn't know the prices. The prescription drug plan has an incentive to maximize their rebates and revenue and profits, not necessarily lower the cost of the program. And they can finagle a way to make the premiums lower without making the total costs lower. And we don't have a way to detect it when we don't have the rebate information to look at its effect on formularies and other decisions being made.

Mr. ANDERSON. You give the pharmaceutical industry a 17-year patent, but it gives them a virtual monopoly to set prices, and if I am the Part D plan and I am negotiating

against a monopoly, I can't do very well.

Mr. SCHONDELMEYER. There are also protected carriers where the prescription drug plan has to take all of the drugs in that category to put them on their formulary, which means they have very little leverage to protect their prices anyway. So we said we are going to call prescription drug programs a private market, and then we took away the tools that they could use in the private market, and we're still calling it a market.

Ms. MCCOLLUM. Mr. Tierney touched on the confusion that many of the people we represent have in providing for plans. I am still hearing from folks in Minnesota. I was out in someone's home the other day, and she had all of these plans laid across her table, 87 years old, trying to figure out what to do.

I also hear from pharmacists that people are bringing their plans in to try to figure out does this plan have the right drugs for the right kind of interaction for, you know, what might be happening in the future; and physicians, too. Has this made this more cumbersome and burdensome on physicians and health care providers as well as pharmacists?

Mr. ANDERSON. I believe it has--I have a paper I can't talk about, it is coming out in the Journal of American Medical Association at the end of the month, that talks about the doughnut hole and the problems that physicians are having

when they are in the doughnut hole, and dealing with low-income Medicare beneficiaries who are saying, I don't have the money to get through the doughnut hole, what do I do? Do I go to the VA? Do I go to other places? Do I go to Canada? And that forces us to remain in the doughnut hole. So this article basically tries to provide some physicians some guidance on what to do when you are Medicare beneficiaries in the doughnut hole, and is low income and doesn't know what to do, and it's something that the doctor has never dealt with before.

Mr. SCHONDELMEYER. In reality, what happens is if I am a consumer, I choose the low-premium, no-deductible plan, lowest cost to me. Then I'm more likely to reach the doughnut hole earlier. But when I choose that low-premium, no-deductible plan, I don't think about the cost of the individual drugs in January when my first prescriptions are being written by the doctor. The doctor provides whatever they want, whatever is on the formulary. If it is a higher price, fine. Then in September or October, I hit the doughnut hole, and I find out the drug costs $160, and the doc says, well, we can change you, come back in for a new office visit. More costs to me. I can change your prescription--and no cost to Medicare, by the way. I can change a prescription to a different drug, and we will have to retitrate your dose, do some new lab tests, and we can put

you on a lower drug that works just as well now that I know you are in the doughnut hole, and it's a fact.

So the way we designed this program results in added costs of physician visits, lab tests and added stress and strain on the patient having to adjust their therapy during the year to try to get a lower price in the market.

Chairman WAXMAN. The gentlelady's time has expired.

Mr. Sali.

Mr. SALI. Mr. Schondelmeyer, I understood you to testify earlier that the amounts that the various government programs actually pay for drugs, individual prescription drugs, that you weren't able to get that information, and that that was part of the reason why you say there is not transparency in the pricing; am I correct about that?

Mr. SCHONDELMEYER. That is a fairly big statement. I am able to get certain government information, but not--I don't know how much an individual patient paid for an individual prescription at the pharmacy versus what is posted on the Web site. Yes, the Web site has a price on there, but I have no way of verifying as a researcher is that the transaction price that, you know, senior citizens would pay if they went into that pharmacy and bought the prescription. I don't know how to verify that as a researcher without--short of data from the government; because of HIPAA and other things, I can't get access to that.

Mr. SALI. You can't get information under HIPAA as a researcher or under the Freedom of Information Act--under HIPAA as a researcher or under the Freedom of Information Act on specific amounts that have been paid by the government?

Mr. SCHONDELMEYER. I can work through HIPAA and Freedom of Information, but I'm not aware that CMF or anybody is making that price information available to researchers at this point in time. And if you are, I would like to know.

Mr. SALI. Have you made a request under Freedom of Information or HIPAA for any of that information?

Mr. SCHONDELMEYER. I have not for that specific information.

Mr. SALI. Mr. Anderson, would you agree with me that the single most important success in reducing drug prices in the last decade was Wal-Mart's offering 333 prescriptions for $4 a month?

Mr. ANDERSON. As a researcher, I don't know if that is true or not. The Wal-Mart program has been in existence for a relatively short time. It is hard to figure out whether or not other companies will follow that. I know that some have, and I don't know what impact it will have on utilization. So I think it's a great step forward, but I couldn't answer your question.

Mr. SALI. Is it your testimony before this committee that you're not aware of the details of Wal-Mart's offer of

330 prescriptions for $4 a month. In spite of that offer and your lack of knowledge about it, you are suggesting today that greater government involvement in drug pricing is the cure for fraud and abuse in drug pricing; is that correct?

Mr. ANDERSON. I think that you have got to look at the 330 drugs that are selling which are pretty much all generic drugs. There are no brand-name drugs on that list, and really the mark-up and the difference that we see is in the brand-name drugs, not in the generic drugs.

Mr. SALI. So you apparently do have some knowledge of Wal-Mart's offer?

Mr. ANDERSON. Not a research knowledge, but a general lay person's knowledge on this.

Mr. SALI. So you have researched everything else but Wal-Mart's offer itself?

Mr. ANDERSON. I have not written a paper. I have not studied in detail. It hasn't been around long enough to do a research analysis on it yet.

Mr. SALI. Mr. Moorman, you were critical a little earlier about the Department of Justice and claiming they have a mechanism to prevent, execute fraud and abuse, but they won't do it and you specifically said that money has been withheld within the--I don't have the information right in front of me--the health care fraud and abuse account, something like that. Let's see. It was the health care

fraud and abuse control account for health care. You claim that money had been withheld from that, and so there weren't attorneys working on these areas.

Are you suggesting that the Department of Justice is really the one, the organization, that we should be investigating for fraud and abuse in this area?

Mr. MOORMAN. I don't think it's fraud and abuse, but I think that this committee has government oversight. Look, each year in recent years the Attorney General and the Secretary of HHS allocate a certain amount of money to the U.S. attorneys and to the Civil Division for health care fraud cases. Thirty million has been the annual figure which has been allocated generally to the U.S. attorneys.

Mr. SALI. Your claim is that money is being withheld. We aren't prosecuting those cases?

Mr. MOORMAN. Attorney General Peter Keisler, in a letter to the House Judiciary Committee on August 11th of last year, said that the U.S. Attorneys were only getting 10 million of the 30 million allocated to them.

Mr. SALI. We have put this program in place in the Department of Justice to go in and investigate this and prosecute it, and now that is not happening. Is your suggestion that we need more government to go control the government and investigate them for fraud and abuse?

Mr. MOORMAN. No. What I am suggesting is this

committee find out why the lawyers who are handling these cases aren't getting the resources that have been allocated to them.

Mr. SALI. And would it be your conclusion, then, if that was done, the drug fraud and abuse, that it would--that it would be curtailed by those activities then?

Mr. MOORMAN. I wouldn't call it fraud and abuse. I would call it some form of government mismanagement. I would like to know what happens to the $114 million that goes to the FBI.

Mr. SALI. My question is we have this account set up, health care fraud and abuse control account.

Mr. MOORMAN. Yes.

Mr. SALI. And if that money were utilized properly, and those attorneys were actually prosecuting those cases, do you believe that that would help curtail the fraud and abuse in drug pricing?

Mr. MOORMAN. There are 180 cases against the pharmaceutical companies--

Mr. SALI. Yes, or no?

Mr. MOORMAN. If they had more lawyers, they could handle those cases better.

Mr. SALI. Do you think it would help or not?

Chairman WAXMAN. The gentleman's time has expired. Yes, it would help, or, no, it wouldn't?

Mr. MOORMAN. Yes, it would help.

Chairman WAXMAN. Mr. Cooper.

Mr. COOPER. Mr. Moorman, citing Peter Keisler's letter that there are a backlog of about 180 cases, and that is probably just in the Medicaid False Claims Act area, are there other cases that we need to know about in the backlog?

Mr. MOORMAN. Yes. There have been cases that have been filed by States' attorney generals sometimes under State false claims act, sometimes under other authorities, and States that don't have them. And there are sort of related class actions that have been filed on behalf of people who pay copays with regard to these frauds.

All told, we don't really know the actual number of cases that are out there against the pharmaceutical company involving this fraud against Medicaid or Medicare-related, but it is a substantial number, and it involves a lot of money. It is at least 180, and we know cases have been filed that he has said that it is at a faster rate than they are being resolved.

Mr. COOPER. They're being resolved at least at about 3 percent a year.

Mr. MOORMAN. Yes.

Mr. COOPER. So at that rate it would take 60 years to resolve these cases?

Mr. MOORMAN. Theoretically, but we know they will never

last that long.

Mr. COOPER. But with the new cases being filed, do we have any idea of the number of new cases being filed?

Mr. MOORMAN. That's hard to pin down because under the False Claims Act the cases are always filed sealed, so the only person who would know that would be the Justice Department.

Mr. COOPER. And we need to ask them that question, but assuming that there are about three new cases filed every year, we would never reduce the backlog at this rate even over 1,000 years?

Mr. MOORMAN. Never. And that is the situation where actually--because more than three are filed. I know from the grapevine that more than that are filed, because whistleblowers call me, and I--who have these kind of cases, and I refer them to lawyers, and I get more than three a year, I can assure you.

Mr. COOPER. To the average person back home, this looks awfully suspicious to have one of the most powerful lobbies in Washington or in any State capital see such a slow legal process and perhaps deliberate underfunding of the very DOJ attorneys who are supposed to be resolving these cases--

Mr. MOORMAN. Yes. I think people would be suspicious of that. I am not making any charges, but I also think that if the--if we acted forcefully with regard to all of these

cases, we could actually perhaps get the pharmaceutical industry to have an attitude change towards Medicare and Medicaid.

Mr. COOPER. As expenditure for government money for every dollar on these DOJ attorneys and U.S. attorneys, can you estimate the return to the U.S. taxpayer in terms of successfully resolved cases?

Mr. MOORMAN. Economist Jack Meyer has done a series of studies on this, and his most recent one last year indicates the Justice Department gets back $15 for every dollar that they spend on these cases--that are spent on these cases. Those estimates, by the way, were made with the assumption that the Justice Department was getting the full amount of HICPAC money that they were entitled to. Since they are getting less, it could well be that they are getting $25 back for every dollar. Some numbers we haven't quite figured out yet, but let me put it this way: We're not losing money in pursuing these cases. It's not--it is very cost-effective.

Mr. COOPER. I am not aware of any other government where for $1 of taxpayer funding we receive a minimum of $15 back and possibly, as you say, $25 for every dollar we spend. Are you aware of any other government spending that is this productive for the taxpayer?

Mr. MOORMAN. I am not.

Mr. COOPER. As Mr. Anderson, Dr. Anderson mentioned

earlier, the 10-year predicted liability for this Medicare Part D drug program is estimated to be $1 trillion. The longer-term liability, according to the Treasury Department, is supposed to be $7.8 trillion. Some people celebrate that because it is actually slightly cheaper than what it was predicted; it is supposed to be $8 trillion as opposed to 7.8-.

I think we need to remind ourselves, looking at the big picture, that most all of this is completely unfunded. There never has been an entitlement program passed in American history that is this unfunded. So that strikes me as truly remarkable because here we are stimulating demand for pharmaceuticals, which you know in many cases we need to do, but we are completely shirking the obligation for paying for those pharmaceuticals because these are numbers that will be added to the national debt, and since China and other countries--or other countries are increasing, our large creditors, those countries are being asked to fund our drug habit, which is a pretty curious situation to put our seniors in, the folks who need these medicines the most.

So I'd like to remind my colleagues that we would be lucky if this program only cost $1 trillion. It is at least 7.8 trillion, and the amount--you say if the estimate, cost estimate, has already doubled just within the last 2 or 3 years, the 7.8 trillion could double, and we are really in a

situation where we have to look at price to get taxpayers and patients value for their dollar.

I see that my time has expired, Mr. Chairman.

Chairman WAXMAN. Thank you.

Mr. Yarmuth.

Mr. YARMUTH. Thank you, Mr. Chairman.

I am glad my colleague mentioned the Wal-Mart situation because when I look at that plan and see that it is possible to buy a prescription for $4 a month, I come to a couple of different conclusions, one of which is that if they can sell it for $4 a month, why shouldn't everybody be able to buy that; and that there is obviously a lot of room to lower prices. Would that be your conclusion from the Wal-Mart plan as well?

Mr. ANDERSON. I think definitely. I think where you are going to see the most reductions, though, where there is competition, where that is in the generic market. I think when you don't have competition in the brand-name markets when it is a sole drug, you won't get Wal-Mart setting those things for $4, and that is where the government, I think, needs to intervene.

Mr. SCHONDELMEYER. I wouldn't necessarily conclude the same thing. First of all, $4 for prescriptions, even if the drug didn't cost Wal-Mart anything, is more than the pharmacist's time to dispense the medication, I am sure of

that. So Wal-Mart then is selling at a loss leader price or predatory pricing level on the $4 plan.

And the Web sites I have checked on Medicare and the prescription drug programs, I haven't seen anyone telling me that I can get that $4 prescription at Wal-Mart under Medicare. Is Medicare getting the advantage of that $4 price? Not that I am aware of. I would encourage the committee to ask Wal-Mart if the Medicare program is getting the price that you are talking about.

Mr. YARMUTH. That segues into another question I have. Some people have mentioned the fact that premiums, some premiums, with the Medicare Part D program have been lowered since its inception, and I have read in some various media that one of the reasons that this happens is not necessarily because they have been able to negotiate lower drug prices, but they have used that plan as a way to market their company to sell a higher-priced Medicare Advantage Plus type of program. Is that--to your knowledge, is that also the case?

Mr. SCHONDELMEYER. I haven't thoroughly analyzed it, but now that we know that seniors have made their second choice, once we have some data, we can begin to look at who shifted and what reasons did they make their shifts. Working at the University of Minnesota, we are currently fielding a study to analyze issues like that. In about 2 or 3 months we will have an answer for you.

Mr. YARMUTH. We talked about research, and the pharmaceutical companies do a lot of research. We know they do. But my experience, at least in talking to people at the University of Louisville and other places, is that most of the initial research done on pharmaceutical, new pharmaceuticals, are done by scientists at places like the University of Louisville where they just developed the cervical cancer vaccine. That research is primarily funded by taxpayer dollars, whether through NIH grants or through the State--just the State subsidy to the higher institutions. And then the pharmaceutical companies, all of that research having been done, come in and take that experimental drug at that point through the process.

So a great deal of the formative research and development is done by--funded by taxpayer dollars exclusively not because they pay for the product, the end result, but because taxpayers are refunding the same result.

Mr. ANDERSON. You just doubled the NIH budget recently because you believed that it would come up with new research, some of it in drugs and some of it in other areas. I applaud you for doing that especially at John Hopkins. I applaud you for doing that, but at the same time we need to work on technology transfer so that when NIH works on these drugs, they become available, especially a lot of the orphan drugs, a lot of the drugs that NIH does specialize in. There is a

market for that.

Mr. SCHONDELMEYER. You testified about an important point there with respect to research and development. At first we have to separate research from development, and by research I mean the work done to discover an innovative new therapy as opposed to the work done to come out with a therapy you can market after you lose your first patent, and you change the shape of the molecule a little bit or you change the dosage form.

Secondly, I would ask does our current market--regulatory and market structure work to reward innovation? I would give, as an example, the company in America, the brand-name company that markets the most cancer drugs has more than 20 cancer drugs. How many of those cancer drugs were discovered by that company? Zero. Now, they're still very profitable and very successful. Is that an example of how the market is rewarding innovation? I don't think so. It's rewarding marketing, it's rewarding development, but not innovation. In fact, it rewards people who are not very innovative.

Mr. YARMUTH. Thank you very much.

Chairman WAXMAN. Thank you.

Mr. Sarbanes.

Mr. SARBANES. You know, if you are the brand pharmaceutical industry, and I really--I distinguish between

the two because I think there is much more criticism that can be made of the brand industry and, frankly, criticism of the way we deal with the brand industry. But if you are that industry, you're a pig in mud.

I think when you listen to this testimony, you know, the industry--it is as though they have a giant console in front of them with 5,000 little buttons, and they can just pick which buttons to press to make sure that the edification of the public and I think of Congress and Washington is maintained depending on what the response happens to be at any given moment in time.

In terms of dealing with the Medicare beneficiary population, I think they have a Plan A and a Plan B. Plan A is the one that is in play right now, and that is okay, great. Government is coming along with a Part D program, and there is going to be government funding now available for all of these beneficiaries to go into the market and purchase prescription drugs. So what we ought to do is first let us make sure that nobody can come negotiate with us directly on behalf of that huge population. That is the first thing we should do.

The second thing you should do is we should endorse the idea of it being an indirect program, not have it directly administered by Medicare, because if it can be indirect, if we can get all of these plans into the mix as kind of sort of

intermediaries, that will help kind of cloud what is going on with the pricing and create the illusion of competition as driving prices down. But in the meantime, we can do all of these other things that you have mentioned to make sure that we can keep the prices up.

Third thing, let us throw the doughnut hole into the whole mix, because right at the point where people who are sick are needing to get that coverage, sort of, you know, they have to step in and pick up the benefit, and that helps the plans, and in turn that will help us because we are standing behind that scheme. So that is Plan A.

What we are talking about now in the last 2 weeks of having authorized the Secretary of HHS to go in and negotiate directly, and I think over time hopefully looking at more direct administration of Part D, the way we have done with Part A and Part D, is maybe we are going to force them into Plan B. But Plan B is pretty good, too, because Plan B is when the government comes directly to bargain with us, let's make sure nobody really understands the prices, AWP and AMP, and this rebate and that and so forth.

Let us say we get to Plan B. How do we nail down what the pricing is that will allow the government to get the best price, to be able to negotiate effectively on behalf of Medicare beneficiaries? And I regard the relationship between the government and the Medicare population as a

fiduciary one. When I hear beneficiary, I hear of a fiduciary relationship. So we ought to be doing everything we can to make sure we get the best price; how do we catch this smoke, and that is what it is, to make sure that the consumers and the beneficiaries and the government and the taxpayers are getting the best price?

Mr. SCHONDELMEYER. I first would like to address that and thank the Member for asking the question, and it is particularly relevant to you. I think I'll tell you why in a moment.

I think first we ask drug companies to report their prices as we have, the average manufacturer price to the government, but I think that reporting should carry with it a required certification by the CEO of the company much like the Sarbanes-Oxley provision.

Mr. SARBANES. I've heard of that.

Mr. SCHONDELMEYER. I think it is a required certification, and the reason I say that is I have had the privilege and/or task of serving as an expert witness in cases involving pricing and drug pricing issues in the marketplace, and while I can't discuss specific cases, specific issues, I have seen more times than I would like to in those cases internal memos inside drug companies showing they fully understand the government policies and regulations. They carefully analyze the options, and they

say, this is a choice that would give us the most revenue and profit. It may not be the best approach in terms of the public, or even may not be legal in some cases, but it is the best business decision even if we have to get caught and pay the costs. So that tells me, first of all, there is not enough accountability. And second, the penalties aren't high enough when they do get caught.

Mr. SARBANES. Thank you.

Mr. ANDERSON. Other countries purchase drugs just like the United States do, and I think one of the things we have got to take a look at is how does the U.K. Do it, how does Canada do it, a variety of other countries there. They're able to get around a lot of the smoke and mirrors.

Chairman WAXMAN. Thank you.

Mr. Welch.

Mr. WELCH. Thank you, Mr. Chairman.

I would ask Mr. Schondelmeyer and Dr. Anderson if you could make two recommendations on what we could do to reward innovation versus marketing and development, what would that be?

Mr. SCHONDELMEYER. One is you have a pediatric provision that says if you do pediatric studies in the marketplace, you get an extension of your exclusivity or patent time. I would move that up so you have to do those studies within the first 2 years of the drug being on the

market to get them. Don't tack it on at the end of 15 years and say, we will find out if it is good for a cause after we have used it for 15 years. Require it up front. That will require innovation and better studies up front.

Secondly, we should develop a government Medicare program and Medicaid program and a private market that rewards paying for true innovative products, and don't keep paying for these marginal manipulations in dosage form or strength or a different-shaped molecule, but will pay the cost of the new true innovative therapies even though it is higher. But take the funds out of--or create real competition across those products that are just simply patent extenders with the fourth or fifth or twelfth patent money given the drug product.

Mr. ANDERSON. I would like to emphasize that essentially what I would call it is looking at the value. And essentially what you would have is NIC, which is the U.K. System, to evaluate--is they are looking for drugs that actually have additional value over the replace--the drugs that they are replacing, and they should do that. And so Congress should spend and either give it to ARC or give it to NIH or somebody, a sizable amount of money to look for value in new drugs, to really take a look and make sure that these drugs that are being developed are valuable, and for those drugs you do need to pay a premium. Companies do invest a

lot of money in these new drugs. You know, Pfizer just spent $900 billion to develop a drug, and then it didn't work for a cholesterol drug. They have to be rewarded for those kinds of things, but it is only for truly innovative drugs.

Mr. WELCH. Next question. What two steps would each of you gentlemen recommend that Congress take to get the best price for our taxpayers and consumers without compromising innovation or eroding the quality of the care that prescription drugs can provide to our citizens?

Mr. ANDERSON. For me, it would be two things. One is price transparency to really know how much the different drug companies are charging, the different Part D plans, and I really care about the lowest price that any of the Part D plans can do.

The second thing I am concerned about is utilization, and essentially what we know is that two-thirds of the drugs and two-thirds of Medicare spending is by Medicare beneficiaries with five or more chronic conditions. And we have got to develop ways to monitor utilization to get appropriate care coordination done for those Medicare beneficiaries of five or more chronic conditions. And if we take it from the marketplace, most of those companies have developed stuff around the healthy population, not the sickest population, you know, basically the workers at various companies. We don't have good models around people

with multiple chronic conditions.

Mr. SCHONDELMEYER. Related to that, I think one is performance-based utilization of pharmaceuticals, and make the medication therapy management provision real and functional in the law. Currently each prescription drug program has to have a plan in place, but from what I can tell, those aren't very effective, and we aren't seeing much impact or effect from those in the marketplace. And utilization deserves a lot more attention than it is getting right now.

Second, I think you could fund evidence-based research both in terms of policy and in terms of drug product. The government does fund a lot of science research that does help find new drugs, but we fund very few studies that compare blockbuster A and blockbuster B.

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Mr. SCHONDELMEYER. Nor do the drug companies fund those because they often don't want to know the answer, or they know the answer and don't want to do the study. So the only people that really have a motivation to do that would be the public or major payers for health care.

So we need a process and a system that funds Blockbuster A versus Blockbuster B with well-defined studies and with scientists that aren't captured by the drug company coattails and research funding coattails and that can make independent decisions about what is the best use of our resources.

Mr. WELCH. Thank you. I yield the balance of my time.

Chairman WAXMAN. Thank you very much, Mr. Welch.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

And, gentlemen, first of all, thank you for your testimony. And, Mr. Moorman, your testimony--all of your testimony--is quite depressing because we are the ones that go into the senior citizens' houses and see people who are choosing between trying to pay for prescription drugs and provide heating and food, and they have to make these choices; and it is so sad. And as I listen to you, Mr. Moorman, I could not help but think that in answer to some other questions you talked about how we have got a situation

where people are basically--pharmaceutical companies are sort of waiting it out because they know that the Justice Department will not get to the cases.

And, you know, it strikes me that as soon as I finish this series of questions, I am going to go out and meet with 12 constituents who walked from Baltimore over here. They are former felons. All of them have been to prison. And they are coming here trying to get a better Baltimore with regard to crime rates.

I think about what you all have said here today, and I am confused. Is there fraud? And if there is fraud, then just like those guys that are standing out there right now in the cold, somebody ought to be going to jail, because what we are doing here is we are literally taking money away from two sets of people.

As a trial lawyer, I can tell you, I have seen it. I have seen folks steal $1,000 and go to jail. On the one hand, you have got taxpayers who are being defrauded and you have got elderly people in my district and every single district, all 35 districts of this country, who are catching hell because they can't afford the prescription drugs.

You know, Dr. Schondelmeyer, you said something that is very interesting when you were talking to my colleague from Baltimore, Mr. Sarbanes.

You talk about Sarbanes-Oxley. I am wondering--this is

a question, and all of you can answer this--is this a question of whether we need more teeth in the law you have or, Mr. Moorman, is it a question of will? In other words, is it--do we have the will to say to folks if you are going to take money away from the citizens of the United States that we are going to prosecute you?

Now I know you talked about the civil cases. But did we have the criminal penalties? Because I am convinced that when you start seeing some of these folks, they do a good job, the folks that do the television piece they show them going to jail handcuffed and everything. And I am just wondering, do you see, Mr. Moorman--when you hear from whistle-blowers, is a lot of this stuff a scheme that you get a impression goes way up the ladder?

Or is it--and it sounds like, Dr. Schondelmeyer, what you just said, if I was a--we have got the U.S. Attorney sitting right behind you, by the way--we are talking about some criminal stuff that somebody ought to be not civilly prosecuted, but should be going to prison.

So I am just wonder where--and others will sit here and say, well, you know we ought to smack them on the wrist. Well, guess what, those guys I am about the meet, nobody smacked them on the wrist; they sent them to prison. So help me with that.

Mr. MOORMAN. Can I address this? I think that in order

to bring these, a lot of them, business plan frauds of companies, I think the way to bring it to a stop is to make them give the money back and take all the profit out of this, this whole thing. This false claims act, for example, provides for triple damages. Yes, maybe a few people should go to jail. But they are going to take the risk as long as there is profit in it. The civil remedy is actually--if it will be pursued more vigorously--will be more effective than the criminal remedy, in my opinion, but the criminal remedy should not be forgotten.

Mr. SCHONDELMEYER. You pose the question as if there were two issues, one teeth; the second, the will to do something about it. I think there is a deficiency in both areas.

I think we don't have enough teeth. But even the teeth that exist, the cases aren't being prosecuted, we don't have the will to prosecute them very effectively. So I think we are deficient in both the will to pursue them and the teeth to make a significant enough penalty that it becomes a deterrent.

Mr. ANDERSON. And I would add a third thing and that is the word "confusion." i think there are so many different formulas out there, and it is very difficult for any person to understand how these formulas are set; so with a lot of confusion, that is the possibility both of fraud but also,

just lots of extra money flowing out because of the confusion.

Mr. CUMMINGS. Thank you very much.

Mr. COOPER. I was wondering where a lot of these fantasy drug prices came from. And looking at the inspector general's testimony, one of them, Mr. Robert Vito of the Philadelphia district, says, Average wholesale prices--which are not defined by law or regulation--are compiled in drug compendia such as Medical Economics' Red Book and First DataBank's Blue Book. As the findings of our reports have consistently demonstrated, the published AWPs that States use to determine their Medicaid drug reimbursement amounts generally bear as little resemblance to the prices incurred by retail pharmacies.

What is you gentlemen's opinion of the Red, Black and the Blue Book? Do they add value to the marketplace?

Mr. SCHONDELMEYER. I think they add value, but I think we need to look at how their practices occur. And in reality the drug companies are the ones who--either drug companies and/or wholesalers report information to these firms. So they largely are a collector and a processor and distributor of information. But there are practices they engage in that can also create problems in the market. And there is a case currently against First DataBank and some issues of changing the price in the market.

There is a case where the AWP was increased over the WAC substantially in about 2001-2002 across the board on all products in the market, which meant that the marketplace and everybody who paid for prescription drugs based on WAC or AWP, which is virtually every government and private program in the country, they paid 8 percent more that year rather than 6 percent more for those drugs just because of that one administrative change in that company.

So I think there is a need for some oversight of those firms. But it is not them alone; it is the prices reported to them also, by the manufacturers that drive it.

Mr. COOPER. You say because one private company made a mistake or a change that we pay 2 percent more for drug prices.

Mr. SCHONDELMEYER. For those drug products that had their drug prices increase, yes, every private payer and every Medicaid and every public payer, yes, that base is a peer WAC and nearly all do, except for a system like the VA. That is entirely closed.

Mr. ANDERSON. I agree with what he said.

Mr. MOORMAN. I would say that there is a considerable amount of evidence that has been developed in cases where average wholesale price has been seriously abused by pharmaceutical companies because the prices tend not to be based on the average or any actual wholesale price whatever,

but are there to give, but are increased incentives, for example, for the pharmacies to use their drugs. In other words, they are inflated for the purpose of increasing incentives to pharmacies to provide their drugs, and cost is borne by the taxpayer improperly.

Chairman WAXMAN. Let me just ask you one bottom-line question. When we have decided we are going to pay for drugs for seniors under Medicare, can you think of any other system that could be even more expensive than the one that was designed by the Republicans? And second of all, can you think of a system that is even more expensive than the one designed by the Republicans?

Mr. ANDERSON. Well, as I look around the world to see, I don't see a more expensive system.

Mr. SCHONDELMEYER. I can't think of a system that would be much more complex, which means then that consumers have difficulty making wise decisions, which means it really isn't an efficient market. So, no, I can't think--we could tweak it and make it a little worse. But I can't think of many ways to make it a lot worse.

Mr. MOORMAN. I would say the complexity in the system magnifies the opportunity for frauds and drives the cost up. It has to be simplified.

Chairman WAXMAN. Sounds like a dream for the pharmaceutical industry. That is a rhetorical comment.

Thank you, very much for your testimony. We appreciate you being with us.

We will now move to our second panel. We have four government witnesses on this panel. John Dicken will be testifying on behalf the General Accounting Office. Lew Morris will be testifying on behalf of the Office of the Inspector General of the U.S. Department of Health and Human Services. Ron Tenpas will be testifying on behalf of the Department of Justice. And Patrick J. O'Connell is the Chief of the Civil Medicaid Fraud Unit of the Texas Attorney General's Office.

STATEMENTS OF JOHN E. DICKEN, DIRECTOR, HEALTH CARE, GENERAL ACCOUNTABILITY OFFICE; LEWIS MORRIS, CHIEF COUNSEL TO THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; RONALD J. TENPAS, ASSOCIATE DEPUTY ATTORNEY GENERAL, U.S. DEPARTMENT OF JUSTICE; AND PATRICK J. O'CONNELL, CHIEF, CIVIL MEDICAID FRAUD SECTION, OFFICE OF THE ATTORNEY GENERAL OF TEXAS

Chairman WAXMAN. We welcome each of you to our hearing today. Insofar as you have a prepared statement, that prepared statement will be entered into the record in its entirety.

It is the practice of this committee that all witnesses testify under oath. So if you would please rise and raise your right hand, I will administer the oath.

[Witnesses sworn.]

Chairman WAXMAN. The record will indicate that each of the witnesses answered in the affirmative.

Mr. Dicken, why don't we start with you. I will keep the timer on for 5 minutes. We ask you to try to keep your oral presentations to around 5 minutes.

STATEMENT OF JOHN DICKEN

Mr. DICKEN. Thank you. Mr. Chairman, members of the Committee, I am pleased to be here today as you examine oversight issues related to drug pricing in Federal programs.

With projected annual Federal spending for prescription drugs from retail sources approaching $100 billion by next year, it is increasingly important to have effective oversight to ensure the accuracy of the price information that drug manufacturers and private plans report to Federal agencies. However, as you have heard, recent litigation involving allegations that drug manufacturers and pharmacy benefit managers reported inaccurate price information has resulted in several of these private organizations agreeing to paying hundreds of millions of dollars to States or Federal programs. These settlements illustrate some of the oversight challenges in this area.

My comments today highlight findings from reports GAO released in 2005 examining rebates that manufacturers pay State Medicaid programs and in 2006 examining maximum prices established for certain federally supported entities known as 340B prices.

I will also discuss the new Medicare Part D program, which shares certain features with these and other Federal

programs that could pose oversight challenges.

Finally, I will discuss several potential areas for future congressional oversight of these programs.

Regarding the Medicaid drug rebate program, we have reported inadequacies in CMS's oversight in price information reported by manufacturers to determine the rebates owed to States. We reported in 2005 that CMS conducted only limited checks for errors in prices manufacturers reported, and that did not generally review the methods and underlying assumptions that manufacturers use to calculate pricing information.

We also noted that CMS did not always provide clear guidance for manufacturers to follow when determining prices including, for example, how to treat sales to PBMs or properly disclose certain price concessions. CMS recently issued a proposed rule that is intended to provide for clarity.

We have also reported inadequacies in HRSA's oversight of the 340B drug pricing program. Because 340B prices are based on data provided by drug manufacturers for the Medicaid drug rebate program, inaccuracies in those amounts also affect the 340B program.

Further, we reported in 2006 that HRSA did not routinely compare the prices actually paid by certain eligible entities with the 340B prices that are intended to be a maximum price.

In fact, we found that many of these entities paid prices for drugs that were higher than the 340B prices.

These oversight inadequacies are confounded by a lack of transparency in 340 B prices. Because 340B prices are not disclosed to the eligible entities purchasing drugs, the entities are unable to determine whether the prices they pay are at or below the 340B prices.

HRSA has made changes to its oversight of the 340B pricing program intended to address some of these concerns.

The Medicare Part D program shares with the other Federal programs certain features that could pose similar oversight challenges. For example, like the Medicaid drug rebate and 340B drug pricing programs, the Medicare Part D program relies on private organizations that sponsor drug plans to calculate and report price information to CMS and relies on CMS to ensure the accuracy of that information. Other features of the Medicaid Part D program, such as its reliance on contracts with multiple insurers to provide drug coverage to beneficiaries through a complex set of relationships and transactions, also suggest areas of potential oversight challenges.

These findings suggest areas the committee may wish to consider as it develops its oversight agenda. For example, the committee may wish to consider the extent to which CMS and HRSA will systematically ensure the accuracy of prices

reported and charged by private sector organizations.

Specifically, once the proposed rule relating to pricing information is finalized for the Medicaid drug rebate program, it will be important to examine whether CMS is effectively ensuring that all appropriate transactions and price concessions are reported, and that clear, up-to-date guidance is available in a timely manner.

As the Medicare Part D benefit begins its second year, it is also important to assess the measures CMS will take to ensure that the price information Part D sponsors report reflects price concessions negotiated with drug manufacturers.

Finally, the committee may wish to examine the extent to which cognizant Federal agencies will effectively monitor and detect for abuses in the reporting of drug price information that affects Federal programs.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you or other members of the committee may have.

Chairman WAXMAN. Thank you very much.

[Prepared statement of Mr. Dicken follows:]

******** INSERT 3-1 ********

Chairman WAXMAN. Mr. Morris, be sure the button is pushed.

STATEMENT OF LEWIS MORRIS

Mr. MORRIS. Good afternoon, Mr. Chairman and distinguished members of the committee. I am Lewis Morris, Chief Counsel at the Department of Health and Human Services, Office of Inspector General. I appreciate the opportunity to appear here today to discuss health care fraud in the pharmaceutical industry.

In my written testimony, I describe three areas of fraud and abuse perpetrated against the Federal health care programs by some in the pharmaceutical industry. In broad terms, these areas include pricing schemes, marketing schemes and fraud in the delivery and dispensing of prescription drugs.

Simply put, the Medicare and Medicaid programs have paid too much for prescription drugs because of fraud in the pharmaceutical industry.

Working collaboratively OIG, the Department of Justice and State Medicaid fraud control units have achieved impressive results in the fight against fraud in this industry. The investigation and prosecution of these schemes

is resource intensive, time consuming and requires extensive coordination between Federal and State agencies. Furthermore, the parties engaged in these frauds are sophisticated, well financed and well versed in the vulnerability of our reimbursement systems.

My colleagues on this panel will describe how these fraud schemes operate and the successes we have achieved in investigating and punishing corporate wrongdoers. Accordingly, I will devote my time this morning to another aspect of the government strategy for achieving greater integrity in the pharmaceutical industry.

The OIG has a unique set of administrative authorities to sanction health care providers engaged in fraudulent and abusive practices. Specifically, OIG has the authority to exclude unscrupulous and untrustworthy individuals and entities from the Federal health care programs.

The effect of exclusion is profound because Medicare and Medicaid will not pay for items or services furnished during the period of an exclusion. An excluded physician or health care company is effectively out of business.

In addition, OIG can use its administrative authority to seek substantial monetary penalties for a range of fraudulent and abusive conduct, including the submission of false claims to Medicare and Medicaid. Of particular relevance to today's discussion, we can impose a penalty of up to $50,000 for each

kickback payment plus up to three times the amount of the kickback. These penalties can be substantial in large fraud schemes and are a powerful deterrent. These administrative sanctions complement criminal and civil antifraud efforts and provide an additional avenue for government enforcement.

OIG is using its authority to impose civil penalties on kickback recipients, such as physicians who may previously have been under the misimpression that they can demand kickbacks from drug companies with impunity. Hopefully, OIG administrative enforcement will prompt those physicians and others who incorrectly believe they can skate under the government's radar to think twice before seeking or accepting kickbacks.

But enforcement standing alone will not address this problem. For this reason, OIG continues to promote the prevention of fraud and abuse by encouraging voluntary compliance efforts by the pharmaceutical industry. To this end, the OIG issued a compliance program guidance for pharmaceutical manufacturers that provides detailed information for drug manufacturers on operating an effective voluntary compliance program.

The guidance identifies fraud and abuse risks, including most of the fraud schemes described in my written testimony. It also describes concrete steps manufacturers can take to reduce their potential liability and thereby promote

integrity in the system.

OIG also issues a range of additional guidance, such as advisory opinions and fraud alerts. We also undertake frequent outreach efforts as part of our overall strategy to encourage compliance by everyone who participates in the Medicare and Medicaid programs.

In conclusion, there are no simple fixes to the problems you have heard about today. Those intent on abusing the Federal health care programs are adept at modifying their schemes to respond to changes in reimbursement systems and government enforcement efforts. Consequently, Federal and State agencies must continue to develop proactive enforcement strategies. Strong reasons make for strong action. Of equal importance, pharmaceutical manufacturers and other participants in the health care systems should be encouraged to embrace policies and procedures that promote compliance with Federal program rules.

Thank you for the opportunity to discuss the IG's fight against fraud in the pharmaceutical industry. I would be pleased to answer any questions.

Chairman WAXMAN. Thank you very much, Mr. Morris.

[Prepared statement of Mr. Morris follows:]

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Chairman WAXMAN. Mr. Tenpas.

STATEMENT OF RONALD J. TENPAS

Mr. TENPAS. Mr. Chairman, I appreciate the opportunity to appear before you to discuss some of the issues that are the focus of today's hearing.

We at the Department of Justice share the concerns expressed by members of the committee this morning that illegal conduct by some in the pharmaceutical industry has caused government health care programs to pay too much for pharmaceutical products.

I am grateful, Mr. Chairman, for this opportunity to discuss our enforcement efforts as you address these issues.

The commitment of the Department of Justice to root out and punish corporate fraud has special urgency in the context of health care fraud where the public dollars are so large and where fraud can also have a direct and negative impact on public health and patient care. That is why the Department of Justice, through the Civil and Criminal Divisions, our United States Attorney's Offices and the Federal Bureau of Investigation, continues to fairly and vigorously enforce the laws protecting our taxpayers and the patients served by our health care system.

In doing so, our prosecutors and agents work closely with Mr. Morris and his colleagues at the Office of Inspector General at the Department of Health and Human Services, with Mr. O'Connell and his fellow State law enforcement officials, and with the various State and Federal agencies who bear the cost of the types of schemes I more fully discuss in my written testimony. We also continue to work closely with "qui tam" whistle-blowers and their counsel.

Many of these whistle-blowers have come from deep inside the pharmaceutical industry, and their assistance has been invaluable. As I know you are aware, Mr. Chairman, in 1996, Congress established the Health Care Fraud and Abuse Control program. The so-called HCFAC program provides a dedicated funding stream to the Department of Justice and others for work in this area.

Since that time, our Criminal and Civil enforcement efforts, funded through that program, have returned nearly $10 billion to the Federal Government, including 8.85 billion transferred the Medicare trust fund. We have secured more than 4,500 criminal convictions. Just last year, for example, in fiscal year 2006, our health care fraud enforcement efforts resulted in recoveries of $2.2 billion. Our United States Attorney's Offices opened more than 830 health care fraud investigations and charged a total of 579 defendants criminally.

Now, those numbers represent our overall health care fraud enforcement efforts. In the area of pharmaceutical fraud alone since 1999, we have recovered over $5.3 billion in matters involving losses to Federal and State programs. We have many matters under investigation, implicating pricing and marketing practices related to hundreds of drugs. Clearly, by any measure, funding for health care fraud enforcement has produced a multifold return for taxpayers and will continue to do so.

A good way to get a feel for the scope of our pharmaceutical enforcement efforts is through a review of the cases we have resolved in recent years. My written testimony, therefore, describes a number of those cases in detail.

In my opening comments, I want simply to summarize several broad categories into which these cases fall. First what one might describe as kickback violations, situations in which a drug company or its representative make payments to somebody with the power to influence the choice of drug for a patient, such as the primary prescribers, individuals making pharm formulary decisions, or pharmacists.

Second are off-label promotion violations. These are deliberate marketing efforts to sell a product for a use that has not been approved by the FDA. As with kickback violations, we are concerned that such marketing efforts can

undermine a doctor's judgment in providing the best medical advice possible to his or her patient and thereby undermine quality of care.

As I more fully explain in my written testimony, these off-label matters are concerned solely with the marketing efforts of pharmaceutical companies to capture larger market share for their products, often in the face of contradictory science.

The third broad category of our cases involve pricing violations. Frequently these schemes arise from the legal requirements to report to the Medicaid program the best price for the particular drug, as well as the pharmaceutical company's average manufacturer price. Whether by hiding discounts provided to certain customers, hiding sales through manipulation of NBC codes, failing to incorporate free samples into price computation or other acts, the common element of these schemes is, the government fails to get an accurate accounting of the prices on which rebates to Medicaid are determined.

These inaccuracies can have pass-through effects to the 340B program.

The fourth category are manufacturing process violations where a pharmaceutical manufacturer departs from an FDA-approved process.

In conclusion, let me thank you again for the

opportunity to be here today. Health care fraud, including violations related to pharmaceuticals, has been and will continue to be an area of great importance for the Department of Justice. We appreciate your interest and I welcome your comments and questions.

Thank you.

Chairman WAXMAN. Thank you very much Mr. Tenpas.

[Prepared statement of Mr. Tenpas follows:]

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Chairman TENPAS. Mr. O'Connell.

STATEMENT OF PATRICK J. O'CONNELL

Mr. O'CONNELL. Thank you, Mr. Chairman, members of the committee, on behalf of Attorney General Greg Abbott of Texas I thank you for the opportunity to come testify to you today.

And I want to make sure that you understand--and I know you do--that the Federal Government is paying a whole lot of money for these programs, the States are also paying a whole lot of money for these programs.

Texas is basically a 60/40 State. So every dollar that gets spent in Texas for drugs that we have overpaid for, 60 cents of that dollar is being paid for by the Federal taxpayers and 40 percent is being paid by Texas taxpayers.

In fiscal year 2005 the Texas Medicaid program paid $2.41 billion thorough pharmaceutical products. The sheer volume of those dollars involved provides a huge enticement for those that would attempt to defraud the program.

To give you a little history about what we have done in Texas, in 1997, then-Governor Bush signed into law the Texas Medicaid Fraud Prevention Act with its "qui tam" provisions, one of the first States to do that.

In 1999, in response to concerns about growing claims of

fraud and abuse, the Texas attorney general created the Special Civil Medicaid Fraud Section within the Attorney General's Office, and I have had the privilege of heading up that section since its inception. We have investigated and pursued and recovered claims against doctors, dentists, hospitals and other providers involving typical claims of false billing, false cost reporting and overbilling. However, the overwhelming majority of our time and efforts have been concentrated on drug manufacturers.

I want to make it clear. Did we target or place special emphasis on drug manufacturers on purpose? No, we did not. What happened was, whistle-blowers brought us cases, insiders from these companies showed us that significant fraud was being perpetrated on the Texas Medicaid program, and so we choose to the pursue though cases which provided the greatest recovery for the Texas Medicaid program. Most of our time has been spent on pricing cases, and we have recovered in excess of $64 million. It doesn't sound like a whole bunch when compared with the billions of dollars that have been recovered nationwide, but we have spent almost all that time in two lawsuits. And Mr. Moorman made a couple of comments and I would like to reiterate. In those two lawsuits we have spent over 6 years fighting six drug manufacturers. We have settled with four of them. We are still fighting with two of them.

And my office, I had three or four lawyers to work on those cases. The Texas attorney general has now upped our section to 10 lawyers and we are doing, you know, the best we can to continue to pursue this litigation. But the fact is that in one current case, for example, one of the drug manufacturers, we have seen 18 lawyers on the other side show up in court or file pleadings or be in negotiations with us. And I have got enough for three lawyers to work on that case. So we are peddling as fast as we can, but we are struggling with those resource issues.

We have also developed--and I want to reiterate again that we have developed close working relationships with the Department of Justice and with the other States. We are doing this in the most efficient, best way we can to try to recover those dollars. Typically, if a fraud has been perpetrated on the State of Texas it has likely been perpetrated in every other State as well. And in that cooperative effort, the amounts that we have recovered from efforts by both the Federal Government and by Texas, working in concert with each other, far exceed $100 million just in Texas alone. And I think we are only about 6 to 7 percent of the total Medicaid budget.

While we have been fighting these battles over the last 5 or 6 years, the question might come to you, gee, is that all the fraud? Are you going to catch up and collect that

money and then we can go on down the road? And, of course, the answer is "no," that, as other members of the panel have indicated, we are seeing from whistle-blowers continuing claims of fraud in the pharmaceutical industry. And those include the ones you have already heard about, mainly in rebate fraud, pricing fraud.

And I want to pay special attention today--and it is in my written comments to off-label marketing which we see as a particularly strong area that we have got to look at. Not only does it cost the taxpayers a tremendous amount of money, but we are seeing evidence, not just in the cost of the drug, but in the cost of the medical care that we are having to give to our Medicaid beneficiaries who have been enticed by inappropriate off-label marketing to use these drugs, that then cause further medical problems for our Medicaid patients.

Again, thank you for the opportunity to visit with you today. And I am available for questions.

[Prepared statement of Mr. O'Connell follows:]

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Chairman WAXMAN. Thank you very much for your testimony.

All four of you are involved in trying to stop fraud in the health care area and particularly in the--specifically, prescription drugs. And, Mr. Tenpas, we heard testimony from Mr. Moorman earlier that there is a big backlog of these cases. You testified that when you pursue them successfully, it brings about a back a lot of money to the taxpayers of this country. Why is there that big backlog?

Mr. TENPAS. Well, I think, as Mr. O'Connell just captured, these are very complex cases. I think the fraud cases that the department deals with certainly rank amongst the most complex because the regulatory regime is complicated. As you have heard, there are--

Chairman WAXMAN. But is it less? Is it the case that less resources are going to the Justice Department to pursue these cases?

Mr. TENPAS. Absolutely not. With all respect to Mr. Moorman, he is simply wrong in suggesting that there has been any hold-back of the money in the health care fraud account of dollars provided to the U.S.

If I may, I think that the confusion here may arise from some testimony that has been provided earlier by the Department of Justice officials about the amount of money going to our U.S. Attorney's Offices for civil cases

specifically. And I think there may be some confusion that suggested that was the only money going to our U.S. Attorney's Offices. In fact, no, there is a substantial additional portion that goes to them to do criminal health care fraud enforcement work.

Chairman WAXMAN. But the civil cases get the money back. And that is really important to get that money back because if the companies realize they can't get away with fraudulently taking money from the government, that there is a chance they can get caught, that would certainly be more money for the government and, hopefully, less fraud. So, is it accurate that there is less money going to pursue civil litigation from the Justice Department on the health care fraud?

Mr. TENPAS. No, there is not less money. We have been fairly constant in the dollars devoted to our civil enforcement efforts. In addition, there is--we do criminal cases; we do them in parallel.

Chairman WAXMAN. You acknowledge there is a backlog of cases?

Mr. TENPAS. We do have a large number of cases that we have in our inventory right now that we would like to handle. We have some increased funding coming on stream thanks to Congress.

Chairman WAXMAN. Well, DOJ reported to the House

Judiciary Committee that the backlog is 180 cases. Does that sound right?

Mr. TENPAS. I think it is a little bit lower than that. We put--at this point, put it at little closer to 150, but it is in the ballpark obviously. It goes up and down.

Chairman WAXMAN. What does the large backlog what impact does that have on the thinking of pharmaceutical manufacturers that are contemplating fraudulent activities?

Mr. TENPAS. I think I would have to defer to them. Obviously, we like to get cases resolved as quickly as we can and get to the bottom of that.

I would observe--

Chairman WAXMAN. Mr. O'Connell said that he has 10 attorneys pursuing these issues for Texas alone. How many does DOJ have for the country?

Mr. TENPAS. We have approximately 50 attorneys in the Civil Division and here in Washington, D.C., every United States Attorney's Office in the country has a health care fraud coordinator, so there are 93 there.

Chairman WAXMAN. How many are pursuing these issues directly?

Mr. TENPAS. I am sorry?

Chairman WAXMAN. How many of those lawyers are pursuing these issues, pharmaceutical?

Mr. TENPAS. I don't know that I can give you a precise

count on that. It is going to move at any time.

Chairman WAXMAN. Let's get it for the record.

Mr. TENPAS. We would be happy to try to follow up.

Chairman WAXMAN. Thank you.

[The information follows:]

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Chairman WAXMAN. Mr. O'Connell, if they have so few attorneys for the whole country, what impact does that have on you?

Mr. O'CONNELL. Well, obviously we feel the pain of having to try these cases with the resources that we have. And every time a State attorney general has to devote resources to the case--and again the Federal Government has the ability to collect the 60 cents of the dollar that has been taken away from Texas, but they don't have the ability to collect the State's 40 cents in Texas. We have to collect that ourselves.

Every time that we have to go do it, then we have to take resources away from and dollars away from other programs, just like the DOJ folks do. And so the more they can pursue cases, the better for me; the more I can pursue cases, the better for them.

And again that is why I said we try to coordinate so that if I know the Department of Justice has spent a lot of time on a particular case, and I have the same case under seal in my office, I will go try to work on something else.

Chairman WAXMAN. What you said is that these cases aren't cases that the government has worked on to figure out what is happening; they are cases that are brought to you by whistle-blowers. Now, can you imagine a whistle-blower coming in and saying, I know there is this fraudulent

activity going on. And then they see that the cases sit there in a backlog for years. That has got to be discouraging to the whistle-blowers and encouraging to the fraudulent drug companies.

I am going to recognize my colleagues because my time has expired. Mr. Yarmuth.

Mr. YARMUTH. Thank you, Mr. Chairman.

Now, Mr. Morris, I want to ask you about illegal kickbacks where pharmaceutical companies offer some type of inducement to the drug companies to prescribe medicines they might not otherwise.

One of the largest settlements of this type involved a company called Serono and resulted in a $700 million settlement, the Department of Justice was able to get.

Can you tell me about the allegations in that particular case that led to such a massive settlement?

Mr. MORRIS. The Serono case? I am not sure, but I think the settlement amount may have been less. Would you be referring to the TAP pharmaceutical case, dealing with a prostate cancer drug, or the Serono case which dealt with AIDS wasting drugs?

Mr. YARMUTH. I was referring to the Serono case. I may have them mixed up.

Mr. MORRIS. I can give you a brief synopsis of both if that will help.

Mr. YARMUTH. We are trying to get information about the types of activities you prosecute and we need to deal with.

Mr. MORRIS. Certainly.

First with your question related to Serono, Serono manufactures an AIDS wasting drug, which obviously is a benefit to the AIDS population. There were evolutions in the pharmaceutical area, in that area, that were facing competition and loss of market share, as part of their effort to maintain and regain that, they engaged, we allege, in a number of illegal behaviors including inappropriate marketing of the drug. They also targeted physicians who were in a position to prescribe the drug and offered them substantial kickbacks and incentives to do so.

One part of their marketing strategy was referred to as the 6 million in 6 days. They targeted high-prescribing physicians with the objective of getting $6 million in prescriptions in 6 days. Those doctors who participated in this scheme were given all-expense-paid trips to Cannes, France, with associates to participate in a medical conference.

The other drug--the other company I referred to was TAP Pharmaceutical. The drug in that case was Lupron, which is a prostate cancer drug. Also, in response to marketing competition from another pharmaceutical manufacturer, it is alleged--and we believe there was substantial evidence to

demonstrate--that TAP Pharmaceutical gave kickbacks to doctors in the form of broad spreads between the charge that they billed the doctor for and what the doctor could then realize by billing the Federal health care programs, as well as other sorts of incentives to get physicians either to continue to prescribe their drug, or--what we feel is even more upsetting--to switch patients from the competitor's drug to the TAP drug so as to realize personal profit.

Perhaps the most alarming aspect of that case is that TAP illegally gave physicians samples, which one would expect to be given free to patients, but knowing that the physicians would, in turn, bill those samples to the programs. And the senior citizens, many of them on fixed incomes, would then be required to pay a 20 percent copay or $100 for a drug which, in fact, did not cost the physician anything.

Mr. YARMUTH. I am curious about where the bar is for what constitutes an illegal marketing practice. Anybody who has been in a doctor's office has seen very attractive men and women bringing cookies in to physicians and their nurses. I was aware of--I think everyone is pretty much aware, but I know of one case in my community in which a restaurant was hosting an event for a pharmaceutical company and the pharmaceutical reps, and this was to invite physicians to have a "continuing education program," so-called; and they are told that we only had $130 a person to spend to entertain

each of these physicians.

Now, in Washington and New York that is probably normal. But in Louisville, Kentucky, that is about twice what you would ever expect to spend. So I am curious to where the bar is as to what constitutes illegal activity and what may be some of the other types of illegal marketing activities you have seen.

Mr. MORRIS. Well, the range of illegal marketing activities are only limited by the imagination of those who are trying to prey on our program.

The critical aspects of the kick--when we look at a case or marketing scheme for kickbacks, I recall, first, that this is a criminal statute. It requires specific intent. And so we look to see whether the purpose of the marketing scheme is to induce referrals or the ordering of prescription drugs.

Certainly the other aspect of our analysis is to see whether the marketing scheme is intended to induce overutilization, induce distortion of the physician's medical decision-making so he or she is thinking more about their personal profit rather than the well-being of their patient. But they are necessarily case-by-case determinations.

And one of the challenges that we face with our partners at the Department of Justice is doing that factual analysis so that we can appropriately target our resources on those kickbacks which are most egregious.

Mr. YARMUTH. Thank you.

Chairman WAXMAN. Thank you, Mr. Yarmuth.

Mr. Cooper.

Mr. COOPER. Thank you, Mr. Chairman.

Mr. Tenpas, I thought I heard in your oral testimony that in the last 10 years the Department of Justice has recovered about $8.5 billion for the taxpayer in various health care fraud recoveries.

Mr. TENPAS. Yes, actually about 10 billion total; 8.85 billion of that ended up returned to the Medicare trust fund.

Mr. COOPER. Wow, that is a lot of money. Are you aware of any other area of our economy that has been guilty or caused so many infractions against the law resulting in such large recoveries?

Mr. TENPAS. There probably is not an area that in terms of recoveries to the United States has produced as much as the health care fraud arena. One way of sort of getting a sense of that, for example, last year, our recoveries were slightly over $3 billion and slightly over 2 of that was health care fraud-related recoveries. And of that 2, there was one major pharmaceutical recovery that played a big role in the 2 billion figure.

Mr. COOPER. And of this total of roughly $10 billion in health care fraud recoveries, over half of that or over $5 billion has come from the pharmaceutical industry?

Mr. TENPAS. Certainly over half. The 5.3 number that I provided went back only to 1999. So there is probably a little bit more on top of that in the couple of years before 1999, but ballpark you have got it about right.

Mr. COOPER. So even though pharmaceutical companies receive roughly 11 percent of total health care reimbursement, they have been guilty of infractions or fraud that are over 50 percent of the recoveries that you have achieved. They get $0.11 of the health care dollar, but here, half the recoveries or more are from this one industry.

Mr. TENPAS. You have got the math about right, yes.

Mr. COOPER. We heard testimony prior that when you prosecute these cases or bring civil cases that the recovery for the taxpayer is at least $15 for every dollar invested in government lawyers. And it might be as high as $25 for every dollar of government lawyers. To your knowledge, is that roughly about right?

Mr. TENPAS. We probably would be a little more modest about, I guess you won't often hear this, but we probably wouldn't put it quite as high as 15-to-1. I think it depends on which dollars you count as part of our base. But we would certainly agree it is a multifold recovery rate.

Mr. COOPER. So that would seem to indicate the government interest in having more attorneys to recover more money. Until you start, recovery is declining.

Mr. TENPAS. Yes. And we that interest. The President's budget last year had proposed an 11 billion--I am sorry, $11 million--increase for the Department of Justice. Because of the concurrent resolution way of dealing with the budget, that money ended up not being appropriated to us. The President's budget this year proposed about a $17.5 million increase. It would be very helpful to us if that were fully funded.

Mr. COOPER. The President's budget, as we heard earlier, also recommends eliminating the best price, which would set us back in terms of recovering money for the taxpayer. Well--so it is a good idea to have more government attorneys.

It is our information that of the 75 attorneys you have in your False Claims Act fraud staff that only about 10 or 12 of those folks actually work on health care false claims. Is that roughly correct? Because there are many types of false claims, and here we have established that health care false claims are remarkably productive for the taxpayer.

Mr. TENPAS. I don't think--I don't think those numbers are accurate. But I am reluctant to give you specifics right here today. I would ask for the opportunity to go back and follow up with you.

Mr. COOPER. If you could supply those numbers for the record that would be helpful because the attorney general on

your left, from Texas, has just testified for his whole State he has gotten 10. So it would be indeed tragic for America if we only had, you know, 10 or 12 or 15 working on this, since these cases seem to be so productive for the taxpayer.

Mr. TENPAS. We agree with you.

And one other thing I would just point out, in thinking about the department's resources devoted to this, you also need to take account of our United States Attorney Offices. We have 93 of them across the country--

Mr. COOPER. We understand that only a small handful are active on these cases. A lot of them claim to be, and they are encouraged by DOJ, but in terms of successful prosecutions and recoveries, it is a small handful. Philadelphia deserves credit, Boston may; but aside from those offices, we are having trouble finding real efforts.

Mr. TENPAS. I think part of that is certainly true. Those offices have been very successful. Part of what we find here is that these cases, because they have national implications, you have national marketing practices and such, we often have sort of some options about which office might best handle something. And because we have developed substantial expertise now in those two offices, there is a certain logic as to some of these cases to then go ahead and place the next case there with attorneys there.

Mr. COOPER. Final question: I see my time has expired.

Do you have any idea how many former DOJ attorneys have then gone to work for the pharmaceutical companies?

Mr. TENPAS. No.

Mr. COOPER. Can you help us with that information for the record, please?

Mr. TENPAS. I don't know of any way that we could determine that information. We don't typically track the ongoing employment.

Mr. COOPER. There is no alumni group of DOJ?

Mr. TENPAS. There is an alumni group of former United States attorneys, but there isn't much of a group with respect to the career prosecutors who may leave our department.

Mr. COOPER. So you don't think taxpayers should worry about a revolving door here?

Mr. TENPAS. I think that is not the first place, if I were in your seat, that I would worry about. We find that they are going to have talented counsel whether they are former Department of Justice officials or not in the pharmaceutical industry. And you don't want to provide a disincentive to talented people coming and joining the department by telling them that you are going to have a lot of limits on what you do, what you do next.

We make sure that if somebody leaves the department they are recused from any matters that they were working on while

in the department. They can't go out you know represent the folks that they were investigating the week before.

Mr. O'CONNELL. I am happy to report that none of the folks who have left my section have gone to work for drug companies.

Mr. COOPER. Good for you, Mr. O'Connell.

Chairman WAXMAN. Thank you, Mr. Cooper.

Mr. Welch.

Mr. WELCH. Thank you, Mr. Chairman. We have been told today about a number of cases of Medicaid fraud that have been successfully prosecuted by DOJ and, in this case, the State of Texas. There are very few ways to uncover the fraud. Usually, the cases are identified as you mentioned only when whistle-blowers come forward.

Mr. O'Connell, as a prosecutor for these cases, can you give us some insight? I am wondering, do the fraud cases that are successfully prosecuted represent just a part of the full spectrum of Medicaid drug pricing fraud? And is it likely that there are many fraud cases out there that we just haven't discovered?

Mr. O'CONNELL. I think it is fair to say that there are a lot of them out there, that have not been discovered. And as long as the False Claims Act, both in the States and in the Federal situation, is strong and provides for recoveries for whistle-blowers, we will keep seeing them. And, yes, I

think we are going to see more we haven't even thought of.

At my office, for example, we spend almost all of our time on what are known as AWP cases, or pricing cases, because those are the ones we started with; and once we opened those lawsuits up, those were the ones that ended up in litigation.

And in the process now we are seeing the off-label marketing cases, the rebate fraud cases, the ANP cases. So there is a myriad of different ways. And as my mates here said, we can't always think of every potential case of fraud that is out there.

Mr. WELCH. Mr. Tenpas, can you offer any perspective on this?

Mr. TENPAS. Well, we certainly believe there is still fraud out there to be found. And Mr. O'Connell is right that the whistle-blower community is an important resource for us in identifying those, there are other places we get referrals you know, anonymous tips, trying to look at data that HHS, itself collects--

Mr. WELCH. Let me ask you this. Can you offer any specific recommendations that would make it easier for your offices to uncover the fraud that is ripping off the taxpayers?

Mr. TENPAS. I think the best thing probably for us--well, first would be to have some funding for prosecutors

and investigators so that we can respond to the cases and referrals that we get through sort of the "qui tam" process so that is probably the single most helpful thing that the department could ask for at this point.

Mr. WELCH. Any changes in legislation?

Mr. TENPAS. We don't have anything that we are proposing at this point. Particularly with the focus on Part D, we are clearly concerned that there could be fraud in that program, but only being a year into it and the first major reconciliation not having occurred yet with the pharmacy companies, we don't have many of the conclusions yet in that arena.

Mr. WELCH. Okay.

GAO's prior reports on Medicaid drug rebates in the 340B program identified some important oversight inadequacies and a record of poor implementation. These reports by the HHS and OIG on the 340B program identified similar problems.

Mr. Dicken, how did these oversight inadequacies contribute to an environment that potentially allows for abuse?

Mr. DICKEN. Well, as you have noted that some of our past reports and work for our colleagues in OIG have found that there is a lack of clarity in some of the guidance and some limited oversight. And in that environment there can be different assumptions that manufacturers may be making. That

is something that we found when we looked at what was reported for the Medicaid drug rebate program. There were different assumptions made by different manufacturers, gives more circumstances that there may be unintentional errors and would seem to create an environment where there could be more potential for abuse.

Mr. WELCH. Mr. Morris, any thoughts?

Mr. MORRIS. On strengthening 340B or the broad question of addressing fraud?

Mr. WELCH. What Mr. Dicken was commenting on.

Mr. MORRIS. We would concur that there needs to be both greater transparency in the pricing mechanism and the way that the ceiling prices are established. We have also recommended in our reports that HRSA have the ability to impose sanctions on manufacturers who do not provide accurate information or do not provide it in a reasonable time.

So, confidentiality and transparency.

Mr. WELCH. Thank you. Mr. O'Connell anything to add?

Mr. O'CONNELL. I was going to add in our pricing cases. One of the things that I think has been helpful to our success is that the Texas Medicaid program was the only State to require manufacturers to certify certain prices to them.

And so we have forms that are required to be filled out by the manufacturers.

Mr. WELCH. Do you make the President and CEO sign that?

Mr. O'CONNELL. No. Unfortunately, it is usually some person down in the marketing department or in the sales department that--

Mr. WELCH. Should it be the President or CEO?

Mr. O'CONNELL. I would certainly think that would be an outstanding thing to do because, in fact, what ends up happening is the person signing the document is the one who doesn't know what the real prices are and doesn't realize that they are giving us a false price. That has been the testimony so far in these cases.

Mr. WELCH. Thank you. I yield my time.

Chairman WAXMAN. Thank you very much. The four of you have been revealing fraud primarily in drug prices in Medicaid or the community clinics because there the government's directly being defrauded. It is hard enough to pursue those cases because for the most part you have to get a whistle-blower to come forward and tell you about it. And then you can pursue it through government functions either at the State or the Federal level. And we do have a "qui tam" ability for lawyers to bring the lawsuits on behalf of the government.

But if you looked to Medicare, Medicare Part D pharmaceutical program is going to cost a trillion dollars over the next 10 years. I think it is $50 billion for this next year. That program has got to be as ripe for fraud as

any other. But, Mr. O'Connell, you will be out of it because it is not going to be a State issue, and since the--most of this is all through private insurance plans, Mr. Morris, if there is fraud going on, what role will you at the Federal Government level have to combat it, or even to know about it?

Mr. MORRIS. Well, I think I can answer it this way. We are bringing our enforcement and our oversight experience that we have gained in the Part B Medicare and the Medicaid programs to bear on the Part D programs, so it rolls out effectively and is the best deal possible for taxpayers.

Our approach is to cover five broad areas of the Part D benefit. Those include enforcement and compliance, payment accuracy and controls, beneficiary access and protections, drug pricing and reimbursement, and information technology and systems.

We currently have about a dozen different projects under way with our auditors, our program evaluators and our inspectors, looking to make sure that the system is going to work well.

Chairman WAXMAN. This is Part B or Part D?

Mr. MORRIS. I am sorry sir, Part D. So we already have a fairly robust set of programs under way to ensure the integrity of the Part D program.

Our work plan gives a great deal more detail about those, and we would, of course, be pleased to give you more

information if you would like.

Chairman WAXMAN. I would like that. If you have a work plan in writing it would like to receive it.

Mr. MORRIS. We would be pleased to submit that for the record.

[The information follows:]

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Chairman WAXMAN. What if there is a collusion? You have a private insurance plan offering the Part D benefit and they make a deal with the drug companies that they will steer people to the higher priced drugs and they will get discounts, but then the discounts aren't even passed on to the government or the beneficiary, but allow them to make more profit, and it is not visible.

Do you have any ability to be able to pierce that?

Mr. MORRIS. Well, I think you have hit on a theme that that has run through all of this testimony, the value of transparency.

Chairman WAXMAN. Don't you think this Medicare Part D system is very opaque? There is very little transparency because it is being handled by these private insurance plans, as opposed to the government?

RPTS STRICKLAND

DCMN SECKMAN

[1:00 p.m.]

Chairman WAXMAN. There is very little transparency because it is being handled by these private insurance plans as opposed to the government through Medicare Part B or Medicaid.

Mr. MORRIS. I don't personally have sufficient experience in the Part D program to be able to answer that. I will tell you that, based on our enforcement experience, that the greater the transparency, the more able government auditors and evaluators are to get raw data, the better we are able to ensure that the programs work the way they are intended. This applies to the Part B program, the Medicaid programs and certainly the new Part D program.

So having access to that data is critical not only to address system vulnerabilities, but it is also part of our enforcement strategy. While we do rely on whistleblowers for a tremendous amount of information, one of the other ways we engage in fraud detection is by doing systemic analysis of data and seeing where there are aberrations and targeting our investigative resources and the Department of Justice's prosecutive resources. So access to data, viable data is very important.

Chairman WAXMAN. Will you receive the data that the

drug companies have submitted to the CMS about their pricing?

Mr. MORRIS. We are currently working with CMS to ensure that we get access to that data.

Chairman WAXMAN. Well, I thank you all very much. I would just conclude by saying that I think this Medicare Part D, which is the most expensive program we have ever had for purchasing prescription drugs, is so complicated and so difficult to find any transparency in it that it just calls out for more fraud and a harder job for those who are trying to detect it and protect the taxpayers.

Thank you all very much. Anybody else have any other questions?

Mr. COOPER. A quick final point. I think the Department of Justice has a sister agency, the IRS, which has done an excellent job pointing out what is called the tax gap, the amount of moneys that are owed to the government but not collected. I would encourage the DOJ to find out more about that model. Because I am worried that there is a significant enforcement gap. Because if Mr. Moorman is even close to correct, that with an ill-defined backlog, you have no concrete idea of a possible $60 billion that are not collected of taxpayer money, that is a truly significant sum, especially in true view of your past successes. So with a few more attorneys, let's find out what that enforcement gap is.

Chairman WAXMAN. Thank you very much. We appreciate your participation, and this hearing has been very useful to us.

Without objection, we will hold the record open for 7 days. Some members may wish to submit questions to you and the previous panel, and we would appreciate a response in writing. Thank you. With that, that concludes our business. The committee stands adjourned.

[Whereupon, at 1:05 p.m., the committee was adjourned.]