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

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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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, DC.

The committee met, pursuant to notice, 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, subcommittee clerk; Kerry Gutknecht, staff assistant; 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, the 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 get 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 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 that 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 to 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 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 the 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. 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.

[The prepared statement of Hon. Henry A. Waxman follows:]

Opening Statement
Rep. Henry A. Waxman, Chairman
Committee on Oversight and Government Reform
Hearing on
Allegations of Waste, Fraud, and Abuse
in Pharmaceutical Pricing: Financial Impacts on
Federal Health Programs and the Federal Taxpayer

February 9, 2007

Today we 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 — the 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've worked hard to expand and improve health care coverage for seniors, for persons with disabilities, and for low-income families. And I've worked just as hard to make sure that taxpayers get their money's worth out of the Medicare, Medicaid, and public health programs.

That's why I'm 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 any time, but in this era 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 that drug manufacturers provide the Medicaid program with the same discounts they provide private purchasers like large HMOs and hospital chains.

But according to whistleblowers 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

We'll also hear about 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 Inspector General have found that these clinics are being overcharged for the drugs they need — costing them tens of millions of dollars annually. I look forward to hearing from the HHS Inspector General, and GAO about how to make this critical public health program work better.

Finally, we'll hear about the Medicare Part D program. This new program has been controversial from the start — passed in the dark of night, amid allegations that 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 the private pharmacy benefit managers and insurers that provide the benefits would be able to obtain 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 the plans are higher than prices in other federal government programs, higher than prices in Canada, and even higher than prices available at Costco and Drugstore.com. Beneficiaries are justifiably puzzled as they see out-of-pocket costs increasing and drug plan premiums skyrocketing at three to four times the inflation rate. Meanwhile, drug companies are reporting massive increases in their profits.

Dr. Schondelmeyer and Dr. Anderson will provide us with insight into what is happening with Part D drug prices.

This Committee will have an aggressive oversight agenda when it comes to pharmaceutical manufactures 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 Medicare Part D program. I am asking that these companies 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 have signed up for

Medicare Part D. This information will be critical as our Committee assesses whether high drug costs are increasing beneficiary costs and wasting taxpayer dollars in the Medicare drug program.

The testimony we hear today will help us establish additional investigative priorities for the next two years. I am looking forward to hearing from our witnesses.

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.

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 program 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 1 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 lacks the best-price provision that Federal price negotiators might get in that 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 10, 2007, CBO analysis into the hearing record.

Chairman WAXMAN. Without objection, it will be entered.

[The information referred to follows:]

CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

January 10, 2007

Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

At the request of your staff, the Congressional Budget Office has reviewed H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, as introduced on January 5, 2007. The bill would revise section 1860D-11(i) of the Social Security Act, which is commonly known as the "noninterference provision" because it prohibits the Secretary of Health and Human Services from participating in the negotiations between drug manufacturers, pharmacies, and sponsors of prescription drug plans (PDPs) involved in Part D of Medicare, or from requiring a particular formulary or price structure for covered Part D drugs.

H.R. 4 would require the Secretary to negotiate with drug manufacturers the prices that could be charged to PDPs for covered drugs. However, the bill would prohibit the Secretary from requiring a particular formulary and would allow PDPs to negotiate prices that are lower than those obtained by the Secretary. The bill would also require the Secretary to report to the Congress every six months on the results of his negotiations with drug manufacturers.

CBO estimates that H.R. 4 would have a negligible effect on federal spending because we anticipate that the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs under current law. Since the legislation specifically directs the Secretary to negotiate only about the prices that could be charged to PDPs, and explicitly indicates that the Secretary would not have authority to negotiate about some other factors that may influence the prescription drug market, we assume that the negotiations would be limited solely to a

discussion about the prices to be charged to PDPs. In that context, the Secretary's ability to influence the outcome of those negotiations would be limited. For example, without the authority to establish a formulary, we believe that the Secretary would not be able to encourage the use of particular drugs by Part D beneficiaries, and as a result would lack the leverage to obtain significant discounts in his negotiations with drug manufacturers.

Instead, prices for covered Part D drugs would continue to be determined through negotiations between drug manufacturers and PDPs. Under current law, PDPs are allowed to establish formularies—subject to certain limits—and thus have some ability to direct demand to drugs produced by one manufacturer rather than another. The PDPs also bear substantial financial risk and therefore have strong incentives to negotiate price discounts in order to control their costs and offer coverage that attracts enrollees through features such as low premiums and cost-sharing requirements. Therefore, the PDPs have both the incentives and the tools to negotiate drug prices that the government, under the legislation, would not have. H.R. 4 would not alter that essential dynamic.

I hope this information is helpful to you. The CBO staff contacts for further information are Eric Rollins and Shinobu Suzuki.

Sincerely,

Donald B. Marron

Donald B. Marron
Acting Director

cc: Honorable Joe Barton
Ranking Member

July 27, 2002

Honorable William "Bill" M. Thomas
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

You asked for further explication of CBO's cost estimate for H.R. 4954, the Medicare Modernization and Prescription Drug Act of 2002, in regard to three issues: the construction of our cost management factor (CMF), the explanation for savings from eliminating Medicaid's "best-price" requirements, and our estimates of participation in the proposed benefit. I appreciate the opportunity to add whatever clarity I can to those issues.

There has been confusion about the meaning of the 30 percent cost management factor that CBO applied in analyzing H.R. 4954. The CMF is an analytical construct to estimate the effects of policy changes on total drug expenditures, not on prices. The CMF does not solely represent expected lower prices. It is an amalgam of three types of savings from management —savings due to price discounts or rebates from manufacturers and pharmacies, savings due to controlling overall drug use, and savings due to changing the mix of drugs used. Many factors dampen the full effect of the CMF. First, many beneficiaries are expected to have drug coverage from another source (such as an employer or Medicaid). To the extent that their other coverage insulates enrollees from out-of-pocket spending, it will be harder for the plan to manage costs. Second, adding or expanding insurance coverage for prescription drugs is expected to increase both the use and price of drugs. Third, if a proposal requires competing plans that bear financial risk, savings from the CMF are offset by the plans' costs for marketing to beneficiaries and for being at financial risk for the benefit (such as the cost of purchasing reinsurance). Thus, the CMF for H.R. 4954 reflects potential savings but not the costs of the mechanisms to achieve those savings. Further,

the savings are stated as a proportion of total spending and do not represent a per-prescription discount.

H.R. 4954 would eliminate the requirement that any discounts realized by Medicare prescription drug plans must be made available to Medicaid (the so-called "best price" provision). As discussed in a CBO study, drug manufacturers offer a variety of discounts and rebates to various purchasers as they compete for sales.[1] The best-price provision constrains price competition. Manufacturers are less willing to give large discounts to private-sector purchasers because they must give the same large discounts to Medicaid, which constitutes about 10 percent of the market for outpatient prescription drugs. Similarly, manufacturers would be less willing to give large discounts or rebates to Medicare purchasers if the best-price provision were to apply. Eliminating the best-price provision would allow Medicare prescription drug plans to negotiate lower prices. CBO estimates that amending H.R. 4954 to make Medicare prescription drug plans subject to Medicaid best-price requirements would increase the costs of the bill by $18 billion between 2003 and 2012.

Finally, you asked about participation by Medicare beneficiaries in the new Part D drug benefit established by H.R. 4954. CBO estimates that in the first year of implementation (2005), 89 percent of beneficiaries enrolled in Part B would participate in Part D. For purposes of our modeling, CBO assumes that 7 percent of beneficiaries, who would have other prescription drug coverage, would not enroll in Part D. Combining those who participate in the new Medicare drug benefit and those who have drug coverage outside Medicare leaves 4 percent of Part B beneficiaries without drug coverage in 2005. By 2007, 3 percent of Part B beneficiaries would be without drug coverage, CBO estimates.

---

1. *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998).

If I can provide any further clarifications of our cost estimate, please do not hesitate to contact me.

Sincerely,

Dan L. Crippen
Director

cc: Honorable Charles B. Rangel
Ranking Democrat

Honorable W. J. "Billy" Tauzin
Chairman
Committee on Energy and Commerce

Honorable John D. Dingell
Ranking Member

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.

[The prepared statement of Hon. Tom Davis follows:]

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

TOM DAVIS, VIRGINIA
RANKING MINORITY MEMBER

ONE HUNDRED TENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

Majority (202) 225–5051
Minority (202) 225–5074

Statement of Rep. Tom Davis
Ranking Member
Committee on Oversight and Government Reform

"Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer"
February 9, 2007

Thank you Mr. Chairman for holding today's hearing to consider the potential for waste, fraud, and abuse in three federal healthcare 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 we 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 our health care delivery system – cost shifts between providers, payers and patients can be difficult to trace. But when payments shift unlawfully into someone's pocket, oversight systems have to be able to detect and recoup those losses.

So I'm 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 call that the "old way of doing things." We'll hear today how those systems have been scammed.

On the other hand, the Medicare Part D Prescription Drug Plan, passed in 2003, relies far more heavily on competitive market forces to get the best price for senior citizens. The Majority mistrusts that mechanism, alleging higher costs and a greater potential for fraud because the Part D program lacks a "best price" provision that federal government negotiators might use to get a better deal. The House recently passed H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, to give the HHS Secretary that negotiating authority.

With than in mind, Mr. Chairman, I hope this hearing is not an exercise in backward oversight: a conclusion in search of facts. There is no evidence the Medicare prescription drug benefit is more costly, or more prone to abuse, than the 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% 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. A recent Congressional Budget Office analysis of H.R. 4 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. [I ask unanimous consent to insert the January 10, 2007 CBO analysis into the hearing record.]

This is great news for America's seniors, and it's a direct result of competition and choice. It's 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. But we shouldn't base our oversight on premature conclusions about the efficiency of the pricing mechanism that is serving 33 million senior citizens so well today.

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 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 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, DC, 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 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 No. 1 in America in terms of prescription drug prescriptions per citizen.

We also rank No. 1 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 referred to follows:]

of Tennessee

Inside Tennessee's Medicine Cabinet

How Much is Enough?

A Blue Report on High Prescription Drug Use in Tennessee
and its Consequences

◆

Part of a Series of Special Industry Reports
From BlueCross BlueShield of Tennessee

Bill Cecil, Ph.D.
Director of Health Policy Research

Mary Thompson
Office of Public Affairs

Published January 2006

The Blue Report series is also made available on the BlueCross BlueShield of Tennessee Web site at BCBST.com

This Blue Report is produced with oversight by the

TENNESSEE MEDICAL ASSOCIATION

It's About Time!

Inside the Medicine Cabinet

More is not always better for health, nor is it affordable.

That's the message for Tennesseans when it comes to their high use of prescription medications.

Consider that the Volunteer State has the highest use per capita for prescription drugs at 17.3 prescriptions per capita and the second highest in per capita prescription drug spending at $1,192.56[1] ; yet, is ranked 47th in health status for its citizens.[2]

If higher overall medical spending, which includes prescription medications, doesn't necessarily equate to healthier populations, then what is the impact on health care outcomes? That's the question addressed in this Blue Report on Tennessee's high prescription drug utilization status.

According to the Institute of Medicine, drug errors injure more than 1.5 million Americans annually and just one error can add as much as $5,800 to a patient's hospital bill.[3] In addition to the problem of medication errors and adverse events, inappropriate use of prescription medications has the high potential for antibiotic resistance and abuse, which can lead to addictions.

Of course, appropriate prescription drug use has an enormous potential to add value and quality to life. But what is appropriate use and what are the use criteria that can provide the maximum health benefits to Tennesseans without undue increases in risks? The state's number one ranking for prescriptions and the consequences that come with that notorious title certainly set the stage for concern and scrutiny among the health care community, policy makers and patients across Tennessee.

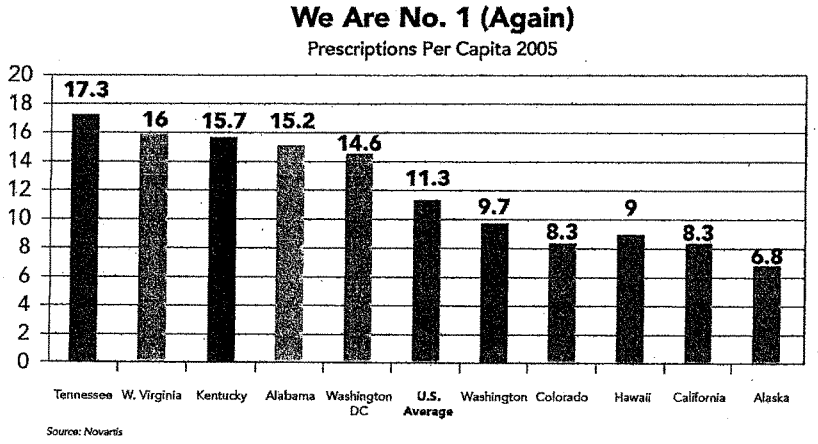
1. Novartis, Pharmacy Benefits Report, Facts and Figures, 2006 Edition
2. United Health Foundation et al, "Your State's Health," http://www.unitedhealthfoundation.org/shr2006/findings.html/#findings (accessed November 2006)
3. Institute of Medicine, "Preventing Medication Errors: Quality Chasm Series," National Academies Press, http://www.nap.edu/catalog/11623.html (accessed October 2006).

Prescription Drug Utilization Trends

Prescription drug spending in America reached $188 billion dollars in 2004 and is forecast to reach $299.2 billion in 2010. By 2013 that figure will double to a whopping $380 billion.[4]

In Tennessee the costs are staggering as well. According to Novartis, the prescription spending for Tennessee alone was $7 billion in 2005.[5]

As costs continue to rise, actual utilization has flattened at the national level, and even declined in Tennessee from 18.1 prescriptions per capita in 2004 to 17.3 in 2005. However, even with the decline, Tennessee still holds onto its # 1 ranking for prescription drug use.[6]



Tennessee remains the highest use per capita state for prescription drugs at 17.3 prescriptions per capita, 2.5 times the use rate in Alaska and 1.5 times the national average.

When it comes to costs, Tennessee is second highest in per capita prescription drug spending at $1,192.56 behind the District of Columbia. The national per capita prescription drug spend average is $835.08, while spending is lowest in Hawaii at $540.01 per capita.[7]

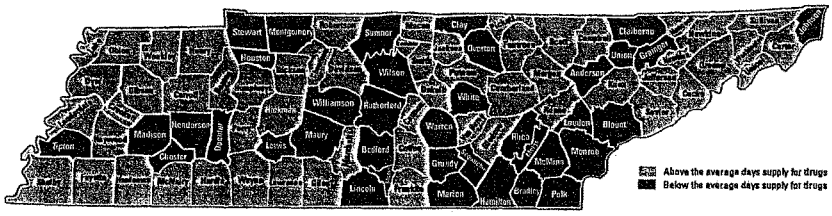
4. MedSolutions Web site. http://www.medsolutionsinc.com. Institute of Medicine, "Preventing Medication Errors: Quality Chasm Series," National Academies Press, http://www.nap.edu/catalog/11623.html (accessed October 2006).
5. Novartis, Pharmacy Benefits Report, Facts and Figures, 2006 Edition
6. Novartis, Pharmacy Benefits Report, Facts and Figures, 2006 Edition
7. Novartis, Pharmacy Benefits Report, Facts and Figures, 2006 Edition

Prescription Drug Use Rates

A review of the geographic distribution of prescription drug use in Tennessee provides a dramatic look at where utilization is highest in the state.

Rate by County

The statewide average days supply per 1,000 BlueCross BlueShield of Tennessee members for all prescription drugs is 249 days. While the average number of prescriptions per member per year is 8.9.[8] When comparing prescription drug use, the days supply of drugs, i.e. 30, 60, 90 days, can be more informative than the number of prescriptions alone.



Source: BCBST commercial population data

In the map above counties are shaded based on number of days supply of a prescription for BlueCross BlueShield of Tennessee members. The top 10 highest prescription drug use counties in descending order are:

1. Lake – 386 days supply
2. Bledsoe – 344 days supply
3. Weakley – 328 days supply
4. Campbell – 324 days supply
5. Lauderdale – 316 days supply
6. Obion – 315 days supply
7. Greene – 310 days supply
8. De Kalb – 310 days supply
9. Crockett – 302 days supply
10. Fentress – 298 days supply

8. BCBST Internal Data

Rate by Region

A look at the major metropolitan areas in Tennessee reveals that Memphis leads with 13 prescriptions per resident per year—8 percent more than the state average.

Region	Prescription Use Rate (Per Resident Per Year)
Memphis	13.0
Tri-Cities	12.7
Knoxville	11.9
Jackson	11.9
Nashville	11.8
Chattanooga	11.6
State-wide	**12.0**

2005 BCBST Commercial Network P data

Prescription Drug Use by Volume

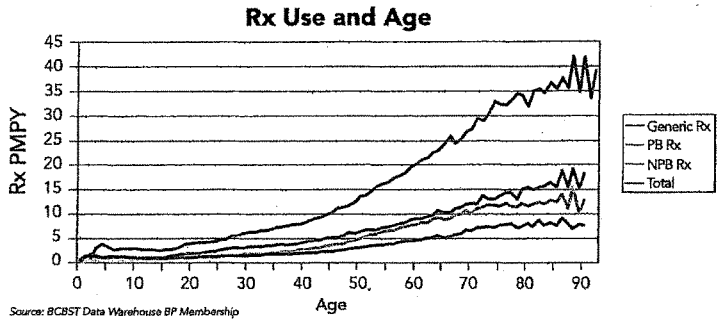
The top 10 most prescribed drugs in Tennessee represent 15 percent of total prescriptions dispensed across the state. The top 10 and their indicated uses are provided in the chart below.

Drug Name	Common Use	Percent of Total Prescription $
HYDROCODONE	Narcotic/Pain	2.8%
LIPITOR	Cholesterol	1.8%
NEXIUM	GERD	1.6%
ALPRAZOLAM	Insomnia/Anxiety	1.5%
LEVOTHYROXIN ESODIUM	Low Thyroid	1.4%
LISINOPRIL	Blood Pressure/Heart	1.4%
ZYRTEC	Allergy	1.2%
HYDROCHLOROTHIAZIDE	Blood Pressure/Water pill	1.2%
AZITHROMYCIN	Antibiotic	1.1%
METFORMIN HCL	Diabetes	1.1%

2nd Quarter 2006 BCBST Commercial Population data

Prescription Drug Use Demographics

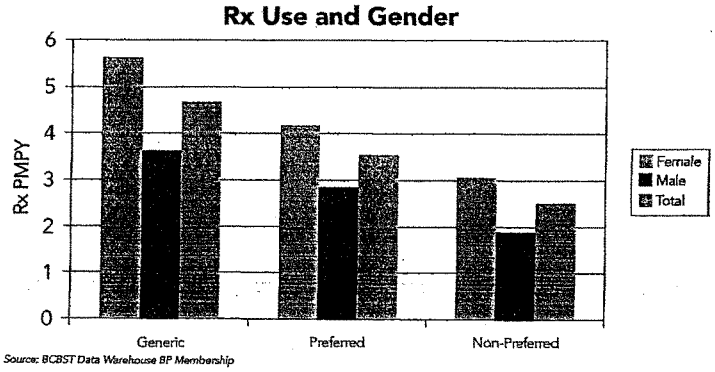
In addition to defining the geographic areas where prescription drug use is highest, it's important to understand who is accessing what types of medications. The following charts reflect the age and gender demographics in the context of medication type.



The relationship between age and drug use in the Tennessee commercially insured population is shown in the chart above by pharmacy benefit tier (PB = preferred brand; NPB = non-preferred brand) and in total.

As individuals age they have the propensity to use more prescription medications.

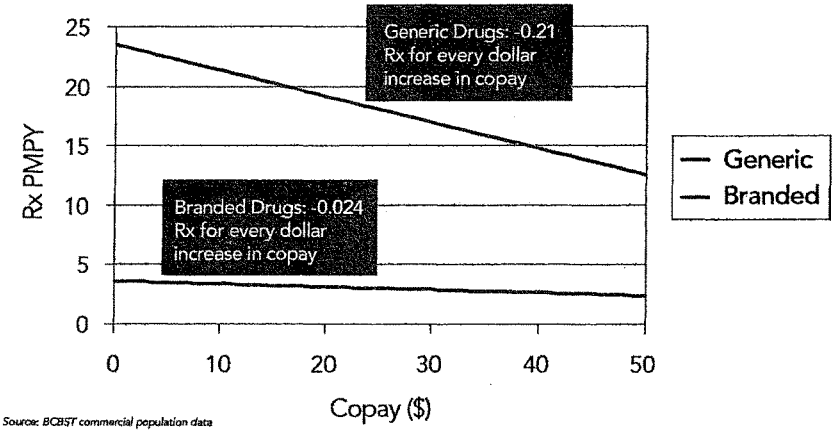
The relationship between gender and drug use by pharmacy benefit tier is shown in the chart below. Females use more prescription drugs than males for every drug benefit tier.



Copay Influence on Prescription Use

Factors beyond demographics also play into drug utilization rates. The prescription drug copay is related to the quantity of prescriptions purchased by an individual.

Relationship Between Rx Use and Copay



Source: BCBST commercial population data

The chart above shows the differences in utilization that are observed with higher copay levels. On average an increase in the copay by $4.76 reduces generic drug use by one prescription. Yet, it takes an increase in the copay by $42 to reduce branded drug use by one prescription.

In general, the higher the copay the fewer number of prescriptions purchased.

Consequences of High Prescription Drug Use

It's clear that Tennesseans are reliant upon prescription medications, but what do all these pill bottles and tablets add up to in terms of the state's health? A closer look at the consequences shows that more is not always better.

During the course of a single week, four out of five U.S. adults will take a prescription drug, over-the-counter medicine, or dietary supplement.[9] These medications can provide relief and miracle cures for many, but with those lifesaving benefits comes a myriad of hidden dangers. From medication errors and adverse side effects to antibiotic resistance and dependence, the inappropriate use of drugs can cause serious injury or death, as well as raise health care costs for everyone.

Medication Errors

The Institute of Medicine (IOM) report, "Preventing Medication Errors"[10] published in July 2006 cites studies indicating that more than 1.5 million Americans suffer from medication mistakes each year. Every day of a patient's hospital stay, he is subjected to a drug administration error. The IOM further estimates that annually there are 400,000 preventable adverse drug events (ADEs) in acute inpatient care hospitals, 800,000 preventable ADEs in long-term care facilities and 530,000 preventable ADEs among the general population.

Over 770,000 people are injured or die each year in hospitals from all (not just preventable) ADEs,[11, 12, 13] which may cost up to $5.6 million each year per hospital[14,15]. National direct ADE-related hospital expenses to treat patients who suffer ADEs during hospitalization are estimated at between $1.5 and $5.6 billion annually.[16,17] With 7,569 hospitals nationwide (US Census Bureau) the estimated total ADE hospital cost is $42.4 billion annually.

For Tennessee with its 136 hospitals, the estimated ADE hospital cost tallies up to $761 million annually.

The cost of physician services and non-hospital costs to treat ADEs and the loss of income are not included in this estimate.

The risk of ADEs is one that extends beyond the confines of the hospital. A study in the Journal of the American Medical Association indicates that more than 700,000 patients were annually treated for ADEs in U.S. emergency rooms during 2004 and 2005. Of those visits, 1 in 6 required additional care, i.e. hospital admission.[18]

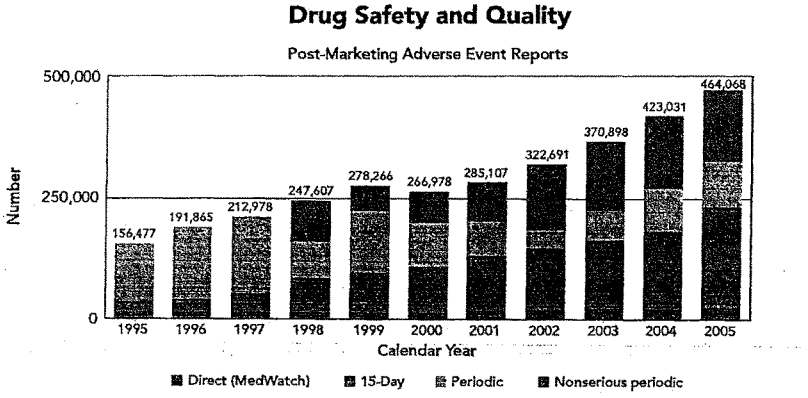
9. Institute of Medicine, "Preventing Medication Errors: Quality Chasm Series," National Academies Press, http://www.nap.edu/catalog/11623.html (accessed October 2006).
10. Preventing Medication Errors: Quality Chasm Series available at: Institute of Medicine, "Preventing Medication Errors: Quality Chasm Series," National Academies Press, http://www.nap.edu/catalog/11623.html (accessed October 2006).
11. DC Classen et al., "Adverse Drug Events in Hospitalized Patients," Journal of the American Medical Association 277, no. 4 (1997): 301-6.
12. DJ Cullen et al., "Preventable Adverse Drug Events in Hospitalized Patients: A comprehensive study of intensive care and general care units," CritCare Med 25, no. 8 (1997):1289-97.
13. DJ Cullen et al., "The Incident Reporting System Does Not Detect Adverse Drug Events: A problem for quality improvement," Journal on Quality Improvement 21, no. 10 (1995): 541-8.
14. DW Bates et al., "The Costs of Adverse Drug Events in Hospitalized Patients," Journal of the American Medical Association 277, no. 4 (1997): 307-11.
15. DW Bates et al., "Incidence of Adverse Drug Events and Potential Adverse Drug Events. Journal of the American Medical Association 274, no. 1 (1995): 29-34.
16. RA Raschke et al., "A Computer Alert System to Prevent Injury From Adverse Drug Events," Journal of American Medical Association 280, no. 15 (1998): 1317-20.
17. EJ Thomas et al., "Costs of Medical Injuries in Utah and Colorado," Inquiry 36, no. 3 (1999): 255-64.
18. Daniel Budnitz et al., "National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events," Journal of the American Medical Association 296, no. 15 (2006): 1858-66.

Adverse Effects

The U.S. Food and Drug Administration (FDA) defines an adverse drug event as: "any undesirable experience associated with the use of a medical product in a patient."[19] The event is SERIOUS and should be reported when the patient outcome is:

1) Death
2) Life-Threatening:
   Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; medication pump failure which permits uncontrolled free flow resulting in excessive drug dosing.
3) Hospitalization (initial or prolonged):
   Examples: Anaphylaxis; Antibiotic associated colitis (pseudomembranous colitis); or bleeding which causes or prolongs hospitalization.
4) Disability:
   Examples: Stroke (Cerebrovascular accident) due to drug-induced excessive clotting (hypercoagulability); toxicity; peripheral neuropathy.
5) Congenital Anomaly:
   Examples: Vaginal cancer in female offspring from use of hormones (diethylstilbestrol) during pregnancy; malformation in the offspring caused by thalidomide.
6) Requires Intervention to Prevent Permanent Impairment or Damage:
   Examples: Acetaminophen overdose-induced liver toxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.

From 1995 through 2005, post-marketing adverse drug events have continued to increase annually—3 times. All of the adverse events shown in the chart below are of the serious category.



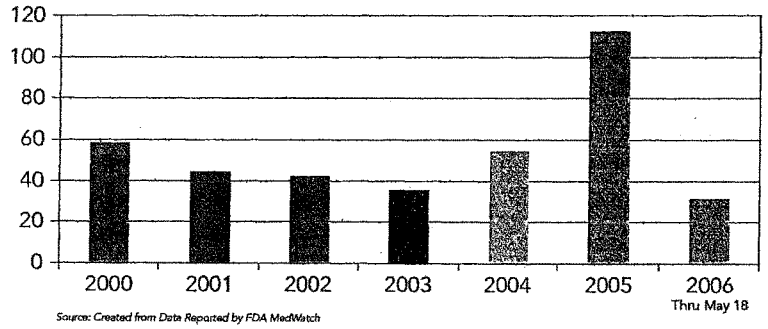
Source: FDA CDER 2005 Report to the Nation

19. U.S. Food and Drug Administration: Med Watch . "What Is A Serious Adverse Event," http://www.fda.gov/medwatch/report/DESK/advevnt.htm (accessed November 2006)

Safety Alerts and Recalls

News headlines concerning the voluntary recall of the popular drug Vioxx™ grabbed the attention of millions in 2004. During that year and those following, more safety alerts and recall headlines would stun patients, leaving them questioning the safety of their medications. From Bextra™ and Celebrex™, which treat arthritic conditions, to anti-depressants like Paxil™, the FDA has issued numerous warnings and recalls in recent years.

FDA Product Safety Alerts for Drugs and Biologicals



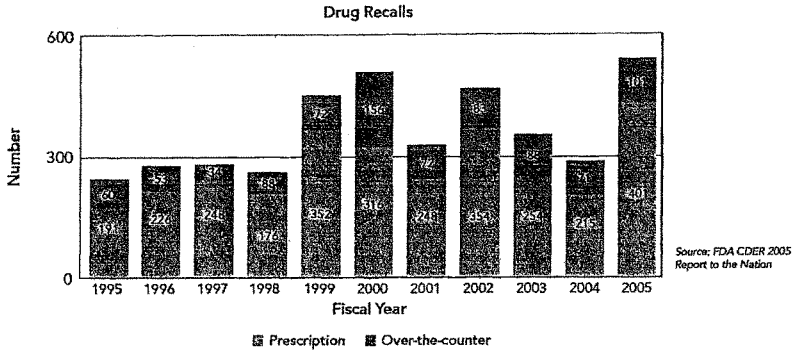
Source: Created from Data Reported by FDA MedWatch

The FDA product safety alerts trend declined through 2003 but has been increasing the last two full years 2004 and 2005. The alert is based on adverse event reports submitted by health care professionals, consumers, and patients.

Even with the recent increase in recalls, the FDA's ability to monitor the safety of drugs has come into question. In October 2006, critics questioned the agency's ability to monitor and authority to recall dangerous drugs, or even to sanction drug companies that fail to comply with required safety studies.[20]

20. Curt Furberg, et al., "The FDA and Drug Safety: A Proposal for Sweeping Changes," Archives of Internal Medicine 166 (2006): 1938-1942.

Drug Safety and Quality



Source: FDA CDER 2005 Report to the Nation

Drug recalls peaked in 2005 but at 502, and 216 of those are prescription medications.

In some cases, a drug product must be recalled due to a problem occurring in the manufacture or distribution of the product that may present a significant risk to public health. These problems usually, but not always, occur in one or a small number of batches of the drug. The most common reasons for drug recalls are listed below. In other cases, a drug is determined to be unsafe for continued marketing and must be withdrawn completely.

Manufacturers or distributors usually implement voluntary recalls in order to carry out their responsibilities to protect the public health. A voluntary recall of a drug product is more efficient and effective in assuring timely consumer protection than an FDA-initiated court action or seizure of the product.

Top 10 Reasons for Drug Recalls in Fiscal Year 2004

- Deviation from current good manufacturing process
- Drug is not potent enough
- Product instability in conflict with the expiration date
- Generic drug or new drug application discrepancies
- Dissolution failure
- Label mix-ups
- Content uniformity failure
- Presence of foreign substance
- pH failures – during storage, the drug or solution becomes too acidic or too basic
- Microbial contamination of non-sterile products

Source: Center for Drug Evaluation Research Report to the Nation: 2004

20. Curt Furberg, et al., "The FDA and Drug Safety: A Proposal for Sweeping Changes," Archives of Internal Medicine 166 (2006): 1938-1942.

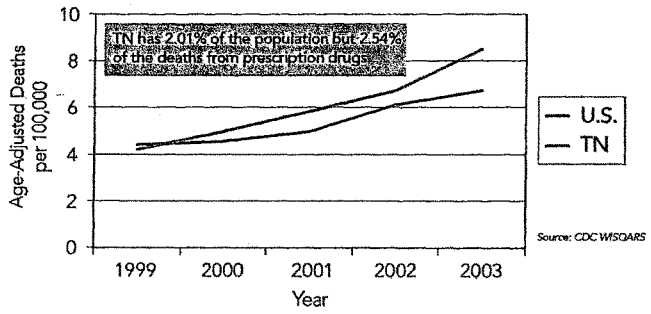
Accidental Poisoning

Another concern for patients, especially in Tennessee, is the potential for accidental poisoning. Accidental poisoning can be caused by an incorrect dosage or unintended drug interaction with another medication or substance. Most at risk are seniors over 65 years old, who according to a 2006 study by Medco Health Solutions, are at seven times greater risk for drug errors due to their multiple medications[21].

In just four years from 1999 through 2003, the Tennessee death rate from accidental drug poisoning by use of legal prescription and over-the-counter drugs has doubled from 4.17 deaths per 100,000 to 8.46 deaths.

Tennessee's accidental poisoning rate stands 26 percent above the national average[22]. Cost estimates for poisonings in 2003 tallied $29.8 billion nationally and $593.6 million for Tennessee.

Accidental Poisoning by Drugs, Medicaments, and Biologicals



The estimated unit costs of a poisoning fatality include $3,586 in medical costs and $1,123,346 in productivity loss. Applying medical inflation cost factors to the medical costs and the overall inflation factor* to the productivity loss and assuming no increase in deaths, the 2006 costs related to deaths by poisoning total $25.9 billion nationally and $657 million in Tennessee.

An editorial note to the study authored by Singleton and others noted that in some of the states studied the *"misuse of prescription drugs (e.g., pain-management opioids such as oxycodone HCl with acetaminophen, hydrocodone with acetaminophen, and methadone) has contributed to the increase in deaths from unintentional poisoning."*[23]

*Through June of 2006, from 2000, according to the Bureau of Labor Statistics medical service prices had increased 30.7 percent while the overall Consumer Price Index rose by 18 percent.

21. Medco Health Solutions, "New analysis: more doctors on the care team correlates with higher risk of adverse drug events in seniors," http://www.medcohealth.com/medco/corporate/home (accessed October 2006)
22. M Singleton et al., "Unintentional and Undetermined Poisoning Deaths —11 States, 1990—2001," Morbidity and Mortality Weekly Report 53, no. 11 (March 26, 2004): 233-238.
23. M Singleton et al., "Unintentional and Undetermined Poisoning Deaths —11 States, 1990—2001," Morbidity and Mortality Weekly Report 53, no. 11 (March 26, 2004): 233-238.

Antibiotic Resistance

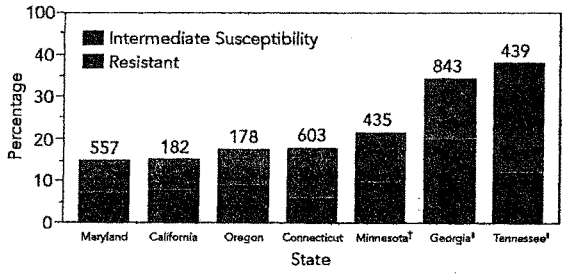
The Tennessee Department of Health defines an antibiotic-resistant infection as "an infection that is difficult or impossible to cure with antibiotics." Common areas for these infections are the throat, sinus, ears, lungs and intestines. The difficulty in treating resistant bacterial infections can lead to more severe illnesses with longer and more expensive treatments, such as hospitalization.

For example, in 1972, 2 percent of hospital acquired staphylococcus aureus (staph) infections were resistant to antibiotics. In 2004, that 2 percent rate increased to 63 percent.[24] A rate so alarming that in October 2006, CDC released new health care setting guidelines to prevent the spread of drug-resistant infection.

In fact, Tennessee has some of the highest rates of antibiotic resistance in the nation. A rate so high that the state is currently engaged in an "Appropriate Antibiotic Use Campaign."

The high level of antibiotic resistance is displayed in the chart below where Tennessee has the highest portion of resistant pneumococcal isolates among states studied by the CDC[25].

Number of invasive pneumococcal isolates and percentage of isolates that were nonsusceptible to penicillin, by geographical area* – United States, 1997



* The surveillance sites were San Francisco County, California; the entire state of Connecticut; the 20-county Atlanta area of Georgia; the six-county Baltimore area of Maryland; the seven-county Minneapolis-St. Paul area; the three-county Portland area of Oregon; and five urban counties of Tennessee.

† p=0.01 compared with proportion of penicillin-nonsusceptible isolates in Maryland

§ p<0.01 compared with proportion of penicillin-nonsusceptible isolates in California, Connecticut, Maryland, Minnesota, and Oregon

Although receiving much attention antibiotic resistance continues to grow:

1) A 37 percent increase in resistance (Campylobacter) to the antibiotic Cipro® from 1997 to 2003
2) A 475 percent increase in resistance to Negram® for one bacteria type (Non-Typhi Salmonella)
3) A 101 percent increase in resistance for another (Salmonella Typhi).
4) Resistance is also growing to antibiotics used on livestock where there has been a 2000 percent increase in resistance to a 3rd generation antibiotic (cephalosporin ceftiofur used in non-Typhi Salmonella).

Besides increased morbidity and even mortality, the overuse of antibiotics carries with it large health care costs which the CDC estimates at $4 billion annually.[26]

24. Centers for Disease Control, "MRSA in Healthcare Settings," www.cdc.gov/ncidod/dhqp/ar_MRSA_spotlight_spotlight_2006.html (accessed November 2006)
25. L Gelling et al., "Geographic Variation in Penicillin Resistance in Streptococcus pneumoniae – Selected Sites, United States, 1997," Morbidity and Mortality Weekly Report 48, no. 30 (Aug. 6, 1999): 656-661.
26. Centers for Disease Control Foundation, "Assessment of Antimicrobial Resistance Along the U.S.-Mexico Border - Mexico and the U.S.," http://www.cdcfoundation.org/fellowships/ochubert/descriptions.aspx#mexico (accessed October 2006)

Prescription Abuse

Once pushed by the World Health Organization to aggressively treat severe cancer pain, opioids are now aggressively pushed by drug dealers on the streets of Tennessee.

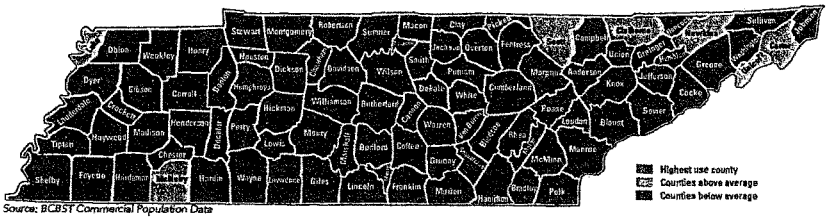
Better known as painkillers, prescription opioids include codeine phosphate, codeine sulfate, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, oxycodone/acetaminophen combination, meperidine/promethazine combination and oxycodone/aspirin combination.

According to the FDA the abuse rate for opioid analgesics (synthetic drugs possessing narcotic properties) has been steadily rising over the past five years while illicit drug abuse has remained stable. The 2004 National Household Survey on Drug Use and Health reports 31.8 million Americans used pain relievers for non-medical purposes at least once during their lifetime.[27] That's a 7 percent increase from 2002 figures.

And again, Tennessee is near the top, ranked among the top 5 states in opioid use[28].

Currently, the prescribing practice patterns of Tennessee physicians are being studied by an appointed task force charged with identifying problems and developing solutions for the abuse.

2005 Narcotic Therapeutic Class Rx's per 1,000 Members



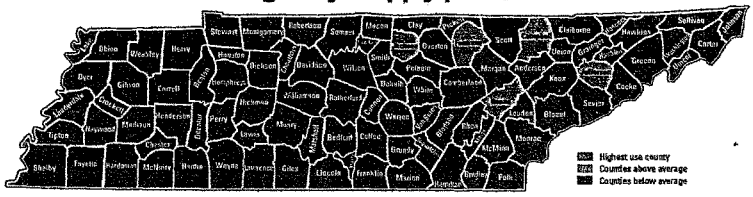
Source: BCBST Commercial Population Data

The chart above shows the highest use county in Tennessee (Morgan) shaded in orange and those that are significantly higher than the average in tan. The geographic variation in narcotics dispensing per prescriber is similar to the geographic variation in per capita use.

27. U.S. Congress, House, Committee on Government Reform, SubCommittee on Criminal Justice, Drug Policy and Human Resources, statement made by Sandra L. Kweder, M.D. Deputy Director, Office of New DrugsCenter for Drug Evaluation and Research Food and Drug Administration U.S. Department of Health and Human Services, www.fda.gov/ola/2006/oxdrugabuse0726.html. July 26, 2006 (accessed November 2006)
28. LH Curtis et al., "Geographic Variation in the Prescription of Schedule II Opioid Analgesics among Outpatients in the United States," Health Services Research 41, no.3 (June 2006).

The Drug Enforcement Administration defines schedules of controlled substances.[29] Below are the classification definitions and per capita use for prescription narcotics in Tennessee counties. On both maps the highest use county is shown in orange and those counties with statistically significant higher use are shown in tan.

Schedule II Drugs Days Supply per 1,000 Members



Schedule II. –

(A) The drug or other substance has a ***high potential for abuse.***

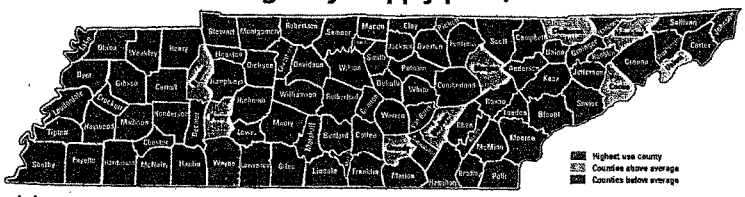
(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule II drug use per capita as shown in the chart above has approximately the same geographic distribution as shown in the previous maps.

Morgan County has the highest use at an average 4,853 days supply of schedule II drugs per 1,000 members while the statewide average days supply per 1,000 members is 1,725.

Schedule III Drugs Days Supply per 1,000 Members



Schedule III. –

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule III drug use shown in the map above has a different distribution pattern than schedule II drugs.

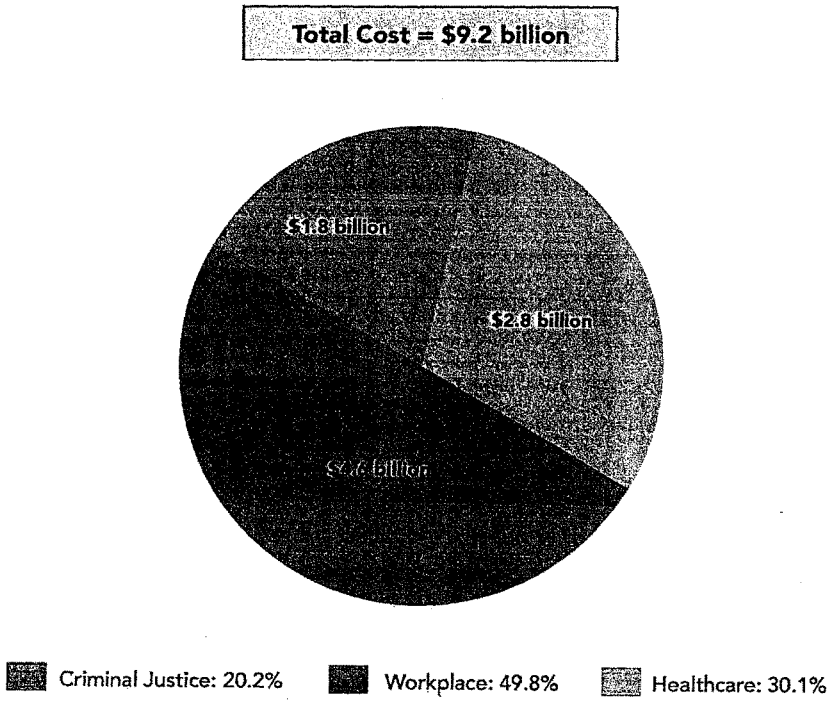
The highest use county for schedule III drugs is Wayne County at 9,125 days supply per 1,000 members, while the statewide average is 5,701 days supply per 1,000 members.

The abuse of opioid puts users at an increased risk for disability and death. Harmful effects can be both biochemical and behavior associated, i.e. increased risk of brain damage, cognitive impairment and suicide.

29. Title 21 - Food and Drugs Chapter 13- Drug Abuse Prevention and Control Subchapter I – Control and Enforcement Part B - Authority To Control; Standards and Schedules, U.S. Drug Enforcement Agency, http://www.dea.gov/pubs/csa/812.htm#b (accessed November 2006)

The abuse of prescription narcotics has dangerous consequences beyond just health risks. The misuse also brings with it an array of harmful implications for addicts' family members and their communities. Just in terms of cost, the impact is staggering. An analysis presented at the 2005 Opioid Risk Management Conference estimates the economic impact of prescription opioid analgesic abuse in America at $9.2 billion in 2001.[30]

The Cost of Rx Opioid Abuse in the United States in 2001



30. Analysis Group, "Costs of Prescription Opioid Analgesic Abuse in the United States in 2001: A Societal Perspective," http://www.thci.org/opioid/documents/birnbaum.pdf (accessed October 2006)

Prescription for Change

Although Tennessee leads the nation in its use of prescription medications per capita, it's not alone in facing the issue of prescription overuse. The problem is one faced by many states. It's also an issue that goes beyond the individual to the responsibility of an entire system, and one that requires the collaboration of many entities to have a positive impact.

In it's "Preventing Medication Errors" report, the Institute of Medicine (IOM)[32] makes several recommendations for improvement. At the top of the list is the use of health information technologies to reduce medication errors. In fact, The IOM recommends that by the year 2010 all prescriptions should be written electronically. Other recommendations include improved relationships between patients and physicians, improved prescription labeling and medication packaging, government paid research and policy changes.

In Tennessee, changes are already underway to improve patient safety and reverse the prescription use trend:

Technology

Great strides in the advancement of Health Information Technology are taking place in both the government and private sectors. From the government side, Governor Bredesen's eHealth Advisory Council, formed in January 2006, is working to coordinate electronic health initiatives while developing and implementing a statewide system of electronic medical records. Additionally, the e-prescribe task force is focusing attention on the importance of advancing the use of electronic prescribing. These state efforts are complementary to Bredesen's November 2006 appointment to lead the National Governors' Association State Alliance for e-Health.

In the private sector, numerous regional health information organizations (RHIOs) are at work sharing patient medical data. And at BlueCross Blue Shield of Tennessee, its subsidiary Shared Health is impacting the care of more than 2 million residents currently in its electronic Clinical Health Record.

In addition to the Clinical Health Record, the company encourages the use of its electronic prescribing application by physicians. Shared Health ePrescribe™ allows authorized physicians to securely order safe and cost-effective medications directly from their personal computers, eliminating traditional paper prescriptions thus helping reduce the risk of medication errors and adverse drug events. Additionally, the application can eliminate the potential of a forged paper prescription.

32. Institute of Medicine, "Preventing Medication Errors: Quality Chasm Series," National Academies Press, http://www.nap.edu/catalog/11623.html (accessed October 2006).

Education
A more informed patient is a better patient. When consumers/patients actively engage in their health care decisions, the more likely their decisions are to positively impact both their health and their wallets.

In Tennessee, BlueCross has promoted the use of generic drugs through its Demand Generics campaign, and the Tennessee Department of Health has engaged in an "Appropriate Antibiotic Use" campaign for the past several years. These campaigns provide information to both providers and patients about safe and cost-effective prescription treatments.

In the example of BlueCross' Demand Generics campaign, the generic dispensing rate among BlueCross members has increased from 37.7% percent in 2001 to 56.1 percent in 2006—a 48.8 percent increase. The increased use of generics has also saved BlueCross members $13 million in out of pocket costs and BlueCross employers $38.2 million in 2005 alone.[33]

Safety Initiatives
The health care community is also focused on initiatives to reduce substance abuse and improve patient safety. Three significant efforts are currently underway in Tennessee.

The Physician Prescribing Practice Task Force assembled by the Tennessee Department of Health is charged with studying prescribing habits of Tennessee physicians and developing initiatives and tools to reverse the drug utilization trend. Initiatives include the development of a controlled substance monitoring database, a Web-based educational program on prescribing practices and the encouragement of electronic medical records.

The Tennessee Board of Pharmacy has launched the Tennessee Controlled Substance Database program, designed to provide doctors with specific data regarding controlled substance use—all with the purpose of eliminating prescription abuse and improving patient safety.

The Tennessee Medical Association has developed CURB-IT, a program aimed at ultimately improving the public health. Areas under focus in the CURB-IT program are patient safety, i.e. avoiding contraindicated prescriptions; improved patient care, i.e. better medication information and improved knowledge about new protocols; and reduction of illicit drug use.

Health information technology, public education efforts and safety initiatives have the potential to not only reduce the drug utilization trend in Tennessee, but also hold the promise of transforming the health care delivery system.

All stakeholders—patients, providers and the health care community—must continue to collaboratively explore these mechanisms of change as they seek appropriate use for prescription drugs in our state. With less, Tennessee may be able to do more to improve the health of its citizens.

33. BCBST Internal Data

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Article published Dec 21, 2006

Bristol-Myers reaches settlement

Bristol-Myers Squibb Co., New York, agreed to a $499 million settlement with the Justice Department and the U.S. attorney's office in Boston over investigations into the company's drug-pricing, sales and marketing practices from the 1990s to 2005. The agreement still needs to be approved by the Justice Department, but the company said there will be no criminal charges. Bristol-Myers will also enter into a corporate integrity agreement with the HHS' inspector general's office. The agreement would end the federal government's investigation into average wholesale prices, but the company still faces litigation on the matter. The allegations in the average wholesale prices lawsuits claim that Bristol-Myers and other manufacturers [redacted]The settlement would also end an investigation into the company's drug Abilify -- used to treat schizophrenia and bipolar disorder -- and the 340B drug pricing program, which limits the cost of covered outpatient drugs to federally-qualified health centers and qualified disproportionate share hospitals. -- *by Joseph Mantone*

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 the 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 hands.

[Witnesses sworn.]

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

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

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

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 9 out of 10 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.

Second, 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 2015 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, 2015, 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.

Second, 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.

Second, 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 data base 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 data bases and transaction data bases 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 Medicaid 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 be-

cause 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.

[The prepared statement of Mr. Schondelmeyer follows:]

Testimony of Stephen W. Schondelmeyer, BS Pharm, MA Pub Adm, Pharm.D., Ph.D., Professor of Pharmaceutical Management & Economics, Director, *PRIME* Institute, College of Pharmacy, University of Minnesota
Committee on Government Reform Briefing on the Medicare Drug Plan
January 20, 2006

Thank you Representative Waxman and other members of the Minority Office of the House Committee on Government Reform for this opportunity to provide information and insights on economic and policy issues related to Medicare Part D drug program. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Director of the *PRIME* Institute. This Institute focuses its research on policy issues related to pharmaceutical economics and the management of drug expenditures at all levels in the society. These remarks are my own views based upon my experience in studying the pharmaceutical marketplace for over twenty-five years and upon my observations of the new Medicare Part D drug program during its preparation phase and in the past few weeks now that it is being implemented.

This briefing on the Medicare Drug Benefit provides a timely forum for examining the successes and failures of this new program as it is being rolled out. Also, this hearing provides an opportunity to look ahead to what we can expect from the Medicare drug benefit in the years ahead, if the current structure of the program remains in place. Today, I will briefly address both short-term and long-term economic impact issues of the Medicare Part D drug program.

Economic Impact of Eligibility Problems

First, let me begin by commenting that coverage of prescription drugs under the Medicare program is, in general, a major step forward for providing appropriate and accessible drug therapy to the nation's elderly. Any public program that is intended to do good things for members of society may achieve its stated objectives and it may have difficulties and problems that were unintended. The difficulties and failures experienced by a public program may result from implementation failures, policy failures, or both. However, it is important to distinguish between those problems that are due to implementation from those that are due to policy failures.

Obviously, the start of the Medicare Part D Drug program has experienced unexpected and unintended difficulties. Others on today's panel have commented on the failure of the Medicare program to properly enroll and provide eligibility information on dual eligibles when they went to the pharmacy to have a prescription filled. This situation is primarily the result of an implementation failure. The consequences of this failure, however, go deeper than may be realized. First, many elderly beneficiaries went to the pharmacy to get a needed medication, only to find out that the pharmacy could not verify their eligibility and had no way to identify in which of the 40 to 70 specific prescription drug plans the Medicare recipient was automatically enrolled. The pharmacist then tries to call either Medicare or one of more of the prescription drug plans (PDPs) that received automatic enrollees. The call lines have been greatly overloaded in the past few weeks and pharmacists may be put on hold for hours by the PDPs or Medicare. This adds time and cost to the pharmacies operation that will never be recovered. In most cases, the pharmacist filled the prescription for the beneficiary even without the needed information or authorization and gave the medication to the patient.

Although all stakeholders are important to the Medicare prescription drug program, the pharmacist is literally the FACE OF THE MEDICARE DRUG BENEFIT to each and every beneficiary. This initial experience, however, created a tension-filled situation for both patients and pharmacists due to no fault of either one. After the patient leaves the pharmacy, another unintended economic consequence develops. A pharmacy can fill a few prescriptions over a few days for a few patients and figure out how to get reimbursed later without major harm. In this case for many pharmacies, many patients were not in the system as eligible and the problem has persisted for two weeks or more. Pharmacies are beginning to experience downstream economic problems. The pharmacy has to order drugs to replace those that have been dispensed, even though it has not been paid for the drugs already provided. The usual payment terms from the wholesaler require the pharmacy to pay for the new stock within 2 weeks. If the wholesaler is not paid in two weeks the pharmacy may suffer economic harm thorough loss of timely payment discounts (i.e., about 2%), taking out a loan or line of credit advance to pay the wholesale bill, pay penalties for late payments, or lose their credit and ability to purchase from the wholesaler. Pharmacies are reporting that their wholesalers are not being flexible about payment for prescription drug orders due to this difficult Medicare situation. This situation has already caused economic harm to community pharmacies and the longer it continues, the more severe the impact will be. Especially hard hit by this situation will be the smaller pharmacies which tend to be in rural or low income areas. This added economic impact from eligibility problems and substantially delayed payment will further compound the concern of pharmacies, and especially those in rural and underserved areas, with the very low payment levels from most PDPs.

Economic Impact of Medicaid to Medicare Shift

In addition to the implementation failure related to dual eligibles, there is a deeper underlying policy failure with the conversion of dual eligibles from Medicaid to Medicare. Prescription drugs paid for under the Medicaid program cost the government less than the same drug will cost under the Medicare program. This cost difference is due primarily to the loss of revenue from the Medicaid drug rebate program with minimum rebates of 15 percent or more and additional rebate payments for best price and inflation adjustment over time. The total rebate may be as much as 20 to 30 percent of the drug product cost. While the private PDPs under the Medicare program may negotiate rebates, any benefit from such rebates that is not passed on to the beneficiary in the prescription price will not be realized by Medicare or the patient. There is no direct mechanism for a drug company or the PDPs to pass rebates on to the Medicare program.

The prices of 25 top prescribed brand name drugs were examined for all PDPs offered in one zip code in Minnesota during the first two weeks of 2006. Based on the total prescription prices found on the CMS website for each of the 41 plans, several general observations were made. Most of the plans had prices posted that were within plus or minus 4 percent of the typical retail price (see Figure 1). The Medicare prices posted were 14 percent to more than 50 percent

above the prices that the government would have paid under the Medicaid program. Most of the Medicare prescriptions were 20 to 30 percent above the Medicaid price for the same prescription.

Knowledge that the Medicare program will be paying more for the same drug than the Medicaid program would have paid has not gone unnoticed by the pharmaceutical companies. At least one drug company has acknowledge to Wall Street that it expects an increase in revenue and earnings due to the higher price it will be paid for prescriptions received by dual eligibles under Medicare versus the price they would have received under the previous Medicaid program.[1] As reported, "the transfer (of dual eligibles) means *Zyprexa* will escape from the Medicaid rebate system, which requires Lilly to pay the government back for any inflationary price increases for the product. Lilly expects a 'modest, one-time price benefit' from that change alone, CEO Sidney Taurel said." Taurel went on to say that "now is probably not the time for headlines suggesting that drugs will be costing the federal government more in 2006 than they did in 2005." This increase in cost of prescriptions for dual eligibles appears to be a policy failure with respect to the design of the Medicare drug benefit.

Not only does the Medicare program lead to higher payments for prescription drugs versus the previous Medicaid system, but the structure for delivery of the private benefit by many entities (i.e., 40 to 70 or more PDPs and managed care plans) will not likely achieve better prices than Medicaid at any point in the future without structural change to the Medicare drug program. To the degree that market leverage and volume influence drug prices, the Medicare drug program will be delivered by many smaller plans within each state, rather than by one large plan (i.e., Medicaid). This smaller volume and diminished market power for the many PDPs is not likely to generate discounts and rebates from manufacturers that approach the historical rebate levels specified under the Medicaid program.

Economic Impact from Plan Choice

Theoretically, the consumer's choices among PDPs and the posting of prescription prices for each PDP could create competition and pressure on prescription prices. However, effective competitive pressure is not likely to occur. The 40 to more than 70 plans available to seniors in a specific region each have different benefit designs and different levels of premiums, deductibles, coverage gaps, copays, coinsurance, and prescription prices. Most seniors when faced with this complex array of information focus on only one or two of these factors when choosing their Medicare PDP. One source has suggested that "the premium is the first element price-conscious consumers will consider."[2] Choosing a plan based only on the premium may not result in the best choice for all beneficiaries or for the Medicare program as a whole. Another feature that often gets the attention of persons trying to chose among plans is the out-of-pocket amount to be

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[1] "Lilly Makes Part D Pay," *The RPM Report* (Windhover Information Inc.), Vol. 1, No.2, January 2006, p.34.
[2] "Playing Offense in Part D: Three Aggressive Medicare Strategies Demand Pharma Attention," *The RPM Report* (Windhover Information Inc.), Vol. 1, No.1 December 2005, pp.23-31.

paid as copays and deductibles. Again this is a useful criteria for comparing PDP plan offerings, but the choice of a PDP based solely on the out-of-pocket costs of various PDPs may not lead to the best economic choice for a specific beneficiary or for Medicare. Furthermore, if a beneficiary chooses a PDP that is best for them based on copays and drug coverage at the beginning of the year, they may find that the PDP has changed the formulary, drug prices, and copays by the end of the year in such a way that the plan is no longer the best choice for that person.

In reviewing the information posted on the CMS web site for PDPs in a specific a region, there was inconsistent information that appeared to include either coding or calculation errors. On the one hand, errors are not unexpected in such a massive program. However, the errant information may was present during the entire period when beneficiaries were making their initial choice of PDPs, and may well have inappropriately steered them from one plan to another based on 'bad' data. Some prescription drugs, for example, had prescription prices listed that were greatly different from other plans (e.g., one-fourth of the price of other plans) and appear to have been copay information entered in the prescription price file for certain plans and not others. Most beneficiaries would not systematically review all plans and all prescription prices to catch these errors. Competition can not possibly work with bad or incomplete information.

In the past few months, I have had the opportunity to meet with many beneficiaries, pharmacists, and physicians in groups or individually. The feedback from these groups is almost always the same. The Medicare drug program is complex which leads to confusion then frustration and ultimately results in anger and desperation. Others have described the various ways that these frustrations develop. This complexity though also leads to market conditions that are not conducive to economically efficient competition.

Three American economists were awarded the Nobel Prize in Economics in 2001 for their work in defining the impact of asymmetric markets such as "The Market for Lemons" or also known as 'used cars'.[3] Asymmetric markets are markets with imperfect and incomplete information for certain participants. The market for pharmaceuticals was already an asymmetric market, that is, an imperfect market in which certain participants, such as drug manufacturers and prescription drug plans, know far more about their products than do consumers. The Medicare Part D Drug Program has added to the imbalance in market information and understanding through complex and widely varying plans, incomplete and changing information on plans, and lack of transparency.

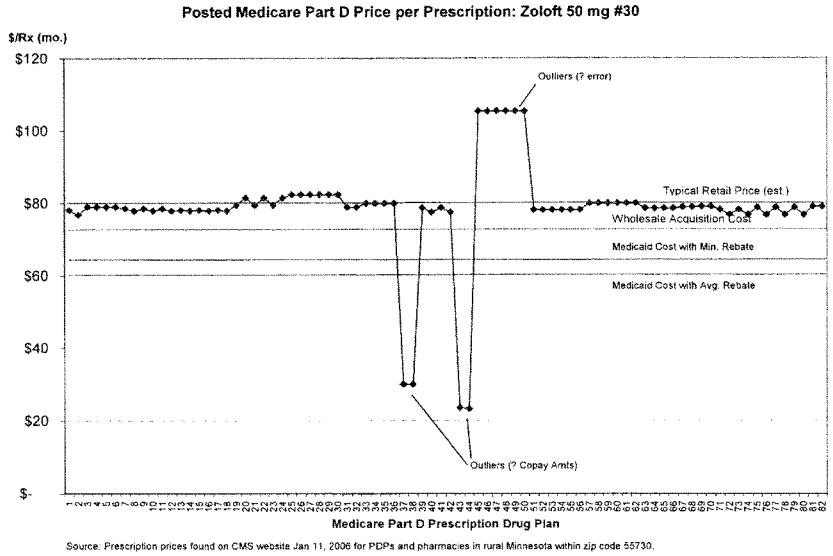
The three American Nobel Laureate economists pioneered the view that "markets, when confronted with imperfections, may not be the best way to allocate resources."[3] These economists concluded that "government must play a strong role in a market system, to prevent damage from imperfect information." When one part of the market knows more than another, it

[3] "3 Americans Awarded Nobel for Economics," New York Times, October 11, 2001.

not only explains various corporate strategies, but it also justifies government intervention. Government intervention has been needed in many markets to correct for imperfect information. Various actions of government that may help the current Medicare situation include increased transparency and disclosures, establishment of one or more standardized drug benefit designs, provision of additional tools to assure efficient purchasing and distribution of pharmaceuticals, and other actions to assure that the Medicare program does provide appropriate and accessible drug therapy in an economically efficient manner through a care process that assures improved health status for all beneficiaries.

Thank you for your time and for the opportunity to give you input on economic and policy issues related to the important Medicare Part D drug program.

Figure 1.



Source: Prescription prices found on CMS website Jan 11, 2006 for PDPs and pharmacies in rural Minnesota within zip code 55730.

Chairman WAXMAN. Dr. Anderson.

STATEMENT OF GERARD F. ANDERSON

Dr. 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, etc., 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?

Dr. 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 av-

erage 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.

[The prepared statement of Mr. Anderson follows:]

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Mr. Waxman and members of the Oversight and Government Reform Committee, thank you for inviting me to testify this morning. I am Gerard Anderson, a professor of Health Policy and Management, Professor of International Health and Professor of Medicine at Johns Hopkins University. I also direct the Johns Hopkins Center For Hospital Finance and Management.

In preparing my testimony today, I examined the problems federal and state governments encounter when they purchase drugs. My analysis suggests that most government programs have two common problems: (1) some government programs do not know the prices they actually pay for drugs and (2) each government program pays a different price for most drugs and it appears that the Medicare Part D plans are paying much high prices for certain types of drugs compared to other government programs. In light of these findings, I have three recommendations for the Committee to consider.

1) Each government program should know the actual price it pays for specific drugs
2) Drug prices should be compared across government programs to find out which government programs are paying the highest prices for specific drugs.
3) Congress should examine whether the federal government should pay different prices for the same drug and whether a more consolidated approach should be considered.

Each Government Program Should Know The Price It Pays For Drugs

My first recommendation is that each government program should know the price it actually pays for each specific drug. Unfortunately, many government programs do not know the prices they pay for drugs. One reason is that the systems the some government agencies use for determining the prices they pay for drugs is so complicated. In other cases, the data is available but not analyzed.

Let me begin with the largest federal purchaser of drugs – the Medicare Part D program. Medicare beneficiaries can go on the Medicare.gov web site and find out how much each Part D plan charges for each drug in their formulary.

However, the Secretary of HHS, the CMS actuaries, CBO, CRS, GAO, etc. do not know the prices the Part D plans actually pay for these drugs. The data is available, but it has not been analyzed by any of the Congressional agencies or the CMS actuaries.

The Secretary of HHS and the Congress should know the prices Part D plans pay for each of the 4300 drugs on one or more of the Part D formularies in order to determine if the Part D market is working. The legislation the House recently passed (HR 4) will require the Secretary of HHS to know the actual prices that the Part D plans are getting. This is a necessary first step before the Secretary knows where to negotiate.

In my opinion, the Secretary does not need to negotiate prices for each of the 4300 drugs. Instead, the Secretary should only negotiate prices where there is market failure and where Part D plans are paying relatively high prices. Let the market work where the market is working effectively; the Secretary should intervene only where there is market failure. This will permit the Secretary to focus attention on the drugs where the market is not working and Part D plans are paying relatively high prices.

The Secretary of HHS should compare the lowest price any Part D plan is getting for each drug to the prices that Medicaid, VA or Canada are paying for the same drug. In making this comparison, it is not necessary to report the prices that every Part D plan is paying. All that needs to be reported is the lowest price that any Part D plan could obtain for each drug because this represents the lowest price the marketplace can obtain. The Secretary of HHS can then concentrate his/her efforts on negotiating lower prices where there is market failure.

The Secretary should compare the lowest price obtained in the marketplace to the VA price because the VA Secretary has negotiated drug prices with pharmaceutical companies. Medicaid prices are an appropriate comparison because this government program has been operating for many years and because Medicaid programs have an extensive formulary. Canada's prices are a relevant comparison because it will show what another country is paying for drugs. Also, if there is a large differential between the Canadian and US prices for drugs, this will cause a substantial number of American seniors to obtain drugs from Canada.

340 B Programs

Many government programs experience difficulties determining the prices that they are actually paying for drugs because the formulas are so complicated. This is particularly true in 340B programs operated by HRSA.

An October 2005 report by the DHHS Inspector General found that HRSA does not know the prices it pays for drugs in the 340 B program. The three major findings of the report were:

1) HRSA needs an accurate record of 340 B ceiling prices to verify that entities receive the discount to which they are entitled by law.
2) HRSA lacks the oversight mechanisms and authority to ensure that 340 B entities pay below the 340 B ceiling price.
3) Participating entities cannot independently verify that they receive the correct 340 B discount due to confidentiality provisions.

In other words, the entities participating in the 340 B program do not know if they are paying the correct prices.

Medicaid Programs

A series of reports by the DHHS Inspector General found a variety of problems with the prices the Medicaid programs were paying for drugs. The reason is that the formulas are very complicated and there is tremendous price variation across the states. As a result CMS cannot monitor if the states are paying the correct price.

One report examining price variation paid by Medicaid programs found that "On average, the highest paying state paid 477 percent more per drug than the lowest paying state". CMS should investigate this large variation and help the states that pay the most.

Another report found that the Medicaid program was overpaying pharmacies to dispense drugs because the formula used by most Medicaid programs is flawed. The problem is that Medicaid reimbursement to pharmacies is based on discounts from average wholesale prices rather than on actual sale transactions. It is difficult for states to determine average wholesale prices. The DHHS Inspector General's Report found that the average sale prices were 49% lower than average wholesale price and yet most Medicaid programs were obtaining discounts substantially less than 49% of average wholesale price under current rules. This gives the pharmacies additional profits because the pharmacies can purchase drugs cheaper than the Medicaid thinks they can and the pharmacies can pocket the difference.

A third report examined the Medicaid federal limit calculation and found that certain drugs were inappropriately excluded resulting in additional spending by the Medicaid program. The report found that "58 new drug products that met all

statutory and regulatory requirements were not added to the Federal upper limit test due to inflated published prices" and this cost the Medicaid program over "100 million per year."

In 2005, Congress passed the Deficit Reduction Act requiring each drug manufacturer to enter into a rebate agreement with CMS and pay quarterly rebates to the state Medicaid program. The problem is that the pharmaceutical manufacturers set the price and then they pay rebates off the price that they set themselves. Another report by the DHHS Inspector General argues that the "existing requirements for determining certain aspects of AMPs [Average Manufacturer Price] are not clear and comprehensive, and manufacturer's methods of calculating the AMPs are inconsistent." The lack of consistency results in fewer rebates being paid to Medicaid program.

In summary, it is clear that the Secretary of HHS does not know the prices the Part D plans are paying for drugs, HRSA does not know the prices that it is paying for 340 B programs and CMS does not understand the prices that the Medicaid directors use to pay for drugs. The problems are that the formulas are so complicated and/or the data is not being compiled.

Price transparency is a virtue in most circumstances. Drug pricing in many government programs is so complicated that many government agencies do not know the actual prices they are paying. The Committee should make sure that the various government agencies know the prices they pay for drugs. This also applies to the Medicare program which should know the prices the Part D plans pay for specific drugs.

II. Comparing the Prices the Various Government Entities Pay

Once the various government agencies learn the actual prices they pay for each specific drug (including discounts, rebates, price concessions, etc), it should be possible to actually compare the prices the various government programs pay. This has been attempted with incomplete data and should be repeated once the pricing data is more reliable and the Part D data becomes available.

Using incomplete data, various organizations have tried to estimate the rates that various government agencies pay. All of the studies suggest wide variations in the amounts the various government agencies pay and that the Part D plans are paying the highest rates for some types of drugs.

Families USA and Consumers Union have recently compared the prices paid by the VA and Part D plans and both studies found that Part D plans were paying substantially higher prices than the VA for drugs.

The Families USA study found that "The price differential between the lowest VA-negotiated price and the lowest price available from a Part D private plan is

often substantial. For example: for Zocor (20 mg), a lipid-lowering agent, the lowest VA price for a year's treatment is $127.44, while the lowest Part D plan price is $1,485.96—a difference of $1,358.52, or 1,066 percent." The report listed numerous other examples of commonly prescribed drugs where the differentials in prices were nearly as large.

Consumers Union compared the drug prices for 6 drugs In Broward Country Florida. Their study found that "VA prices were 54 percent lower than "full-cost" prices under Part D plans. The average per drug VA price for the six drugs surveyed was $22.06 per drug; the average "full-cost" price under the Medicare Part D plans in Broward County was $48.38. Full-cost price refers to that paid by beneficiaries who fall into the "doughnut hole" coverage gap."

Both studies have been criticized on methodological grounds, however, in my opinion; both studies are the best that can be done using available data. Of course, having actual data would eliminate much of the methodological debate. I would also note that the price differences are very large and any methodological issues are going to have only a small impact on the differences. Finally, the critics of these studies have not presented any alternative evidence.

Various government agencies have produced studies comparing the prices paid by different government agencies but I have not identified a study that compares the actual prices paid by Part D plans to the prices paid by government agencies. This should be a priority.

In 2005, The Congressional Budget Office made an attempt to compare the drug prices various government agencies pay for drugs at the aggregate level. I emphasize "made an attempt" for two reasons. The first section of my testimony emphasizes that some federal agencies do not know the actual prices they are paying. This makes price comparisons difficult. I also emphasize "at the aggregate level" because the CBO comparison did not look at the price variations for specific drugs and there is reason to suspect that there is more variation for certain types of drugs than other types of drugs. Finally this report was written in June 2005 and did not examine the prices paid by Part D plans.

The CBO report shows significant variations in aggregate drugs prices across the various government programs. The report compared the discount that various federal agencies received to the average wholesale price (AWP). Average wholesale price is the "publicly available, suggested list price for sales of drugs by a wholesaler to a pharmacy of other providers." CBO selected the average wholesale price "as the reference price for the analysis because it is commonly used in pharmaceutical transactions". CBO noted that the pharmaceutical companies will often provide discounts, rebates, and other price concessions and so the average wholesale price is not the actual price the wholesalers pay. It is also not the price that most patients pay.

CBO estimated that average price paid by the Medicaid program was 51% of average wholesale price and the 340 B ceiling price was also 51% of AWP. In comparison, the VA paid only 42% of the average wholesale price and the DOD military treatment facility average price was 41% of AWP. In contrast, the average manufacturer price (the price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies) was 79%.

The CBO report calculates the discounts other government programs receive.

Because of provisions in the Medicare Modernization Act, data on the actual prices that Part D plans pay for drugs is not publicly available. CBO cannot compare prices obtained by the Part D plans because the data is buried somewhere in Baltimore at CMS headquarters and the CMS actuaries, CBO, CRS, GAO have not examined the data. At the present time, CBO and CRS are not even authorized to review the data.

I was interested in estimating the prices that Part D plans are paying for drugs to see if they are getting reasonable prices. In order to estimate the actual prices paid by the Part D plans, I relied on numbers produced by the CMS actuaries.

(Table 1 is from the CMS actuaries report) In their 2006 report on the projected costs in the Part D program, the CMS actuaries assume a 21 percent reduction in average wholesale price and a 6 percent rebate for a total of 27 percent reduction from the average wholesale price. **It appears that the CMS actuaries assume that the Part D plans pay 73% of the average wholesale price.**

First, it should be noted that the price reduction obtained by Part D plans is considerably less than what the VA or Medicaid have obtained. The 73% number is comparable to the 51% reduction by the Medicaid program and 42% reduction by the VA. **In other words, Part D plans are paying 22 percent more than Medicaid and 31 percent more than the VA.**

The CMS actuaries assume that Part D spending will exceed $1 trillion dollars in the 2006 to 2015 time period. **A 22 percent or a 31 percent reduction in drug prices would save the Medicare program $200 to $300 billion dollars during this time period.**

Second, it is important to notice in Table 1 that the **CMS actuaries do not anticipate that the Part D plans becoming any more effective over the years in negotiating price reductions from the pharmaceutical companies.** In the CMS projections, the discounts are constant over the years from 2006 to 2015. **Between 2006 and 2015 Part D expenditures are forecast to increase 10.3 percent per year on average.**

There is confirming evidence to suggest that Part D plans are paying high rates for drugs. One comparison is the prices states were paying for drugs for the dual eligibles. The Medicare Modernization Act moved millions of dual eligibles from Medicaid to Medicare for prescription drug coverage.

One simple way to estimate the higher prices that Part D plans are paying for drugs is to compare the CBO estimates of the discounts that the Medicaid program and the private sector receive for "brand name" drugs. According to the CBO report, the average manufacturer price is 79% of the average wholesale price. The average manufacturer price is the "average price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies". The CMS actuaries' then subtract an additional 6% discount for rebates. This suggests that the Part D plans are paying 73% of average wholesale price. However, Medicaid was paying only 51% of average wholesale price. **This suggests that Medicare is now paying 22 percent more than Medicaid was paying for the same drugs for the same dual eligibles.**

There is further collaborating evidence of the Medicare part D plans paying higher rates based on the pharmaceutical companies' own reports to the financial industry. Pharmaceutical companies are required to file 10Ks and 10Qs with the Securities and Exchange Commission whenever a major event occurs that could influence the stock price. There are indications in some of the 10Ks and 10Qs filed by the pharmaceutical companies that they are getting higher prices from Medicare than they did from Medicaid. For example, Pfizer acknowledged that they paid fewer rebates, price concessions and gave fewer discounts due "to the impact of the Medicare Act". Specifically on page 34 of their 10Q report dated October 1st 2006, Pfizer states that "Our accruals for Medicaid rebates, Medicare rebates, contract rebates and charge backs totaled $1.5 billion as of October 1, 2006, a decrease from $1.8 billion as of December 31, 2005, due primarily to the impact of the Medicare Act". There are similar examples in other 10K and 10Q submissions by the pharmaceutical industry.

III. Understanding The Variations in Drug Prices And A Suggested Remedy

Once the price data has been validated and the price comparisons conducted, Congress should consider three questions:

1. *Are the price variations across the government agencies across the board or mostly for certain types of drugs?*

The theory and limited available data suggests that most government entities are paying similar prices for generics and widely different prices for "brand name" drugs. Orphan drugs and drugs without therapeutical equivalents may be special cases and show even greater variation across

government programs. It is important to know what categories of drugs are responsible for most of the variation.

Without the actual data we can not know if most of the variation occurs in certain types of drugs, however, there are some indications that it does.

In 2004, I coauthored a paper that was published in the peer reviewed journal Health Affairs. In the paper we compared the prices for the 30 most commonly sold drugs in the United States to the prices for the same 30 drugs in Canada, the United Kingdom and France in 2003. What we found was that the United States was paying substantially higher prices for the market basket of the 30 most commonly prescribed drugs. We assumed that the private sector would obtain a 20% reduction from the average wholesale price (AWP). **We then calculated that the United States consumer was paying 52% more than people in the United Kingdom, 67% more than people in Canada, and 92% more than people in France for the market basket of 30 drugs.**

However, in conducting the analysis, we also found that the markups were not uniform across the 30 drugs. This illustrates why it is important to analyze the relative prices for each individual drug.

Table 2 compares the prices in the US to the prices in the other countries for each of the 30 drugs. For example, in 2003, **10 doses of Lipitor cost 36% more in the US than Canada, 86% more than in France and 65% more than in the UK. 20 doses of Zocor cost 42% more in the US than Canada, 190% more than in France, and 69% more than in the UK**. Sometimes the US gets the lowest price (Viagra) and in most cases the US pays the highest price.

2. *What explains the variations in prices*?

Each of the government agencies has a somewhat different approach to determine the price that will be paid for each drug. As a result price variations are to be expected. Some of the government agencies use a formula, others use negotiation, and others rely on the market price. It will be interesting to learn which of the approaches is able to obtain the lowest overall prices and which approach can get the lowest prices for different types of drugs.

My expectation is that the price differences will vary by whether the drug is generic or brand name and whether it is an orphan drug or a drug without a therapeutic equivalent. My expectation is that the generic drugs will show the least variation and the most unique drugs will show the most variation.

3. *Should the federal government consolidate its approach to purchasing drugs?*

Most other industrialized countries have a single entity that purchases drugs for the government. This may be a more effective way for the federal government to pay for drugs. As shown earlier, the US pays the highest prices for most drugs. Having multiple purchasers of drugs within the government could make the US a less effective purchaser of drugs if the objective is to pay the lowest price for drugs.

More important, the current system of each component of the federal government purchasing drugs independently does not seem to be working. This testimony has relied on numerous studies suggesting that several government programs such as 340 B plans and Medicaid do not know the actual prices they are paying for drugs. The Medicare program does not know the prices that the Part D plans are paying for drugs. There are numerous studies documenting fraud, abuse, and waste in the purchase of drugs. Finally the limited data that is available suggests that there are substantial variations in how much federal government agencies are paying for drugs.

Given the likely variation in prices the different government agencies pay for drugs, I wonder if there is any rationale for the variation in prices across government agencies. I have trouble finding a rationale.

I have trouble understanding why certain government programs should pay more for drugs than others. Should the Medicare program pay more than the Veterans Administration? Should the military pay more than community health centers? Should Medicaid programs pay more than the Indian Health Service? The question becomes what government entity and ultimately what government beneficiary is entitled to pay the lowest price for drugs because they are most deserving.

Currently it seems that the Military and the VA are paying the lowest prices. Both Secretaries negotiate for drug prices.

Because I cannot answer the question of which government program should pay the lowest price, **I believe the Congress should consider greater consolidation of government drug pricing.**

Thank you for the opportunity to testify this morning and I would be happy to answer any questions.

Table 1

Key Factors for Part D Expenditure Estimates

Calendar Year	Annual Per Capita Drug Cost Increase	Cost Management and Discounts	Manufacturer Rebates	Plan Administrative Expenses
Intermediate estimates				
2006	7.1%	21.0%	6.0%	12.5%
2007	7.2	21.0	6.0	11.8
2008	7.3	21.0	6.0	11.9
2009	7.4	21.0	6.0	11.6
2010	7.5	21.0	6.0	11.5
2011	7.5	21.0	6.0	11.3
2012	7.6	21.0	6.0	11.1
2013	7.7	21.0	6.0	10.9
2014	7.7	21.0	6.0	10.7
2015	7.7	21.0	6.0	10.4

Source: CMS Actuaries, 2006 Report

Table 2 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003

Product	Dose	US: Canada	US: France	US:UK
Lipitor	10	1.36	1.86	1.65
Lipitor	20	1.64	.	1.49
Lipitor	40	1.63	1.41	2.13
Lipitor	80	1.67	1.89	1.64
Zocor	20	1.42	2.90	1.69
Zocor	40	1.80	1.79	1.75
Zocor	10	1.00	.	1.30
Zocor	80	1.27	.	1.24
Zocor	5	1.46	1.78	.
Prevacid	30	1.59	.	.
Prevacid	15	1.47	.	.
Paxil	20	1.60	2.48	2.07
Paxil	40	.	.	.
Paxil	10	1.62	.	.
Paxil	30	1.52	.	1.21
Zoloft	100	1.45	.	1.21
Zoloft	50	1.27	1.96	1.62
Zoloft	25	3.41	2.56	.
Celebrex	200	2.29	2.06	2.14
Celebrex	100	2.95	2.65	2.75
Celebrex	400	.	.	.
Norvasc	5	0.96	1.58	1.26
Norvasc	10	1.09	2.63	1.46
Norvasc	2.5	.	.	.
Neurontin	300	1.21	1.38	1.08
Neurontin	100	1.29	1.86	1.09
Neurontin	400	1.24	1.42	1.12
Neurontin	600	1.13	1.36	0.89
Neurontin	800	1.03	1.32	0.94
Effexor	75	1.23	.	1.27
Effexor	37.5	1.94	2.75	1.69
Effexor	25	.	4.08	.
Effexor	100	.	.	.
Effexor	50	.	2.76	1.22
Pravachol	40	2.00	1.93	1.93
Pravachol	20	1.45	2.00	1.16
Pravachol	10	1.74	.	2.15
Pravachol	80	.	.	.
Vioxx	25	2.46	1.73	1.76
Vioxx	12.5	2.07	1.60	1.59
Vioxx	50	.	.	.

Table 2 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003 (Continued)

Fosamax	70	1.68	1.22	1.22
Fosamax	35	.	.	.
Fosamax	10	1.24	1.34	1.25
Fosamax	5	1.62	1.32	1.18
Fosamax	40	1.50	.	.
Wellbutrin	75	.	.	.
Wellbutrin	100	2.39	.	.
Zithromax	250	1.59	2.03	1.61
Zithromax	600	1.40	.	.
Zithromax	500	.	.	1.71
Zithromax	1000	.	.	.
Zithromax	250	.	.	.
Singulair	10	1.32	1.42	1.41
Singulair	5	1.97	1.44	1.43
Singulair	4	2.13	.	1.39
Ambien	10	.	9.62	9.01
Ambien	5	.	.	9.98
Levaquin	500	2.02	.	.
Levaquin	250	2.00	.	.
Levaquin	750	.	.	.
Viagra	100	0.89	0.78	0.78
Viagra	50	0.89	0.93	0.95
Viagra	25	0.93	0.99	1.04
Premarin	0.63	6.27	3.39	3.28
Premarin	1.25	5.16	2.85	3.63
Premarin	0.3	5.36	.	.
Premarin	0.9	4.18	.	.
Premarin	2.5	.	.	5.71
Claritin	10	3.64	5.43	5.37
Augmentin	875	2.95	.	.
Augmentin	500	3.46	4.13	.
Augmentin	250	2.54	3.17	.
Toprol	50	2.99	.	9.10
Toprol	100	2.66	1.21	8.34
Toprol	25	.	0.79	.
Toprol	200	4.29	2.27	5.60
Synthroid	0.08	5.70	.	.
Synthroid	0.1	6.65	.	.
Synthroid	0.05	8.84	.	.
Synthroid	0.13	6.68	.	.
Synthroid	0.15	7.98	.	.
Synthroid	0.03	4.94	.	.
Synthroid	0.11	5.84	.	.

Table 2 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003 (Continued)				
Synthroid	0.2	8.55	.	.
Synthroid	0.18	6.84	.	.
Synthroid	0.3	6.34	.	.
Ortho-tri-cyclin	0	2.98	3.19	.
Allegra-D	60	3.02	.	.
Glucotrol	10	.	1.61	.
Glucotrol	5	.	1.68	.
Glucotrol	2.5	.	.	.
Zestril	20	2.74	0.99	1.12
Zestril	10	1.11	.	1.22
Zestril	40	.	.	.
Zestril	5	1.41	2.81	1.55
Zestril	30	.	.	.
Zestril	2.5	.	.	1.34
Amoxicillin	500	.	0.72	0.74
Amoxicillin	250	.	.	0.70
Amoxicillin	875	.	.	.
Atenolol	50	.	0.32	0.66
Atenolol	25	.	.	0.74
Atenolol	100	.	0.29	0.99
Flonase	—	2.41	3.90	2.36

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 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.

[The prepared statement of Mr. Moorman follows:]

Testimony of James W. Moorman, President and CEO
Taxpayers Against Fraud
on
The False Claims Act and Fraud Against Medicaid by Drug Manufacturers
before the
Committee on Oversight and Government Reform
United States House of Representatives
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Summary of Testimony

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 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.

So far there have been 16 settlements 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, it's likely to be in the $60 billion range.

There is a serious danger that the Justice Department will be unable to resolve most of these cases in a timely and satisfactory manner. The reason is a lack of resources and top-level leadership. Cases are being resolved at the rate of less than three a year. Many cases are over a decade old. A seriously inadequate number of lawyers are assigned to the cases. Only a few U.S. Attorneys offices (principally Boston and Philadelphia) are seriously involved. Money allocated from the Health Care Fraud and Abuse Control ("HCFAC") Account for health care fraud cases has been withheld. Support from investigative agencies is skimpy. 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 provides the government with an opportunity to close a multi-billion dollar fraud gap---

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*. The top officers of the Department must take an active interest in these cases; adequate resources must be deployed quickly; HHS must provide more support; full support by investigative agencies is mandatory; the Civil Division's fraud section must be augmented; more US Attorney 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.

Introduction

My name is James W. Moorman and I am the President of Taxpayers Against Fraud, also known as "TAF" and as "The False Claims Act Legal Center," a position I have held for the past seven years. I am an attorney by training and served as an Assistant Attorney General of the Department of Justice under Attorneys General Griffin Bell and Benjamin Civiletti. Between my service at Justice and TAF, I was a partner in the law firm of Cadwalader, Wickersham & Taft.

Taxpayers Against Fraud and its sister organization, Taxpayers Against Fraud Education Fund, are non-profit charitable organizations dedicated to combating fraud against the Federal Government and state governments through the promotion of the use of the *qui tam* provisions of false claims acts, especially the federal False Claims Act, 31 U.S.C. §§ 3729- 33 ("FCA"). *Qui tam* is the mechanism in the FCA that allows persons with evidence of fraud involving government programs or contracts to bring suit on behalf of the federal government. The cases are filed in federal court under seal, giving the Justice Department an opportunity to review the allegations and decide if it wants to intervene. Under the FCA, those that commit fraud are subject to triple damages and civil penalties.

Thanks to the efforts of whistleblowers that use false claims acts, their lawyers, lawyers on the fraud team in the Civil Division of the Department of Justice, Assistant United States Attorneys in several very active US Attorneys offices, and certain members of Congress, the public, over the past few years, has become aware of fraud against government health care programs and the potential of the FCA and its whistleblower provisions to curb such fraud. Since the enactment of the 1986 amendments to the FCA, settlements and judgments related to health care fraud have totaled more than $12 billion. This money has, further more, been recouped very efficiently. As health economist Jack Meyer concluded in a report, updating earlier reports and released by TAF Education Fund, the federal government has realized $15 in direct recoveries for every $1 it has invested in investigating and prosecuting health care fraud through the FCA. [1]

Types of Fraud Against Medicaid

My testimony focuses on fraud by some drug manufacturers against Medicaid, which, until the enactment of Medicare Part D, was the largest government purchaser of drugs and remains the second largest. TAF Education Fund has been monitoring cases in

[1] Jack Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck*, July 2006. See www.taf.org

this area, the first of which was settled in 2001. We have published two reports on the subject that are posted on our website, and we are about to release a third. [2]This testimony draws upon the information in these reports.

Over the past six years, there have been 16 settlements of FCA cases involving allegations of fraud by drug manufacturers against federal health care programs, 14 of which have involved Medicaid. These settlements total nearly $4 billion, including $3 billion in civil damages recouped by the federal government and the states, as well as nearly $1 billion in criminal penalties.[3]

The settlements involve three general categories of fraud: concealment of best price; inflation of average wholesale prices (AWP); and off-label marketing:

- **Concealment of Best Price**. In order for a drug manufacturer to sell its prescription drug products to Medicaid, the manufacturer must enter into an agreement with the Secretary of HHS to provide rebates to the federal and state governments for the drugs that Medicaid buys on behalf of its beneficiaries. In the case of generic drugs, the rebate is 11% of average manufacturer price, or AMP (the average price paid by wholesalers to manufacturers for drugs distributed to retailer pharmacies.) In the case of brand-name drugs, the rebate amount is the greater of (1) 15.1% of AMP or (2) the difference between AMP and the "Best Price" (the lowest price a manufacturer sells its product to most customers.) Manufacturers must report AMP and Best Price information to HHS, which calculates the rebates due based on the data. More than half of the FCA settlements involve manufacturers concealing Best Prices that they gave to customers on brand-name drugs in order to avoid paying higher Medicaid rebates. As a result, the cost of these drugs to federal and state governments was higher than it should have been. Nine of the settlements to date, totaling over $2.5 billion, have involved concealment of Best Price.

* **Average Wholesale Price (AWP).** When State Medicaid programs pay for prescriptions, they pay the pharmacist a dispensing fee plus the estimated cost to the pharmacist of acquiring the drug from the wholesaler or directly from the manufacturer. Many states base their estimated acquisition cost on a drug's "Average Wholesale Price," or "AWP," which is reported by the manufacturer to price reporting services or, in some cases, directly to the state. AWP fraud occurs when a manufacturer reports inflated prices that bear no relation to the actual price that the pharmacist pays for the drug. The pharmacist keeps the difference between what the Medicaid program pays for the drug and the price the pharmacist actually pays the wholesaler or the manufacturer. Manufacturers use this differential in order to incent

[2]Andy Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers*, November 2003; Andy Schneider, *The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update*, November 2004; see www.taf.org

[3] Attachment B contains tables and figures summarizing these settlements. Attachment C is a list of citations of the cases.

pharmacies to purchase their drug instead of that of a competitor. This is often referred to as "marketing-the-spread." The result is that Medicaid pays inflated prices for the ingredient cost of the drug.

* **Off-label Marketing.** Medicaid covers all prescription drugs approved by the Food and Drug Administration when they are prescribed by a physician and are medically necessary. The FCA approves drugs only for specific purposes, which appear on the drug's labeling materials. Doctors are legally permitted to prescribe drugs for unapproved, or "off-label" uses as well, and many physicians do so. Manufacturers, however, may not lawfully promote or market their products for unapproved, off-label uses to physicians or others. However, such marketing does occur, often accompanied by the use of illegal kickbacks. When off-label marketing induces physicians to prescribe drugs for unapproved uses and Medicaid pays for those prescriptions, Medicaid spending goes up.

Best Price Fraud

As noted, FCA settlements involving concealment of Best Price account for the largest share of recoveries to date. While this may change as future settlements are announced, I want to explain this type of fraud in more detail because of the importance of drug coverage to Medicaid beneficiaries and the importance of the Medicaid rebate program to lowering Medicaid spending on prescription drugs. The more the federal government can reduce fraud against the Medicaid rebate program, the farther that federal and state tax dollars will go in purchasing needed medicines for low-income Americans.

Assume that a manufacturer reports to HHS that the average manufacturer price, or AMP, of a specific unit of one of its brand-name drugs is $79. If the manufacturer charges all of its customers $68 or more for that unit of that drug, then the rebate the manufacturer is required to pay on each prescription sold to Medicaid is 15.1% of the AMP, or $11.93. Thus, if Medicaid buys 100 prescriptions, the rebate owed is $1193.

Now assume that the manufacturer charges a customer $64 for that unit of the drug in question. In that case, $64 becomes the Best Price and the rebate that the manufacturer has to pay on each prescription sold to Medicaid is AMP ($79) minus Best Price ($64), or $15 dollars. If Medicaid pays for 100 prescriptions of the drug, the rebate owed becomes $1500.

Best Price fraud involves concealing the $64 Best Price from HHS, so that HHS calculates the rebate amount to be 15.1%, or $11.93. The gain to the manufacturer is the difference between $11.93 and $15, or $3.07, multiplied by the number of prescriptions Medicaid buys. Thus if Medicaid buys 100 prescriptions, that amount is $307 ($1,500 minus $1,193 equals $307). In other words, $307 is the loss to Medicaid and federal and state taxpayers, who are paying $307 more for the 100 prescriptions than federal law allows.

There are several ways Best Price has been concealed from HHS. The most straightforward is to simply not report the cash discounts given to a customer. That is what happened in the $49 million settlement with Pfizer in 2002. Pfizer marketed Lipitor

to the Ochsner Health Plan by giving it cash discounts to list the drug in its formulary. The cash discount reduced the price of Lipitor to Ochsner. However, when Pfizer reported its Lipitor prices to HHS, it did not report the discount to HHS. Because the discounts were not reported, the rebate amount on the drug was less than it should have been, and Medicaid ended up paying over $20 million more for Lipitor than it should have during the time period covered by the case.

A variation on this theme is the $345 million settlement with Schering-Plough in 2004. In order to place its most profitable product, the anti-histamine Claritin, on the formularies of certain national HMOs, Schering-Plough paid the HMOs kickbacks disguised as "data fees" or "risk share" payments. These kickbacks had the effect of lowering the price of Claritin to the HMO, but when Schering-Plough reported to HHS the price charged to the HMO, it did not report the price net of the "data fees" or "risk share" payments. As a result, Schering-Plough paid a significantly smaller rebate to Medicaid than it was required to pay.

An even more creative approach to concealing Best Price is known as "lick and stick." This is what happened in the $257 million settlement with Bayer Corporation in 2003, which involved, among other drugs, the antibiotic Cipro. An HMO insisted on a deep discount, but Bayer did not want to give Medicaid a rebate based on that discounted price. In order to evade reporting that price as its Best Price, Bayer placed the HMO's National Drug Code number instead of its own on the label of the drugs it sold to the HMO at the deeply discounted price. Bayer did not include the price of the mislabeled drugs in its reports to HHS.

It is worth stressing that in each of these settlements (and others), the reason the federal government found out about the fraud was not because of a government audit or HHS oversight. Rather, it was because a private whistleblower, using the FCA, brought the information to the federal government's attention.

The Extent of the Fraud

The scale of the fraud problem with the pharmaceutical manufacturers is only hinted at by the sixteen settlements (nine of which included Best Price fraud) and the $4 billion in civil damages and criminal penalties they have produced. In addition to those sixteen cases, there are a very large number of cases on file involving extensive fraud liability that have not been resolved. Because of a peculiarity of the False Claims Act, cases brought by whistleblowers under the Act are filed under seal and remain under seal while government investigations are undertaken. For that reason, it is difficult to obtain precise information about this litigation. However, Mr. Peter Keisler, the Assistant Attorney General for the Civil Division of the Justice Department informed the House Judiciary Committee on August 11, 2006 that the Department had "over 180" such cases on its docket.[4] Added to these cases would be cases filed in state courts under state false claims acts and cases filed by state attorneys general under other statutes.

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[4] *Written Responses of Peter D. Keisler, Assistant Attorney General, Civil Division, before the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, United States House of Representatives, Concerning Budget and Resource Needs of the Justice Department Civil Division for Fiscal Year 2007*, submitted August 11, 2006

In addition to the cases under seal, there are some cases out from under seal that have not been resolved, most prominently a series of cases against Abbott Laboratories in California, Florida, Massachusetts, and Texas. In addition to Abbott, cases now out from under seal in Massachusetts involve at least 48 drug companies.[5] Also, a preliminary settlement for half a billion dollars with Bristol Myers Squibb has been announced, though details have not been released. As recently as January 29, 2007, the Justice Department announced that it had unsealed and joined a case against Boehringer Ingelheim Roxane, Inc alleging damages of $500 million.

It is also difficult to get a precise handle on the amount of the potential liability involved in the unresolved cases, but it appears to be very large. The announced half-billion dollar settlement with Bristol alone equals 12% of the $4 billion recovered in the sixteen previous settlements. The alleged half-billion dollars of damages owed by Boehringer is another 12%. The potential liability in the cases against Abbott and others out from under seal are in the same magnitude or larger. There are indications that many of the other cases under seal also involve quite large liabilities. Thus it would not be unreasonable to assume that the total potential liability of the 180 outstanding cases could be somewhere in the $60 billion range, or above.

The Dangers and Opportunities Presented

This astounding situation presents us with a danger and with an opportunity. The danger is that these cases will not be satisfactorily resolved; that one way or another the drug manufacturers will find a way to dodge their liability; and that they would be able to continue to develop and implement business plans and practices designed to plunder Medicaid and other government health programs, damaging those programs, taxpayers, and the beneficiaries of these programs.

The opportunity to be found in these cases is that the leaders of the departments responsible for pursuing the drug company fraud cases, the Attorney General and the Secretary of Health and Human Services, could, if they chose, use these cases to force the drug manufacturers to disgorge their fraudulently obtained funds. At the same time they could impose corporate integrity agreements with the settling companies that would put an end to the fraudulent practices and establish honest dealing with Medicaid and other health care programs. Such agreements could become the keystone of the companies' future good citizenship.

As things stand now, failure is far more likely than that the opportunity will be grasped. A drift toward failure is the current *status quo*, while grasping the opportunity would require a change of course.

Major Program Insufficiencies

The Committee will no doubt be interested in why the current course of conduct will lead to failure, especially in the light of the successes so far. The answer is complex, involving insufficiencies in manpower and the leadership necessary to bring the cases to a satisfactory resolution.

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[5] See Attachment A.

To begin with, the Department of Justice attorneys handling the cases against the drug manufacturers are simply overwhelmed and unable to prosecute a large portion of the cases in a timely manner. This is not because they are not good lawyers or because they are not trying. To the contrary, the Justice Department's attorneys involved in cases against drug manufacturers are very capable, hard working and dedicated. They are simply stretched to the breaking point.

The Justice Department in recent years has been able, on an annual basis, to resolve only between 90 and 100 FCA cases of all kinds. Of those cases, in the last six years, they have averaged less than three drug fraud cases resolved per year. At that rate, it will take many decades to resolve the 180 cases against drug manufacturers currently on the Departments docket. Actually, the backlog is not declining and cannot decline under the *status quo*, because more cases against drug manufacturers are filed each year than are resolved.

A further indication of the Justice Department's resource problem is the length of time the cases in question remain under seal. Many have remained under seal for ten years or more. When the Justice Department recently unsealed and joined a case against Abbott Laboratories that it could not settle, the case had been under seal for eleven years. The reason for this situation relates directly to the shortage of resources. The FCA provides that cases brought by whistleblowers be filed under seal in order to give the government a chance to investigate the cases in order to determine whether they wish to join the cases or leave them to the whistleblowers to pursue. A complicated fraud case, such as those against the drug manufacturers, could easily require two or three years of intensive investigation. However, the extensive time periods that drug fraud cases remain under seal indicates that the Department does not want to decline the cases, but does not have the resources to make timely investigations or to litigate the cases it cannot settle. Furthermore, the manufacturers are aware of this and are attempting to use Justice's lack of resources as leverage to reduce the amount they are required to repay or to delay settlement indefinitely with the hope of running out the clock on Justice.

A review of the Department's resources dedicated to FCA cases indicates that funds available for such a major set of cases are woefully inadequate. The monetary resources available for FCA cases at the Civil Division, which houses the central FCA fraud section, has been in the $20 million to $23 million range in the years FY2004 through FY2006. This pays for a fraud section that includes about 70 or so attorneys and is responsible for all civil matters involving fraud against the United States. How many of these have been deployed on drug manufacturer fraud cases in recent tears is not clear to me, but I estimate, very uncertainly, that it adds up to a dozen or so full time attorneys.

The money available for all FCA cases in the U.S. Attorneys offices has dropped from $58.5 million to $57.3 million in the years from FY2004 to FY2006. It is unclear, however, how much of the money and how many attorneys in the U.S. Attorneys offices are actually working on FCA cases, much less working on drug fraud cases. It appears that the money referred to is widely distributed to the various U.S. Attorneys offices, but that only a small percentage of those offices evidence concerted efforts to pursue FCA cases. Thus, an unusually large percentage of cases seem to be lodged in only a few U.S. Attorneys offices – for example, in Boston and Philadelphia, which appear to be completely swamped by the cases. A few other offices may also have begun to pursue a

significant number of cases, but most U.S. Attorneys offices are simply missing in action. Though a guess, probably about 25 Assistant U.S. Attorneys are pursuing the 180 cases against the drug manufacturers on a full time basis. Whatever the precise number, though, there are simply far too few attorneys deployed to seriously pursue all of these huge cases.

The lack of resources available to pursue drug FCA cases cannot be a matter of economy. To the contrary, the resources deployed by the Justice Department in health care fraud cases have been repaid many fold. As noted above, health economist Jack Meyer calculates that the government, principally the Justice Department, gets back $15 for every dollar it spends on health care FCA cases. Despite this outstanding return-on-investment, it appears that the Department is actually withholding funds intended for health care fraud cases from the offices pursuing such cases. The Attorney General and the Secretary of Health and Human Services have routinely reported that they are providing $14.5 million to the Civil Division and $30 million to the U.S. Attorneys offices for health care fraud. Money appropriated to the Health Care Fraud and Abuse Control (HCFAC) Account is allocated annually by the Attorney General and the Secretary of HHS.[6] In FY 2005, for example, the HCFAC Report[7] reveals that $30,400,000 was allocated to U.S. Attorneys and $14,459,000 to the Civil Division for "anti-fraud activities." These numbers are typical of such allocations in recent years. However, as reported by Assistant Attorney General Peter Keisler to the House Judiciary Committee on August 11, 2006, it seems that only $10 million was actually provided to the U.S. attorneys in each of the years 2004-2006 and a varying amount as low as $6.5 million to the Civil Division in those years.

It also appears that the key investigative agencies have not stepped up to the plate to support these cases. Jack Meyer, in making the report mentioned above, determined that the Office of Inspector General at HHS is only supporting the Justice Department's health care FCA cases to the amount of $10 million or less.[8] The FBI, which has been provided $114 million from the HCFAC Account on an annual basis to combat health care fraud, simply spends nowhere near that amount to support health care FCA cases. While this cannot be quantified without the FBI's cooperation, the FBI appears to be spending far, far less, but has not been candid about what it has spent.

It is not just resources that are lacking, it is also leadership that is lacking. The Department of Justices fraud section is lodged within the Commercial Litigation Branch of the Civil Division. Its attorneys do not have the standing within the government to command additional resources from within or without their own Department or to cause other elements of the government to give priority to any particular set of their cases. Only the Attorney General and the Deputy Attorney General have such standing. Thus, the actual attorneys struggling with the fraud cases are not going to receive the additional assistance they need without leadership initiative from above.

The consequences of allowing the FCA drug cases to drift along on their current course, with only two or three cases resolved each year, no matter how much effort the

[6] See Sections 112C(a) and 1817(k)(5) of the social security Act.
[7] oig.hhs.gov/publications
[8] Jack A. Meyer, *Fighting Medicaid Fraud, More Bang for the Federal Buck*, July 2006 (Table 4, p.10); see www.taf.org

current set of attorneys put into them, is predictably negative. A few more cases will be settled with apparent good results, but eventually this set of cases will falter. One cannot predict with certainty how they will falter, but falter they will. One way they could falter would be as the result of an unexpected judicial development. Recently the Court of Appeals for the Second Circuit ruled that the government, when it unsealed an FCA case and filed its own complaint, could not, for purposes of the statute of limitations, take advantage of the date when the whistleblower filed the original complaint.[9] Because the government has been forced to keep the drug cases under seal for so long, were that ruling to be followed and applied to the drug cases, many could falter on that ground alone. That is but an example of how an unexpected development could undermine the drug cases. Certainly, as time drags on, legal, political and other developments can and, over time, are likely to occur that will erode the government's ability to prevail. If not timely pressed to resolve these matters, eventually the companies could find a way to beat the rap.

Program Opportunities

One can hope that the faltering of the cases against drug manufacturers through delay and want of prosecution does not occur, for surely they present us with golden opportunities, including

- An opportunity to bring many billions of dollars defrauded from the government back to the taxpayers;
- An opportunity, going forward, to greatly reduce fraud against Medicaid and other government health care programs;
- An opportunity to redirect important companies that have become addicted to bilking Medicaid and Medicare;
- An opportunity for the pharmaceutical companies to put a shameful era of questionable billing practices behind them; and
- An opportunity to set rules of conduct in corporate integrity agreements that would prevent any one company from gaining an economic advantage over its competitors by cheating Medicaid and Medicare.

Recommendations

In order to grasp these opportunities, the following things must occur:

1. First and foremost, the highest officials of the Department of Justice, the Attorney General and the Deputy Attorney General, should act now to provide leadership, in word and deed, to force a resolution of the FCA cases against the pharmaceutical manufacturers on a basis favorable to the government.
2. The resource shortage dragging down the Justice Department's fraud fighters must be addressed quickly and affirmatively. The fraud team requires significant augmentation. Its status should be raised to the branch level. The missing HCFAC Account money should be immediately provided to both the Civil Division's fraud team and to the U.S. Attorneys Offices that are actually engaged. More U.S. Attorneys offices should be recruited into the action. The

[9] *U.S. ex rel. Cosens v. The Baylor University Medical Center,* 468 F.3d 263 (2d Cir. Nov.16 2006).

missing FBI's HCFAC Account funds should be located and put to their appointed use.

3. The full support of the Department of Health and Human Services is necessary from the Secretary on down. The full support, with significantly augmented resources, by the HHS--OIG and by CMS should be insisted on to provide support of the FCA cases against drug manufacturers.
4. The Departments of Justice and of Health and Human Services should use their full authority and leverage to bring the pharmaceutical companies to the table and impose agreements that will end the fraudulent practices that characterize the FCA cases. Only the direct efforts of these officials can end the manipulations on a basis that prevents any one company from victimizing its competitors and the taxpayers by cheating.
5. The Attorney General should take all possible action to keep the clock from running out on these cases and to prevent these cases from languishing.

Conclusion

If the recommended actions are taken, we could see an end to the business plan frauds by the pharmaceutical manufacturers against Medicaid and other government programs. If the *status quo* continues, we can expect the FCA cases against drug manufacturers to limp along with some more settlements, but at some point the effort will fail and there will be no reform of the massive fraud drug practices weighing down Medicaid and other health care programs.

- Attachment A -

Pharmaceutical Companies in Unsealed Medicaid Fraud False Claims Act Cases

- Abbott Laboratories
- Amgen
- Armour Pharmaceutical
- Aventis Pharmaceuticals
- Baxter Healthcare
- Bedford Laboratories
- Ben Venue Laboratories
- Boehringer Ingelheim Pharmaceuticals
- Braun of America
- C.H. Boehringer Sohn
- Centocorps Inc.
- Dey Pharmaceuticals
- Forest Pharmaceuticals
- Grundstucksverwaltung GMBH & Co.
- EMD
- Geneva Pharmaceuticals
- GlaxoSmithKline
- Glaxo Wellcome
- Burroughs Wellcome
- Hoechst Marion Roussell
- Hoffman-LaRoche
- Hospria Inc.
- Immunex
- Ivax-Pharmaceuticals
- Janssen Pharmaceutical Products
- Johnson & Johnson
- Lipha
- McGaw
- Merck
- Mylan Laboratories
- Mylan Pharmaceuticals
- Novartis
- Ortho Biotech Products
- Pfizer
- Pharmacia

- Attachment B -

Settled False Claims Act Cases Against Pharmaceutical Companies

Company	Settlement Date	Product	Total Recovery	Fraud Type	Whistleblower
AstraZeneca	6/20/03	Zoladex	$355 million	Marketing the spread and concealment of best price	Sales exec from competitor at TAP Pharmaceuticals
Baxter International	6/13/06	Generic drugs made by Baxter	8.5 million	Marketing the spread	Independent pharmacy
Bayer I	1/23/01	Kogenate, Koate-HP, Gamimmune	$14 million	Marketing the spread and concealment of best price	Independent pharmacy
Bayer II	1/23/01	Adelat CC, Cipro	$257 million	Concealment of best price	Bayer marketing executive
Dey I	6/11/03	Albuterol	$18.5 million	Marketing the spread	Independent pharmacy
Dey 2 (Connecticut FCA)	8/7/04	Albuterol	$2.5 million	Marketing the spread	Independent pharmacy
GlaxoSmithKline I	4/16/03	Paxil, Flonase	$88 million	Concealment of best price	Derived from Bayer marketing executive allegations.
GlaxoSmithKline II	9/17/05	Zofran, Kytril	$150 million	Marketing the spread	Independent pharmacy
King Pharmaceutical	10/30/05	Altace, Aplisol, Lorabid, and Fluogen	$124 million	Concealment of best price	Executive of King Pharmaceuticals
Pfizer I	10/28/02	Lipitor	$49 million	Concealment of best price	National account manager for Pfizer subsidiary
Pfizer II	5/13/04	Neurontin	$430 million	Off-label marketing	Medical liaison to physicians for Pfizer subsidiary
Roxane Labs, Boehringer Ingelheim Pharmaceuticals, and Ben Venue Laboratories (Texas FCA)	11/25/05	Albuterol	$10 million	Marketing the spread	Independent pharmacy
Schering-Plough I	5/3/04	Albuterol	$27 million	Marketing the spread	Independent pharmacy
Schering-Plough II	7/29/04	Claritin	$345 million	Concealment of best price	Three employees of Schering-Plough subsidiary
Schering-Plough III	8/26/06	Temodar, Intron-A, K-Dur, Claritin RediTabs	$435 million	Concealment of best price, Marketing the spread	Three employees of Schering-Plough
Serono	10/17/05	Serostim	$704 million	Off-label marketing and kickbacks	Five Serono employees in two states.
TAP Pharmaceuticals	10/3/01	Lupron	$875 million	Marketing the spread and concealment of best price	HMO Physician and TAP sales executive
TOTAL			**$3.894 Billion**		

- Attachment C -

Citations for Settled False Claims Act Cases Against Pharmaceutical Companies

DEFENDANT	CASE CITATION
AstraZeneca	*U.S. ex rel. Durand v. AstraZeneca Pharmaceuticals LP*, No. 03-122-JJF (D. Del. 2003)
Baxter International	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc. et. al.*, No. GV401286 (District Court Travis County, 201st Judicial District 2006)
Bayer I	*U.S. ex rel. Ven-A-Care v. Bayer Corporation*, No. 95-1354-Civ. (S.D. Fla. 2001)
Bayer II	*U.S. ex rel. Estate of Couto v. Bayer Corporation*, No. 00-10339 (D. Mass. 2001)
Dey I	*U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. Dey Pharmaceuticals*, No. GV002327 (District Court Travis County, 53rd Judicial District 2004)
GlaxoSmithKline I	*U.S. ex rel. Estate of Couto v. Bayer Corporation. et al*, No. 00-10339 (D. Mass. 2003)
GlaxoSmithKline II	*U.S. ex rel. Ven-A-Care of the Florida Keys Inc. v. GlaxoSmithKline PLC*, docket number sealed, settlement announced (D. Mass. 2005)
King Pharmaceuticals	*U.S. ex rel. Bogart v. King Pharmaceuticals, Inc.*, No 03-1538 (E.D. Pa 2005)
Pfizer I	*U.S. ex rel. Foster v. Pfizer*, No.1:00-cv-00246 (E.D. Tex. 2002)
Pfizer II	*U.S. ex rel. Franklin v. Warner-Lambert*, No. 96-11651-PBS (D. Mass. 2004)
Roxane Labs et al.	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Roxane Laboratories Inc.*, No. GV3-03079 (District Court Travis County, 201st Judicial District) and No. GV002327 (District Court Travis County, 53rd Judicial District 2005)
Schering-Plough I	*State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering-Plough*, No. GV002327 (District Court Travis County, 53rd Judicial District 2004)
Schering-Plough II	*U.S. ex rel. Alcorn v. Schering-Plough Corporation*, No. 98-5868 (E.D. Pa. 2004)

Schering-Plough III	*In re Pharmaceutical Industry Average Wholesale Price Litigation*, No. 01-CV-12257-PBS settlement announced (D.Mass. Aug. 10, 2006).
Serono	*U.S. ex rel. Driscoll v. Serono Laboratories, Inc.*, C.A. No. 00-11680 (D. Mass. 2000)
TAF Pharmaceuticals	*U.S. ex rel. Gerstein v. TAP Holdings, Inc.*, No. 00-10547 (D. Mass. 2001)

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?

Dr. 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?

Dr. 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?

Dr. 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.

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 drugs that I use?

Dr. 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 pre-

cluded 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 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 is 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, DC, 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 encourag-

ing 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.

Dr. 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 referred to follows:]

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON
January 11, 2007

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington D.C. 20515

Dear Madam Speaker:

I commend the Administration and the Congress for their continued efforts to make prescription medications more available and affordable for the Medicare population. The Medicare Part D prescription program has provided an important benefit for all Americans.

However, I am concerned that as Congress considers legislation to address possible price negotiation authority for the Medicare Part D program that any new legislative authorities not inadvertently interfere with the Department of Veterans Affairs' (VA) nationally recognized formulary processes or our ability to achieve low pharmaceutical prices. These two critical and complimentary aspects of VA's pharmaceutical benefit strategy have allowed us to provide necessary prescription medication to America's veterans at reasonable prices. The Veterans Health Administration is the largest managed health care system in the United States. While it is gratifying that many recognize the success of VA's pharmacy benefit program, it is important to recognize that the VA and Medicare Part D programs differ significantly in their constituencies, strategies and structure.

The best intentions may result in unintended consequences. In early 1990, Congress was struck by the savings VA was able to achieve through its formulary management and contract negotiation process. Many contrasted VA pricing with Medicaid reimbursements for similar prescription products and uncovered significantly higher prices paid by the Medicaid program.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) was an attempt by Congress to reduce Medicaid's prescription drug costs by requiring that drug manufacturers give state Medicaid programs rebates for outpatient drugs. The rebates were based on the lowest of the "best" prices drug manufacturers charged other purchasers, such as health maintenance organizations and hospitals.

Instead of beginning to pay "best price" rebates to state Medicaid programs, pharmaceutical manufacturers began raising prices to all purchasers, including Federal purchasers. This also resulted in a decrease in rebates for the state Medicaid programs (GAO/HEHS-94-194FS Medicaid: Changes in Best Price). In response, Congress created additional legislation to provide statutory discounts to major Federal purchasers. The discount legislation was included in the Veterans Health Care Act of 1992 (VHCA). The VHCA eliminated Federal prices from best price rebate calculations and mandated that statutory discounts (known as Federal Ceiling Prices) be made available to VA, DoD, the Coast Guard now within the Department of Homeland Security and the Public Health Service (PHS) and Indian Health Service (IHS) within the Department of Health and Human Services. The VHCA included additional price protections for Federally Qualified Health Centers (FQHCs) and FQHC look-alikes.

VA maintains that Congress must recognize the success of VA's formulary process in providing optimal pharmaceutical care to veterans. VA's policy is to provide all medically necessary pharmaceuticals to treat the patient's medical condition. We accomplish this through a comprehensive national and regional based formulary system. While VA's goal is to include on its formulary those medications which best serve the needs of veterans, an exception process also exists to address those clinical situations in which the formulary drug does not produce the desired clinical outcome. This exception process permits the local facility to provide non-formulary medication when the local clinical leadership determines that the medication is clinically necessary for treatment of the patient's medical condition.

VA's vertically integrated health care system facilitates the provision of pharmaceutical care from prescriber to dispenser (pharmacy) to veteran. This fully integrated structure, along with the use of VA's electronic health record, supports an effective formulary management process and allows VA to provide the highest quality health care to veterans and monitor their progress.

VA's success in formulary management is due to the grassroots nature of its process; buy-in from front line physicians; reliance on medical evidence for decision-making; commitment to using the best drug(s) possible in the veteran population; and mechanisms specifically designed with available infrastructure and processes in mind. The cost of an individual drug is important, but is outweighed by the requirement to provide the right drug to the right patient at the right time. VA's overall pharmaceutical expenditures, as a percentage of its health care dollar, have increased at reasonable rates and I anticipate they will continue to increase at reasonable levels for the long-term benefit of veteran patients.

VA's prescription drug program has frequently been externally reviewed, including inspections by the Government Accountability Office and the Institute of Medicine. These reviews have concluded that VA operates a clinically and economically sound cost-effective prescription benefit plan. Additionally, patient and provider satisfaction with VA's prescription benefit program consistently ranks high in independently conducted surveys such as those directed by the American Customer Satisfaction Institute.

In conclusion, I ask that as Congress considers possible changes to the Medicare Part D program, it allow VA to continue on its proven path of success without interference. Now, more than ever, VA must ensure it has a continued capability to provide the services that are needed for those men and women who have served our Nation while in uniform.

Thank you for your continued support of veterans and the Department of Veterans Affairs. The Majority Leader and Minority Leader have also received similar letters.

Sincerely yours,

R. James Nicholson

CC:
The Honorable Charles B. Rangel, Chairman, House Committee on Ways and Means
The Honorable John D. Dingell Chairman, House Committee on Energy and Commerce
The Honorable Bob Filner, Chairman, House Committee on Veterans' Affairs
The Honorable Jim McCrery, Ranking Member, House Committee on Ways and Means
The Honorable Joe Barton, Ranking Member, House Committee on Energy and Commerce
The Honorable Steve Buyer, Ranking Member, House Committee on Veterans' Affairs

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?

Dr. 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 $1.013 trillion. 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 2½ years the program wasn't in effect.

Dr. 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.

Dr. 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?

Dr. 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?

Dr. 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?

Dr. 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. 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?

Dr. 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?

Dr. 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.

Dr. 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.

Dr. 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.

Dr. 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?

Dr. 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?

Dr. 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.

Dr. 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 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 have to 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 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.

Dr. 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?

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

Mr. TIERNEY. How large?

Dr. 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?

Dr. 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 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 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 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?

Dr. 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.

Dr. 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?

Dr. ANDERSON. Sure. But essentially what we have 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 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.

Dr. 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?

Dr. 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 have 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 priced 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 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 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?

Dr. 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?

Dr. ANDERSON. I think that you have 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?

Dr. 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?

Dr. 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 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 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 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 we acted forcefully with regard to all of these cases, we could actually perhaps get the pharmaceutical industry to have an attitude change toward 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 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 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 trillion.

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 un-

funded. 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?

Dr. 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. 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.

Dr. 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.

Second, 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 OK, 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.

Dr. ANDERSON. Other countries purchase drugs just like the United States do, and I think one of the things we have 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.

Second, 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 4th or 5th or 12th patent money given the drug product.

Dr. 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 de-

velop 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?

Dr. 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 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.

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 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 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 taxpayers who are being defrauded and you have 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 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.

Dr. 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.

Dr. 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?

Dr. 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 of the Government Accountability 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.

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 hands, 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.

STATEMENTS OF JOHN E. DICKEN, DIRECTOR, HEALTH CARE, GOVERNMENT 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

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.

[The prepared statement of Mr. Dicken follows:]

United States Government Accountability Office

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PRESCRIPTION DRUGS

Oversight of Drug Pricing in Federal Programs

Statement of John E. Dicken
Director, Health Care

February 9, 2007

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Highlights

Highlights of GAO-07-481T, a testimony before the Committee on Oversight and Government Reform, House of Representatives

PRESCRIPTION DRUGS

Oversight of Drug Pricing in Federal Programs

Why GAO Did This Study

Several federal programs help pay for or reduce the costs of prescription drugs for eligible individuals and entities. Three examples are the Medicaid drug rebate program, part of the joint federal-state Medicaid program that finances medical services for certain low-income people; the 340B drug pricing program, which provides discounted drug prices to certain eligible entities such as community health centers; and the Medicare Part D program, which provides a Medicare drug benefit for the elderly and certain disabled people. The price information drug manufacturers report under these federal programs affects related federal spending. Spending is also affected by the extent to which federal oversight ensures the accuracy of this information.

GAO was asked to provide information related to the oversight of prescription drug pricing practices that affect these federal programs. This testimony focuses on the oversight of drug pricing related to the three programs and the implications for future congressional oversight. This testimony is based on recent GAO reports examining these programs and related work by the Department of Health and Human Services Office of Inspector General and others.

www.gao.gov/cgi-bin/getrpt?GAO-07-481T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Dicken at (202) 512-7119 or dickenj@gao.gov.

What GAO Found

Regarding the Medicaid drug rebate program, GAO and others have reported inadequacies in the Centers for Medicare & Medicaid Services' (CMS) oversight of the prices manufacturers report to CMS to determine the statutorily required rebates owed to states. For example, GAO and others have reported a lack of clarity in CMS's guidance to manufacturers for calculating these prices. Several recent legal settlements under which manufacturers agreed to pay hundreds of millions of dollars to states because they were alleged to report inaccurate prices to CMS highlight the potential for abuse under the program. CMS recently issued a proposed rule intended to provide more clarity to manufacturers in determining the prices they report.

GAO and others have reported inadequacies in the Health Resources and Services Administration's (HRSA) oversight of the 340B drug pricing program and problems related to the lack of transparency in the maximum prices, called 340B prices, charged to eligible entities. GAO reported that HRSA did not routinely compare the prices actually paid by certain eligible entities with the 340B prices and that many of these eligible entities paid prices higher than the 340B prices. Because these prices are not disclosed to the entities, the entities are unable to determine whether the prices they pay are at or below these prices. In addition, because 340B prices are based on information reported by drug manufacturers for the Medicaid drug rebate program, inaccuracies under that program affect these prices. HRSA has made changes to its oversight of the program intended to address some of these concerns.

The Medicare Part D program shares in common with other federal programs certain features that led to federal agency oversight challenges. For example, Part D relies on multiple private organizations to report to CMS certain price concessions from manufacturers, similar to the Medicaid drug rebate program. Also, Part D relies on CMS's oversight to ensure that price information reported to it by private organizations are accurate, similar to the Medicaid drug rebate and 340B drug pricing programs. Other features of Part D, such as its reliance on contracts with private insurers to provide drug coverage to beneficiaries through a complex set of relationships and transactions with private entities, also suggest potential oversight challenges.

Oversight inadequacies, inaccurate prices, lack of price transparency, and the potential for abuse suggest areas the Committee may wish to consider as it develops its oversight agenda. The Committee may wish to consider the extent to which CMS and HRSA will systematically take steps to ensure the accuracy of prices reported and charged by private organizations that participate in federal programs. The Committee may also wish to consider the extent to which federal agencies will effectively monitor for and detect abuses in the reporting of drug price information that affect these three federal programs.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you examine prescription drug pricing practices that affect federal programs that help pay for or reduce the cost of prescription drugs, and the implications for future congressional oversight of the programs. Spending on prescription drugs in this country has risen by about 11 percent on average each year from 1998 through 2005 at retail outlets, faster than the average 7 percent yearly rate of increase in total U.S. health expenditures for health care services and supplies during the same period. Retail spending on prescription drugs from all sources in 2005 totaled about $201 billion, of which the federal government spent about $33 billion under various programs.[1] The federal spending amount precedes the 2006 introduction of the Medicare prescription drug benefit, known as Medicare Part D, which increased federal spending on prescription drugs.[2] The amount the federal government spends for prescription drugs is related in part to the price information drug manufacturers report to federal programs. In addition, federal oversight designed to ensure the accuracy of that price information is an important part of the effort to control federal spending.

To assist this committee as it develops its oversight agenda, you asked us for information pertaining to federal agency oversight of prescription drug pricing practices that affect the Medicaid drug rebate program, the 340B drug pricing program,[3] and the Medicare Part D program. Accordingly, my

[1]Centers for Medicare & Medicaid Services (CMS), Trustees, National Health Expenditure, Historical Data (Baltimore, Md: Centers for Medicare & Medicaid Services, 2007), http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp (accessed Jan. 9, 2007). The prescription drug spending figures reflect spending on prescription drugs through retail outlets, such as retail pharmacies, but do not account for spending through nonretail outlets, such as inpatient hospital or nursing home facility settings.

[2]The total federal contribution to Medicare Part D for 2006 is estimated at $58.3 billion, rising to $67.7 billion in 2007. See 2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Washington, D.C.: May 1, 2006).

[3]The joint federal-state Medicaid program finances medical services for certain low-income individuals. Within the Medicaid program, the Medicaid drug rebate program requires participating drug manufacturers to pay rebates to states as a condition of the federal contribution for covered outpatient prescription drugs. The Medicaid and Medicaid drug rebate programs are administered by the Centers for Medicare & Medicaid Services (CMS). Another federal program, the 340B drug pricing program, requires drug manufacturers that participate in the Medicaid program to provide drugs at discounted prices to eligible entities such as community health centers. The 340B drug pricing program is administered by the Health Resources and Services Administration (HRSA).

testimony today will focus on the oversight of drug pricing related to these three federal programs and the potential implications for future congressional oversight. My remarks today are based primarily on our 2005 and 2006 reports examining federal programs that help pay for or reduce the cost of prescription drugs, which were done in accordance with generally accepted government auditing standards.[4] I will also refer to related work by the Department of Health and Human Services Office of Inspector General (OIG) and others.

In summary, oversight inadequacies by federal agencies and a lack of transparency in drug pricing practices that affect federal programs have important implications for federal spending on prescription drugs. Regarding the Medicaid drug rebate program, we and others have reported inadequacies in the Centers for Medicare & Medicaid Services' (CMS) oversight of the price information reported by manufacturers to determine the rebates owed to states, including a lack of clarity in CMS's guidance to manufacturers for calculating that price information. Recent litigation involving allegations that drug manufacturers reported inaccurate prices to CMS resulted in several manufacturers agreeing to pay about $88 million, $257 million, and $345 million to states, thus highlighting the potential for abuse under the program. CMS recently issued a proposed rule intended to provide more clarity to manufacturers in determining the prices they report to CMS.

We and others have also reported inadequacies in the Health Resources and Services Administration's (HRSA) oversight of the 340B drug pricing program, a lack of transparency in the 340B prices, and overpayments to drug manufacturers. We reported in 2006 that HRSA did not routinely compare the prices actually paid by eligible entities with the 340B prices and that many entities we reviewed paid prices for drugs that were higher than the 340B prices. Because 340B prices are not disclosed to the eligible entities, the entities are unable to determine whether the prices they pay are at or below the 340B prices. In addition, because 340B prices are based on information reported by drug manufacturers for the Medicaid drug rebate program, inaccuracies in that information may affect 340B prices.

[4]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005); GAO, *Ryan White Care Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, GAO-06-646 (Washington, D.C.: Apr. 26, 2006); and GAO, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*, GAO-06-78R (Washington, D.C.: Oct. 28, 2005).

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

The Medicare Part D program shares in common with other federal programs certain features that led to federal agency oversight challenges related to the reporting of inaccurate price information in those programs. For example, the Medicare Part D program relies on private organizations that sponsor drug plans to calculate and report price information to CMS, much like the Medicaid drug rebate program relies on drug manufacturers to calculate and report drug pricing and price concession information to CMS. Also, the Medicare Part D program relies on CMS's oversight to ensure that price information reported to it by private organizations is accurate, similar to the Medicaid drug rebate and 340B pricing programs. Other features of the Medicare Part D program, such as its reliance on contracts with multiple private insurers to provide drug coverage to beneficiaries through a complex set of relationships and transactions with private entities, also suggest areas of potential oversight vulnerability.

Although actions taken by both CMS and HRSA may address some of the oversight inadequacies we and others have reported, it is too soon to know how effective these actions have been in improving program oversight. Thus concerns about oversight inadequacies, inaccurate price information, lack of price transparency, and the potential for abuse associated with federal programs that help pay for or reduce the cost of prescription drugs 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 take steps to systematically ensure the accuracy of price information reported by private sector organizations that participate in federal programs, and the extent to which cognizant federal agencies will effectively monitor for and detect abuses in the reporting of drug price information that affects the Medicaid drug rebate, the 340B drug pricing, and the Medicare Part D programs.

Background

The Medicaid drug rebate program, the 340B drug pricing program, and the Medicare Part D program help pay for or reduce the costs of prescription drugs for eligible individuals and entities.

The Medicaid Drug Rebate Program

Medicaid is the joint federal-state program that finances medical services for certain low-income adults and children. CMS, an agency of the Department of Health And Human Services (HHS), administers and oversees the program. While some benefits are federally required, outpatient prescription drug coverage is an optional benefit that all states have elected to offer. State Medicaid programs, though varying in design, cover both brand and generic drugs. Retail pharmacies distribute drugs to Medicaid beneficiaries, then receive reimbursements from states for the acquisition cost of the drug and a dispensing fee. In 2004, Medicaid outpatient prescription drug spending reached $31 billion, of which $19 billion was paid by the federal government.

To help control Medicaid drug spending, federal law requires manufacturers to pay rebates to states as a condition for the federal contribution toward covered outpatient precription drugs.[5] Rebates manufacturers must pay states for brand drugs under the Medicaid drug rebate program are based on two prices that drug manufacturers must report to CMS: the average manufacturer price (AMP) (the average price paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade) and best price (the lowest price available from the manufacturer to any purchaser with certain exceptions).[6] Both amounts are to reflect certain financial concessions that are available to drug purchasers. The statute governing the program and the standard rebate agreement that CMS signs with each manufacturer define AMP and best price and specify how these prices are to be used to determine the rebates due to states. CMS provides additional guidance to manufacturers regarding the calculation of these amounts. After manufacturers report the required price information to CMS, CMS uses it to calculate the rebate due for each unit of a brand drug and reports this to the states. The state Medicaid programs use the information to determine the amount of rebates to which they are entitled from the manufacturers based on the volume of drugs paid for by the programs.

[5]*See* 42 U.S.C. § 1396r-8.

[6]The basic unit rebate amount for a brand name drug is the difference between best price and AMP or 15.1 percent of AMP, whichever is greater.

The 340B Drug Pricing Program

The 340B drug pricing program[7] gives more than 12,000 eligible entities of various types—community health centers, disproportionate share hospitals, and AIDS Drug Assistance Programs (ADAP)[8] among them—access to discounted drug prices, called 340B prices. To access these prices, entities must enroll in the program, which is administered by HRSA. Drug manufacturers must offer covered drugs to enrolled entities at or below 340B prices in order to have their drugs covered by Medicaid.[9] Enrolled entities may generally purchase drugs in two ways. They may choose the direct purchase option to receive the 340B prices up front, or they may choose the rebate option, typically purchasing drugs through a vendor and later receiving a rebate from the manufacturer covering any amount they paid above the 340B prices. Enrolled entities spent an estimated $3.4 billion on drugs in 2003.

To determine the 340B prices, HRSA uses a statutory formula that relies on AMP and Medicaid rebate data that it receives from CMS.[10] Manufacturers separately calculate the 340B prices for their drugs using the statutory formula, and use these calculations as the basis for the prices they charge eligible entities. HRSA does not share the 340B prices with the eligible entities due to the statutory provisions regarding the confidentiality of information used to determine them.[11]

[7]The 340B drug pricing program is named for the statutory provision authorizing it, section 340B of the Public Health Service Act (codified at 42 U.S.C. § 256b).

[8]Among other services, community health centers offer primary and preventive health services to low-income individuals. Disproportionate share hospitals are hospitals that serve a relatively large volume of low-income patients and are eligible for payment adjustments under Medicare or Medicaid. ADAPs purchase HIV/AIDS drugs for enrolled low-income people who are uninsured or underinsured.

[9]If a drug manufacturer fails to sell drugs at or below the 340B prices, it can be dropped as a participating drug provider in the 340B and Medicaid programs.

[10]In general, the 340B price for a covered outpatient drug is based on AMP and the total unit rebate amount for the drug. HRSA began calculating the 340B prices on October 1, 2005. Previously, CMS performed the calculations.

[11]According to OIG, the confidentiality provision in the Medicaid drug rebate program statute related to AMP has been interpreted to mean that HRSA may not reveal the 340B prices to the entities. Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services, before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, December 15, 2005.

The Medicare Part D Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created a voluntary outpatient prescription drug benefit effective January 1, 2006, as Part D of the Medicare program.[12] Under Part D, Medicare beneficiaries may choose a prescription drug plan (PDP) from multiple competing PDPs offered by private organizations, often private insurers, that sponsor the plans. PDP sponsors enter into contracts with CMS, the agency that administers Medicare. PDPs may differ in the drugs they cover, the pharmacies they use, and the prices they negotiate with drug manufacturers and pharmacies. PDP sponsors may use pharmacy benefit managers (PBM) to negotiate with drug manufacturers and retail pharmacies for the prices of the drugs that each PDP covers.[13,14] PDP sponsors are required to report to CMS the price concessions they negotiate; these price concession include discounts, rebates, direct or indirect subsidies, and direct or indirect remunerations.

[12]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101 to 1395w-152). MMA redesignated the previous Part D of title XVIII of the Social Security Act as Part E and inserted a new Part D after Part C.

[13]In the private health insurance market, health plans typically contract with PBMs to help manage their prescription drug benefits. PBMs negotiate rebates or payments with drug manufacturers, encourage substitution of generic drugs for therapeutically similar brand drugs, and negotiate discounted prices with networks of retail and mail-order pharmacies, passing along at least some of the savings to health plans and enrollees. PBMs influence price negotiations with manufacturers through formulary development and management and through the large market share they often represent.

[14]MMA prohibits the Secretary of Health and Human Services from interfering with price negotiations between PDP sponsors and drug manufacturers and pharmacies. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-111(i)).

Oversight Inadequacies in the Medicaid Drug Rebate Program Raise Concerns about the Accuracy of Rebates Paid to States

We and others have reported inadequacies in CMS's oversight of the price information reported by manufacturers under the Medicaid drug rebate program, including a lack of clarity in CMS's guidance to the manufacturers for calculating prices. We reported in 2005 that CMS conducted only limited checks for errors in manufacturer-reported drug prices and that it did not generally review the methods and underlying assumptions that manufacturers use to determine AMP and best prices.[15] We also noted in that report that OIG found that CMS did not provide clear program guidance for manufacturers to follow when determining those prices—for example, how to treat sales to certain health maintenance organizations (HMO) and PBMs.[16] OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, a lack of manufacturer documentation, or both. Our review also examined the pricing methodologies of several large drug manufacturers and found considerable variation in the methods they used to determine AMP and best price, and some of these differences could have affected the accuracy of these prices and thereby reduced or increased rebates to state Medicaid programs. OIG similarly identified problems with manufacturers' price determination methods and their reported prices in four reports issued from 1992 to 2001.[17]

Recent litigation has highlighted the importance of the accuracy of prices manufacturers report to CMS and the rebates they pay to states. For example, two drug manufacturers agreed to pay about $88 million and $257 million, respectively, to states in 2003 to settle allegations that they failed to include in their best price determinations certain sales to an HMO.[18] Another manufacturer agreed to pay $345 million to states in 2004

[15]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

[16]When the Medicaid drug rebate program began in 1991, PBMs played a much smaller role in the market.

[17]See Department of Health and Human Services, Office of Inspector General, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program*, A-06-91-00092 (Washington, D.C.: November 1992) and *Medicaid Drug Rebates: Sales to Repackagers Excluded from Best Price Determinations*, A-06-00-00056 (Washington, D.C.: March 2001). The other two reports focused on individual manufacturers and are not publicly available. Federal law permits the Secretary of Health and Human Services to verify manufacturer-reported prices, and the Secretary has delegated that authority to OIG. OIG regularly conducts audits, evaluations, and investigations pertaining to HHS programs.

[18]Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2003* (Washington, D.C.: 2004).

to settle several allegations, including that it did not account for drug discounts provided to two health care providers, resulting in an overstated best price for one of its top-selling drugs and reduced state rebates.[19]

CMS issued a proposed rule in December 2006[20] to, among other things, implement provisions of the Deficit Reduction Act of 2005[21] (DRA) related to prescription drugs under the Medicaid program. This rule is intended to provide more clarity to manufacturers in determining AMPs reported to CMS, by indicating which sales, discounts, rebates, and price concessions are to be included or excluded. For example, it specifies that sales to PBMs and mail-order pharmacies must be included in AMP. The proposed rule also specifies that best price must include sales to all purchasers, including HMOs, that are not explicitly excluded and specifies the prices that must be included or excluded from those sales. Recognizing the evolving marketplace for the sale of prescription drugs, the proposed rule states that CMS plans to issue future clarifications of AMP and best price in an expeditious manner. In its notice of proposed rulemaking, CMS also referred to the DRA requirement that CMS disclose AMP data to states and post these data on a public Web site. AMP data are currently not made public. The changes represented by this proposed rule would likely affect the prices that manufacturers report to the federal government. Only after these regulations are finalized and implemented will there be an opportunity to assess the extent to which they improve the accuracy of prices reported and rebates paid by manufacturers.

[19]Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2004* (Washington, D.C.: September 2005).

[20]71 Fed. Reg. 77174 (Dec. 22, 2006).

[21]Pub. L. No. 109-171, §§ 6001-6003, 120 Stat. 4, 54-61.

Oversight Inadequacies and Lack of Transparency in the 340B Drug Pricing Program Raise Concerns about Overpayments to Drug Manufacturers

We and others have reported inadequacies in HRSA's oversight of the 340B drug pricing program, problems related to the lack of transparency in the 340B prices, and overpayments to drug manufacturers. OIG recently reported that some of the 340B prices that HRSA calculated were inaccurate and that HRSA did not systematically compare the 340B prices with those that were separately calculated by drug manufacturers for consistency.[22] In addition, we recently reported that HRSA did not routinely compare 340B prices with prices paid by certain eligible entities. We and OIG both found that many entities reviewed paid prices for drugs that were higher than the 340B prices.[23] OIG estimated that 14 percent of total drug purchases made by entities in June 2005 exceeded the 340B prices, resulting in $3.9 million in overpayments. We also found that the prices of the eligible entities using the rebate option reported to HRSA did not reflect all rebates they later received from manufacturers, and thus we could not determine whether these entities paid prices that were at or below the ceiling established by the 340B prices. Because the 340B prices are not disclosed to eligible entities, the entities cannot know how the prices they pay compare with the 340B prices. Finally, because 340B prices are based on AMP and Medicaid drug rebate data, inaccuracies in those amounts affect the 340B drug pricing program.

Recent legal settlements related to drug manufacturers' overstatement of best prices used in the Medicaid rebate program also led to settlements related to the 340B program. This was because overstated best prices could affect rebates and result in inaccurate 340B prices.

HRSA has made changes to its oversight of the 340B drug pricing program that are intended to address some of the concerns we and OIG raised in our respective reports. For example, while manufacturers are not required to submit their calculated 340B prices to HRSA, the agency has requested that each manufacturer voluntarily submit its calculated 340B prices for comparison to the 340B prices calculated by HRSA.[24] It has also indicated

[22]See Department of Health and Human Services, Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: October 2005), and *Review of 340B Prices*, OEI-05-02-00073 (Washington, D.C.: July 2006).

[23]See GAO, *Ryan White Care Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, GAO-06-646 (Washington, D.C.: Apr. 26, 2006). We found that in 2003, all of the ADAPs we reviewed that used the direct purchase option reported paying prices higher than the 340B prices for at least 1 of the top 10 HIV/AIDS drugs purchased in 2003.

[24]HRSA indicated that as of July 2006, more than 50 manufactures had submitted their data.

that it was planning to develop systems to allow eligible entities to check that the drug prices they are charged are appropriate while still maintaining the confidentiality of those prices. Because AMP is used to calculate 340B prices, the requirement under DRA that AMP become publicly available may enable HRSA to improve the transparency of these prices. However, the public reporting of AMP, which is only one element of the 340B price calculation, can only partially improve the transparency of 340B prices.

Medicare Part D Shares Features with Other Federal Programs and Has Certain Features That Suggest Potential Oversight Challenges

The Medicare Part D program shares in common certain features with other federal programs that help pay for or reduce the cost of prescription drugs. Because these features presented oversight challenges with other programs, they may also present challenges for Part D. Some of the common features include the following:

- Under Medicare Part D, PDP sponsors are required to calculate and report to CMS aggregate price concessions they negotiate. Similarly, the Medicaid drug rebate program requires manufacturers to calculate and report certain price information to CMS and to include various price concessions in the calculations.
- Medicare Part D relies on PDP sponsors to pass on to beneficiaries the benefit of price concessions they negotiate with drug manufacturers. Similarly, the Medicaid drug rebate and 340B drug pricing programs rely on manufacturers to pass on to states or eligible entities the rebates or discounted prices to which they are entitled under the programs.
- Medicare Part D relies on CMS to audit PDP sponsors to ensure proper disclosure of price concessions negotiated with manufacturers. Similarly, the Medicaid drug rebate and 340B drug pricing programs rely on federal audits of manufacturers to ensure that the prices reported and charged are appropriate.

Further, the Medicare Part D program shares in common with the Medicare prescription drug discount card program—which preceded Part D—features related to oversight inadequacies we identified with the discount card program. Under the discount card program, private sponsors negotiated drug discounts for beneficiaries and required the card sponsors to report price concessions they received for drugs and pass a share of these on to beneficiaries. We reported in 2005 that some card sponsors found that the guidance relating to the reporting of price concessions provided by CMS lacked clarity, and CMS reported that the

quality of price concession data provided by card sponsors was questionable, with problems such as missing data.[25]

Two other features of the Medicare Part D program suggest potential oversight challenges. The first relates to the transition of the nearly 6 million typically high-cost individuals who qualify for both Medicaid and Medicare—referred to as dual eligibles—from Medicaid to Medicare Part D for prescription drug coverage. While the Medicaid drug rebate program is designed to help control prescription drug spending by requiring manufacturers to pay rebates to states, Medicare Part D relies on PDP sponsors to negotiate drug prices, including price concessions. Part D provides no assurance that the PDP sponsors will be able to negotiate price concessions that are as favorable as the rebates required under the Medicaid program. It is not yet known how the federal cost of prescription drug coverage for dual eligibles under Part D will compare with the costs incurred for these individuals under Medicaid.

The second feature relates to the Part D program's reliance on contracts with private PDP sponsors. The PDP sponsors provide prescription drug coverage to beneficiaries through a complex set of relationships and transactions among insurers, PBMs, and drug manufacturers. These relationships have similarities to the Federal Employees Health Benefits Program (FEHBP), the health care program for federal employees, in which the federal government contracts with private organizations to provide drug benefits, and these organizations often contract with PBMs to negotiate with manufacturers and provide other administrative and clinical services.[26] The relationships and transactions between PBMs and

[25]See GAO, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*, GAO-06-78R (Washington, D.C.: Oct. 28, 2005). To assist Medicare beneficiaries with their prescription drug costs before the new benefit became available, the MMA required the establishment of a temporary Medicare Prescription Drug Discount Card and Transitional Assistance Program, which began in June 2004. *See* Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2131. The drug discount card program offered Medicare beneficiaries access to discounts off the retail price of prescription drugs at the point of sale. The program was discontinued when the new Part D drug benefit became available in 2006.

[26]FEHBP covers about 8 million federal employees, retirees, and their family members, making it the largest employer-based health insurance program in the country. In 2003 we reported on the relationships between the private insurers that provide coverage to federal employees under the FEHBP and the PBMs that administer the prescription drug benefit for most FEHBP enrollees. See GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, GAO-03-196 (Washington, D.C.: Jan. 10, 2003).

drug manufacturers within FEHBP and other federal programs have been the subject of litigation. For example, a large PBM agreed to pay about $138 million to the federal government in 2005, including about $55 million to the FEHBP, to settle allegations that it had received payments from drug manufacturers in exchange for marketing certain drugs made by those manufacturers to providers who are reimbursed by federal programs.[27]

Potential Areas for Future Congressional Oversight

Although actions taken by both CMS and HRSA may address some of the oversight inadequacies we and others have reported, it is too soon to know how effective these have been in improving program oversight. Thus, concerns about prescription drug pricing inaccuracies in the Medicaid drug rebate and 340B drug pricing programs and overpayments to drug manufacturers highlight the importance of federal oversight of prices reported by drug manufacturers under these programs. Because the new Medicare Part D program shares certain features in common with these programs, oversight of the price information reported under Part D is important as well. As the Committee develops its oversight agenda relating to federal programs that help pay for or lower the costs of prescription drugs, it may wish to consider the following areas.

- The extent to which federal agencies will take steps to systematically ensure the accuracy of price data associated with federal programs, specifically,
  - the extent to which CMS will ensure that AMP and best prices reported by manufacturers under the Medicaid drug rebate program include all appropriate transactions and price concessions—particularly once the proposed rule is finalized;
  - the extent to which HRSA will ensure the completeness and accuracy of the 340B prices it maintains, obtain final prices paid by all covered entities, and more systematically compare prices paid by entities with the 340B prices; and

[27]Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2005* (Washington, D.C.: August 2006), and the Office of Personnel Management, Office of the Inspector General, *Semiannual Report to Congress* (Washington, D.C.: Nov. 1, 2005).

- the measures CMS will take to ensure that the price information Part D sponsors report to CMS include aggregate price concessions sponsors negotiate with PBMs and drug manufacturers.

- Recognizing the evolving nature of purchasers and sellers in the prescription drug market, the extent to which CMS will be effective in updating and revising Medicaid drug rebate program pricing guidance for manufacturers as circumstances warrant.

- The extent to which the transition of dual eligibles from Medicaid to Medicare Part D will affect federal spending.

- The extent to which cognizant federal agencies will monitor for and detect abuses in the reporting of drug price information that affects federal programs.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other Members of the Committee may have.

GAO Contacts and Acknowledgments

For future contacts regarding this testimony, please contact John Dicken at (202) 512-7119 or at dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Randy DiRosa, Assistant Director; Gerardine Brennan; Martha Kelly; Stephen Ulrich; and Timothy Walker made key contributions to this statement.

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.

[The prepared statement of Mr. Morris follows:]

Testimony

Before the
House Oversight and Government Reform Committee

U.S. House of Representatives

"Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer"

Testimony of Lewis Morris

Chief Counsel to the
Inspector General

February 9, 2007
10:00 a.m.
2154 Rayburn House Office Building

Office of Inspector General
Department of Health and Human Services
Daniel R. Levinson, Inspector General

Testimony of:
Lewis Morris
Chief Counsel to the Inspector General
U.S. Department of Health and Human Services

Good morning, Chairman Waxman, Ranking Member Davis, and distinguished members of the Committee. I am Lewis Morris, Chief Counsel at the Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to appear before you today to discuss health care fraud and abuse involving the pharmaceutical industry.

OIG has successfully pursued specific cases of fraud and abuse and conducted audits, inspections, and program evaluations to identify systemic vulnerabilities related to prescription drug coverage under Federal health care programs. My testimony today will focus on the enforcement work that OIG and our law enforcement partners have undertaken to combat fraud in the pharmaceutical industry. I will describe three categories of fraudulent and abusive schemes that OIG has identified: fraud in prescription drug pricing, fraud in prescription drug marketing, and fraud in the delivery and dispensing of prescription drugs. I will conclude by presenting some of OIG's strategies to address the problems identified.

The Medicare and Medicaid programs have paid too much for prescription drugs because of fraudulent and abusive schemes targeted at Federal health care programs. Some of this behavior increases health care program costs and can distort medical decisionmaking by putting the financial interest of the prescribing physician ahead of the well-being of the patient. In other cases, unscrupulous providers exploit vulnerabilities in the reimbursement systems, resulting in additional costs to taxpayers.

Prescription drugs play an increasingly critical role in health care. Consequently, expenditures for drugs by the Federal health care programs, including Medicare and Medicaid, are growing rapidly. Medicaid expenditures for prescription drugs in 2005 were estimated at $41 billion, a more than four-fold increase over the $8.9 billion spent in 1994.[1] Prior to 2006, Medicare covered a limited number of prescription drugs. Even so, Medicare expenditures for prescription drugs increased from approximately $1.4 billion in 1994 to $10 billion in 2005.[2] In 2006, the Medicare Part D drug benefit greatly expanded Medicare's coverage of prescription drugs.

Health Care Fraud Involving the Pharmaceutical Industry

Federal and State law enforcement agencies are devoting substantial resources to investigating and prosecuting fraud schemes involving manufacturers and others in the pharmaceutical industry. Working with our law enforcement partners, OIG has

[1] Sources: National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* and CMS, State Drug Utilization Data.
[2] Source: OIG analysis of data from Medicare's Part B Extract Summary System.

participated in the investigation of pharmaceutical fraud cases that have resulted in more than $4 billion in recoveries.[3] Although the specifics of each case vary, the cases can be generally divided into three categories: 1) pricing schemes, 2) marketing schemes, and 3) drug delivery and dispensing schemes.

Fraud in Prescription Drug Pricing

Average Wholesale Price Manipulation

Prior to 2005, the Medicare Part B and Medicaid programs paid for prescription drugs based on the manufacturer's "Average Wholesale Price" (AWP), as described below. The Medicare program has now changed its reimbursement methodology, but many States continue to use AWPs as the basis for Medicaid reimbursement for certain drugs.

Generally, pharmaceutical manufacturers set an AWP for each of their drugs and report the AWPs to data collection agencies. Each State, in turn, obtains the AWP information from the data collection agencies and uses it in setting Medicaid reimbursement for prescription drugs. However, the AWP payment methodology is susceptible to abuse. For example, if a manufacturer reports an inflated AWP, Medicaid reimbursement for the drug will, in turn, be inflated. By reporting an AWP that far exceeds the price at which the drug actually is sold to providers, including physicians, the manufacturer creates a significant price differential between the provider's cost for the drug and the amount the provider will receive in reimbursement for the drug from Medicaid. This price differential is known as "the spread," and physicians who buy drugs administered to their Medicaid patients can profit from it.

Some manufacturers have aggressively used an inflated price spread as a marketing tool to gain market share for their products. Purposeful manipulation of the spread to induce purchases of federally payable drugs implicates the criminal Federal anti-kickback statute (discussed below). For example, a manufacturer manipulated a drug's AWP to create an artificially high spread and then had its sales representatives show doctors reimbursement comparison sheets that graphically demonstrated the profits the doctors would realize by purchasing one product over another.

The Government has settled several cases involving price manipulation schemes of the sort I have described. These settlements illustrate how manufacturers have used the spread to sell drugs in particularly competitive sectors of the pharmaceutical market. For example, Glaxo Wellcome and SmithKline Beecham Corporation were competing with each other in the market for anti-emetics, drugs that help control nausea in patients receiving oncology and radiation treatments. According to the Government's investigation, both companies reported fraudulently inflated AWPs and used the resulting spreads to gain market share. The companies eventually merged, and in 2005, GlaxoSmithKline settled a $149 million case with the United States in connection with the illegal pricing and marketing of these drugs.

[3] This figure includes criminal and civil resolutions with pharmaceutical manufacturers, pharmacy benefit managers, retail pharmacy chains, and institutional pharmacies since 1999.

The Government also resolved criminal and civil cases against two other market competitors who used an artificial AWP spread to promote their products to treat prostate cancer. In 2001, TAP Pharmaceutical Products, Inc., pleaded guilty to criminal charges and paid a total of $875 million to resolve an investigation relating to the marketing of Lupron. In 2003, AstraZeneca Pharmaceuticals LP entered into a $355 million settlement with the Government for similar conduct relating to its drug, Zoladex. During the investigation, OIG learned that the sales representatives of the two companies had routinely called on the same urologists and employed a variety of tactics, including "marketing the spread," to persuade the physicians to prescribe their respective company's drug. Over time, the companies continued to inflate their AWPs to create an even more lucrative illicit spread for their drugs, and some physicians even switched their patients back and forth between Lupron and Zoladex to profit from the artificially inflated spreads. Moreover, the Government contends that the scheme enabled the companies to pass the cost of the physicians' extra profits on to the Federal health care programs.

Fraud in the Medicaid Drug Rebate Program

Another area of pricing fraud involves the Medicaid drug rebate program. This program, designed to reduce expenditures by the Medicaid program, mandates that drug manufacturers provide Medicaid with certain rebates on drugs provided to Medicaid patients. The amount of a rebate is determined by a statutorily defined rebate formula. Manufacturers must report to CMS certain pricing information by drug, including the "Average Manufacturer Price" and, for some drugs, the "Best Price." OIG cases have focused primarily on abuses related to Best Price, which, subject to certain exceptions, should be the lowest price (net of most discounts and rebates) at which a manufacturer sells the drug. For many drugs, the lower a manufacturer's Best Price is, the higher that manufacturer's potential rebate liability will be.

Most discounts must be included in the Best Price calculation, and manufacturers understand that providing a discount could increase the rebate owed to the Medicaid program. Because the rebates are based on the total volume of the drug reimbursed by the State, even a small per unit increase in the rebate can dramatically increase the amount of the total rebate owed to the State. To avoid this, some manufacturers have knowingly mischaracterized discounts by structuring them as educational grants, sham data processing fees, or similar arrangements in an attempt to disguise their status as discounts. The objective is always the same—the preferred customer gets the drug at a deep discount and the manufacturer avoids additional rebate obligations to the State Medicaid programs.

Two cases illustrate how pharmaceutical manufacturers have circumvented the Medicaid drug rebate program. In the first case, according to the Government's investigation, Warner-Lambert paid unrestricted grants to a managed care organization (MCO) in return for favorable formulary treatment for its drug Lipitor. The grant, in effect, substituted for a discount in the price of the drug. However, Warner-Lambert did not include the value

of this grant when calculating its Best Price for Lipitor. In 2002, the United States entered into a $49 million settlement with Pfizer Inc., the company that acquired Warner-Lambert, to resolve the case.

In the second case, the Schering-Plough Corporation allegedly provided financial incentives to two MCOs after they threatened to remove Claritin from their drug formularies, absent deeper discounts on the product. Schering-Plough chose not to lower its price. Rather, it offered the MCOs an array of incentives, including a series of large cash payments described as "data processing fees." Schering-Plough did not include these incentives and "fees" in its calculation of the Best Price for Claritin. In reality, the investigation showed that the data furnished in exchange for the fees had no practical value to Schering-Plough and were already required under the MCO's contract with the manufacturer. According to the Government's investigation, the phantom data processing fees simply substituted for a discount in the price of Claritin. In 2004, the United States entered into a global settlement for almost $293 million with Schering-Plough relating to this scheme.

Impact of Medicaid Drug Rebate Fraud on the 340B Program

Errors or fraud in Medicaid drug rebate information also adversely affect the 340B program. The 340B program, which is managed by the Department's Health Resources and Services Administration (HRSA), provides for sales of outpatient drugs at or below a specified maximum price to certain health care safety net providers (340B entities) such as disproportionate share hospitals, federally qualified health centers, and the Ryan White CARE Act's AIDS Drug Assistance Programs. HRSA estimates that the nearly 12,000 340B entities will spend $4 billion on outpatient drugs in FY 2007.

Although the 340B program differs fundamentally from Medicare and Medicaid in that it does not entail the submission or direct payment of claims, the prices at which 340B entities purchase drugs are statutorily linked to the Medicaid drug rebate program. Under the 340B program, participating drug manufacturers sign an agreement stipulating that they will charge 340B entities at or below a maximum amount, known as the 340B "ceiling price." Ceiling prices are guaranteed whether the 340B entity purchases drugs directly from a manufacturer or through a wholesaler. The ceiling price for each drug is calculated using a statutorily defined formula that is based on the drug's Average Manufacturer Price and the Medicaid rebate amount per unit. Thus, if a drug manufacturer reports a Best Price that does not include all discounts for Medicaid rebate purposes, both the rebate amount and the 340B ceiling price may be adversely affected—the Medicaid program may receive smaller rebates, and the 340B entities may pay too much for the drug.

In view of the connection between the Medicaid drug rebate program and the 340B program, the Government has resolved the 340B pricing fraud during settlement negotiations in Medicaid drug rebate cases. In several instances, manufacturers (including King Pharmaceuticals, Inc., Schering-Plough, Bayer Corporation, and GlaxoSmithKline) have agreed to reimburse the 340B entities for what the Government

believes were overpayments that resulted from illegal manipulation of the Medicaid drug rebate data.

Fraud in the Marketing of Drugs

Illegal Kickbacks

The Federal anti-kickback statute is a criminal prohibition against remuneration (in any form, whether cash or in-kind, direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care business. Marketing practices involving remunerative arrangements implicate the statute. Thus, sales practices that may be common or longstanding in other business sectors are not necessarily acceptable or lawful when Federal health care programs are involved. Illegal marketing activities, including the payment of kickbacks to prescribing physicians or the use of kickbacks to promote drugs for unapproved uses, pose a risk to patients, as well as to the integrity of Federal health care programs. Perpetrators of unlawful kickback schemes may be subject to criminal, civil, and administrative sanctions.

The anti-kickback statute exists for a number of important reasons, two of which are particularly relevant in the context of the marketing and sale of prescription drugs. Kickbacks potentially increase the costs to Federal programs because they encourage overutilization and may encourage the prescribing of more expensive drugs when clinically appropriate and cheaper options (such as generic drugs) may be equally effective. Equally troubling, kickbacks can compromise the independence of medical decisionmaking by putting the financial interests of the physician ahead of the welfare of the patient.

In OIG's experience, kickbacks offered to prescribing physicians by pharmaceutical manufacturers take a variety of forms, ranging from free samples for which the physician bills the programs to all-expense-paid trips and sham consulting agreements. For example, the TAP and AstraZeneca cases discussed previously involved several different kickback schemes designed to increase sales of the companies' prostate cancer drugs. One scheme involved manipulating AWPs and "marketing the spread." The artificially inflated profits realized by the physicians were, in the Government's view, unlawful kickbacks to induce the purchase of the companies' products.

Under a second scheme, TAP and AstraZeneca sales representatives gave physicians free samples of their prostate cancer drugs in return for ordering their products. Although a drug manufacturer may lawfully give a physician drug samples for use by his or her patients, the physician may not sell the samples. If the samples are sold, the profits realized are remuneration that may implicate the anti-kickback statute. The sales representatives knew and expected that the physicians would bill Medicare and other Federal health care programs for the samples and be reimbursed between $400 and $500 for each unit of the drug. The consequence for patients was harmful as well. Senior citizens suffering from prostate cancer paid their physicians a 20 percent Medicare

copayment (approximately $100) for drug samples that should have been provided to them for free.

OIG has found that some drug companies, aided by aggressive sales forces intent on meeting their sales goals, can be very creative in finding ways to induce physicians to order their products. For example, one aspect of the $704 million global settlement with Serono, Inc. involved a kickback in the form of an all-expenses-paid trip for a select group of high-prescribing physicians (and their guests) to a conference in Cannes, France. This trip was part of a concerted sales campaign by the Serono sales force to generate $6 million in sales of its AIDS wasting drug in 6 days from those same physicians.

The $430 million settlement with Pfizer Inc., demonstrates another common form of kickback: the sham consulting agreement. In that case, OIG's investigation showed that physicians received substantial fees for attending expensive dinners or conferences, purportedly for serving as "consultants." The physicians also participated in promotional events, including lavish weekends at resorts and events held at the 1996 Atlanta Olympics and in Hawaii. The Government's investigation found that, in reality, the physicians provided few or no significant consulting services.

Off-Label Promotion

Another significant area of fraud involves improper "off-label promotion." Off-label promotion is the promotion of a product for a use not approved by the Food and Drug Administration (FDA). FDA approves drugs for only those particular uses proven to be safe and effective and sometimes approves a product for only a single, narrow use. While physicians may lawfully prescribe a drug for an off-label use, manufacturers are prohibited from promoting a drug for uses other than FDA-approved uses.

OIG has identified many instances in which promotional and marketing efforts have gone far beyond the approved use. By promoting their products for non-FDA-approved uses, manufacturers may cause the submission of false or fraudulent claims to Medicare, Medicaid, and other Federal health care programs. Moreover, many of these off-label marketing schemes also involve illegal kickbacks to induce sales for non-FDA-approved uses.

OIG's investigations suggest that some pharmaceutical manufacturers may be engaged in a wide range of abusive practices that provide false and misleading information about the safety or efficacy of products for non-approved uses. These practices include:

- using so-called "medical science liaisons" that present themselves (often falsely) as scientific experts in a particular disease to promote off-label uses;

- sponsoring purportedly objective "independent" medical education events designed to discuss off-label uses. In fact, the manufacturer provides extensive subjective input about the topics, speakers, content, and participants of these events; and

- proffering ghost-written articles about off-label uses. In these schemes, manufacturers pay physicians to "write" advocacy articles about off-label uses of products that are, in fact, written by the manufacturer. This practice is particularly insidious, because the publication of such articles in certain medical compendia may be sufficient to qualify the off-label use for reimbursement under some State Medicaid programs.

Financial harm to Medicare and Medicaid is only one problem caused by off-label promotion. Off-label promotion may lead physicians to prescribe a product for a non-approved use based on false, misleading, or erroneous information to the medical detriment of their patients. In addition, off-label promotion fundamentally circumvents the FDA drug approval process, on which Americans rely to evaluate the safety and efficacy of pharmaceutical products.

Fraud in the Delivery of Prescription Drugs

In addition to investigating fraud by pharmaceutical manufacturers, OIG has investigated and resolved cases involving pharmacies and pharmacy benefit managers (PBMs). These schemes typically involve fraud and abuse in the delivery of drugs or other operational aspects of the programs.

For example, OIG has investigated a number of cases involving retail pharmacy chains that allegedly billed Medicaid for prescription drugs that were not provided to beneficiaries. Since the late 1990s, the United States has entered into a series of settlements with national retail pharmacy chains (including CVS, Eckerd, and Rite-Aid) relating to claims submitted by these pharmacies to Medicaid for alleged "short-filled" prescriptions. Based on our investigations, the Government found that when pharmacies were unable to provide the full amount of the medication prescribed, they nonetheless billed Medicaid for the entire amount of the prescription. In total, this short-fill fraud resulted in the collection of more than $30 million in settlements with these pharmacy chains.

OIG and its law enforcement partners also have pursued cases in which pharmacies switched the drug prescribed to the patient to exploit Medicaid reimbursement rules. For instance, in November 2006, the Government entered into a $49.5 million settlement with Omnicare, Inc., a nationwide institutional pharmacy that exclusively serves nursing home patients. The investigation found that Omnicare switched generic Zantac tablets with capsules to avoid a Federal payment upper limit set by CMS and the "maximum allowable cost" set by State Medicaid programs for the tablets. By these and other drug switches, Omnicare gained additional Federal and State dollars to which it was not otherwise entitled.

PBMs undertake several functions in the provision of prescription drug benefits. These functions may include price negotiations with drug manufacturers, the development of formularies, and the provision of mail order pharmacy services to members of health

plans. The Government's recent $155 million settlement with the Medco Health Solutions, Inc., a PBM, involved a range of alleged improper conduct that harmed Medicare and other Federal programs, including the Federal Employee Health Benefits Program. The Government's investigation found that Medco had solicited and received kickbacks from manufacturers to induce Medco to promote their products submitted false claims to health plans for services allegedly provided by Medco's mail order pharmacy business, and offered and paid kickbacks to health plans to induce them to enter contracts with Medco.

These cases serve as cautionary tales about the activities of pharmacies, PBMs, and others who play a role in the delivery of drug benefits and who have incentives to exploit the reimbursement rules at the expense of the public and program beneficiaries.

OIG Strategies To Promote Integrity

Federal and State law enforcement agencies continue to investigate many fraud schemes similar to those outlined in my testimony. Criminal and civil investigations are resource intensive, time consuming, and require extensive coordination between Federal and State agencies. Furthermore, the parties engaged in these frauds are adept at modifying schemes in response to Government efforts to strengthen program integrity. The large and growing size of Federal expenditures for prescription drugs will continue to attract those intent on defrauding Medicare and Medicaid. Accordingly, we intend to enhance our existing fraud prevention and detection efforts to meet new challenges as they arise.

OIG is increasingly using its administrative authorities to sanction individuals engaged in fraudulent and abusive practices. Administrative sanctions complement criminal and civil enforcement, providing an additional avenue for Government enforcement. OIG has the authority to exclude individuals and entities from the Federal health care programs and to impose civil monetary penalties for a range of abusive practices, including kickbacks and false claims.

For example, OIG has pursued administrative cases involving kickbacks to physicians, including those involved in the TAP and AstraZeneca schemes described previously. A physician who accepts a kickback from a pharmaceutical manufacturer in return for prescribing its drugs to Medicare patients is as culpable as the drug company that provided the kickback. In some cases, the physician has initiated the crime by demanding the kickback as a condition of prescribing a drug to patients.

In the past, criminal prosecutors targeted their limited resources on companies paying kickbacks and generally did not focus on these physicians. This may have created the misimpression by some physicians that they can demand kickbacks from drug companies with impunity. However, OIG has stepped into this breach and is using its authority to impose program exclusion and significant monetary penalties to target these kickback recipients. Hopefully, OIG administrative enforcement also will prompt physicians to think twice before accepting kickbacks from pharmaceutical companies.

"Pay-and-chase" enforcement alone will not adequately address the problem. For this reason, OIG remains fully committed to promoting the prevention of fraud and abuse through voluntary compliance efforts by the regulated community. We are committed to working with industry stakeholders to ensure the integrity of the Federal health care programs. OIG cannot do it alone.

To this end, OIG issued a "Compliance Program Guidance for Pharmaceutical Manufacturers" (CPG), one in a series of compliance program guidances that OIG developed for the various health care sectors. The CPG provides detailed information for drug manufacturers on establishing and operating an effective internal compliance program and identifying fraud and abuse risk areas. The guidance describes the relevant fraud and abuse authorities and the major risk areas under these laws. It also offers concrete suggestions on ways manufacturers can mitigate their risk. The risk areas include, for example:

- reporting data used to establish or determine Government reimbursement,
- discounts,
- product support services,
- educational grants,
- research funding,
- relationships with formulary committees,
- payments to PBMs,
- formulary placement payments,
- Average Wholesale Price,
- "switching" arrangements,
- consulting and advisory payments,
- business courtesies and other gratuities,
- relationships with sales agents, and
- drug samples.

Although the guidance is targeted at manufacturers, much of its content pertains to PBMs, customers, prescribers, and other parties involved in the provision of prescription drugs. It is important guidance for participants in the new Part D drug benefit. OIG also encourages health care entities who uncover violations of program requirements to use OIG's Self-Disclosure Protocol to resolve their potential liabilities. The Protocol has proven a successful means for OIG to collaborate with health care companies in resolving issues that are identified as part of an effective compliance program.

In addition, OIG issues advisory opinions, fraud alerts, and advisory bulletins on issues of concern to the pharmaceutical industry and other health care entities as part of its overall strategy to encourage compliance. These guidance products, including the CPG, are available to the public on OIG's web site at www.oig.hhs.gov. OIG supplements these guidance efforts with frequent outreach efforts to the regulated industry, its counsel, and the public.

Conclusion

As I have testified, the Medicare and Medicaid programs are vulnerable to fraud and abuse through a number of schemes related to prescription drug pricing, marketing, and delivery. There are no simple solutions to these problems. Those intent on gaming Federal health care programs are adept at modifying their schemes in response to changes in the reimbursement systems and Government enforcement tactics. Consequently, Federal and State agencies must continue to develop proactive enforcement strategies. Of equal importance, pharmaceutical manufacturers and other participants in the health care system should be encouraged to embrace policies and procedures that promote compliance with Federal program requirements.

OIG shares the Committee's commitment to protect the integrity of Federal health care programs and the health and safety of beneficiaries. We will continue to fight fraud in Medicare and Medicaid and promote compliance by the pharmaceutical industry. We will also bring our enforcement and oversight experience to bear as we work to protect the integrity of the Medicare Part D drug benefit. As set forth in more detail in the OIG's 2007 Work Plan, we are undertaking an ambitious effort to monitor the integrity and effective operation of this benefit.

This concludes my testimony. I would be pleased to answer your questions.

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 U.S. 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 U.S. 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.

[The prepared statement of Mr. Tenpas follows:]

Department of Justice

STATEMENT

OF

RONALD J. TENPAS
ASSOCIATE DEPUTY ATTORNEY GENERAL
DEPARTMENT OF JUSTICE

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING

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

PRESENTED ON

FEBRUARY 9, 2007

Testimony
of

Ronald J. Tenpas
Associate Deputy Attorney General
U.S. Department of Justice

Committee on Oversight and Government Reform
United States House of Representatives

"Allegations of Waste, Fraud, and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer"

February 9, 2007

Chairman Waxman, Ranking Member Davis, I appreciate the opportunity to appear before you to discuss some of the issues that are the focus of today's hearing. We are grateful for the Committee's leadership on this important topic and to you, Mr. Chairman, for allowing us this opportunity to discuss our enforcement efforts.

I have been asked to provide testimony concerning the efforts of the Department of Justice to combat fraud and abuse by drug manufacturers and others in connection with the delivery of pharmaceuticals. The Department of Justice remains committed to root out and punish corporate wrongdoers, and to recover dollars lost through fraud on our Federal programs, and that commitment takes on even added urgency in the context of health care fraud, where the public dollars are so large and where fraud often has a direct impact on public health. That is why the Department of Justice, through the Civil and Criminal Divisions and through the U.S. Attorney's Offices, continues to fairly and vigorously enforce the various laws at our disposal to deal with those companies and individuals that steal from the taxpayers.

By no means, however, is the Department of Justice alone in the fight to combat fraud and preserve the integrity of the country's health care system. We work closely with our colleagues at the Centers for Medicare and Medicaid Services (CMS), at the Department of Health and Human Services and its Inspector General, with the Food and Drug Administration (FDA), with the Federal Employees Health Benefits Program (FEHBP), at the Office of Personnel Management and it Inspector General, and with our State law enforcement partners in their Offices of Attorneys General and Medicaid Fraud Control Units. Working with our colleagues, since 1999 the Department has obtained recoveries, including criminal fines, as well as Federal and State civil settlements in pharmaceutical fraud matters involving losses to Federal

and State programs that have exceeded $5.3 billion. We have many matters currently under investigation, implicating pricing and marketing practices relating to hundreds of drugs.

It is clear from our experience that drug company violations of the law are causing government healthcare programs to pay too much for prescription drugs. We are not seeing isolated instances of misconduct, but repeated practices within the industry that have resulted in significant losses to Federal health care programs, including Medicare, Medicaid and the Federal Employees Health Benefits Program, among others. We are looking at alleged unlawful practices in the way manufacturers have reported prices which have been historically relied on by Medicare and Medicaid to set their reimbursement rates.

We are also investigating allegations that manufacturers knowingly mis-report to the government the "best prices" for their pharmaceuticals, thereby reducing the rebates they owe by law to the Medicaid program, which funds healthcare for the needy in this country. We have seen fraud in the manner in which pharmacy benefit managers (known as PBMs) administer the drug benefits in our Federal health care programs. And a significant portion of our law enforcement effort is focused now on the practices of manufacturers to promote the sale of their pharmaceuticals for "off label" uses, that is, those not approved by the FDA. These types of illegal conduct can be best illustrated by the successful investigations we have brought, many of which have been initiated by *qui tam* relators possessing "inside" knowledge. The lessons learned from these cases may prove useful to you as you consider possible reforms.

As I mentioned, one of our focuses has been a practice involving the manner in which manufacturers have historically reported their prices to national reporting services which have been used, in turn, by Medicare and Medicaid to establish rates of reimbursement under those programs for pharmaceuticals. This practice has been called "marketing the spread." The manufacturer inflates the prices it reports to the reporting services, and the Federal programs establish a reimbursement rate in reliance on those inflated prices. The manufacturer then charges its customers -- often physicians or other providers -- lower prices, and in many cases much lower, than Medicare and Medicaid reimbursement rates. The manufacturer is then able to market, as an inducement to buy its products, the "spread" between the purchase price and the amount the purchaser will receive from Medicare and Medicaid. We have also seen in connection with some of these cases other inducements offered by the manufacturers to influence purchases. We have successfully pursued a number of manufacturers on this theory.

In the largest settlement of its kind, **TAP Pharmaceutical Products Inc. (TAP),** a joint venture between Abbott Laboratories and Takeda Chemical Industries, paid $875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing of the cancer drug, Lupron. Under an agreement with the Department in 2001, TAP pled guilty in the District of Massachusetts to a conspiracy to violate the Prescription Drug Marketing Act and paid a $290 million criminal fine. To resolve its civil liability under the False Claims Act, TAP agreed to pay the United States $559.4 million for filing fraudulent

claims with Medicare and Medicaid, and to pay $25.5 million for filing fraudulent claims with the States.

Many State Medicaid programs, and during the time period that was at issue, the Medicare program, reimbursed covered drugs in part, on Average Wholesale Price (AWP). The government alleged that TAP set and controlled the price at which the government programs reimbursed physicians for the prescription of Lupron by misreporting its AWP as significantly higher than the average sales price TAP offered physicians and other customers for the drug. TAP allegedly marketed the spread between its discounted prices paid by physicians and the significantly higher Medicare and Medicaid reimbursement based on AWP as an inducement to physicians to obtain their Lupron business. The government further alleged that TAP concealed from Medicare and Medicaid the true discounted prices paid by physicians, and falsely advised physicians to report the higher AWP rather than the real discounted price for the drug. Another component of this case concerned TAP's failure to include the costs of the contingent free goods it offered to physicians in its "patient start program"(under which urologists received free goods for every patient they switched to Lupron) in the best price calculations it reported to CMS.

Similarly, **AstraZeneca Pharmaceuticals LP (AstraZeneca)** pled guilty in the District of Delaware to violating the Prescription Drug Marketing Act and paid $355 million to resolve criminal charges and civil liabilities in connection with its drug pricing and marketing practices arising from its sales of Zoladex, a drug used primarily for the treatment of prostate cancer and the main competitor product to TAP's Lupron.

As part of the plea agreement, AstraZeneca paid a $63.9 million criminal fine, paid $266.1 million to resolve allegations that the company caused false and fraudulent claims to be filed with the Medicare, TriCare and the Railroad Retirement Board Medicare programs, and paid $24.9 million to resolve allegations that its drug pricing and marketing misconduct resulted in false State Medicaid claims.

Our investigation revealed that from January 1991 through December 31, 2002, employees of AstraZeneca provided thousands of free samples of Zoladex to physicians, knowing and expecting that certain of those physicians would prescribe and administer the free drug samples to their patients and thereafter bill those free samples to the patients and to Medicare, Medicaid, and other federally funded insurance programs. In order to induce certain physicians, physicians' practices, and others to purchase Zoladex, AstraZeneca offered and paid illegal remuneration in various forms that included free Zoladex, unrestricted educational grants, business assistance grants and services, travel and entertainment, consulting services, and honoraria.

Also, to induce physicians to purchase Zoladex, the United States alleged that AstraZeneca marketed a "Return-to-Practice" program to physicians. In a scheme similar to that engaged in by TAP, AstraZeneca inflated the Average Wholesale Price used by Medicare and

Medicaid for drug reimbursement, deeply discounted the price charged to physicians for the drug, and then marketed the spread between the AWP and the discounted price to entice physicians with the additional profit they stood to gain from Medicare and Medicaid. AstraZeneca set the AWP for Zoladex at levels far higher than what the majority of its physician customers actually paid. As a result, AstraZeneca's customers received reimbursement from Medicare and State Medicaid programs at levels significantly higher than the physicians' actual costs or the wholesalers' average price.

Much like in the TAP case I just mentioned, AstraZeneca also had an extensive free goods discounting program for urologists, including a program under which urologists received free goods for every patient switched to Zoladex, purportedly designed to familiarize office staff and patients with the delivery method of the drug. Because it did not include free goods in its calculations of best price for Zoladex, Zeneca falsely reported its best price to CMS in each of the 24 quarters we examined and consequently underpaid its rebates to the States.

We have reached other civil False Claims Act settlements with a number of manufacturers to resolve allegations of "marketing the spread".

In 2005, **GlaxoSmithKline** paid over $155 million to settle Federal and State civil claims that it had marketed the spread and offered the spread as an inducement in violation of the False Claims Act and Medicare-Medicaid Anti-Kickback statute in connection with its anti-emetics, Kytril and Zofran, used primarily in conjunction with oncology and radiation treatment. As part of a condition for doing business in the future with providers who do business with the Medicare and Medicaid programs, GlaxoSmithKline agreed to enter into an addendum to an existing Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services that, among other things, requires the company to report accurate average sales prices and average manufacturer's prices for its drugs covered by Medicare and other Federal healthcare programs.

Bayer Corporation entered a $14 million settlement in 2001 with the Department to resolve allegations arising from its sale of pharmaceuticals and biological products to government health care programs. The Government alleged that Bayer reported inflated wholesale acquisition costs (WACs), used to establish Medicaid reimbursement, and falsely reported that certain products were not sold to wholesalers and, therefore, no WACs existed.

In 2004, **Warrick Pharmaceuticals Corporation**, agreed to pay the United States and Texas $27 million to settle allegations that it had defrauded the Texas Medicaid program by inflating its reported WACs to national reporting services. In 2003, the State of Texas and the Department settled similar allegations involving the Texas Medicaid program with **Dey, Inc.** for $18.5 million.

We are now in litigation in a multidistrict proceeding in Boston with three manufacturers -- **Abbott, Dey** and **Boehringer Ingelheim Roxane** -- where we have alleged the companies violated the False Claims Act and the Medicare-Medicaid Anti-Kickback statute for marketing the spread in connection with certain of their drugs.

Another area we have targeted in our law enforcement efforts has involved allegations that manufacturers knowingly violated the Medicaid Drug Rebate Statute. In general, the statute requires that with respect to single source or innovator multiple source drugs, manufacturers must report their best price to Medicaid and rebate the difference between the average manufacturers price (AMP) and best price, or a specified percentage of the AMP, whichever is greater. The purpose of the rebate program is to ensure that the Nation's insurance program for the poor receives the benefit of discounts on drugs available in the marketplace. This best price is defined as the lowest price available from the manufacturer to any "wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity within the United States" with certain specified exclusions. The law requires that manufacturers determine best price "without regard to special packaging, labeling, or identifiers on the dosage form or product or package." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(II). It also requires that with respect to single source or innovator multiple source drugs manufacturers pay rebates to each State Medicaid program each quarter, calculated as the product of (I) the total number of units of each dosage form and strength paid for under the State plan in the rebate period, and (ii) the greater of either the difference between average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price. §§ 42 U.S.C. 1396r-8(c)(1)(A) and (B). By overstating the best price (as well as understating the average manufacturer's price), a drug company unlawfully reduces its obligation to pay rebates in violation of the Medicaid program.

In 2003, **Bayer** and **GlaxoSmithKline** entered into agreements to resolve similar allegations of fraud in connection with their reporting under the Medicaid Rebate Statute. We determined through our investigations that "private labeling" is a device used by some manufacturers to affix the customer's label and, more importantly, the customer's National Drug Code (NDC) to the drug to avoid the manufacturer's statutory reporting or payment obligations with respect to that drug. Although private labeling has legitimate uses in the industry, for example, where a chain pharmacy wants to offer a store brand in addition to a brand name product, the practice may run afoul of the Medicaid Rebate program where it is done to avoid the manufacturer's best price reporting or rebate obligations.

In the Bayer investigation, the United States Attorney's Office in Boston alleged that Bayer private labeled two of its most popular drugs, Cipro and Adalat CC. The government alleged that Bayer's private label arrangements were intended to provide deeply discounted prices on these drugs to the HMOs while evading its statutory and contractual obligations to provide the same favorable prices to the Medicaid program. In addition, Bayer submitted false statements to the Office of Audit of the Inspector General for the Department of Health and

Human Services and to the FDA to further conceal its obligation to pay additional Medicaid rebates in connection with private labeling.

The Government's investigation concluded that Bayer failed to pay rebates owed to the Medicaid program and overcharged certain Public Health Service entities at least $9.4 million. Bayer pled guilty in the District of Massachusetts to a one count criminal Information of violating the Food, Drug & Cosmetic Act, 21 U.S.C. §§ 331(p), 333(a)(2), and 360(j), and failing to list the private label product with the FDA, and it paid a criminal fine of nearly $5.6 million. Together with the agreed-upon civil settlement amount of $251.6 million, the total resolution was $257.2 million.

In a related investigation, **GlaxoSmithKline (Glaxo)** paid $87.6 million to settle similar allegations based on its relationship with the HMO, Kaiser Permanente Medical Care Program (Kaiser). We learned that at the time of our investigation, Kaiser provided care and treatment to more than 6 million persons and often purchased drugs directly from drug manufacturers to save on costs for its members. That is perfectly legal. However, we learned also that Glaxo – much like Bayer had done – provided discounted prices to Kaiser for its drugs and engaged in "private labeling" for Kaiser, affixing different labels to its drug products to avoid reporting the low prices to CMS. Glaxo also repackaged and privately labeled Paxil, an anti-depressant, and Flonase, a nasal spray at discounted prices for Kaiser and then failed to report these lower prices as part of its mandated "best price" calculation submitted to the government.

Both settlements also ensured full repayment to the Public Health Service program, a safety net for the Nation's most vulnerable citizens, which provides certain drug pricing protections to clinics, community health centers and hospitals that treat the country's poorest citizens. Drug companies are required to offer pricing concessions to PHS entities based in part on the Medicaid rebates they owe. Both companies executed a corporate integrity agreement with HHS-OIG, designed to ensure that they accurately report their "best price" information to the Government.

In 2004, **Schering Plough** paid $292.9 million to resolve allegations arising from its contracts with two managed care customers. The government alleged that Schering entered into two contracts to ensure that its drug, Claritin, stayed on the customers' formularies while evading its Medicaid rebate obligations and derivative Public Health Service liability. The government alleged that from 1998 through 2000, Schering provided additional "value" to PacifiCare to ensure that Claritin stayed on PacifiCare's formulary. Our investigation revealed that, with one exception, the value of these additional price concessions was not credited in Schering's calculation of the Medicaid "best price" reported to CMS and not used by the manufacturer in determining rebate obligations.

The investigation, conducted in the Eastern District of Pennsylvania, also determined that from 1999 through 2002, Schering provided additional "value" to Cigna to ensure that Claritin

stayed on Cigna's formulary. Once again we concluded that none of the value of these additional price concessions was credited in Schering's calculation of its Medicaid best price reported to CMS and was not used in determining rebate obligations. Schering paid more than $282.3 million to settle its Medicaid liability, and more than $10.6 million to resolve its liability to the Public Health Service.

A parallel criminal investigation was conducted against Schering and, as a result, Schering Sales Corporation pled guilty to one count of offering and paying a kickback in violation of 42 U.S.C. §1320a-7b. The plea arose from Schering Sales Corporation's payment of a "data fee" for data already obtained in connection with Schering's efforts to maintain formulary status for Claritin at Cigna. Schering Sales Corporation paid a criminal fine in the amount of $52,500,000 pursuant to the plea, over and above the $292.9 million paid to resolve its civil liability.

King Pharmaceuticals, Inc. paid $75 million in 2006 to resolve allegations that it underpaid rebates owed under the Medicaid program. King paid an additional $50 million to several State governments based on the same allegations. The settlement addressed King's alleged understatement of the "average manufacturer price" as well as its overstatement of its "best price." In a similar matter against **Parke-Davis,** a subsidiary of **Pfizer,** we alleged that the company provided discounts to a large managed care account in Louisiana without properly reporting those discounts to CMS under the obligations created by the Medicaid Rebate program. Our investigation revealed that Parke-Davis provided at least $250,000 of discounts to the Louisiana managed care account in exchange for an agreement that the managed care account extend unrestricted drug formulary status to Lipitor and sign a contract to buy Lipitor. The government alleged that these discounts were reported neither to the CMS as part of the best price calculations, nor to the States. The matter settled when Pfizer paid $49 million to settle State and Federal Medicaid claims.

A third area we have addressed relates to the services provided to Federal healthcare programs by pharmacy benefit managers. In the past several years, the Department has resolved matters with **Advance PCS** and **Medco Health Solutions,** two of the Nation's largest PBMs.

Advance PCS paid $137.5 million in 2005 to resolve its civil liability under the False Claims Act and the Public Contract Anti-Kickback Act arising from payments made by pharma manufacturers for favorable treatment in connection with its drugs, and payments by Advance PCS to customers and potential customers who had contracts with federally funded healthcare plans to ensure Advance PCS was selected or retained as their PBM.

In 2006, **Medco** agreed to pay the United States $155 million plus interest to settle allegations that the Parsippany, N.J.-based company submitted false claims to the government, solicited and accepted kickbacks from pharmaceutical manufacturers to favor their drugs, and paid kickbacks to health plans to obtain business. Medco manages the prescription drug benefits

of over 60 million Americans, including millions of Medicare beneficiaries. We had alleged that Medco submitted false claims for mail order prescription drug services it was required by contract to provide to millions of Federal employees, retirees and their families under the Federal Employees Health Benefits Program. Additionally, we alleged that the company cancelled valid prescriptions it could not timely fill in order to avoid paying penalties under its contract; shorted pills from prescriptions it filled; failed to conduct concurrent drug utilization review for all prescriptions in order to identify potential adverse drug interactions; and, when filling prescriptions, used drugs other than those prescribed by the physician to earn undisclosed rebates from drug manufacturers. The government also alleged that the company violated the Public Contract Anti-Kickback Act by soliciting payments from pharmaceutical companies to favor their products on Medco's published list of drugs, and by paying kickbacks to induce health plans to award contracts to provide the mail order pharmacy benefits for plan beneficiaries. As a condition of continued participation in government health programs, the United States required that Medco enter into a corporate compliance agreement with the Office of Inspector General, Department of Health and Human Services; and with the Office of Inspector General of the Office of Personnel Management.

Finally, as I alluded to earlier, the most active area for the Department in recent years has arisen from allegations involving violations of the Food, Drug and Cosmetic Act, including off label marketing and unlawful promotional activities.

One of the leading cases in this area involved **Warner-Lambert**, which was acquired by Pfizer in 2000, acting through its wholly-owned pharmaceutical division, Parke-Davis. The allegation was that Parke Davis engaged in the illegal marketing and promotion of the prescription drug Neurontin for uses that were not approved by the FDA. This was another matter initiated by the filing of a *qui tam* that alleged that the drug Neurontin, which had been approved by the FDA as an adjunct therapy for epilepsy, had been marketed by Pfizer for numerous other "off-label" and unapproved uses, such as for the treatment of pain and psychiatric conditions.

While doctors are permitted to prescribe drugs for uses that are not approved by the FDA, pharmaceutical companies must specify the intended use of a product in its new drug application to the FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses - any use not specified in an application and approved by FDA. As a general proposition, the Federal law and regulations governing Medicaid reimbursement do not provide for reimbursement for off-label prescriptions where the use is not medically accepted. The government alleged that Parke-Davis' marketing scheme induced physicians to prescribe Neurontin for off-label uses through a variety of means, including the fraudulent practices of the payment of kickbacks to doctors and distribution of false statements to doctors about the safety, efficacy and approval status of Neurontin. Neurontin was launched into the marketplace in February of 1994; from mid-1995 to at least 2001, the growth of off-label sales was tremendous. While not all of these sales were the consequence of Warner-Lambert's illegal marketing, the

marketing scheme was very successful in increasing Neurontin prescriptions for unapproved uses.

Under the terms of the settlement, Warner-Lambert pled guilty in the District of Massachusetts to a criminal information charging it with violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 333(a)(2). Because Warner-Lambert had previously been convicted of criminal violations under the FDCA in 1996, these misdemeanor offenses became felonies under 21 U.S.C. §333(a)(2). As part of the $430 million settlement amount, Warner-Lambert paid a criminal fine of $240 million and paid $190 million to resolve Federal and State Medicaid claims, and to resolve State consumer protection claims. **Pfizer Inc.**, Warner-Lambert's parent company, agreed to comply with the terms of a corporate compliance program, which ensures that the changes Pfizer made after acquiring Warner-Lambert in June 2000, are effective in training and supervising its marketing and sales staff, and ensures that any future off-label marketing conduct is detected and corrected on a timely basis.

In the wake of the **Parke Davis** settlement, we have resolved a number of very significant cases. In 2005, the Swiss corporation **Serono, S.A.**, one of the world's largest biotech manufacturers, paid $704 million to resolve criminal charges and civil liabilities in connection with several illegal schemes to promote and sell its drug, Serostim. These schemes had resulted in the submission of false claims to Medicaid and other federally funded health care programs. The FDA had granted accelerated approval for Serostim in 1996 to treat AIDS wasting, a condition involving profound involuntary weight loss in AIDS patients, then a leading cause of death in AIDS patients. Following the advent of protease inhibitor drugs, the incidence of AIDS wasting markedly declined, and Serono launched a campaign to create a market for Serostim.

Serono pled guilty to conspiring with RJL Sciences, a medical device manufacturer, to unlawfully promote a device called a bioelectrical impedance analysis (BIA) device, for use in measuring body cell mass ("BCM") and diagnosing so-called "BCM wasting." This was an adulterated medical device because the FDA had not approved the devices for these uses. RJL and its owner also pled guilty to their roles in the conspiracy. In addition, Serono pled guilty to conspiring to offer doctors kickbacks in the form of free trips to Cannes, France, to induce them to prescribe Serostim.

The $704 million Serono settlement consisted of $305 million (plus accrued interest) paid by Serono to resolve civil False Claims Act allegations, $262 million plus interest paid to State Medicaid programs, as well as $136.9 million in criminal fines. The government alleged that Serono knowingly caused the submission of false claims for Serostim that were not eligible for reimbursement because they were for medically unnecessary or medically unaccepted indications and because the claims were for prescriptions induced by kickbacks to physicians and pharmacies.

This past year, **Eli Lilly and Company** agreed to plead guilty and to pay $36 million in connection with its illegal promotion of its pharmaceutical drug Evista. In pleading guilty to a criminal count of violating the Food, Drug, and Cosmetic Act by misbranding its drug Evista, the Indianapolis-based company agreed to pay a $6 million criminal fine and forfeit to the United States an additional sum of $6 million. In addition to the criminal plea, Lilly agreed to settle civil Food, Drug, and Cosmetic Act liabilities by entering into a consent decree of permanent injunction and paying the United States $24 million in equitable disgorgement.

Evista is approved by the FDA for the prevention and treatment of osteoporosis in postmenopausal women. The government alleged that the first year's sales of Evista in the U.S. were disappointing compared to Lilly's original forecast; the company reduced the forecast of Evista's first year's sales in the U.S. from $401 million to $120 million. In order to expand sales of the drug, it was alleged, Lilly sought to broaden the market for Evista by promoting it for off-label uses, such as for the prevention and reduction in risk of breast cancer, and the reduction in the risk of cardiovascular disease. Lilly promoted Evista as effective for reducing the risk of breast cancer, even after Lilly's proposed labeling for this use was specifically rejected by the FDA.

In another case concluded during the past year, **InterMune, Inc.** agreed to enter into a deferred prosecution agreement and to pay nearly $37 million arising out of its illegal promotion of Actimmune. The Information, filed in the Northern District of California, charged InterMune with violating the Food, Drug, and Cosmetic Act by promoting Actimmune for the treatment of idiopathic pulmonary fibrosis (IPF), a condition for which the drug has not been approved by FDA. Actimmune has been approved to treat rare conditions affecting a small number of patients. InterMune sought to increase the market for Actimmune by promoting it for IPF, a debilitating, fatal lung disease for which there is no FDA-approved treatment and which afflicts a significant number of patients.

The illegal conduct involved, in particular, a press release issued by InterMune that deceptively portrayed the results of a clinical trial for Actimmune as demonstrating the drug's survival benefit in patients with IPF. In fact, the trial had failed as to all of the endpoints specified in the study protocol, including patient survival. With InterMune's approval, the misleading information in the press release was distributed both to pulmonologists who treat IPF and directly to their patients. InterMune disseminated this misleading information despite having been informed by FDA representatives that more clinical evidence was required to demonstrate Actimmune's safety and efficacy before the agency could approve the drug to treat IPF.

Also this past year, **Schering-Plough Corporation**, together with its subsidiary, Schering Sales Corporation, agreed to pay a total of $435 million to resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for its drugs Temodar, used in the treatment of brain tumors and metastasis, and Intron A, used in the treatment of

superficial bladder cancer and hepatitis C. The resolution also pertained to Medicaid fraud involving Schering's drugs Claritin RediTabs, a non-sedating antihistamine, and K-Dur, used in the treatment of stomach conditions.

Schering Sales Corporation agreed to plead guilty to charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry concerning certain illegal promotional activities by the company's sales representatives at a national conference for oncologists. The false statements were designed to reassure the FDA that the promotional activities were isolated ones and not directed by the home office when, in fact, the activities were widespread and part of the national marketing plan. In addition, the company sought to falsely lull the FDA into believing it had taken appropriate steps to reinforce the message to its sales force that such promotion was prohibited when, in fact, the company knew and expected that those activities would continue.

Schering Sales also agreed to plead guilty to charges that it conspired with others to give free Claritin Redi-Tabs to a major health maintenance organization (HMO) to disguise a new lower price being offered to the HMO to obtain its business. Under the Medicaid Rebate statute, drug companies must report their best price on certain drugs provided to certain commercial customers, including HMOs, to HHS, and to pay quarterly rebates to the Medicaid program, in order to ensure that Medicaid obtains the benefit of that low price. From April 1998 through 1999, the company reported a false best price to the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) which failed to include the new low price of Claritin Redi-Tabs provided to the HMO, in order to avoid paying millions in additional rebates to Medicaid.

The $435 million settlement included a criminal fine of $180 million, a civil settlement under the False Claims Act for $159 million, as well as a resolution of the company's liability to the States and the District of Columbia for $91 million. The Public Health Service programs that were also entitled to a lower price on certain drugs received $3.9 million. In addition, Schering Sales was permanently excluded from participation in Federal health care programs and Schering Plough Corporation agreed to amend an existing corporate integrity agreement and extend that agreement by two years.

Now, I would like to quickly add here that under no circumstances are our attorneys attempting to inhibit the professional judgment of medical professionals who prescribe drugs for purposes not yet approved by the FDA. We know that physicians are permitted to prescribe medications for off label uses as they see fit in their medical judgment. A drug manufacturer's dissemination of reprints of peer reviewed medical journal articles, reference textbooks, and independent continuing medical education regarding the safety and efficacy of drugs can be beneficial to health care practitioners and their patients. However, as we saw in the Parke-Davis and Serono cases, certain companies may seek to vastly increase their market share by promoting their products for off-label purposes, by disseminating false and misleading evidence

to support those unapproved uses, and by bestowing gifts and other remuneration on doctors to influence their prescription writing practices. Clearly, the law does not give drug manufacturers carte blanche to promote drugs for off-label uses by any means. Nor does the law create vast exceptions that render the Food Drug and Cosmetic Act or the Anti-kickback statute inapplicable to pharmaceutical manufacturers.

From these efforts, we have learned that pharmaceutical manufacturers engage in very aggressive -- and sometimes illegal -- methods to assure the commercial success of their products. We also have learned:

- By manipulating and then marketing the "spread" between the Medicare or Medicaid reimbursement rate and the amount the pharmacy or doctor actually pays for a drug, the manufacturers are able to induce purchases of their drugs and obtain market share, all at the expense of government programs. Although the MMA redresses this problem on a going-forward basis for Medicare Part B reimbursed drugs by using average sales prices as the operative reimbursement benchmark, the Medicaid program remains vulnerable to the schemes at issue in the TAP, AstraZeneca, Warrick, and Dey cases.

- Manufacturers have engaged in abuses of the Medicaid Rebate statute, a law that was designed to ensure that the Medicaid program obtain the savings that manufacturers offered to other large commercial customers, however those savings were passed along. A close examination of the statute and the potential need for enhanced provisions is timely and warranted by the issues that have arisen in our enforcement efforts.

- By providing free pharmaceuticals to physicians and then instructing them how to bill Medicare and Medicaid for the free products, manufacturers have surreptitiously caused the government to pay for the illegal kickbacks with which they induce physicians to prescribe their drugs. By disguising the true nature of these free products, manufacturers obscure their best prices and deny these cash strapped programs of the full benefit of the rebate program. Best price violations that affect Medicaid also directly impact Public Health Service entities, whose prices are based on a derivative formula.

- By inducing physicians to prescribe for uses that have not been approved by the Food and Drug Administration, either by promoting compromised "science" or offering financial incentives, manufacturers are subverting a healthcare system that necessarily relies on the objective medical judgment of practitioners, and their actions may also harm the public health.

- The Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), remains a vital law enforcement tool in assuring that sound medical judgment is not subverted by the payment of inducements that sometimes cause medical professionals to prescribe drugs based on financial considerations and not medical necessity or safety.

CONCLUSION

As you can see, the Department has been very active in this area. We have been greatly assisted by industry insiders who have taken advantage of the *qui tam* provisions of the False Claims Act, but we also have been fortunate to have prosecutors who have waded into these complex and difficult cases in a successful effort to protect the integrity of the Nation's health system.

As you well know, the government is providing prescription medication to our Nation's elderly and often neediest citizens, and it is doing so at a time when resources are increasingly scarce. We simply cannot afford to let government-funded health care programs be victimized by the schemes that I have discussed here today. Toward that end, I know I speak for Attorney General Gonzales when I say that the Department of Justice will continue to work with this Committee and its staff to identify problems and work toward formulating solutions.

Again, I thank the Committee for seeking the views of the Department of Justice on these issues. The Committee can be assured that the Department will continue to play a lead role in policing the healthcare system for fraud and abuse, and will work with this Committee in addressing the myriad issues which I have briefly discussed this morning.

Chairman WAXMAN. 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 for 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 pursue those 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 enough for three lawyers to work on that case. So we are pedaling 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 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.

[The prepared statement of Mr. O'Connell follows:]

Testimony of Patrick J. O'Connell
Chief, Civil Medicaid Fraud Section
Office of the Attorney General of Texas

Mr. Chairman and members of the Committee:

Good morning. My name is Patrick O'Connell. I am an Assistant Attorney General and Chief of the Civil Medicaid Fraud Section of the Texas Attorney General's Office. Thank you for inviting me to testify this morning. In fiscal year 2005, the combined federal and state spending by the Texas Health and Human Services Commission on Medicaid was nearly $18 billion. Payments for prescription drugs by Texas Medicaid for that same time period amounted to $2.413 billion. The sheer volume of the dollars involved provides a huge enticement for those who would attempt to defraud the program.

In 1999, in response to concerns about growing claims of fraud and abuse, the Texas Attorney General created a special Civil Medicaid Fraud Section within the AG's office, and I have had the privilege of heading up the section since its inception. We have investigated and pursued claims against doctors, dentists, hospitals and other providers which involved typical claims of false billing, false cost reporting and over-billing; however, the overwhelming majority of our time and efforts have been concentrated on drug manufacturers. Did we target or place special emphasis on drug manufacturers on purpose? The answer is : No. The fact is that whistle blowers brought us cases which showed significant fraud in amounts which dwarfed the cases against

other providers. Because of the limited number of staff and resources we can bring to any one case, we chose to pursue those cases which provided the greatest recovery for the Medicaid program.

Texas was the first state to intervene in a qui tam case involving pharmaceutical manufacturer pricing fraud and aggressively pursue those claims. In the last six years, we have recovered $64.1 million from four manufacturers, and we continue to pursue cases against other wrongdoers. It is important to remember that these were Texas state settlements only. We have developed close and cooperative working relationships with the United States Department of Justice and with other state attorneys general who have instituted similar litigation. While Congress has made great strides in passing legislation to curb this type of fraud in Medicare and Medicaid and litigation continues in pricing fraud cases, some unscrupulous manufacturers continue to devise ways to defraud Medicaid. Besides pricing fraud, there are a number of other ways in which we believe drug manufacturers are defrauding the Medicaid system. These methods include the following:

1. Rebate fraud

In order to allow the free market system to determine prices while allowing the Medicaid programs to obtain the best price available for drugs, you passed legislation which required drug manufacturers to pay rebates to the State Medicaid programs based upon either a percentage of the Average Manufacturer Price("AMP") or the difference

between the AMP and the manufacturer's "Best Price" as reported to CMS. Some manufacturers have failed to accurately report their AMP and/or their Best Price. When they do so, the Medicaid program does not end up paying the lowest price as the legislation intended. Methods used to perpetrate this fraud include fraudulent reporting AWP or the wholesale cost of drugs, fraudulent reporting of AMP by failing to account for discounts, rebates and chargebacks and fraudulent reporting of Best Price through the use of what is known as nominal pricing and/or bundling.

A) Reports of false AWP or Wholesale Cost

The rebate system assumes that the Medicaid program has paid an estimated acquisition cost that is reasonably close to the actual acquisition cost. Then, the rebate brings the program's price down near the Best Price. If the estimated acquisition cost is inflated due to fraud, the rebate does not bring the net price to the program down to the Best Price. Congress attempted to resolve this problem in the last session changing the methodology of creation of the Federal Upper Limit("FUL") on multi-source drugs to 250% of the lowest published AMP. Our experience in Texas shows that multi-source drugs are sold in a very narrow range in the market place, and we are concerned that an FUL of 250% does not limit the potential for fraud enough.

B) Reporting of AMP/Best Price

The reporting of AMP/Best Price is supposed to take into account all rebates, discounts and chargebacks for sales to the retail class of trade. The AMP for a generic product is 11% of the AMP. The lower the AMP, the lower the rebate. So, if discounts are applied in a calculation of AMP that should not have been applied, the AMP is fraudulently reduced. The AMP for a branded product is 15.1% of the AMP or the difference between AMP and Best Price, whichever is greater. If discounts are not applied to the Best Price calculation, the Best Price remains artificially high and the difference between AMP and Best Price is reduced. Consequently, the rebate is reduced. This fraud can be accomplished in a number of different ways. The main method is to provide free goods and services, educational grants or other valuable monetary incentives to influence the purchasing decision. These incentives are not reported as discounts, thereby artificially inflating the Best Price.

C) Bundling fraud

Bundling is the practice of selling a number of drugs by a manufacturer with the provision of a discount so long as the purchase is of all of the drugs in the transaction. For example, a manufacturer tells a provider that they can obtain a 25% discount on four of the manufacturer's drugs so long as the provider buys a particular drug at a higher undiscounted price. Under the current rules, the discount is to be apportioned across all of the drugs in the transaction. If the discount is all applied to the generic drugs in the

transaction, the rebate for the generics stays unchanged; however, the rebate for the branded products could have been affected because the Best Price for the branded product could have been lower than the reported Best Price.

D) Nominal pricing fraud

In addition, when calculating Best Price, manufacturers do not have to include sales to entities at " merely nominal pricing". This provision was designed to allow manufacturers to provide product to charitable entities at little or no cost without requiring them to use that price to calculate their rebates. CMS issued a ruling that said that any sale at less than 10% of AMP was "nominal". Some manufacturers have illegally used this provision to discount the prices of their drugs to their normal customers without reporting a lowered Best Price. For example, some manufacturers have provided their drug to hospitals at 8% of the regular rate under an agreement with the hospital that the drug is used more than 80% of the time or if the drug has been declared to be the preferred drug on the hospital's formulary. In other words, the low price is tied to a performance measure. We believe this is not "merely nominal", and it has the effect of improperly influencing prescription decisions at the hospital or in the future for that patient.

2. Off-label marketing fraud

As you know, a drug manufacturer may not market a drug for use against a particular condition or disease unless the FDA has approved the drug for such use. We have seen numerous instances of such behavior, and there have been a number of settlements completed in this area already. The Texas Attorney General just recently unsealed a case against Jannsen, a subsidiary of Johnson & Johnson, for the off label marketing of its drug Risperdal for use in children when the FDA has not approved it for such use. Jannsen's aggressive marketing caused the Texas Medicaid program to pay for $117 million of Risperdal over the last 5 years. Not only has Texas paid this sum, but we do not know yet the increased costs of medical care for those children who used Risperdal and developed other symptoms such as diabetes.

3. Misrepresentation of safety and effectiveness

The Texas Medicaid program has for years had an open formulary. That is, if a drug was approved by the FDA and a drug manufacturer signed a rebate agreement and the manufacturer asked to be placed on the Texas Medicaid formulary, the drug was placed on the formulary and was reimbursable under the Texas Medicaid rules. When the drug manufacturer asks for its drug to be included on the formulary, the manufacturer must swear to its safety and efficacy. If, in fact, the drug is not safe, the Medicaid program is

reimbursing for a drug that it would not otherwise have paid for. The Texas Medicaid program paid for $57 million for Vioxx prior to the time Merck voluntarily removed it from the market. Texas and a number of other states have sued under our state false claims act for the return of these funds.

When Texas and other states pursue these types of Medicaid fraud, we are often met with a scorched earth defense where we are forced into extensive pre-trial discovery battles. These maneuvers not only increase the cost to the State to try the lawsuit but place an inordinate burden on the Medicaid program. The monetary and time burdens on the Medicaid agency take away from the funds and time which would otherwise be available to the program to provide the very benefits it is designed to provide.

The Medicaid program places a great amount of trust in our pharmaceutical manufacturers to provide accurate figures to the program. Some of these manufacturers have not earned that trust, and, without strong false claims acts and without strong administrative rules to punish such behavior, many manufacturers will continue to violate that trust. Furthermore, without the funding and staffing to pursue false claims act cases, neither the Department of Justice nor the Texas Attorney General will be able to utilize these laws to effectively deter continued diversion of the taxpayers dollars.

My time is about up. Thank you for your attention. I am happy to answer any questions.

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 with 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 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 United States.

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 and 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, DC, every U.S. 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 pharmaceutical issues?

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. I would be happy to try to followup.

Chairman WAXMAN. Thank you.

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 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, KY, 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 decisionmaking 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 billion of that was health care fraud-related recoveries. And of that $2 billion, 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 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 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. 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. 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 followup 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 U.S. 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 U.S. 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. OK.

GAO's prior reports on Medicaid drug rebates in the 340B program identified some important oversight inadequacies and a record of poor implementation. Three reports by the HHS 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, the 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 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 I would like to receive it.

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

[The information referred to follows:]

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

TOM DAVIS, VIRGINIA
RANKING MINORITY MEMBER

ONE HUNDRED TENTH CONGRESS

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February 16, 2007

John E. Dicken
Director, Health Care
General Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dicken:

Thank you for your testimony and participation at the Committee's February 9, 2007 hearing, "Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer." I ask that you answer the following question for the official hearing record.

1. The CMS Office of the Actuary, which is responsible for actuarial, economic and demographic studies to estimate CMS program expenditures under current law, released a 2007 midseason review of the estimated Medicare Part D costs on February 9, 2007. (Please find attached) In this review, the Office of the Actuary reported that their original estimates for the years 2006-2016 were artificially high – by approximately $117.5 billion over the same period. Moreover, in 2006 actual cost of Part D was $12.7 billion less that that office originally predicted.

    a. Did you take this study into consideration as you prepared your analysis of the Medicare Part D Program?

    b. If not, would you reconsider your analysis of the programs reliance on contracts with private prescription drug plan sponsors in light of the information that demonstrates the effectiveness of the market based system adopted by Medicare Part D?

If you have any questions regarding this letter please contact Kristina Husar, Professional Staff, at (202) 225-5074.

Sincerely,

Tom Davis
Ranking Member

Enclosure

Comparison of the Office of the Actuary's cost estimates for Medicare Part D
[in billions]

Estimated Medicare Part D costs	Fiscal year - cash estimates											Total,		
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2004-13	2006-10	2006-15
Original Estimate	42.7	62.2	68.1	74.4	81.3	89.0	99.3	111.4	—	—	—	633.5	328.7	—
FY 2006 President's Budget	45.8	64.8	70.9	77.4	84.3	91.5	101.2	112.6	125.1	138.9	—	650.0	343.3	912.7
FY 2006 Mid-Session Review	46.6	65.9	71.9	78.5	85.5	92.8	102.6	114.2	126.9	141.0	—	659.4	348.4	925.9
FY 2007 President's Budget	36.8	56.8	62.3	66.9	73.6	84.3	86.3	99.1	109.7	121.4	139.3	567.3	296.2	797.1
FY 2007 Mid-Session Review	30.0	48.0	56.1	62.0	68.5	78.4	79.8	91.9	101.8	112.7	129.6	516.0	264.6	729.1

Note: The estimated total impact on the Federal government include the savings to the Medicaid program from the dual eligibles being covered by Part D. Ur original estimates, the estimated net Federal cost for fiscal years 2004-2013 was $511 billion.

Estimated Medicare Part D plan payments	Fiscal year - cash estimates											Total,		
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2004-13	2006-10	2006-15
Original Estimate	56.2	81.4	88.8	96.8	105.6	115.3	128.0	143.3	—	—	—	820.4	428.8	—
FY 2006 President's Budget	58.9	83.9	92.2	101.0	110.5	120.2	132.9	147.6	163.6	181.1	—	848.6	446.5	1,191.9
FY 2006 Mid-Session Review	59.8	85.1	93.4	102.3	111.8	121.7	134.6	149.5	165.6	183.5	—	859.5	452.4	1,207.2
FY 2007 President's Budget	46.5	70.9	79.0	85.6	94.2	107.0	111.3	126.5	139.7	154.3	175.5	722.3	376.2	1,015.0
FY 2007 Mid-Session Review	37.6	61.3	73.0	81.1	89.6	101.5	105.3	119.9	132.5	146.3	166.6	670.5	342.5	947.9

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 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?

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.]

[NOTE.—No response was received for the following questions:]

"Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer"
Committee on Oversight and Government Reform
February 9, 2007

Questions submitted for the Record
Congressman Dan Burton

- Transparency in pharmaceutical drug pricing under the Medicare Part D program is non-existent, according to the testimonies we heard during this hearing. Our seniors are unable to even search for the most accurate, lowest price offered by the various plans for the drugs they need. In your opinion, what will be the average cost to a senior citizen who unwittingly subscribes to a program that doesn't offer the lowest price for the prescription they need?

- Why do you suppose there is no transparency in this process? Is this a result of bureaucracy? Or is it because the pharmaceutical companies are better able to get away with inflating prices, and offer kickbacks to the various programs offered by Medicare Part D?

- If drug importation into this country – from places like Canada, Spain, Germany and other industrialized nations which offer some of these drugs at one tenth the price of what they cost in the United States – were permitted, and the programs offered through Medicare Part D were permitted to take advantage of that, could Medicare Part D be salvaged, and better able to save our seniors and the taxpayers more money?

- Would pharmaceutical companies be more forthcoming and transparent with regard to drug pricing if drug importation into this country was permitted? Would it drive drug prices down?

- Many countries which offer prescription drugs at lower prices are only able to do so because of the research and development done by the pharmaceutical companies in the United States – which are enabled to achieve these results by free markets and tax incentives. If we opened up the United States to importation of drugs, what would the likely affect be on the research and development expenditures of the pharmaceutical companies?