

THE MEDICARE DRUG BENEFIT: ARE PRIVATE INSURERS GETTING GOOD DISCOUNTS FOR THE TAXPAYER?

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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THE MEDICARE DRUG BENEFIT: ARE PRIVATE INSURERS GETTING GOOD DISCOUNTS FOR THE TAXPAYER?

THURSDAY, JULY 24, 2008

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:10 a.m., in room 2154, Rayburn House Office Building, Hon. Henry A. Waxman (chairman of the committee) presiding.

Present: Representatives Waxman, Cummings, Kucinich, Tierney, Watson, Higgins, Yarmuth, Braley, Van Hollen, Murphy of Connecticut, Sarbanes, Speier, Davis, Burton, Shays, Platts, Issa, Marchant, McHenry, Foxx, Bilbray, and Jordan.

Staff present: Kristin Amerling, general counsel; Caren Auchman and Ella Hoffman, press assistants; Phil Barnett, staff director and chief counsel; Jen Berenholz, deputy clerk; Brian Cohen, senior investigator and policy advisor; Miriam Edelman, Jennifer Owens, and Mitch Smiley, special assistants; Earley Green, chief clerk; Karen Lightfoot, communications director and senior policy advisor; Karen Nelson, health policy director; Andy Schneider, chief health counsel; Leneal Scott, information systems manager; John Williams, deputy chief investigative counsel; Lawrence Halloran, minority staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Ali Ahmad, minority deputy press secretary; Larry Brady, minority senior investigator and policy advisor; Patrick Lyden, minority parliamentarian and Member services coordinator; Brian McNicoll, minority communications director; John Ohly and Molly Boyl, minority professional staff member; and Jill Schmaltz, minority senior professional staff member.

Chairman WAXMAN. Good morning. The committee will please come to order.

Today, the committee is holding another hearing in our series on how to make government work better. Our subject is the Medicare Part D program that provides a prescription drug benefit to seniors and individuals with disabilities.

Providing drug coverage to seniors and the disabled is essential, but it is also expensive. Over the next decade, the benefit will cost taxpayers hundreds of billions of dollars. We need to make sure this money is spent responsibly and with good value for the taxpayers.

This committee has been investigating Medicare Part D for 18 months. During our investigation, we have conducted the only in-

depth oversight of the Part D program. GAO and the Congressional Budget Office have been unable to review how well the program is working because the Centers for Medicare and Medicaid Services won't give them the data; and CMS, which does have access to data, refuses to acknowledge fundamental flaws in the program.

Last October, I and other members of the committee released a staff report that examined the administrative costs of Medicare Part D. We found that the private insurers that delivered the Medicare benefit are charging taxpayers and beneficiaries \$4.6 billion in administrative costs annually. In percentage terms, that is over six times more than it costs to run traditional Medicare. And we found that the Part D program is exceptionally lucrative for private health insurers. They made a billion dollars in profit last year alone.

Today, I am joining with 10 members of the committee to release a new staff report, which I ask to be made part of today's hearing record. Without objection.

[The information referred to follows:]



UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
MAJORITY STAFF
JULY 2008

MEDICARE PART D: DRUG PRICING AND MANUFACTURER WINDFALLS

PREPARED FOR
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EXECUTIVE SUMMARY

This report uses confidential information on drug prices to compare the costs of drugs purchased under the new Medicare Part D program with the costs of drugs purchased under traditional Medicaid. It finds (1) that Medicare Part D pays on average 30% more for drugs than does Medicaid and (2) that this discrepancy in pricing produced a windfall worth over \$3.7 billion for drug manufacturers in the first two years of the Medicare Part D program.

Unlike traditional Medicare, which is administered by the federal government, the new Medicare Part D prescription drug program depends on private insurers to provide drug coverage. This reliance on private insurers has sparked a debate about the consequences of privatizing the delivery of Medicare services. A staff report released by Rep. Henry A. Waxman and other members in October 2007 compared the administrative expenses incurred by the private Part D insurers with the administrative expenses incurred under traditional Medicare. That report found that the administrative expenses and profits of the private insurers accounted for nearly 10% of the costs of Medicare Part D, nearly six times as much as the administrative expenses of traditional Medicare.

This new report compares the drug prices negotiated by the private Part D insurers with the drug prices paid by Medicaid, a federal-state program that provides health care to over 60 million low-income Americans. In particular, the report focuses on the cost to the taxpayer of providing drug coverage through Medicare Part D to six million "dual eligible" beneficiaries. These are elderly and disabled individuals who qualify for both Medicare and Medicaid. Prior to enactment of Medicare Part D, dual eligible beneficiaries received prescription drugs through Medicaid. The Medicare Part D law transferred their drug coverage to Medicare starting on January 1, 2006. The drugs used by dual eligible beneficiaries now account for more than half of total prescription drug plan (PDP) drug costs under the Part D program. These costs are paid almost entirely by federal taxpayers.

To compare Medicare Part D and Medicaid drug prices, the Committee obtained confidential information on drug expenditures for dual eligible beneficiaries from the ten largest Part D insurers. The Committee also obtained confidential information on Medicaid drug prices directly from the drug manufacturers. The Committee asked both the Part D insurers and the drug manufacturers to provide pricing information for the 100 prescription drugs used most often by dual eligible beneficiaries. Both the insurers and the drug manufacturers provided this information to the Committee voluntarily.

This report finds that the prices paid for the drugs used by the dual eligible beneficiaries under Medicare Part D are significantly higher than the prices paid by Medicaid for the same drugs. The higher prices for the top 100 drugs produced a windfall of \$1.7 billion for drug manufacturers in 2006, the first year of Medicare Part D. The higher prices produced an even larger windfall of \$2 billion for the drug manufacturers in 2007.

Comparison of Medicare Part D and Medicaid Drug Prices

In 2006 and 2007, the private Part D insurers spent \$18.7 billion to purchase the top 100 drugs for dual eligible beneficiaries. On average, the Part D insurers received rebates and other

discounts from drug manufacturers that reduced these costs by 14%, lowering the total cost of providing these drugs to dual eligible beneficiaries to \$16.2 billion.

Medicaid purchases the same drugs for low-income beneficiaries who are not dual eligible and pays significantly lower prices. If the private Part D insurers had paid the same prices as Medicaid, their total cost for the drugs used by the dual eligible beneficiaries would have been \$12.4 billion. The higher prices paid by the private Medicare Part D insurers increased the costs to the taxpayer for these drugs by 30%.

The price increases were especially large for the drugs on the "protected list" maintained by the Centers for Medicare and Medicaid Services (CMS). The drugs on the protected list are essential medications, such as anti-depressants, anti-psychotics, and AIDS drugs, that CMS requires all Medicare Part D plans to offer. For the 16 drugs among the top 100 that are on the protected list, the private Medicare Part D insurers obtained rebates and discounts of only 7%. The Medicare Part D insurers paid almost 40% more for these essential medications than Medicaid pays.

The 100 top drugs used by the dual eligible beneficiaries are sold in over 1,200 different strengths and forms. For 97% of these formulations, the private Part D insurers paid more for the drugs than does Medicaid. For 74% of these formulations, the Part D insurers received no rebates or discounts at all from the drug manufacturers.

Drug Manufacturer Windfalls

The transfer of drug coverage for the dual eligible beneficiaries from Medicaid to Medicare Part D has resulted in large windfalls for the drug manufacturers. There are 29 large drug manufacturers who produce the 100 drugs used most often by dual eligible beneficiaries. In total, these manufacturers received \$3.7 billion more from the Medicare Part D insurers in 2006 and 2007 than they would have received if the dual eligible beneficiaries had obtained the drugs through Medicaid.

Johnson & Johnson received the largest windfall: \$615 million in 2006 and 2007, including over \$500 million in additional revenue from sales of just one drug, the anti-psychotic Risperdal. Bristol-Myers Squib received a windfall of \$400 million, including over \$200 million in additional revenue from sales of its heart-attack and stroke medication Plavix. Over 13 drug manufacturers had windfall revenues of over \$100 million in 2006 and 2007 as a result of the switch in coverage for the dual eligible beneficiaries.

Nine drugs each generated over \$100 million more in revenues under the Medicare Part D program than they would have generated had Medicare Part D insurers been able to get the same discounts that Medicaid gets. For these nine drugs, the manufacturers charged the private Medicare Part D insurers 46% more than they charged Medicaid.

The actual windfall for drug manufacturers is probably larger than \$3.7 billion because dual eligible beneficiaries use many drugs that are not included in the list of the top 100 drugs. If the price discrepancy between Medicare Part D and Medicaid is the same for these other drugs as it is for the top 100 drugs, the manufacturer windfall could be worth billions of dollars more.

Estimates of Potential Cost Savings

Because dual eligible beneficiaries have low-incomes, the federal taxpayer pays over 98% of their drug costs under Medicare Part D. Over the next ten years, dual eligible beneficiaries are expected to use \$432 billion worth of drugs. If drug manufacturers provided the Medicare Part D program with the same prices that Medicaid receives, these drug costs could be reduced by as much as \$86 billion, a large savings for taxpayers.

The dual eligible beneficiaries account for over half of drug spending under Medicare Part D. The costs of providing drugs to other Medicare Part D beneficiaries are shared by the federal taxpayers and the beneficiaries. If Medicare Part D paid the same price as Medicaid for all drug purchases, the total savings to the taxpayer over the next ten years could be as much as \$156 billion. Beneficiaries could also save up to \$27 billion.

I. INTRODUCTION

The legislation creating the Medicare Part D drug program was signed into law by President Bush in November 2003. The program went into effect on January 1, 2006, and is now in its third year of operation. In 2006 and 2007, the Medicare Part D program cost the federal government \$47 billion and \$49 billion, respectively. Over the next decade, Medicare Part D coverage is estimated to cost the federal government \$900 billion.¹

The new Medicare Part D program differs significantly from Medicare Part A, which covers hospital expenses, and Medicare Part B, which covers outpatient care. Unlike Part A and Part B, the Part D program is not administered directly through the federal government. Instead, private insurers contract with Medicare to deliver Part D coverage. Medicare Part D allows the insurers to offer multiple plans with different premiums, copays, and formularies.

The new Medicare Part D program also differs significantly from Medicaid, which is a federal-state partnership that provides health care to 61 million low-income Americans, primarily children, mothers with young children, seniors, and individuals with disabilities. Prior to 2006, low-income seniors and individuals with disabilities who were eligible for both Medicaid and Medicare typically received their health care and drug coverage through Medicaid. The law creating Medicare Part D, however, required these “dual eligible” beneficiaries to obtain their drug coverage exclusively through Medicare Part D, effective January 1, 2006.²

The use of private insurance companies to provide the Medicare Part D benefit has been the subject of a vigorous debate. This debate, which started during congressional consideration of the Medicare drug law, continues today. On one side, President Bush, other senior administration officials, Republican leaders in Congress, and the insurance and pharmaceutical industries argue that competition among many private insurers is the most effective way to keep prices low for seniors and taxpayers. In October 2003, as Congress was debating the Medicare legislation, the President claimed:

The best way to provide our seniors with modern medicine, including prescription drug coverage ... is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices.³

Republicans on the House Ways and Means Committee maintained that the Part D structure “will allow competitive forces in the private market to generate the best savings for seniors.”⁴

¹ Department of Health and Human Services, 2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds (2008).

² Medicare Prescription Drug, Improvement, and Modernization Act, § 103 (PL 108-173) (2003).

³ The White House, President Calls on Congress to Complete Work on Medicare Bill (Oct. 29, 2003).

⁴ Committee on Ways and Means, Hearing on Negotiating Lower Prices for America's Seniors, 108th Cong. (Dec. 11, 2003).

Senate Majority Leader Bill Frist argued that “competition through the private sector, through bulk purchasing and negotiation, is a more effective means to hold down prices.”⁵

Pharmaceutical and insurance industry representatives have consistently made similar assertions. According to representatives of the drug industry, “low Part D bids have largely been driven by plans’ ability to secure substantial price discounts and rebates on drugs furnished to Medicare beneficiaries.”⁶ The industry organization representing many Part D insurers has claimed that the insurers are providing “deeper than expected discounts”⁷ and “tremendous savings.”⁸

On the other side of the debate, Democratic members of Congress and public health groups have raised questions about the cost and effectiveness of the private Part D insurers. In 2006, analyses of Medicare drug plan prices released by Rep. Henry A. Waxman indicated that the Part D insurers were failing to provide seniors with significant price discounts at the pharmacy counter and were unable to control rapid increases in drug costs.⁹

In October 2007, Rep. Waxman and other members of the Committee on Oversight and Government Reform released an analysis of the administrative costs of the Medicare Part D program. This analysis found that the administrative expenses, sales costs, and profits of the private insurers offering Medicare Part D coverage would cost taxpayers and beneficiaries \$4.6 billion in 2007, nearly 10% of total program and beneficiary costs. These administrative expenses are almost six times greater than the administrative costs of traditional Medicare.¹⁰

The October 2007 report also examined the drug pricing data submitted by the private Part D insurers to CMS. This data provided indications that the private insurers were not successful in obtaining large discounts from drug manufacturers.¹¹

II. OBJECTIVE AND METHODOLOGY

The debate over the effect of privatizing the delivery of Medicare Part D coverage has been largely theoretical. Answering the questions about the performance of the private Part D insurers requires access to the actual cost and pricing data of the insurers and drug manufacturers. These data are proprietary and closely guarded. This has often left Congress and the public without

⁵ *Does Medicare or Private Insurance Do a Better Job of Controlling Health Care Costs?*, The New York Times (Nov. 27, 2003).

⁶ Biotechnology Industry Organization, *Medicare Part D Plans Deliver Significant Savings on Innovative Breakthrough Medicines* (2007).

⁷ Pharmaceutical Care Management Association (PCMA), *PCMA Statement on U.S. House Approval of H.R. 4* (Jan. 4, 2007).

⁸ Pharmaceutical Care Management Association (PCMA), *Beneficiaries in Part D Enjoying Broad Savings and Broad Access on Their Prescription Drugs* (May 2, 2007).

⁹ See, e.g., Minority Staff, Special Investigations Division, House Committee on Government Reform, *New Medicare Drug Plans Fail to Provide Meaningful Drug Price Discounts* (Nov. 2005); Minority Staff, Special Investigations Division, House Committee on Government Reform, *Medicare Drug Plan Prices Are Increasing Rapidly* (Nov. 2005).

¹⁰ Committee on Oversight and Government Reform, Majority Staff, *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage* (Oct. 2007).

¹¹ *Id.*

access to the information needed to assess the performance of the Part D private insurers and to compare their performance with traditional Medicare.

To provide insight into the effectiveness of the Part D program, this report uses confidential information on drug prices to compare the costs of drugs purchased through the new Medicare Part D program with the costs of drugs purchased through Medicaid. Under Medicare Part D, drug prices are established through negotiations between the private Part D insurers and the drug manufacturers. By contrast, drug prices in the Medicaid program are regulated by the 1990 Medicaid drug rebate law.¹²

Under the Medicaid law, drug manufacturers are required to provide Medicaid significant price discounts as a condition for their participation in the program. For brand-name drugs used by Medicaid beneficiaries, manufacturers are required to provide the drug to Medicaid at the lower of (1) their "best price," which is defined as the lowest price at which they sell the drug to private purchasers, or (2) 15% below their "average manufacturer price," which is defined as "the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."¹³ For generic drugs, manufacturers are required to provide a discount of 11% off of their average manufacturer price.¹⁴ In the case of brand-name drugs, the Medicaid drug rebate law also protects the program from rapid price increases, requiring additional manufacturer price concessions if a drug's cost increases faster than the overall inflation rate.¹⁵

To ensure an accurate comparison between the Medicare Part D program and Medicaid, the report focuses on the drugs used by dual eligible beneficiaries. These are seniors or individuals with disabilities who are eligible for Medicare and are eligible for Medicaid because of their low income and resources. There are approximately six million dual eligible beneficiaries. Compared to other Medicare beneficiaries, dual eligible beneficiaries have a high level of drug use. Dual eligible beneficiaries are generally the oldest and least healthy members of the Medicare population and use significantly more drugs than the average Medicare Part D beneficiary. Although they account for only approximately one-third of Medicare Part D beneficiaries enrolled in Part D Prescription Drug Plans (PDPs), data submitted to the Committee by the Part D insurers indicates that dual eligible beneficiaries account for 57% of the total PDP drug costs.

Prior to 2006, the six million dual eligible beneficiaries received their drug coverage through Medicaid. On January 1, 2006, the coverage for these six million dual eligible beneficiaries was switched from Medicaid to Medicare Part D. Taxpayers continue to subsidize this coverage, which is now provided by the private Part D insurers. The federal government pays an estimated 98% of the drug costs of the dual eligible beneficiaries under Medicare Part D.¹⁶

¹² Section 1927 of the Social Security Act, as added by section 4401 of the Omnibus Budget Reconciliation Act of 1990, P.L. 101-580.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Actuarial Research Corporation and Henry J. Kaiser Family Foundation, *Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006* (Nov. 2004). Dual eligible Part D enrollees who are not

The data used in this report come from two primary sources: (1) the private Part D insurers and (2) the drug manufacturers. From the insurers, the Committee received detailed information on 2006 and 2007 drug utilization, rebates, and discounts. The Committee requested information from the ten leading providers of Medicare Part D PDPs.¹⁷ Combined, these insurers provided Part D coverage to over 14 million beneficiaries, accounting for 82% of all PDP enrollees.¹⁸ Their enrollment in 2007 included 5.8 million dual eligible beneficiaries, approximately 95% of all dual eligible beneficiaries.

The Committee's request asked the insurers to provide information for all strengths and forms — brand and generic — of each of the 100 drugs most frequently prescribed for dual eligible beneficiaries.¹⁹ Combined, these 100 drugs account for 56% of drug expenditures for dual eligible beneficiaries, and account for 57% of all Medicare PDP drug expenditures. The Committee requested drug-by-drug information on the quantity of the drug dispensed, the total cost paid for the drug, and the total value of the rebates and other discounts received for the drug. The insurers were asked to provide this information in the aggregate for all Part D beneficiaries, as well as separately for dual eligible beneficiaries. All ten insurers cooperated with the Committee request voluntarily.²⁰

From the drug manufacturers, the Committee received detailed information about sales to the Medicaid program. There are 29 major pharmaceutical manufacturers that produce the top 100 drugs used by dual eligible beneficiaries.²¹ For each of these drugs, the Committee asked that the manufacturer provide information on the rebates provided to the Medicaid program in 2006 and 2007. All 29 drug manufacturers cooperated with the Committee request voluntarily.

The analysis in the report compares drug costs paid by the private Medicare Part D insurers for the top 100 drugs with the amounts paid by Medicaid for the same drugs. The data provided by the insurers and the drug manufacturers allow for cost comparisons to be made for over 1,200 formulations of the top 100 drugs.

residents of a nursing home or medical institution must pay a share of their drug copay, up to \$1.05 per prescription for generic drugs and up to \$3.10 per prescription for brand-name drugs. *Id.*

¹⁷ The ten insurers are Aetna, CVS/Caremark, Coventry, Humana, Medco, Memberhealth, United, Universal American, Wellcare, and Wellpoint. The analysis did not include information on Medicare Advantage Prescription Drug (MA-PD) Plans because these plans do not provide drug coverage to a significant number of dual eligible beneficiaries.

¹⁸ Centers for Medicare and Medicaid Services, Medicare Prescription Drug Plans (PDPs) by Total Enrollment in Parent Organization (2007).

¹⁹ U.S. Department of Health and Human Services, Office of Inspector General, *Dual Eligibles Transition: Part D Formularies' Inclusion of Commonly Used Drugs* (Table 4) (Jan. 2006).

²⁰ In some cases, manufacturers provide Part D plans with "differential rebates," with the plans accruing larger rebates for sales to dual eligible beneficiaries than they accrue for sales to other Part D beneficiaries. In these cases, the analysis used the larger differential rebate amounts provided for dual eligibles as the basis of the comparison to the rebates provided to the Medicaid program.

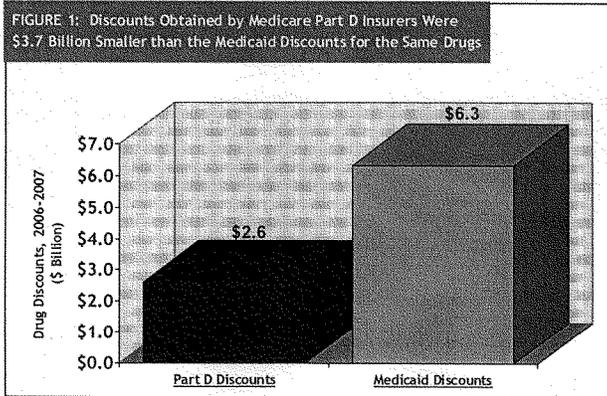
²¹ The 29 manufacturers were Abbott, Apotex, AstraZeneca, Barr Pharmaceuticals, Baxter, Boehringer Ingelheim, Bristol Myers, Eisai, Eli Lilly, Forest Pharmaceuticals, Glaxo, HoffmanLaRoche, Johnson & Johnson, King Pharmaceuticals, Merck, Mylan, Novartis, NovoNordisk, Pfizer, Proctor and Gamble, Purdue Pharma, Sandoz, SanofiAventis, Schering Plough, Takeda, TAP, Teva, Watson Pharmaceuticals, and Wyeth.

III. FINDINGS

A. Comparison of Medicare Part D and Medicaid Drug Prices

In 2006 and 2007, the private Medicare Part D insurers paid \$18.7 billion to purchase the top 100 drugs for dual eligible beneficiaries. They received \$2.6 billion in rebates and discounts from the drug manufacturers, reducing their total drug costs by 14% to \$16.2 billion.

These price reductions were substantially smaller than the Part D insurers would have obtained had they received the same rebates that the Medicaid program receives. If the Part D insurers had been able to obtain the Medicaid discounts for the top 100 drugs, the Part D insurers would have reduced their total drug costs for the dual eligible beneficiaries by over twice as much, \$6.3 billion. Figure 1. This would have cut their total drug costs to \$12.4 billion. The higher prices paid by the private Medicare Part D insurers increased the cost to the taxpayer for these drugs by 30%.



Almost every drug is more expensive under Medicare Part D than under Medicaid. There are over 1,200 formulations of the top 100 drugs for which a comparison can be made between the discounts obtained by the Medicare Part D insurers and the Medicaid program. For over 95% of these formulations, the Medicaid prices were lower than the Medicare Part D prices. For 74% of these formulations, the Part D insurers received no rebates or discounts at all.

Under Medicare Part D, there are approximately 230 drugs that insurers are required to include on their formulary, including 16 of the top 100 drugs. These drugs are listed on CMS's

“protected list” and fall into six classes: anti-depressants, anticonvulsants, antipsychotics, HIV-AIDS drugs, immunosuppressants, and antineoplastics (drugs used to treat tumors).²² For these essential medications, the private Medicare Part D insurers consistently paid higher prices than the Medicaid program. For the 16 top 100 drugs on the protected list, the rebates and discounts received by the Part D insurers reduced the drug costs by only 7%. In comparison, Medicaid receives rebates that reduce the costs of these drugs by 33%, over four times as much.

In 2006 and 2007, dual eligible beneficiaries used \$6.1 billion worth of the 16 top 100 drugs on the protected list. If the Part D insurers had received the same price for these drugs as Medicaid pays, costs to the taxpayer would have been reduced by over \$1.5 billion.

Another subset of drugs for which the Part D insurers have been unable to obtain significant discounts and rebates are generic drugs. The insurers have been successful in encouraging the use of generic drugs, with Part D generic utilization rates that are higher than those achieved under the Medicaid program.²³ However, the inability of the insurers to obtain rebates or discounts on these generic drugs means that significant savings have not been realized.

In 2006 and 2007, dual eligible beneficiaries used \$1.7 billion worth of generic drugs that were among the 100 top drugs, representing almost 10% of drug spending for dual eligible beneficiaries. The Part D insurers obtained no rebates or discounts on 98% of the formulations of these generic drugs. Overall, the rebates and discounts received by Part D insurers on these generic drugs decreased their cost by only \$261,000. If the Part D insurers had obtained rebates that were the same size as the Medicaid rebates for these drugs, they would have cut these drug costs by \$103 million.

The difference between Medicare Part D drug costs and Medicaid drug costs for the top 100 drugs actually increased between 2006 and 2007. In 2006, drugs for dual eligible beneficiaries cost the Part D insurers \$1.7 billion more than they would have cost had these insurers been able to obtain the Medicaid drug prices. In 2007, the excess charges increased by almost 20% to \$2 billion.

One explanation for the rising gap between Medicare Part D drug costs and Medicaid drug costs is the difference in the vulnerability of the two programs to rapid increases in brand-name drug prices. The Medicare Part D program is susceptible to increases in drug prices because the Part D insurers typically adjust their prices based on the manufacturer’s list prices, which are called “average wholesale prices.”²⁴ In contrast, brand-name drug prices cannot increase faster than the inflation rate under the Medicaid program without subjecting the manufacturer to a financial penalty. Under Medicaid law, if drug manufacturers increase prices at a rate that exceeds the

²² See Centers for Medicare and Medicaid Services, Q&A Formulary Guidance (2005) (online at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidanceAllorSubAll.pdf), Congressional Research Service, Drugs Required to be Covered By All Medicare Part D Plans (July 2008).

²³ Committee on Oversight and Government Reform, *supra* note 9.

²⁴ Committee on Oversight and Government Reform, *supra* note 9.

inflation rate, they are required to pay an additional rebate, known as the inflation rebate, to make up the difference.²⁵

This susceptibility to drug price inflation increased the costs of drugs to the Medicare Part D program in 2007. The per-prescription cost of the average brand-name drug used by a beneficiary in a Part D plan increased from \$119.52 in 2006 to \$127.41 in 2007. This is a 6.6% price increase, over twice the inflation rate in 2006.

B. Drug Manufacturer Windfalls

The higher prices under the Medicare Part D program have created a windfall for drug manufacturers. If the legislation creating the Medicare Part D program had not transferred the dual eligible beneficiaries from Medicaid to the new Medicare Part D program, the manufacturers would have continued to receive the lower Medicaid prices for the drugs used by the six million dual eligible beneficiaries. In 2006 and 2007, the amount of this taxpayer-funded windfall was \$3.7 billion for the manufacturers of the top 100 drugs used by dual eligible beneficiaries.

For many drug manufacturers, the windfall revenues were large. Thirteen manufacturers received windfall revenues exceeding \$100 million in 2006 and 2007. Johnson & Johnson had the largest windfall of any company, receiving over \$600 million in 2006 and 2007 in additional payments for drugs used by dual eligible beneficiaries. Bristol-Myers Squibb had the second largest windfall, receiving over \$400 million in additional payments. Abbot had the third largest windfall, receiving nearly \$300 million in additional payments. These three manufacturers provided the private Part D insurers with average drug discounts of 5% or less. In contrast, the Medicaid rebates on the drugs offered by these companies would have resulted in discounts of 31% or more. See Table 1.

The drug responsible for the greatest increase in manufacturer revenues was Risperdal, an anti-psychotic manufactured by Johnson & Johnson. In 2006 and 2007, Johnson & Johnson received over \$500 million more under the Medicare Part D program for Risperdal prescriptions for dual eligible beneficiaries than the company would have received if Risperdal had been purchased under Medicaid. This windfall for Johnson & Johnson may not continue in the future, however, because a generic version of Risperdal became available in June 2008.

Other drugs that produced significant windfall revenues for their manufacturers are Depakote, an anti-psychotic made by Abbott; Zyprexa, an anti-psychotic made by Eli Lilly; and Plavix, a heart attack and stroke medication made by Bristol-Myers Squibb. In each case, the manufacturers realized windfall revenues in excess of \$200 million in 2006 and 2007. In total, there were nine drugs among the top 100 that generated more than \$100 million in increased revenues as a result of the higher prices paid by the Medicare Part D program for drugs used by dual eligible beneficiaries. See Table 2.

²⁵ CMS, *supra* note 17.

Table 1: Drug Manufacturer Receiving the Largest Windfalls in 2006 and 2007	
Manufacturer	Amount of Windfall Revenue (2006-2007)
Johnson & Johnson	\$615,000,000
Bristol-Myers Squibb	\$401,000,000
Abbott	\$301,000,000
GlaxoSmithKline	\$291,000,000
Eli Lilly	\$273,000,000
Merck	\$262,000,000
Wyeth	\$239,000,000
Pfizer	\$235,000,000
Boehringer Ingelheim	\$157,000,000
Sanofi Aventis	\$137,000,000
Novartis	\$136,000,000
Eisai	\$135,000,000
AstraZeneca	\$123,000,000
All Other Manufacturers	\$434,000,000
Total Manufacturer	\$3,739,000,000

For individual drugs, the differences in the prices under the Medicare Part D program and the Medicaid program can be large. For one common antibiotic, the manufacturer charged Medicare Part D insurers almost \$10 more per pill than the manufacturer charged Medicaid. The manufacturer of a frequently used anti-convulsant drug provided the Part D insurers with an average discount of less than 3% compared to a 70% discount for Medicaid. The manufacturer of a popular sleep medication provided the Part D insurers with an average discount of less than 10% compared to a 65% discount for Medicaid.

The total windfall received by the drug manufacturers in 2006 and 2007 is probably larger than \$3.7 billion. The \$3.7 billion windfall represents the additional revenues that the manufacturers received from sales of the top 100 drugs used by dual eligible beneficiaries. The top 100 drugs account for only 54% of sales for dual eligible beneficiaries. If the price differential between Medicare Part D and Medicaid were the same for the other drugs used by dual eligible beneficiaries, the size of the total windfall would be nearly twice as high, almost \$7 billion.

Table 2: Drugs Providing the Largest Windfalls in 2006 and 2007

Drug	Manufacturer	Drug Use	Amount of Windfall Revenue (2006-2007)
Risperdal	Johnson & Johnson	Anti-psychotic	\$510,000,000
Depakote	Abbot	Anti-psychotic	\$300,000,000
Zyprexa	Eli Lilly	Anti-psychotic	\$225,000,000
Plavix	Bristol-Myers Squibb	Heart Attack, Stroke	\$220,000,000
Abilify	Bristol-Myers Squibb	Anti-psychotic	\$147,000,000
Ambien	SanofiAventis	Insomnia	\$137,000,000
Aricept	Eisai	Alzheimer's Disease	\$134,000,000
Advair	GlaxoSmithKline	Asthma, COPD	\$133,000,000
Protonix	Wyeth-Ayerst	Reflux	\$127,000,000

C. Estimates of Potential Cost Savings

Over the next ten years, dual eligible beneficiaries will use an estimated \$432 billion worth of drugs under the Medicare Part D program.²⁶ In 2006 and 2007, the costs of providing the top 100 drugs to these beneficiaries was 30% higher under Medicare Part D than it would have been if the Medicare Part D insurers had paid Medicaid prices for the drugs. Assuming this cost differential remains constant, the Medicare Part D program would save \$86 billion over the next decade if the Part D insurers had access to Medicaid drug prices.

The actual cost savings to the Medicare Part D program from access to Medicaid prices could be even higher because of the impact of the Medicaid inflation rebate, which caps Medicaid brand-name drug price increases at the rate of inflation. Over the last decade, prescription drug prices increased at a faster rate than inflation. Over time, if brand-name drug prices continue to rise faster than the inflation rate, the difference between Medicare Part D prices and Medicaid prices will continue to increase.

In addition to covering the cost of drugs used by dual eligible beneficiaries, the Medicare Part D program provides a "Low Income Subsidy" (LIS) to 3.3 million beneficiaries who are not eligible for Medicaid. Over the next ten years, LIS beneficiaries will use an estimated \$202 billion worth of drugs under the Medicare Part D program.²⁷ Assuming the current cost differential remains constant, the Medicare Part D program would save \$40 billion over the next decade if the Part D insurers had access to Medicaid drug prices for these LIS beneficiaries.

²⁶ HHS, Office of the Actuary, Summary of Part D Estimates — CY 2008 Trustees Report (2008).

²⁷ *Id.*

There are proposals in Congress to allow the federal Medicare program to negotiate directly with drug manufacturers for price discounts. If this legislation were enacted and the Medicare program negotiated price discounts equivalent to the Medicaid prices, the additional savings to taxpayers and beneficiaries would be large. Over the next ten years, Medicare beneficiaries in PDP plans who are neither dual eligible nor eligible for the low-income subsidy will use an estimated \$275 billion worth of drugs under the Medicare Part D program.²⁸ The federal government will pay almost one-half of this amount through various forms of payments to the Part D insurers. The beneficiaries will pay the remainder, primarily through premiums, copays, and drug purchases in the Medicare Part D “donut hole.” Assuming the current cost differential remains constant, federal taxpayers would save \$29 billion and Medicare beneficiaries (other than dual eligibles and LIS individuals) would save \$27 billion over the next decade if the Medicare program negotiated prices equivalent to the Medicaid prices.

The potential cumulative cost savings to federal taxpayers if the Medicare Part D program negotiated prices equal the Medicaid prices is the sum of the potential savings for providing drug coverage to dual eligible beneficiaries, LIS beneficiaries, and beneficiaries who are neither dual eligible nor LIS beneficiaries. This total potential savings for taxpayers over ten years is \$156 billion.

CONCLUSION

This analysis of confidential data on Medicare Part D and Medicaid drug prices shows that the private Medicare Part D insurers pay significantly higher prices for prescription drugs than does the Medicaid program. In the case of the six million dual eligible beneficiaries, the Medicare Part D insurers paid \$3.7 billion more in 2006 and 2007 to purchase the top 100 drugs for dual eligible beneficiaries than they would have paid if they had access to the lower Medicaid drug prices. This increase in costs represents a windfall to drug manufacturers.

Eliminating the drug manufacturer windfall would realize substantial savings to federal taxpayers. Over the next ten years, taxpayers would save \$86 billion if the Medicare Part D insurers paid Medicaid prices for drugs used by the dual eligible beneficiaries. If Medicare negotiated directly with drug manufacturers and obtained prices equivalent to the Medicaid prices for all Medicare beneficiaries, the potential savings to taxpayers increases to \$156 billion.

²⁸ *Id.*

Chairman WAXMAN. Last year's report looked at the profits of the private insurers. Today's report examines the windfall revenues of the drug manufacturers. In this report, we compare the prices that the drug companies charge the new Medicare Part D program with the prices that the companies charged the Medicaid program.

What we discovered is that the taxpayers are paying far more for drugs under Medicare Part D than they do under Medicaid. In effect, Medicare Part D has given the major drug companies a taxpayer-funded windfall worth billions of dollars.

Our report focuses on the cost to the taxpayer of providing drugs to the 6 million beneficiaries who are enrolled in both Medicare and Medicaid. These are Americans who are old or disabled enough to qualify to be on Medicare, and they are poor enough also to qualify for Medicaid. They are often the oldest and sickest Medicare beneficiaries and their drug coverage is almost fully subsidized by Federal taxpayers. "Dual eligibles" is what they are called, and these dual-eligible beneficiaries account for about half of all drug spending in Medicare Part D.

The multibillion-dollar windfall is a result of a provision in the Medicare Part D law that switched drug coverage for the dual eligibles from Medicaid to Medicare Part D. The transfer took effect 2 years ago. Since then, the drug manufacturers have been paid billions more for the drugs used by the dual-eligible beneficiaries than they would have been paid if the dual eligibles had continued to receive their drug coverage through Medicaid.

Under Medicare Part D, the 6 million dual-eligible beneficiaries take the same drugs they got under Medicaid; the only difference is that the Federal taxpayer is now paying 30 percent more. Add it up and it amounts to a drug manufacturer windfall worth at least \$3.7 billion in just the first 2 years of the Medicare Part D program. In fact, the actual windfall could be worth billions more if all drugs used by dual-eligible beneficiaries were taken into account.

Let me describe some examples. Johnson & Johnson earned over \$500 million in additional profits, much of it from just one drug, the antipsychotic medication Risperdal. Bristol Myers earned a windfall of almost \$400 million thanks to the higher prices for the stroke medication Plavix. This is an enormous giveaway, and it—it has absolutely no justification. The drug companies are making the same drugs, they are being used by the same beneficiaries, yet because the drugs are being bought through Medicare Part D instead of Medicaid, the prices paid by the taxpayers have ballooned by billions of dollars.

The privatization of Medicare Part D is a great deal for the drug companies, And it is a great deal for the private insurers. It is the taxpayers who are taking it on the chin.

The circumstances that led to passage of the Medicare Part D were controversial. The chairman of the House committee that wrote the Part D law now runs PhRMA, the drug manufacturers trade association. The administration's top negotiator left the government to lobby for health insurers and drug companies.

There were allegations of threats and arm-twisting on the House floor. But that is not the focus of today's hearing. The Medicare

drug benefit is providing real help to seniors and the disabled, and it is going to be part of our health care landscape for years to come.

The key question for us is, how we can fix the program so that more of the benefit goes to seniors and the disabled and less winds up in the pockets of the drug companies and insurers.

Medicaid is one proven model for how the government can use its purchasing power to ensure that it gets low prices. Medicaid is a voluntary program. No drug manufacturers are required to participate. Medicaid gets its low prices by making discounts a condition of manufacturers participating. The program says that if a manufacturer wants to sell their drugs to Medicaid beneficiaries, they have to offer Medicaid their lowest prices. The manufacturers also have to agree to protect the taxpayers from price increases that exceed the rate of inflation.

We have well over a decade of operational experience with the Medicaid rebate. It works. It delivers \$10 billion annually in savings to the Federal and State governments. In many ways, this is the exact opposite of what is going on under Medicare Part D. Under Part D, the drug manufacturers can charge essentially what they want. Despite their high administrative costs and billion dollar profits, the private insurers have been unable to stand up for the interest of the taxpayers.

Now, many of our hearings on waste, fraud and abuse identify problems that the executive branch can fix administratively; that is not the case with Medicare Part D. The waste in this program is the direct result of the statutory design of the law. Congress wrote this law and must lead the way to a solution. To start this process, I will soon be introducing legislation that will protect the taxpayer by bringing down the high drug prices in Medicare Part D. This bill will guarantee that Federal taxpayers cannot be charged higher prices for the dual-eligible beneficiaries under Medicare Part D than under Medicaid.

The potential savings to Medicare and the Federal taxpayers are enormous. Passage of reform legislation could save the taxpayer almost \$90 billion over the next 10 years; even more could be saved if the Federal Government were to authorize to negotiate prices on behalf of all Medicare beneficiaries.

I am looking forward to hearing more about this issue today and working together with the members of this committee to improve the Part D program. I will be introducing our witnesses, who I'm grateful are here today. All of them are here voluntarily.

But before we do that, I want to recognize Mr. Davis for an opening statement.

[The prepared statement of Chairman Waxman follows:]

**Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
The Medicare Drug Benefit: Are Private Insurers Getting
Good Discounts for the Taxpayer?
July 24, 2008**

Today the Committee is holding another hearing in our series on how to make government work better. Our subject is the Medicare Part D program that provides a prescription drug benefit to seniors and individuals with disabilities.

Providing drug coverage to seniors and the disabled is essential. But it is also expensive. Over the next decade, the benefit will cost taxpayers hundreds of billions of dollars. We need to make sure this money is spent responsibly and with good value for the taxpayer.

This Committee has been investigating Medicare Part D for 18 months. During our investigation, we have conducted the only in depth oversight of the Part D program. GAO and the Congressional Budget Office have been unable to review how well the program is working because the Centers for Medicare and Medicaid Services won't give them the data. And CMS, which does have access to the data, refuses to acknowledge fundamental flaws in the program.

Last October, I and other members of the Committee released a staff report that examined the administrative costs of Medicare Part D. We found that the private insurers that deliver the Medicare drug benefit are charging taxpayers and beneficiaries \$4.6 billion in administrative costs annually. In percentage terms, that's over six times more than it costs to run traditional Medicare.

And we found that the Part D program is exceptionally lucrative for the private health insurers. They made a billion dollars in profits last year alone.

Today, I am joining with ___ of my colleagues on the Committee to release a new staff report, which I ask be made part of today's hearing record. Last year's report looked at the profits of the private insurers. Today's report examines the windfall revenues of the drug manufacturers.

In this report, we compared the prices that the drug companies charge the new Medicare Part D program with the prices that the companies charge Medicaid. What we discovered is that the taxpayers are paying far more for drugs under Medicare Part D than they do under Medicaid.

In effect, Medicare Part D has given the major drug companies a taxpayer-funded windfall worth billions of dollars.

Our report focuses on the costs to the taxpayer of providing drugs to the six million beneficiaries who are enrolled in both Medicare and Medicaid. These are Americans who are old or disabled enough to qualify for Medicare and poor enough to qualify for Medicaid. They are often the oldest and sickest Medicare beneficiaries, and their drug coverage is almost fully subsidized by federal taxpayers. These dual eligible beneficiaries account for about half of all drug spending in the Part D program.

The multi-billion dollar windfall is the result of a provision in the Medicare Part D law that switched drug coverage for the dual eligibles from Medicaid to Medicare Part D. The transfer took effect two years ago. Since then, the drug manufacturers have been paid billions more for the drugs used by the dual eligible beneficiaries than they would have been paid if the dual eligibles had continued to receive their drug coverage through Medicaid.

Under Medicare Part D, the six million dual eligible beneficiaries can take the same drugs they got under Medicaid. The only difference is that the federal taxpayer is now paying 30% more. Add it up, and it amounts to a drug manufacturer windfall worth at least \$3.7 billion dollars in just the first two years of the Part D program.

In fact, the actual windfall could be worth billions more if all drugs used by dual eligible beneficiaries were taken into account.

Let me describe some examples. Johnson and Johnson earned over \$500 million in additional profits, much of it from just one drug, the anti-psychotic medication Risperdal. Bristol Myers earned a windfall of almost \$400 million, thanks to higher prices for the stroke medication Plavix.

This is an enormous giveaway. And it has absolutely no justification. The drug companies are making the same drugs. They are being used by the same beneficiaries. Yet because the drugs are being bought through Medicare Part D instead of Medicaid, the prices paid by the taxpayers have ballooned by billions of dollars.

The privatization of Medicare Part D is a great deal for the drug companies. And it's a great deal for the private insurers. It's the taxpayers who are taking it on the chin.

The circumstances that led to passage of the Medicare Part D law were controversial. The chairman of the House committee that wrote the Part D law now runs PhRMA, the drug manufacturer's trade association. The Administration's top negotiator left the government to lobby for health insurers and drug companies. There were allegations of threats and arm-twisting on the House floor.

But that is not the focus of today's hearing.

The Medicare drug benefit is providing real help to seniors and the disabled, and it's going to be a part of our healthcare landscape for years to come. The key question for us is how we can fix the program so that more of the benefit goes to seniors and the disabled — and less winds up in the pockets of the drug companies and insurers.

Medicaid is one proven model for how the government can use its purchasing power to ensure that it gets low prices. Medicaid is a voluntary program. No drug manufacturers are required to participate. Medicaid gets its low prices by making discounts a condition of manufacturer participation. The program says that if manufacturers want to sell their drugs to Medicaid beneficiaries, they have to offer Medicaid their lowest prices. The manufacturers also have to agree to protect the taxpayer from price increases that exceed the rate of inflation.

We have well over a decade of operational experience with the Medicaid rebate. It works. It delivers \$10 billion annually in savings to the federal and state governments.

In many ways, this is the exact opposite of what is going on with Part D. Under Part D, the drug manufacturers can charge essentially whatever they want. Despite their high administrative costs and billion-dollar profits, the private insurers have been unable to stand up for the interests of the taxpayer.

Many of our hearings on waste, fraud, and abuse identify problems that the executive branch can fix administratively. That's not the case with Medicare Part D. The waste in this program is a direct result of the statutory design of the law. Congress wrote this law and must lead the way to a solution.

To start this process, I will soon be introducing legislation that will protect the taxpayer by bringing down the high drug prices in Medicare Part D. This bill will guarantee that federal taxpayers cannot be charged higher prices for the dual eligible beneficiaries under Medicare Part D than under Medicaid.

The potential savings to Medicare and the federal taxpayer are enormous. Passage of reform legislation could save the taxpayer almost \$90 billion over the next ten years. Even more could be saved if the federal government were authorized to negotiate prices on behalf of all Medicare beneficiaries.

I'm looking forward to hearing more about this issue today and working together with members of this Committee to improve the Part D benefit.

Mr. DAVIS OF VIRGINIA. Well, thank you, Mr. Chairman.

The Medicare prescription drug program, known as Part D, has successfully provided needed medicines to millions of American seniors. The proof is in the pudding: Overwhelming number of seniors have opted into this program. It is an optional program that speaks for its success. While only in its third year of operation, Part D continues to come in below initial budget projections.

Nevertheless, even with all of its successes, Medicare Part D, like any Federal program, could benefit from thoughtful, evenhanded oversight; and I hope that is our goal here today. But I'm not convinced there is much constructive to be learned simply by comparing controlled prices under Medicaid and market prices under Part D and labeling the entire difference a windfall.

The majority staff analysis released this morning focuses on dual eligibles, seniors eligible for both Medicare and Medicaid. Before 2006, they received prescription drug insurance through Medicaid which uses statutory price controls. At the request of States and many senior citizen advocates, dual eligibles were included under Part D. Not surprisingly, market-negotiated drug prices for this special population were found to be higher than the legally mandated, below-market Medicaid rates.

But any alleged windfall, however large, tells really less than half the story. That difference buys dual-eligible seniors access to drugs not available under Medicaid's more restrictive pharmacy rules, and capturing the alleged savings would be short lived and painful. It would come at a very, very high cost as other segments of the health care delivery system, nongovernment segments—we are talking about employer plans, union plans—payments for the uninsured would then absorb the cost shifts that are inevitably generated by price controls.

This is not just a theoretical argument about how free markets work. The Federal Government does have almost 20 years of experience with the implications of prescription drug price controls. The Congressional Budget Office and the Government Accountability Office both have repeatedly found that Medicaid price controls increase prescription drug prices to every other purchaser.

Transplanting Medicaid price controls onto Part D could have other unwanted implications. We should be very concerned about a Federal Government process to set Part D prices that would turn into a political exercise. There would be enormous political pressure to pick winners and losers.

Elsewhere in Medicare, relentless lobbying shifts and shapes reimbursement policies for some services or specialties over others; and it is not a very pretty process. Just a couple of weeks ago, Medicare physicians almost took a 10 percent reimbursement cut at the hands of a government-run pricing system.

Given the critical role of Medicare in caring for seniors as they age, we should conduct oversight of the program, but it strikes me that this committee's discussion of Part D is stuck in a rut. With every new report and each successive hearing, I understand Yogi Berra's concept of "deja vu all over again." Repeatedly making economically and plausible arguments about the efficiency of government-run drug pricing or plucking artificial windfalls from thin air won't make Part D, a good program, work any better.

It is running well under the original 2003 budget projections, due largely to lower-than-anticipated bids from prescription drug plans. That is what happens in the free, competitive market. And most importantly, opinion surveys report that 85 percent of Part D beneficiaries are happy with the program, the 15 percent obviously on the other side of the aisle here, with the satisfaction rate even higher among the dual eligibles.

Meanwhile, other aspects of the program urgently need scrutiny. We could be talking about Medicare payments for durable medical equipment prescribed by physicians or the serious financial trouble facing Part A, Medicare hospital insurance, which is due to go bankrupt in 11 years.

The bedrock of the program, Part A, is in dismal shape. The Medicare trustees reported this year the Hospital Insurance Trust Fund will be insolvent in 2019. When that happens, payments can no longer be made to cover seniors' hospital care. There is no authority in current law to allow general revenue funding of that shortfall. We obviously—we fund Part B.

I look forward to our oversight hearings on these pressing issues today.

Chairman WAXMAN. We are pleased to welcome for our first panel, Dr. Stephen Schondelmeyer, who is a Ph.D. and professor and head of the Department of Pharmaceutical Care and Health Systems at the University of Minnesota; Dr. Gerard Anderson, Ph.D., professor and director for the Center for Hospital Finance and Management, Bloomberg School of Public Health at Johns Hopkins University; Fiona M. Scott Morton, Ph.D., professor of economics, Yale School of Management, Yale University.

We are pleased to have the three of you here today. It is the practice of this committee that all witnesses testify under oath. So if you would please stand.

Mr. DAVIS OF VIRGINIA. Mr. Chairman, could I just note for the record, Dr. Schondelmeyer is the majority's witness who, 2 weeks ago, was given notice of this; and we have not yet received written testimony from him.

Our minority witness has submitted his for the record ahead of time for scrutiny. Thank you.

Chairman WAXMAN. Thank you, Mr. Davis. If the three of you would please stand and raise your right hands.

[Witnesses sworn.]

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

Dr. Schondelmeyer, we are going to start with you, but Mr. Davis made a very good point that we expect witnesses to submit their statements in advance under the rules. Please go ahead.

Did you submit a statement to us, a written statement?

Mr. SCHONDELMEYER. I have not yet. I can after this meeting. I do apologize.

Chairman WAXMAN. Turn on the mic. Yes, there is a button on the mic.

Mr. SCHONDELMEYER. I do apologize. I accepted this assignment with many other commitments, and this was a very tight schedule for me, given other commitments. But I was pleased to do so and—

Chairman WAXMAN. We're happy to have you here anyway. Thanks.

We are going to ask each of you, as we will all of our witnesses, to try to keep within 5 minutes. I think you all have been informed of that in advance. And if you have submitted written statements, they will be part of the record in full. We're going to have a clock that will be green for 4 minutes, yellow for 1 minute and then when the 5 minutes is up, it will turn red. We're not going to be abrupt in stopping you, but I hope that red will be an indication that it is time to get ready—get ready and to conclude.

Thank you. Please go ahead.

STATEMENTS OF DR. STEPHEN SCHONDELMEYER, PHARM.D., Ph.D., PROFESSOR AND HEAD, DEPARTMENT OF PHARMACEUTICAL CARE AND HEALTH SYSTEMS, UNIVERSITY OF MINNESOTA; DR. GERARD ANDERSON, Ph.D., PROFESSOR AND DIRECTOR, CENTER FOR HOSPITAL FINANCE AND MANAGEMENT, BLOOMBERG SCHOOL OF PUBLIC HEALTH, JOHNS HOPKINS UNIVERSITY; AND FIONA M. SCOTT MORTON, Ph.D., PROFESSOR OF ECONOMICS, YALE SCHOOL OF MANAGEMENT, YALE UNIVERSITY

STATEMENT OF DR. STEPHEN SCHONDELMEYER, PHARM.D., Ph.D.

Mr. SCHONDELMEYER. Thank you, Mr. Chairman, for inviting—Chairman WAXMAN. Pull your mic a little closer.

Mr. SCHONDELMEYER. Thank you for inviting me and thank you to the rest of the committee. I will skip the normal formalities and broad background descriptions, because you've done that well in your introduction.

The dual eligibles, as was noted, however, represent a large share of the expenditures both under the previous Medicaid program and under the current Medicare Part D program. Just to put that in perspective, in the year 2005, total Medicaid drug expenditures were about \$43 billion a year. In 2006, after those dual eligibles moved from Medicaid over to Medicare, the Medicaid drug expenditures dropped to less than half of that \$43 billion, somewhere around \$21 billion. So it is very real that this shift did move dollars from the State-run Medicaid programs to the private, market-run Part D Medicare programs.

At the same time that shift occurred, also the access to the rebates under the State-run Medicaid programs disappeared.

Let me put in perspective rebates, briefly, under Medicaid. The Medicaid drug rebate program began back in 1991 and continues to this day. There is a Federal component to the Medicaid drug rebate program which mandates 15.1 percent rebate for all brand-name drugs, and in addition for brand-name drugs, they are subject to a best-price additional rebate and an inflation adjustment rebate that often adds substantially beyond that 15.1 percent for all brand-name drugs. For generic drugs, all generic drugs must provide an 11 percent rebate.

Now, notice in both brand-name and generic drugs, all prescription drugs are subject to rebates. That is not necessarily the case today. Under the Medicare Part D program, not all drugs are sub-

ject to rebate; and particularly those drugs that are covered under the must-cover categories, the categories where the Part D plans can't negotiate or opt to cross different drug categories, those don't appear to receive as much rebate, although under the Medicaid program they did receive the same amount of rebate—at a minimum at least—as the other brand-name drugs.

Second, the amount of rebates from 1991—it took a year or two to get the program stabilized. From 1993 to 2000, about 18 to 19½ percent of total drug spending came back to Medicaid programs as rebates. So about 18 to 19½ percent came back.

Beginning in 2000–2001, though, the States woke up and realized that the Medicaid legislation also authorized States' supplemental rebate programs. In those State supplemental rebate programs, it said States could negotiate on their own rebates above and beyond the Federal rebate, and that has started to grow.

In the early—2000 through 2003, we saw rebates grow to 20–21 percent. And then we saw a dramatic growth; in 2004 rebates grew to 24 percent of the total drug spend, 2005 rebates under Medicaid grew to 28.8 percent of the drug spend.

Unfortunately, to the best of my knowledge, CMS has not released the rebate data for the years 2006 and 2007 under Medicaid, so we can't look to see what the total amount is. As best I can tell from talking with various States out there, however, the number is probably somewhere above 30 to 31 percent total drug spend returned in rebates.

Now, that compares with—this committee did a report a year ago that suggested only about 8 percent of the drug spend under Medicare Part D was coming back as rebates, and that wasn't for all drugs and all classes. So if you compare 28.8 or 30 percent rebates on Medicaid to 8 percent on Medicare—and I understand your new report shows that the number has gone up under Medicare Part D, but it is still less than half of what the rebate amount was under the Medicaid program—it is obvious that if these same dual eligibles remained in the Medicaid program, the taxpayers and the beneficiaries themselves would benefit from lower drug spend, as you pointed out, Mr. Chairman, on the same drug, the same people. It—just at a lower price in the marketplace. And those are based on State-negotiated supplemental rebates, not mandated rebates. They are negotiated with the States above and beyond the Federal rebate.

So it is also important to realize, under the Medicare Part D program, that the dual eligibles and the people on the private side do not receive the benefit of these rebates in lower drug price for most cases. You can find the odd drug, there may be a handful of 10 or 15 drugs where a lower price is actually passed on to the recipients, but for the most part, lower prices are not passed onto the recipient. And the coverage gap, the person pays the entire cost of the drug without the benefit of any of the rebate. And for specialty drugs, where they may be paying 50 to 75 percent coinsurance, they're paying the entire cost of the drug without the benefit of the rebates.

In conclusion, it is not just observations of State accountants and academics like myself that say this was a shift in resources. Also Wall Street and corporate annual reports in both 2006 and 2007

noted that drug companies had substantially increased revenues that heretofore had been unexpected due largely, in part, to volume increases under Medicare Part D and the decreased payment for rebates under Part D versus under Medicaid.

Thank you very much, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Schondelmeyer.

Dr. Anderson.

STATEMENT OF DR. GERARD ANDERSON, Ph.D.

Mr. ANDERSON. Thank you, Chairman Waxman. It is a pleasure to return to this committee to talk about the issue of drug pricing.

My testimony can be summarized in two observations and three recommendations.

My first observation is that Part D plans paid even higher prices for drugs than Medicaid programs were paying. My second observation is the United States pays significantly higher prices for prescription drugs than other countries and that, in the United States, the private sector pays generally 20 percent higher prices than the public sector pays for drugs.

These two observations lead me to three recommendations. First, there should be greater price transparency in the pharmaceutical market. Second, drug pricing data should be readily accessible to congressional agencies and academic researchers so they can easily know if Part D plans are paying higher prices than Medicaid. And third of all, all government agencies should be paying the same prices for drugs.

The remainder of my testimony will explain in greater detail the rationale behind these observations and recommendations.

When the responsibility for providing drug coverage for the dual eligibles was transferred in 2005, the expectation, or even the hope, was that Part D plans would be able to obtain lower prices than the Medicaid programs. Unfortunately, a growing body of data, including the report today, suggest that Part D plans are paying even higher prices than Medicaid programs. Amazingly, all the data seems to confirm that the windfall to the drug companies is about \$2 billion a year.

The first indication of higher prices came from the disclosures by the pharmaceutical companies themselves in their 10-Ks and 10-Qs filed with the Security and Exchange Commission. My written testimony cites specific documents, showing that the pharmaceutical companies were getting higher prices than Part D. Pfizer alone, for example, estimated in its 10-Q an additional \$300 million in profits.

Second, in my report, I show how CBO-CMS actuary data estimate using that data that Part D plans were paying 22 percentage points more than Medicaid was paying for the same drug. This committee says 30 percent; the CMS testimony today says 20 percent. So they are all in pretty much the same range.

The third indication was the report by this committee last year. So basically all the different sources—and as a researcher you want to have multiple sources—then, the transfer from the dual eligibles will result in about a \$2 billion annual windfall to the drug companies; and it is currently in line with the report of this committee.

Surprisingly, the Medicare program is not the insurer paying the highest prices for drugs in the United States. Typically, the private sector pays 20 percent more for drugs than the Medicare and Medicaid programs.

The fact that Part D plans were unable to obtain substantial discounts from the pharmaceutical companies is surprising to me, given the difficulties that the Medicaid agencies have obtaining actual transaction prices to set their own rates. In a series of recent court decisions, judges and juries have found that this lack of price transparency has made it difficult for the Medicaid agencies to actually set prices.

President Bush has argued that there should be greater price transparency in the health care sector. When the Bush—while the Bush administration has promoted major efforts to increase the level of price transparency in the hospital and physician sectors, surprisingly there has been very little emphasis on price transparency in the pharmaceutical sector.

In order to make greater price transparency, I believe the Secretary of Health and Human Services should determine in the markets are actually working for pharmaceuticals. One way to determine this is to compare the lowest prices that any of the Part D plans are obtaining and compare to the prices that the Medicaid programs, the VA or even Canada are obtaining.

Unfortunately, provisions in the MMA limit disclosure of information on drug prices and drug utilization. This data should be given to CBO, CRS, MedPac and other government agencies to analyze the effectiveness of the Part D program. It should also be given to academic researchers.

My third and final recommendation is that all government programs should pay the same rate for each drug. I cannot think of a compelling reason, either economically or ethically, why one government program, save the VA, should pay a higher price or a lower price through the Medicare program; all the money comes from the taxpayers. Governments in other countries manage to pay one price for drugs. Why not the United States?

Thank you for the opportunity to testify this morning.

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

[The prepared statement of Dr. Anderson follows:]

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Mr. Chairman, members of the Committee; my name is Dr. Gerard Anderson. I am a professor of Health Policy and Management and a professor of International Health at the Bloomberg School of Public Health and professor of Medicine in the School of Medicine at Johns Hopkins University.

Today, I would like begin by making two observations and then make three recommendations regarding the high prices that are being paid by the Medicare Part D prescription drug plans.

My first observation is that after Medicare assumed responsibility from Medicaid for providing drug coverage for dual eligibles, ***Part D plans paid even higher prices than Medicaid programs were paying for the same drugs.***

My second observation is that the ***United States pays significantly higher prices for prescription drugs than other countries.***

These two observations about drug pricing in Part D plans lead me to make three recommendations for this Committee to consider.

First, there should be ***greater price transparency in the pharmaceutical market.***

Second, de identified ***drug-pricing data should be readily accessible to Congressional agencies and academic researchers.***

Third, ***all federal governmental agencies should be paying the same price for drugs,*** rather than having each federal agency pay a different price for the same drug.

The remainder of my testimony will explain in greater detail the rationale behind each of these observations and recommendations.

Its Prices Stupid; Medicare Part D Prices Are Even Higher Than Medicaid Prices

When the responsibility for providing drug coverage for the dual eligibles was transferred from Medicaid to Medicare in 2005, the expectation, or perhaps the hope, was that the Part D plans would obtain lower drugs than the Medicaid programs obtained. Unfortunately, a growing body of data including the Report issued today suggests that the Medicare Part D plans are paying even higher prices than Medicaid was paying. This can be seen from several perspectives including from the data presented today.

The first indication that the Medicare Part D plans were paying more than the Medicaid programs were paying comes from disclosures made by pharmaceutical companies. 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 suggest that the pharmaceutical companies are getting higher prices from Medicare Part D plans than they did from Medicaid. For example, in its 10Q report dated October 1st 2006, Pfizer acknowledged that Pfizer paid fewer rebates, price concessions and gave fewer discounts due “to the impact of the Medicare Act”. On page 34 of their report, 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”. This represents an additional \$300 million to one drug company for one year.

In a report for the Brookings Institution, Richard Frank and Joseph Newhouse examine the cost implications of the transfer of responsibility of drug coverage for the dual eligibles from Medicaid to Medicare. In their report, they reach a similar conclusion. “Manufacturers have realized significant gains simply from the change in responsibility for purchasing from Medicaid to Medicare.”

The second indication that Part D plans are paying high prices is a comparison of the prices that the Medicare Part D plans were paying to the prices that state Medicaid programs. This is based on CBO and CMS actuary data. CBO compares the rates that Medicaid and the private sector pay for “brand name” drugs. According to a 2005 CBO report, the average manufacturer price (AMP) is 79% of the average wholesale price (AWP). 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 private sector pays 73% of average wholesale price (AWP). However, according to the same CBO report, the Medicaid programs pay only 51% of average wholesale price (AWP). This suggests that Medicare Part D plans are paying 22 percentage points more than Medicaid was paying for the same drugs for the same dual eligibles.

The third indication was the report by this committee that was published last year. In this report, the committee was able to obtain administrative expenses, sales costs, profits and drug rebates from 12 of the leading insurers in the Medicare Part D program. This report showed that the Medicaid program received rebates that were three times greater than the

Medicare Part D program obtained. The estimate according to this report is that pharmaceutical companies received an additional \$2.8 Billion in 2007 as a result of the transfer from Medicaid to Medicare. This corresponds to the estimates obtained from the disclosures by the drug companies in their 10K's and 10Q's.

The most persuasive evidence, however, is what this Committee uncovered and is being released today.

Its Prices Stupid: United States Pays Too Much for Prescription Drugs

The Medicare program is not insurer paying high prices for drugs in the US. The data shows that the US pays higher prices for drugs than any other country and typically the private sector pays higher prices than Medicare and Medicaid.

In a paper that I coauthored in Health Affairs in 2004, I compared the prices for the 30 most commonly sold drugs in the United States to the same drugs in Canada, the United Kingdom and France. We observed that the US pays 52% more than people in the UK, 67% more than those in Canada and 92% more than the people in France for the market basket of these 30 drugs.

We also noted that the higher prices the United States paid for drugs were not uniform across all 30 drugs. Table 1 compares the drug prices for each drug. For example the psychiatric medication, Zoloft, cost 27% more in Canada, 96% more in the UK and 62% more in France compared to the US. One interesting statistic to note is that the United States does pay the lowest price for one of these 30 medications - Viagra.

Senator Nelson from Florida asked me to perform the same comparison using the prices paid by the VA as the comparison group. The empirical results were remarkably similar to the earlier findings in the Health Affairs article. It appears that the VA is paying approximately the same prices as Canada, France and the United Kingdom.

Richard Frank, a professor at the Harvard Medical School, published a perspective in the New England Journal of Medicine showing that the prices of brand name prescription drugs are 35-55% lower in other industrialized countries compared to the United States. Another paper in the New England Journal of Medicine by Scherer compared the drug price differences between the United States and Canada and found similar differences. Price differentials are one reason why many US citizens want to go to Canada to purchase drugs that are produced by American drug manufacturers.

My review of peer reviewed articles and other studies shows that the United States consumer pays significantly higher prices than consumers in other countries. The data also suggests that both the private and public sectors pay high prices for drugs compared to the prices in other countries.

The fact that Part D plans were unable to obtain substantial discounts for the pharmaceutical companies is surprising given the difficulties Medicaid agencies were already having obtaining information of actual transaction prices. In a series of recent court decisions, judges and juries have found that this lack of price transparency has made it difficult for Medicaid agencies to estimate the prices that pharmacies are paying for drugs. This was discussed in testimony I presented to this committee in January 2007.

Recently, I have been asked by several state Medicaid agencies to serve as an expert witness in their court challenges against the pharmaceutical companies concerning the reporting of prices by the pharmaceutical companies. This year, I have already testified in two cases regarding the pharmaceutical pricing of drugs in the Medicaid program. In the first case, \$215 million was awarded to the Alabama Medicaid program against the drug company Astra Zeneca. In the second case, \$114 million was awarded to the Alabama Medicaid program against Glaxo Smith Kline and Novartis.

Solving the Problem: Greater Price Transparency is Needed

The data showing that (1) Medicare Part D plans pay higher prices than Medicaid, (2) that Medicaid was already paying higher prices than necessary because of false prices, and (3) the U.S. pays higher prices for drugs than other countries leads me to make three recommendations.

President Bush has argued that there should be greater price transparency in the health care sector. The Bush Administration has promoted major efforts to increase the level of price transparency in the hospital and physicians sectors. Surprisingly, there has not been the same emphasis on price transparency in the pharmaceutical sector.

I find that the lack of policy focus on price transparency in the pharmaceutical sector quite puzzling. It is much more difficult to compare prices in the hospital and physician sectors than it is in the pharmaceutical sector because there is more variation in the hospital and physician products than there is in pharmaceutical products. Each drug has exactly the same chemical compound every time it is administered. In contrast, there are differences across hospitals, doctors and patients making each hospitalization and doctor visit different. Price comparisons for drugs should be much easier than price comparisons for hospital or physician services.

The question is how could we get greater price transparency for pharmaceuticals? I believe that there is a need for government reporting of drug prices when there is market failure.

Let me begin by stating that I believe in markets. Now let me qualify that statement. I believe in markets when there is price transparency and markets operate efficiently. The higher prices paid by Part D plans for drugs than the Medicaid programs suggest market failure.

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In the case of pharmaceuticals, I believe the Secretary of Health and Human Services should determine if markets are actually working for pharmaceuticals. One way to determine if markets are working is for the Secretary of Health and Human Services to identify the lowest price that any of the Part D plans were able to obtain from the pharmaceutical companies. It is likely that one Part D Plan will have obtained the lowest price for drug A, while another Part D plan will have obtained the lowest price for drug B. All that should be included in the Secretary's report is the lowest price that any Part D Plan was able to obtain for each drug. The Secretary's report would not disclose the price that each Part D plan paid or the name of the Part D plan that paid the lowest price. It represents the lowest price the market place could obtain. The price should include all discounts, chargebacks, price concessions and rebates.

This information is currently not available on www.Medicare.gov. The prices on <http://www.medicare.gov> reflect the prices that Medicare beneficiaries pay for the drugs and not the purchase prices of the Part D plan.

Congress should then require the Secretary to prepare a semi-annual report that compares the lowest price that any of the Part D plans obtain to the prices obtained by the VA, Medicaid program, and Canada for each drug. The report will show where the market is working and where there is market failure. It is likely that Part D plans are getting good prices for some drugs and not others. The VA is one appropriate comparison point because the VA Secretary negotiates prices with the pharmaceutical industry. Medicaid prices are a second comparison point because the Medicaid is a government program that has been paying for drugs for many years. Canada is an appropriate third comparison point because it is a government entity that pays for drugs. More important, if the price differential between US and Canadian prices is large, then millions of Americans will go to Canada to obtain drugs.

.....
It is important to compare the prices at the individual drug level since the market place will be more competitive for certain drugs than for other drugs. With this information, the Secretary of Health and Human Services will be able to compare the lowest prices that the market place can obtain. This will give the Secretary and the Congress the necessary information to determine where the market place is effective and where there is market failure.

Unfortunately, the prices that the Part D plans are paying for individual drugs remains confidential. CMS collects the data on prices, price concessions, rebates, and discounts but is prohibited by the MMA from sharing this data or even analyzing it internally. As a result, no one knows the rebates, price concessions or discounts that the Part D plans receive. The MMA prevents CBO, GAO, CRS and university researchers from obtaining this data. The data obtained by this committee is beginning to lift the veil of secrecy and increase the level of price transparency. This leads to my second observation.

Solving The Problem: Expanding Access to Information

When the MMA legislation was passed, there were provisions that kept much of drug pricing data private. The rationale was to allow the Part D plans and the pharmaceutical manufacturers to be able to negotiate lower prices under confidential arrangements. However, as the report issued today suggests, the Part D plans are paying substantially higher prices than Medicaid programs were paying. All of this suggests that the confidentiality agreements have not resulted in lower prices.

The limitations in the MMA have had a major deleterious impact on the ability of the CBO, CRS, GAO, MedPAC, and other government agencies to analyze effectiveness of the Part D program. It has also limited the ability of academic researchers to analyze the data. There are long run benefits to making information accessible to government officials and academic researchers. Congress should consider the tradeoffs in making more data available.

The Medicare drug data provides multiple opportunities for government officials and independent researchers to examine important policy, economics and clinical questions. There are many possible studies that could be done with the data. Let me suggest two. First, it is important to compare the cost impact of one drug compared to another drug. Without data on the actual prices of either drug, it is impossible to compare the cost effectiveness of alternative drug regimens. Secondly, often, drugs can often replace medical or surgical treatments. While we know the cost of the medical or surgical treatment from Medicare data, without data on the cost of the drug, it is impossible to perform a rigorous study comparing the cost of drug treatment to the cost of medical or surgical treatment. These are just two of many examples of studies that the GAO, CBO, MedPAC and CRS and academic researchers would like to do if the drug data were available.

There is some movement towards the release of data by the CMS. However, the preliminary information we have received from the CMS suggests that there will be severe restrictions on what data will be released, to whom, and under what circumstances. Given that public money and public beneficiaries are involved, it is unclear why there needs to be such level of secrecy. The level of secrecy is much lower for hospital and physician services. My fellow researchers and I have had access to hospital and physician data from the Medicare program for many years and no one has suggested that it has resulted in higher prices.

Solving the Problem: Paying One Price for Drugs

Because of numerous laws and regulations, different federal healthcare entities pay different prices for each drug. The VA pays different prices for drugs than DOD, PHS, federal prisons, VA, and all other government agencies that purchase drugs. Each Medicaid program pays different prices for drugs. The availability of formularies in some programs, rebates and discounts in other programs contributes to the different prices that different government agencies pay for exactly the same drugs.

My third and final recommendation is to create an environment where all federal healthcare programs pay the same rate for each drug. I am unable to identify any compelling economic or ethical reason why one government program should get or deserves lower drug prices than another government program. Governments in other countries manage to pay one price for drugs. I realize that this would require a major change to how the federal government would pay for drugs. It should be so considered a long run objective.

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 1 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	-	-

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
Fionase	---	2.41	3.90	2.36

Chairman WAXMAN. Dr. Morton.

STATEMENT OF FIONA M. SCOTT MORTON

Ms. MORTON. Good morning to the chairman and members of the committee. Thank you very much for inviting me to testify. I just have some short remarks.

The report that was released this morning repeatedly says that manufacturers charge more to Part D than they charge to Medicaid. I just would like everyone to keep in mind that the manufacturers—under Medicaid, they sell to drugstores in the normal way, and then they are required to give a rebate back to the government. And that is how we get a net price; it is not a charged price.

And the size of that rebate is set in law; and the important thing, I think, that we see today, that we didn't see in the early 1990's, was the size of the inflation component of that. And that is not something that Part D can negotiate for. That inflation component is big, and it is mandated under Medicaid.

So I would say that the findings of the report are completely predictable in the sense that we knew that Medicaid was required to get the lowest price, and we knew it had these big rebates. And so, of course, that is going to be, as Mr. Davis said, the place where you've got the lowest prices, and we wouldn't expect Part D to be able to do as well as that.

So I think if Congress is concerned about just the cost of covering duals, then you should move them back into Medicaid. I mean, that is where you're going to get the lowest prices for these people. It would also reduce confusion for them and plan shifting as the plan they are in becomes too high cost and they're moved to another plan that—I believe that kind of transition is difficult.

Second, the report finds that the protected classes in Part D get small discounts. Again, I'm going to take this opportunity to say that when I testified for the Senate in January 2007, I predicted this, because you can't move market share in these groups. The formularies are restricted and the Part D plans have to cover all drugs, essentially; and if you can't bargain with the manufacturer, saying, I'm going to move market share to Drug A from Drug B, you can't get a discount. And I think it is very reasonable then to see that you're not getting discounts in these protected classes.

Again, this is something you could change with respect to the regulation. You could have fewer protected classes, you could loosen the formulary restrictions so that plans can do a bit more shifting of market share from one drug to another; and then you'd expect to see bigger discounts.

Third, we have talked a lot about the windfall that has arisen from moving guys from Medicaid into Medicare. I have some research looking at the opposite effect, which is the movement of the uninsured from paying cash to having coverage under Medicare, and there the windfall appears to have gone in the opposite direction. So the prices that an uninsured, cash-paying person pays are a lot higher than—now, I don't have the same access to information as you do, Mr. Waxman, so I'm inferring it from some less-good data, but it looks like the prices are going down quite drastically.

So we do have success of the program in helping the uninsured get access to drugs at lower prices. But—so I just would like to

point that out, since we have the windfall going the other way as well.

Then two—just points that are longer run. First of all, I think this committee might want to return to this question next year because the way the negotiations work is, they happen in February for prices to set in November for the next year. So when you think about the experience with the program, it wasn't until February 2007 that plans and everybody could watch a whole year of operation of this program. And so it wasn't, therefore, until prices were set for 2008 that you see kind of informed outcomes, as opposed to just guessing what are people going to do and where are they going to enroll. So I think we can learn more going forward.

And then, last, it seems messy and costly to me to try to have a Medicaid rebate applied to some purchases inside Medicare. It seems just—because you get those rebates. The supplemental rebates come from shifting, having a preferred drug; the Medicare Part D rebates come from having a preferred drug. So trying to get a plan to have a Medicaid rebate for a guy who is in their Medicare plan that they are trying to negotiate over with the manufacturers, that seems very complex to me. I think it would be just easier to move them, for the plan.

And I think that—oh, the last thing about the Medicaid rebates is, they are large and they really reduce the profitability, of course, of selling to the Medicaid program. I think that works partly because the Medicaid program is small, so if it is 12, 15, 18 percent of the Nation's drug spending, the manufacturers can afford and should be interested in providing medications at low cost to those poor people who are also sick.

But when you think about Medicare, 40 percent of all prescriptions are doled out to people who are eligible for Medicare. I mean, by the time you add on Medicaid—that's half the market—you're then talking about a very serious change in the market structure of the pharmaceutical industry.

Thank you. That's all.

Chairman WAXMAN. Thank you very much.

[The prepared statement of Ms. Morton follows:]

Testimony before the House Oversight and Government Reform Committee**“Medicaid Rebates, the Economics of the Pharmaceutical Industry,
and the Medicare Part D Program”****24 July 2008**

Fiona M. Scott Morton
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Senior Associate Dean for Faculty Development
Yale School of Management
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I am Fiona Scott Morton, Professor of Economics at the Yale University School of Management. I have been conducting research on the economics of the pharmaceutical industry for the last 15 years, and several of my projects have focused on procurement of pharmaceuticals for the Medicaid and Medicare programs. These remarks represent my own views based on my research and interactions with other academics in the area, industry participants, and policy-makers.

1. Industry Background

The pharmaceutical industry is characterized by large up-front costs to discover and develop a new drug. The new drug may be very effective at treating a widespread condition, or it may be less effective or treat a narrow condition, or it may fail entirely. This variation in success rates creates risk for the innovator as well as high fixed costs. However, production costs of drugs, once discovered, are typically very low. Thus, consumers see market prices for drugs far in excess of production costs, and what look like large profits.¹ Government payors then face the temptation of using their power to force prices below market levels. Because production costs are so low and the R&D that produced the drug was sunk long ago, in such instances pharmaceutical companies are willing to sell at low prices rather than not sell at all.

However, entrepreneurs and scientists who set out to discover new drugs are funded by venture capitalists and other providers of financial resources. These agents are motivated by the financial returns that can be earned on an innovative new drug. If expected future profits from a new drug fall, less will be invested. With less investment, society will enjoy fewer new drugs than it otherwise would.² The available academic research with which I am familiar has estimated that

¹ Calculating return on assets to compare to other industries is difficult because R&D is a major “asset” of pharmaceutical research firms and it is difficult to value. Given profits, any variation in the level of assets clearly affects the calculated returns to those assets.

² Page 11 of Hahn (2007) “Federal Drug Price Negotiation: Implications for Medicare Part D” CRS Report for Congress notes that no relationship has been found between research expenditures and new NDAs. One would not expect a fixed relationship. As science progresses, the cost of discovering a new drug will rise or fall over time. The same number of dollars spent in different decades will result in a different number of NDAs due to the state of basic medical knowledge.

society gains greatly from new drug innovation; thus it is in all of our interests that research into new therapies continues.

The Medicare Part D program vastly increases the market share of the government as a buyer and makes this problem more salient for the US. When the government provides private firms with a large portion of their returns from an innovation, procurement pricing policy is not innocuous; the public pricing scheme used to pay for drugs invented and developed in the private market will strongly affect the level of innovation in the industry.

2. Medicaid Rebates

The Medicaid programs of the various states receive rebates from manufacturers whose drugs are dispensed to Medicaid enrollees. These rebates were established in the Omnibus Budget Reconciliation Act of 1990. The motivation for the rebates was to lower the net cost of prescription drugs to the government without reducing payments to pharmacies. Instead, a state Medicaid program reimburses a pharmacy for a prescription dispensed to a Medicaid enrollee. Then the manufacturer of the drug pays the state Medicaid program a rebate, which lowers the net price to the Medicaid agency. There are two components to Medicaid rebates on branded drugs: the basic rebate and, in some cases, an inflation adjustment.³ For brands the basic rebate is the lower of a) a flat rate (currently 15.1%) of the Average Manufacturer Price (AMP) or b) the difference between AMP and the best, or lowest, price offered to any private buyer. For example, if a manufacturer offers an HMO a price that is more than 15.1% below its AMP, that price would be a “best price” and sales to all 49 Medicaid programs⁴ would get that same discount. Even if the manufacturer sells to only one customer at a very low price, that price triggers a large discount for all the sales of that drug that the manufacturer makes to all state Medicaid programs. One can immediately see that the existence of the best price component of the rebate makes it expensive for manufacturers to give discounts to some buyers. When discounts are expensive, firms tend either to eliminate discounts, or not give as many. In turn, this means prices rise for many buyers, as does the average price. This experience was documented by the GAO and other government agencies when the Medicaid rebate was first introduced, and Congress amended the rebate statute to exempt sales to certain governmental agencies from the best price provision.

The basic rebate on brand-name drugs is augmented by a CPI component, which limits price increases to the rate of inflation. If the drug’s price has increased more than the rate of inflation, then the incremental price increase must be included in the rebate in addition to the basic amount. Rebates now comprise a large fraction of the revenue brand-name drug manufacturers receive on sales made drugs to state Medicaid programs. On average, Medicaid programs receive rebates in excess of 31 percent of the average manufacturer price for brand drugs.

³ The basic Medicaid rebate on generic drugs is a flat 11% of the AMP. Some states also negotiate directly with drug manufacturers for supplemental rebates in addition to the mandatory Medicaid rebates.

⁴ All 50 states have Medicaid programs and all cover drugs, but Arizona’s program does not participate in the Medicaid rebate program. In addition, sales made to Medicaid recipients who are members of privately-run Medicaid managed care programs are not eligible for Medicaid rebates.

3. Medicaid net prices are lower than net prices in Medicare Part D

As is clear from the OBRA rebate rules, state Medicaid programs get the benefit of the lowest prices offered to the private sector. In addition, Medicaid rebates include an inflation component. Since no other private buyer, including Part D plans, is mandated to get the lowest price in the country, we would expect that the rebates Medicaid receives are larger than any private sector rebate. While Part D rebates are not publicly available information, the rebate rules make it clear that Medicaid should pay the lowest net price. According to the CBO, "... the net prices Medicaid pays for brand-name drugs are, on average, as low as Federal Supply Schedule prices... And Medicaid prices are significantly lower on average than the lowest prices paid to manufacturers by private-sector purchasers (as reported by manufacturers under Medicaid's rebate program). So in terms of net payments to manufacturers for brand-name drugs, Medicaid does as well as many other federal purchasers and better than the private sector."⁵

Given that Medicaid is required to receive the lowest private price in the nation, the cost of medications for dually-eligible citizens will be higher in any private plan, including Part D, relative to Medicaid. If the federal government is interested in minimizing the cost of treatments for this group, it may want to consider moving them back into the Medicaid program.

Also, keep in mind that the structure and generosity of the formulary is different between Medicaid, Medicare Part D, and other plans. CMS has mandated fairly significant limits on the formulary restrictions Part D plans can employ. By contrast, many state Medicaid programs negotiate for supplemental rebates by creating preferred drug lists. The Veterans Administration has by all accounts, one of the strictest formularies in the country. The rebates a plan or program can negotiate depend greatly on the plan's ability to exclude a drug. We would expect therefore, that the VA and Medicaid would pay lower prices, on net, than Medicare Part D plans.

4. Medicare-eligible consumers make up too large a group to pay a below-average price; they are the average.

Medicare Part D enrollees combined with Medicaid enrollees generate close to 50% of prescription drug spending in the United States.⁶ While of course legislators would like to obtain discounts for low-income Americans and seniors, with a substantial proportion of all spending being generated by these groups, whatever price they pay will tend to be the average price in the market. It is arithmetically very challenging for such a large group to receive below-average prices.

Lowering the absolute level of prices can be achieved (though it will affect research into new drugs), but obtaining prices that are substantially lower than the national average for a combined Medicare/Medicaid population probably cannot.

⁵ CBO, "Payments for Prescription Drugs Under Medicaid," Testimony of Douglas Holtz-Eakin before the Special Committee on Aging, US Senate, July 20, 2005, pp. 6-7.

⁶ This is a rough calculation, but will soon be an underestimate in any case. The Medicare percentage will grow for three reasons: people are living longer, the baby boomers will soon begin joining Medicare, and the disability rolls are growing.

5. Expanding Medicaid Rebates to Medicare Part D will raise prices because Medicare is a large purchaser

As I discussed above, the rebate rules for brands base the price to Medicaid on prices in the private sector, namely a 15.1% discount off AMP, or the minimum price, whichever is less. Note that both the average and the minimum prices here are generated by private, not government, buyers of pharmaceuticals. Tying a government price to a private price can work when the proportion of the market covered by the scheme is small. For example, if government sales represent 6% of the sales of a cholesterol drug, then the manufacturer is selling the great bulk of its output to private plans and individuals and its pricing decisions are driven by their demand. However, pegging the price the government pays to the private price does not work well when the government share gets large. Suppose the government share (Medicare plus Medicaid) of a drug were 70%. The government price under the Medicaid rebate rules would be the average price in the market minus 15.1%. In this circumstance the manufacturer of the drug has a strong incentive to raise its prices. High prices may drive away some sales to individuals and plans, however, the higher price does not reduce government sales. Indeed, the firm would collect a higher price (minus 15.1%) on all prescriptions sold to Medicare and Medicaid. The group of buyers getting the mandatory discount is so large that the manufacturer will effectively set its prices for the government group, not the individuals and plans buying the drug in the private sector.

Thus, applying the Medicaid rebate rule to Medicare Part D would likely result in higher prices for consumers in the private sector. Furthermore, any price increase will negatively impact the net cost of Medicare and Medicaid because the rebate will be calculated off a higher price level. In general, tying the price of a large government customer to a reference price (e.g. average price, discount off of average price, minimum price) is poor policy because the effect on government sales is so large the firm prefers to distort its choices for the rest of the market.

Put another way, Medicare is now so large it would be rational for pharmaceutical companies to raise almost any reference price rather than accept a low price from Medicare. For example, if Medicare announced it would only pay the level of price charged in country X, drug manufacturers would raise prices in country X. If Medicare chose to pay the average price based on a sample of HMOs, manufacturers would raise prices to those HMOs in order to earn more on their Medicare sales. Nor will a reference price combined with a discount provide a solution. If Medicare decides to pay 50% less than the private price, instead of 15% less, manufacturers will have a large incentive to raise the private price. This approach to controlling prices harms all other consumers of pharmaceuticals in the US and is poor policy.

In addition to likely raising prices, expanding the use of the best price rebate to the Medicare Part D enrollees will tend to make prices more uniform across customers. This limits plans' abilities to create price competition, as I describe in the next section. This price competition is critical to keeping down the costs of healthcare.

6. In the pharmaceutical industry, the ability to exclude a drug or “move market share,” is the most effective way to get a low price

One feature of the pharmaceutical industry that makes it difficult to regulate is consumer behavior. Many consumers have insurance for their healthcare expenditures. An insured consumer is not price-sensitive (or quantity-sensitive) in the way that she would be if she were bearing the full cost of her medication. The fact that demand is not very responsive to prices means that there is less of an incentive for manufacturers to keep prices down. Of course, it is desirable for consumers to be insured for those times when they experience an adverse health event and do not have the financial resources at hand to pay for their drugs. However, insuring consumers for their pharmaceutical purchases removes the major source of price competition, because when consumers pay only a small part of the price they do not have much of an incentive to shop for the lowest price. One important role for the Part D plans - as distinct from the enrollees - is to re-introduce price competition by negotiating with manufacturers over which drug will be ‘preferred’ by a plan. Preferred drugs have greater market share within the plan by careful design of incentives (such as having fewer restrictions on prescribing or lower co-payments). Therefore, a manufacturer will offer a plan a low price for its drug in order to obtain preferred status and more sales within the plan. This form of price competition is critical in lowering the cost to consumers of prescription drugs with patent protection.

Let me illustrate this problem with an example. In a simpler market, such as that of a consumer purchasing toilet paper at Costco, one can see two factors at work. First, Costco is a large buyer and can extract a discount from manufacturers for that reason. However, Costco also typically only offers a couple of brands of toilet paper. One is the store brand (or generic), and there might be one or two others. Let’s imagine the other brand is Scott’s. A significant fraction of Costco customers who like Charmin but who cannot find it at Costco will buy Scott’s instead. In this way Scott’s gains market share vis-à-vis Charmin. Costco can extract a low price from Scott’s because it can promise Scott’s that it will “move market share,” which means getting Charmin customers to purchase Scott’s. When Costco was negotiating with Scott’s over the purchase price of the toilet paper, Costco could walk away at any time and open a negotiation with Charmin instead. Costco considers the different brands of toilet paper to be substitutes and can exclude one or more brands very easily.

In the pharmaceutical industry the situation is analogous. HMOs and PBMs have committees of physicians and pharmacists that meet to consider which drugs are therapeutic substitutes (cure the same diseases). When two or more drugs are found to be close substitutes, the plan considers which one is less costly. The manufacturers of those drugs essentially bid for the business of the buyer, with the lowest priced drug winning. The winner gains market share at the expense of its substitutes because the plan makes the winner the default choice for its physicians and consumers. (Typically, the competing drugs are only available to patients when there is medical need as determined by a physician.) The more market share the plan can “move”, the more valuable a contract with that plan is to a manufacturer. Part D plans engage in this negotiation and design formularies that reflect these tradeoffs. A common Part D plan puts drugs in “tiers” so that preferred drugs are on a low tier and have a lower out-of-pocket cost to consumers.

It is certainly the case that overseeing many Part D plans creates administrative costs relative to running only one. Also, a single plan would be bigger, and others have argued that would make it more effective in bargaining. However, notice that if there is only one plan, it cannot bargain for low prices unless it is willing to exclude either drug A or drug B. Suppose it chose A as preferred. Seniors who have a strong preference for drug B will not want the plan, and yet have no alternative. In a world with many plans, those consumers can join a plan that prefers drug B. Therefore, a single plan covering all enrollees in a region would likely be resisted by seniors because it would restrict their choice of drugs. Furthermore, if the single plan covered all drugs it would have no ability to prefer one drug over another, so prices would be high. Secondly, the manufacturer of the drug that is not preferred by the single plan will face a drastic reduction in sales. Manufacturers would be expected to prefer a system with multiple plans so they are not in the situation of having only one customer.

7. Rebates lower the cost of Part D

The rebates plans receive through negotiation are passed on to consumers and the government in the form of lower bids by plans. If a plan did not include expected rebates in its costs, its bid would be higher than the bids of its competitors. Competing plans would then have lower premiums and would be more attractive to enrollees. The low premium plans would gain market share at the expense of higher-cost plans. In this way the market mechanism forces the rebates paid to Part D plans to benefit both enrollees and the taxpayer; of course, the rebates do not appear as a lump sum or a line item labeled "rebates," but nonetheless reduce the cost of the benefit.

Chairman WAXMAN. I'll start off the question—5 minutes of questions.

That was an interesting point you just raised about the Medicaid population being so much smaller than the Medicare population, but when we talk about dual eligibles, we are talking about half the budget for pharmaceuticals under Part D.

You're shaking your head. You acknowledge that fact?

Ms. MORTON. Yes, I think not everybody who is Medicare eligible is enrolled in Part D. So the current proportion of duals is quite high relative to all the people who could be signing up for Part D going forward.

Chairman WAXMAN. If we paid the Medicaid price for those dual eligibles, there would be a tremendous savings. Do you agree?

Ms. MORTON. Oh, there would. Because we used to have them in Medicaid where these regulated prices were below market level. Absolutely.

Chairman WAXMAN. Do you think that did any harm to the ability of the prescription drug industry to do their research, market their products?

Or is it a small amount so that the controls on those prices, requirements of discounts—it did not have an adverse effect?

Ms. MORTON. It is hard to know what the ideal amount of research and development is, so I won't tread in that area. But in terms of where we were before with kind of 18 percent of spending in Medicaid, seemed like, you know—if you take that as a benchmark, you know, it seemed not so terrible to me; whereas I feel like half of all spending being subject to these rules is really pretty drastically different and moves us a lot more toward a single payer—you know, national health almost.

Chairman WAXMAN. As I hear the testimony of the three of you, you all seem to agree that our report is accurate. Is that a fair statement?

Start with Dr. Schondelmeyer.

Mr. SCHONDELMEYER. Yes, it is. I think it is quite accurate. And I'm not sure it takes fully into account the effect of State supplemental rebates.

I would point out that your own State of California gets about 40 percent of their total drug spend back in rebates. And those State supplemental rebates are negotiated, not government-set prices. They are negotiated with the drug companies based on movement of market share and the same tools that the private Part D plans have available.

So why is it that States can negotiate up to a 40 percent rebate, an additional 20 percent on top of what the Federal rebate is, and the private Part D plans can only get 8 to 14 percent rebates? I don't know.

Chairman WAXMAN. And, of course, our report was only on the 100 most-prescribed drugs. There are other drugs beyond that, as well, for which there could be a greater savings or that we are paying far more for than we otherwise might have to.

Mr. SCHONDELMEYER. Could—but given what I know about the market and how rebates work, I would be willing to wager that there are even smaller rebates on the rest of the drugs in the market than the 100 you looked at.

Chairman WAXMAN. I see. OK.

Dr. Anderson, what is your view?

Mr. ANDERSON. I agree that these numbers are quite accurate.

I think you have to look at it from a variety of different perspectives. One is from the 10-Ks and the 10-Qs, and you add up those that they report, you'll get to about \$2 billion. Then you sort of look at the differential in the prices between Medicare and Medicaid, and it is about a 20–25 percent differential. You do those and you get about a \$2 billion number.

So I think, from a variety of sources, we are seeing that your numbers are quite accurate; and I wish we had access, actually, to your numbers so we could look at them. As researchers, I think it is really important.

Chairman WAXMAN. And, Dr. Morton, as I heard your testimony, you confirmed the committee staff's findings? You can't tell us exactly that we are correct because you don't have the same data, but you confirmed the fact that we're paying far more under Part D for these dual eligibles?

Ms. MORTON. That's consistent with what I know.

The States get supplemental—can negotiate for supplemental rebates. They get the best price on a brand and there is the inflation component, and Part D can't mimic those latter two. They can mimic the supplemental, but they can't get the inflation piece, for example.

And then, second, looking outside the drugs that you examined, I would actually think the rebates would be bigger for Part D. And the reason is—

Chairman WAXMAN. You would agree with Dr. Anderson?

Ms. MORTON. Yes. Because the big drugs for the duals are largely in the protected classes where, as I said, there is less ability to negotiate.

Outside the protected classes, you would expect more negotiation, more market share shifting and bigger rebates.

Chairman WAXMAN. These are protected classes because they are drugs that—there is no other alternative to those drugs and they are life saving; is that basically right?

Ms. MORTON. I think there is also a second factor, which is that you're trying to stop Part D plans from engaging in adverse selection, from cream-skimming in taking healthy people. And if you offer only one HIV drug on your formulary, you're not going to attract the sick people.

Chairman WAXMAN. So we protect those classes of drugs, and it is important that we do so for the well-being of the people.

Ms. MORTON. That's right.

So in some sense that is why I suggest moving these guys back into Medicaid, given—if you're concerned, for this reason, about having a restrictive formulary, then, you know, that going to cost you.

Chairman WAXMAN. Thank you.

Mr. Davis.

Mr. DAVIS OF VIRGINIA. Thank you.

Of course, the problem is, these folks don't want to go back into Medicaid. But that is a political issue the other side will have to deal with.

Dr. Scott, let me ask you. We keep referring to private sector price controls that would result from Medicaid price regulation being extended to Part D. Can you elaborate on the expected impact of extending price controls to the Part D program on the following groups: employers, employees, unions and uninsured?

Ms. MORTON. Certainly. If you have—the best price provision of the Medicaid rebate rules is the critical thing. So if I, as a manufacturer, offer a low price to any private-sector buyer, I have to offer that same—effectively, the way the rebate works—I have to offer that same low price to Medicaid. So the bigger—so that gets expensive as the group that gets that forced rebate gets bigger.

So as that group getting bigger and bigger, which it would be if you put in duals or all of Medicare or whatever, then I don't want to give a discount anymore, as a manufacturer, because if I give a discount to even one party, I have to give to the entire portion of the market covered by that best price. And that causes discounts for private-sector employers, for everybody else.

Mr. DAVIS OF VIRGINIA. The extension of the philosophy over there is just, why not just fix prices for everybody; that at the end of the day, if you fix prices, that somehow the drug companies are going to go along and just take it?

What you are arguing is, they make it up somewhere else along the way.

Ms. MORTON. Well, they are going to have an incentive to eliminate those discounts elsewhere in the economy and will move toward a more uniform pricing where everybody pays the same price and nobody can negotiate for a discount.

And that is dangerous, I believe, because the way we run our intellectual property is that these brands have patent protection, and the way to create price competition when two molecules have patent protection is to threaten to substitute one for the other and get a discount. If you can't do that because of the best price regulation, then you undermine price competition.

Mr. DAVIS OF VIRGINIA. One of the problems with Medicaid is that you don't get the same breadth of offerings, isn't that right, that you would get Medicare Part D?

Ms. MORTON. Technically, it is supposed to be an open formulary, but I believe the supplemental rebate States are negotiating for depend most now on having a preferred drug and then a list where the physician has to get prior authorization to prescribe the drug, so that effectively you're getting a narrow formulary. That's right.

Mr. DAVIS OF VIRGINIA. Dr. Anderson, do you want to comment?

Mr. ANDERSON. I would say, if you would compare the formularies between Medicaid and any of the private-sector plans, you would see that Medicaid has a much broader formulary than most of the private-sector plans.

Mr. SCHONDELMEYER. I would agree with that.

Mr. DAVIS OF VIRGINIA. But they limit the number of prescriptions that can be filled at any one time, right?

Mr. ANDERSON. Some of the States do have those as ways to control expenditures, yes. But the formularies are quite extensive.

Congress essentially mandated that in OBRA 1990 and essentially said that all State Medicaid programs had to offer all drugs

and have access provisions in there to make sure that they are available to all communities, all beneficiaries.

So it is quite an open program.

Mr. DAVIS OF VIRGINIA. But does a large formulary matter if you can't fill the prescription?

Mr. ANDERSON. Essentially, that is the problem of the States having not enough money in their Medicaid programs, and so they are making choices here as to how to save money; and I would not do that, but that's the choices that they have, given limited resources.

Mr. DAVIS OF VIRGINIA. Well, I know in Virginia we have gone from Medicaid, 10 years ago, being zero percent of the State budget to, now, 17 percent of the State budget. It has crowded out education and everything else. It is a huge—I wouldn't say completely unfunded Federal—but it is a Federal mandate that carries with it a lot of costs.

And, of course, States have to balance their budgets. We don't. There is just, I think, a huge problem.

Let me ask, long term on price controls; I'll ask each of you. Are you surprised to learn that in the first 4 years after the government mandated Medicaid price controls in order to control prescription drugs spending, that spending actually increased by 40 percent? Does that surprise anybody?

Dr. Morton.

Ms. MORTON. I think spending on drugs—it doesn't surprise me, but it might be due partially to the best-price legislation that was passed in 1991, but it also might be due to technological change. We invent new drugs, people want to consume them. The population is aging, more people are on the disability rolls; we're just consuming more health care.

Mr. DAVIS OF VIRGINIA. Do prescription drug price controls hold down spending over time? I mean, immediately, obviously, price controls, we know they have an immediate effect; but over time, how does the marketplace reflect that?

Ms. MORTON. One of the things you have to realize when you're engaging in this kind of price regulation is that the manufacturer will have some kind of optimal response. So they will raise prices or alter their mix of drugs or change their forms or whatever, if that is going to get them bigger reimbursement. So that is one thing to keep in mind.

Then the second thing to keep in mind is just the research and development consequences. If we cut by half our spending on pharmaceuticals, then, you know, that's going to help us today, but it has consequences for future generations because we have privately funded R&D. And unless we're willing to think of some other way to do R&D, I think we have to make sure there is some money to be earned for somebody who develops a novel therapy.

Mr. DAVIS OF VIRGINIA. Of course.

Mr. SCHONDELMEYER. Earlier, you asked all three of us to respond to the question, are we surprised that 40 percent expenditure increase occurred in the first 4 years. That is expenditure increase, not price increase; and the number of recipients increased in that time and a number of other factors unrelated to price.

Also I point out, you ask, do price controls result in lower prices or higher prices over time. I would point out, the other major governments around the world that do have price controls—I'm not saying we have to do that—but do have price controls, do pay lower prices than we do. So price controls for many markets in many governments seem to work.

The last thing I'd point out is, the United States—today, our government pays for 50 to 60 percent of all drugs in the United States. We have become the largest buyer in the marketplace. Whether you act as a regulator of price or a prudent buyer in the marketplace, you're going to have an impact in the marketplace. But I would say our government is not working as a prudent buyer in a market—in a marketplace. And there are behaviors that they can undertake that do facilitate markets, but use the power of a 50-to-60 percent player in a marketplace.

Mr. DAVIS OF VIRGINIA. Governments are rarely prudent buyers is my observation.

Mr. SCHONDELMEYER. You guys can change that.

Mr. DAVIS OF VIRGINIA. I don't think you want Congress to get involved.

Chairman WAXMAN. Thank you, Mr. Davis.

Mr. CUMMINGS.

Mr. CUMMINGS. I have sat here and I have listened to all of you; and I have to tell you, I'm confused. Because the bottom line, Dr. Anderson and Dr. Schondelmeyer, as I understand it, is that the government is spending more money now, in moving these folks to Medicare Part D, than they were before. Is that the bottom line?

Mr. ANDERSON. That's \$2 billion more per year.

Mr. SCHONDELMEYER. True.

Mr. CUMMINGS. OK.

Now, maybe I'm missing something, but Mr. Davis, whom I have tremendous admiration for, talked about "deja vu, here we go again." But the fact is that Americans, hardworking taxpayers that are watching this right now, are probably sitting there scratching their heads and saying, OK, what does all this mean?

Now, Dr. Morton has given us a few suggestions. And as I sat here and I listened to the suggestions, this is what I asked myself. I asked myself, what is the problem with her suggestions? And I want you all to answer.

One of the things she says, we should move the folks that are now on Medicare Part D—correct me if I'm wrong—back to Medicaid. Is that right?

Ms. MORTON. Just the duals. I mean, my understanding is, Mr. Waxman's concern is just the duals.

Mr. CUMMINGS. So that we won't be confused and the public won't be confused—see, what happens here in Washington is, people talk past each other, and so then—but when the bottom-line clears, we are still in the same predicament. And we'll be in the same predicament 10 years from now, but it will be far worse.

Is there something wrong with what she said? Is there an issue with that?

Mr. ANDERSON. Well, I think you could do that. The problem is that you want to have one program really be in charge for the person's health care, and that should be through the Medicare pro-

gram or the Medicaid program. And by putting—in the past, they have been separate, so drugs have been part of the Medicaid program, and lots of other things have been part of the Medicare program; and that makes it much more difficult to get good, quality care.

So there are pricing reasons why you should follow her ideas, but there are clinical reasons why you might not want to.

Ms. MORTON. Now, can I say, the clinical side is not represented so well by our current system of a PDP and then a set of doctors who aren't part of the same organization.

I agree with you, but I think we could fix it for everybody.

Mr. ANDERSON. We should fix this for everybody, and essentially, potentially having separate payment systems makes it more difficult to solve it, because you want to have one system, one insurer really being responsible for the care of an individual.

Mr. SCHONDELMEYER. I agree that could work, to shift them back to Medicaid; but a downside of that is, markets work also based on the principle of volume, and larger volume should get lower price.

But here we have the government paying 50 to 60 percent of the drugs on the market, and paying a higher price and moving the dual eligibles from Medicare Part D back to Medicaid means that the government is dividing up their pie again to lots of smaller pieces, and essentially Medicare Part D does that. Instead of the government saying, we're going to pay for all Medicare Part D under one pricing system, we're going to let each plan and hundreds of these plans across the country negotiate prices. So we want a whole bunch of small people negotiating instead of one big party negotiating. So we structurally built into Medicare Part D principles that fight against markets working well in ways that do derive better prices in the marketplace.

So we need to ask, should we keep them in Medicare Part D and find ways to better use the government's role in the marketplace.

Mr. CUMMINGS. Dr. Morton, I'm running out of time. What was your second most powerful suggestion?

Ms. MORTON. I think that we need to study the protected classes quite carefully. I think what Mr. Waxman said about how these are vulnerable populations that are very sick and need access to correct drugs is absolutely right. However, when you give the plans no tools to shift market share or weak tools, then you are going to have expensive prices.

Mr. CUMMINGS. Dr. Anderson, would you react to that, please?

Mr. ANDERSON. Sure.

Essentially what we did when we passed OBRA 1990 was, we said everybody in the Medicaid program had—for all the drugs, and so essentially you took out the ability to do formularies. But then you gave them the ability to do rebates.

So essentially what you'd want to do in these protected classes is to institute either the best price or the rebate system, so that when there is no competition, the Federal Government or the dual eligibles get the best prices.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Chairman WAXMAN. Mr. Marchant.

Mr. MARCHANT. Thank you, Mr. Chairman.

Dr. Morton, in your testimony, you explained that expanding Medicaid, the Medicaid best-price requirement, to Part D would make prices more uniform across the board. Dr. Anderson seems to advocate uniform prices.

What would be the implication of a uniform prescription price policy?

Ms. MORTON. The implications are twofold. One is that because the production cost of these drugs is quite low relative to the research and development costs, it is worth giving them—it is worth selling at low prices to people who are poor or who can't pay, because you're still covering your manufacturing costs and you're extending the benefit of the drugs to those people. If you have to charge a uniform price to everybody, then those people can't afford it, they don't buy and you don't get as many people being helped. So it is useful to be able to sell at different prices to different consumers.

Second, plans—PBMs and insurers and HMOs—in this country have invested a lot in changing their organizations to be able to shift market share from one molecule to another, and that requires education of doctors and a lot of organizational effort. And that ability to shift market shares is what drives prices down, because it creates price competition between drugs. I buy A and you buy B. A and B compete. I get a good price on B; that is why I bought it. You get a good price on A; that is why you bought it.

So your price on A is low and mine is high because we've engaged in this kind of bargaining. And if you make everything uniform, then all of that system of extracting price concessions is no longer worth doing.

Mr. MARCHANT. Thank you.

Dr. Anderson, you seemed to express surprise that Part D prices are higher than Medicaid. Does any other payer in the United States get Medicaid prices?

Mr. ANDERSON. Sure. The VA actually gets lower prices, DOD gets lower prices than Medicaid does in most cases.

Mr. MARCHANT. Does GM get Medicaid prices despite their—the fact that they are a very large purchaser?

Mr. ANDERSON. I haven't—I don't have access to it. That's where we need price transparency to know whether or not GM gets the same prices at Medicaid. We don't, as researchers, have access. My guess is that they do not, which is what I'm concerned about, that the marketplace for drugs does not seem to be working.

All the discussion that Fiona Scott Morton talks about in terms of the marketplace is resulting in the private sector paying 20 percent more than the public sector. And why would I want to emulate a system where you're paying 20 percent more?

Mr. MARCHANT. Well, it seems to me that someone in their 20's or 30, that had a disease that they felt like there was a time horizon available to them for that disease or that—to be cured with some kind of a medicine, would hope that the drug companies would not just flatten their product line to a price point, but would build something into the product line for profit and R&D, so that there would be some hope later. And, of course, the government would have that hope, too.

Mr. ANDERSON. And I would share in that hope. Right now, however, the pharmaceutical industry is spending anywhere from 14 to 18 percent of its revenues on R&D. It is spending 30 percent on marketing and spending 25 percent on profits.

So I would love them to increase the percentage—certainly as a researcher, certainly as a professor at Johns Hopkins—to increase them from 14 percent to 20 percent or 25 percent. But that is not what has happened, and as the profits have increased, the percentage has remained absolutely stable.

Mr. MARCHANT. Ms. Morton, do you see a danger in that theory?

Ms. MORTON. The marketing expenses of a pharmaceutical firm are all driven toward getting more revenue, which—and those expenses wouldn't be spent if they weren't worthwhile in bringing in more revenue, so that increases the incentive to invent something. The more revenue you can collect from it, then the more incentive you have to invent it.

So the marketing, per se, is not a disaster. Profitability is very difficult to calculate here because the percent profit has to be calculated on something—percent of sale, percent of assets, percent of whatever—and typically we would do it as percent of assets. And R&D is an asset for these firms, but it is not counted as such when the accountants look at assets. So pharmaceutical companies look like they have tiny assets and few factories when, in fact, they spend millions on R&D.

So I'm just always leery of profit numbers, because they can—you can calculate them so many different ways.

Mr. MARCHANT. Thank you, Mr. Chairman.

Chairman WAXMAN. Mr. Yarmuth.

Mr. YARMUTH. Thank you, Mr. Chairman. I want to thank all the witnesses for their testimony.

I think we are in general agreement that the treatment of dual eligibles through Medicare Part D is costing the government and the taxpayers more money than it otherwise would. And the staff report estimates that the savings to the taxpayer down the road, or the additional cost to the taxpayer for failure to do something different, would be in the neighborhood of \$85 billion over that 10-year period.

Dr. Schondelmeyer and Dr. Anderson, does that seem like a reasonable estimate to you? Is that possible? Is that understating it?

Mr. SCHONDELMEYER. I think if the program continues as designed, that is a reasonable estimate. But I would point out that it is probably even more than that because the States have gained even more in their supplemental rebates in the last year or two, and I think the savings could be even greater than what that represents.

So it is probably a reasonably accurate estimate if not an underestimate.

Mr. ANDERSON. And I would agree.

Mr. YARMUTH. And it is possible, because the States have the protection of the inflation cap, essentially, it could be more than that in terms of savings if the inflation rate ended up being significantly higher as it has been in many years.

Mr. ANDERSON. I think in OBRA 1990, that was a very smart thing to include in there, to put it in, because when the drug com-

panies increase the prices, then essentially the Medicaid programs gets the advantage of that. And that doesn't exist in Medicare Part D.

Mr. YARMUTH. Dr. Morton, you said in your testimony that the result of the study, the staff study, the staff report was predictable given what we're talking about.

Would you say that the impact that we've seen over the last few years was predictable when the legislation was passed to create Medicare Part D?

Ms. MORTON. Certainly, the magnitude, I wouldn't have wanted to speculate on. But the fact that Medicaid has a required best-price provision for brands and then the inflation component on top of that makes me think that it would be extremely difficult for a private sector—I mean, it would be impossible if the Part D plans were included in the best-price provision.

But actually they are exempted, so you could give Part D a low price, and it wouldn't trigger a Medicaid rebate.

But having said that, I still think it would be very difficult to match the Medicaid price.

Mr. CUMMINGS [presiding]. Mr. Bilbray.

Mr. BILBRAY. Mr. Chairman, with your condolence—I mean, your support, I'd like to yield my time to the ranking member.

Mr. DAVIS OF VIRGINIA. He is always happy to give you his condolences.

Dr. Schondelmeyer, let me ask you. Prior to 2006, dual-eligible seniors who qualify for both Medicare and Medicaid had prescription drug coverage through Medicaid. Of course, now they're moved into the Part D.

The majority report argues that by moving dual-eligible seniors from Medicaid price controls to Part D market prices, prescription drug companies receive a financial windfall.

Do you disagree with CBO's assessment that mandating Medicaid price controls in Part D would increase the cost of drugs to all other private payers?

Mr. SCHONDELMEYER. I haven't looked recently at CBO's assessment or quantification of that.

I would point out that the Medicaid rebate is partly based on the best price, which comes from a price negotiated in the marketplace. And it means that there are at least one—

Mr. DAVIS OF VIRGINIA. The total marketplace or a restricted marketplace?

Mr. SCHONDELMEYER. In various buyers in the private marketplace.

So there is at least one other buyer in the marketplace that is smaller than Medicaid and smaller than Part D plans that have negotiated a better price. And I find it contradictory that the larger Part D plans can't negotiate similar prices in the private marketplace that the best-price buyer—so I would argue that not all of the prices are regulated.

I would give you that the mandated rebate amounts are set by government law or regulated, but any rebate above and beyond that is affected by the best price of negotiations in the marketplace.

Mr. DAVIS OF VIRGINIA. Dr. Scott Morton, let me just ask you. You have to look at the marketplace as a whole; isn't that right?

When you are cutting in one place, don't costs somehow rise—the drug companies, or whoever, in their marketplace are going to make allowances for that?

Ms. MORTON. Yes.

I think we have a problem in our country because, for our government purchases, we tend not to like to say we will pay \$2.43 for that pill. We like to say we are going to pay as much as the private sector pays, or 15 percent less than the private sector, or we are going to pay as much as Canada pays.

And then the problem for all those sorts of reference prices is that industry then would like—if they can move the reference price, they can shift how much Medicaid and Medicare pay for their drugs.

So if we say “average prices,” then the private sector prices are going to go up, because that is what triggers—

Mr. DAVIS OF VIRGINIA. It is kind of like everybody taking the lowest seat price on the airplane. If everybody paid the lowest price that somebody pays on an airplane, they would be in worse shape than they are.

Ms. MORTON. They would raise the lowest price. That lowest price wouldn't be where it was before.

Mr. DAVIS OF VIRGINIA. And that is basically the argument here, as I understand. It is economics that I took.

Mr. ANDERSON. But I am not sure why the Federal Government should pay the highest price.

Mr. DAVIS OF VIRGINIA. Well, they don't in many cases.

Mr. ANDERSON. They don't. But essentially—

Mr. DAVIS OF VIRGINIA. Dr. Morton, do you think the government is paying the highest prices?

They don't pay the highest prices. In fact, Medicare, Part D, the increases are way below what was initially estimated as we bring some marketplace into health care. One of the problems today is the Federal Government is such a large buyer, you don't have basically a market in some of these places.

Dr. Morton, would you react to that?

Ms. MORTON. I think you said it correctly before, Gerry, when you said that Medicaid pays the lowest and then Medicare and then the private sector. So I think the private sector is paying the highest prices, and the danger of having a best-price provision that extends to a large group of consumers is that those prices go up.

Mr. DAVIS OF VIRGINIA. So are senior taxpayers paying unfairly high prices for prescription drugs in Part D?

Ms. MORTON. I think—since I am an economist, I am not going to comment on the “unfair” part. I think my own research shows there is a huge benefit to moving the cash-paying uninsured into a plan, OK, because then you have someone larger working on your behalf.

Mr. DAVIS OF VIRGINIA. They are the ones that took the brunt of it, aren't they, before this?

Ms. MORTON. Our data show that is a big effect. Moving into a plan, having been uninsured, means you get access to much better prices, and of course, your utilization goes up.

Mr. DAVIS OF VIRGINIA. You would agree with that, wouldn't you, that the biggest beneficiaries of this are the uninsured, the poor,

in terms of moving them into Part D, that they get a great reduction?

Mr. ANDERSON. Oh, absolutely, the same thing as, we should try to cover the uninsured in the United States. I mean, we want to cover as many people as possible. So absolutely you want to do that; you just don't want to pay more than you need to pay for services. And I think that is what this committee's report shows, that you are paying too much for services. And \$2 billion is \$2 billion.

Mr. DAVIS OF VIRGINIA. Are they saying too much, or are they saying they are not paying what Medicaid pays, which is clearly the lowest? I think there is a difference between "too much" versus what Medicaid pays.

If you argue that everything over Medicaid prices is too much and you put Medicaid prices across the board, it couldn't happen, could it, economically? Wouldn't it raise Medicaid prices?

Mr. ANDERSON. I don't think it would raise Medicaid prices.

Mr. DAVIS OF VIRGINIA. So if you think the drug companies, across the board, charged everybody at Medicaid rates, that life would just go on and there would be no ramifications throughout the system?

If that is your opinion, that is fine.

Mr. ANDERSON. They still would be paying more, the United States would still be paying more than Canada would be paying. You would have to bring the rates down to VA in order to get down to Canada or U.K. or French rates.

Mr. DAVIS OF VIRGINIA. One thing we have with the U.K. is you do not have—and a lot of veterans have complained about this—you don't have the choices in VA because not everybody is bringing their costs down to those levels.

They can't afford to sell their drugs at that level, isn't that correct?

Mr. ANDERSON. Well, they essentially have a formulary, and within a therapeutic class they will have a one-drug, which is exactly the same thing that the Part D plans have; they don't offer every drug. It is Medicaid that offers every drug.

Mr. DAVIS OF VIRGINIA. I have one more question.

Dr. Scott, when proponents of a national formulary are confronted with the counterargument that a structure would limit seniors' ability to get drugs, their response is often that seniors can just appeal the decision.

I would ask, are the lower prices on formularies only achieved by the ability to move market share?

Ms. MORTON. My understanding is, that is the main reason why you get a low price, that you can promise to move market share. And if you are a senior and you look at PlanFinder, for example, in the Part D context, you can see which plans have a preferred—have a good price on the drug you are interested in. If it is A versus B, you can see that, and then you can join the plan that has the low price on the one you want.

Mr. DAVIS OF VIRGINIA. On the one you want, you get more choice. Thanks.

Mr. CUMMINGS. Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman.

Whenever we have a hearing on the pharmaceutical industry or drug pricing, I feel like I am in a magic show because it is all sleight of hand. I mean, it is incredible, the questions.

When you say, well, if the price is this much higher than you would get in another way, isn't it really lower because of X, Y and Z? I mean, people see that the prices are higher. The report makes it clear that we have spent \$2 billion or \$3 billion more as taxpayers than we needed to.

By the way, yesterday we were considering trying to get full funding for the LIHEAP program, which is the Low Income Home Energy Assistance Program. The cost of that is about \$2 billion to \$3 billion. Just so people understand, when you lose that much money that the taxpayers have put forward, you can't do other things that we ought to be doing to help people.

To me, this is a classic case of, if it's not broken, why would you fix it? Not only is it a chief criticism of the Medicare Part D program that you didn't take advantage of the opportunity to create a beneficiary pool that could negotiate in a significant way with the pharmaceutical industry directly, but in fact with the dual eligibles, what you did was, you took 6 million people out of a pool that was in a position to negotiate directly with the pharmaceutical industry and you put them into a place where they couldn't.

Not only that, you took a system where you had PhRMA on this side, the pharmaceutical industry on this side, the beneficiaries on the other side, and you interposed the insurance companies and the insurance plans and insurance industry in the middle, which is notoriously inefficient in terms of its administrative costs.

So you took a situation where you were paying 3 to 5 percent overhead administrative costs through the Medicaid program; you put in the middle of the stream, the dollar stream, a system that has overhead costs of about 17 to 20 percent, right—which is very inefficient—which is a great result for both the pharmaceutical companies who now get all this interference run between them on the pricing, right, so you can hide the ball very easily, and it is good for the insurance companies, who get to come in here and charge these huge overhead costs.

It is absolutely madness.

So my first question is, what was the reasoning? What possible rationale was offered up to justify taking the dual eligibles and moving them from Medicaid as the payer to Medicare as the payer?

Mr. ANDERSON. Well, I think it was, as I explained to Mr. Cummings, that essentially you wanted to have them in one system, and that would be the Medicare system as being the controlling system for insurance. And what it meant, unfortunately, is a \$2 billion windfall to the pharmaceutical companies.

Mr. SARBANES. That is a neat idea to get them into one system, but you could move them into one system that works or you can move them into one system that doesn't work. So what they did was, they moved them into one system that they made sure wasn't going to work by setting them up in a way that we couldn't negotiate.

Mr. ANDERSON. Well, essentially, you put them into a system with 20 percent higher administrative costs and paying 20 percent

higher prices, and then trying to say “provide good care.” And that is really hard, because you are down at 40 percent already.

Mr. SARBANES. Isn't central to this the fact that the Medicare Part D program is not a directly administered program? You have Medicare Part A, which is directly administered for hospital benefits. You have Medicare Part B, which is directly administered for physician services. You have Part C, which is a managed care program, which isn't working so well.

But Part D was not designed that way. Part D is not directly administered. Part D is a subsidy to the commercial industry, which has all of these inefficiencies in it. So why you would want to set it up that way, who can imagine?

Now, on the price control thing, we keep talking about price controls, but you put it better. This is really just about a customer called the U.S. Government that goes into the marketplace and has a lot of bargaining power, presumably.

Do people have to sell? Do insurance plans that provide drugs and prescription drugs, do they have to sell to the government, are they required to sell to the government? Or do they want to sell to them because it is a big pool of beneficiaries that they can make money on?

Mr. SCHONDELMEYER. They don't have to sell to the government. And I would point out, when we talk about using market share movement under State supplemental rebates or VA, we call it “price controls.” When we talk about using market share movement under Part D private plans, we call it “the market.” It is the same mechanism.

So you can't call VA's—VA gets a lower price largely because it is a closed system and a very tightly controlled market share movement formulary, and that works. And Medicaid did that because they could do that much better than the Part D plans are right now.

Mr. SARBANES. If we are going to pray at the altar of market economics, we ought to at least bring the basic principles of how you negotiate in the market to the table, right?

Thank you.

Mr. CUMMINGS. Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman.

Market distortion is a serious concern, and I think for all three of you, you have been trying to deal with it—perhaps in different ways.

Because, Dr. Morton, none of you are here to make a political statements, I will make a short, simple one to open this up. I come from California, where we mandate prevailing wage. I come to Congress where we vote back and forth and debate and argue, over partisan lines, prevailing wage.

Now, prevailing wage, in at least this Congressman's opinion, is distorted, so we pay a lot more to build our homes—not our homes, but our schools and our roads, at least in California, than we would pay if the large buyer, this \$150 billion entity called California, went out and went to the low bidder and said, you know, You don't have to pay higher wages to build roads just to please the State of California. So I want to be sensitive here that we don't send that message from the government.

Dr. Morton, I will start with you. VA is a buyer-seller, we want a good price, and we may not buy every drug if it isn't the best price, or we may not dispense two competing drugs as often, if it is more expensive. Would you say that was, as a buyer, as a government buyer, a fair market relationship as an economist?

Ms. MORTON. Yes, I think it is, and I think it is something that most Americans think that they don't want, that they would like something better than that, because it is a very tight formulary.

Also, there is no retail component. So the VA pulls its truck up to the factory, gets the drugs and brings them to VA hospitals. You can't go down to your local pharmacy and get a VA-dispensed drug.

Mr. ISSA. Dr. Morton, I happen to have Indian health care in my district, quite a bit of it, and they get that rate, and they are thrilled to get it. And my centers, my Native Americans, take advantage of it. And by the way, they also look, in some cases, to buy outside those formularies, and they pay a lot more, but they do it with discretion because of the obvious price advantages.

When we are looking at Medicare Part D, as we are here today, is it fair to say from a pure economic standpoint that if you take VA's advantage of single buying, low administration, back-up-the-truck-to-the-dock, that in fact you're going to spend more when you offer people individual, broad formulary choices and you add the administrative burden, that it is essentially where you are, not where we are? And have you ever calculated that cost?

In other words, if we were to take—because I want to do a reality check on whether or not we are distorting and whether or not we are paying too much. If you take the VA rate and you take those elements, where should you end up as a hypothetical for Medicare Part D and where do you end up?

Ms. MORTON. That is a really good question. I haven't done that calculation, but that is exactly the right way to think about it. And part of what makes this difficult is that I know that there are some components; most of these Federal agencies have some component of mandated discounts and some component of "we negotiated it because we have a tight formulary." And you would want to just look at the cases where it is negotiated, as opposed to mandated.

Mr. ISSA. Let me ask a question I think for all three of you, because this is of interest to me.

Obviously, when we deal with seniors and we deal with drugs developed only for seniors in America, we are dealing under Medicare Part D, Medicare in general, that is the market.

So my question is, how does the U.S. Government, in each of your opinions, ensure that drugs which are geriatric in nature only are fairly priced if there is very little alternative way of buying it, other than our VA seniors? Except for that group for the most part, some of these things have no other market in the United States.

So each of you, have you thought about how we get the fair interpretation? Because I am here today believing that I can't use Medicaid because it is a distorted market. I can use VA, but I have to add those costs that I mentioned with Dr. Morton. So if that is all true, when I have a drug that is limited in its reach. Other than seniors in VA and Native Americans, how do I fairly make sure that the price is achieved?

Mr. SCHONDELMEYER. Actually, we have at least one drug that falls into the category you described. There is a drug called Epogen that 80 to 90 percent of the market is the government, and the government is the only payer. So there really is no such thing as a market-based price, because the government is the monopolistic buyer in that market; and the government does set and establish the payment rates for that drug, and they come up with the value of, here is what it is worth.

I think Dr. Morton earlier said the government is afraid to say, here is what we will pay for a drug. But on the one hand, they do try to do that, but any time they do that, we call it “control” rather than “market behavior.”

I think we have to look for the line between price regulation and prudent market behavior for government. Let’s focus on the prudent market behaviors and try to avoid the regulation that drives up the price. But I think you can do prudent buying as a large buyer government and keep some element of market in place.

Mr. ANDERSON. We have done that. Just to explain in a little more in detail, for SRD and renal disease drugs, I think we have gotten good value for those, and we have essentially with a government-administered price.

The other thing, Mr. Issa, I would suggest, is the United States is not the only place where there are seniors. There are millions, billions of them around—a billion of them around the world, and pharmaceutical companies are not just selling to the United States, but they are selling to the U.K. and Canada and other places as well; and we have to recognize that.

Mr. ISSA. Dr. Morton, quickly.

Ms. MORTON. I would say, one of the things that you will get in Part D is this same substituting and bargaining, and I can shift share from A to B. So if your drug for seniors has substitutes, therapeutic substitutes, then I think you can trust to a PBM or a Part D plan to be able to extract discounts on that drug.

I think the very difficult question, which we aren’t facing at the moment so hugely, is what happens if somebody invents a pill that cures Alzheimer’s, and it is the only one, or something like that? Then really the government becomes the only buyer, and there is no good substitute, and how are you ever going to get a discount in that circumstance?

But as long as there are therapeutic substitutes, they buy like everybody else buys.

Mr. ISSA. Thank you, Mr. Chairman, for your indulgence. Hopefully the followup will be how government gets better if we are going to set prices. Obviously, it hasn’t been one of our strengths, but I look forward to working with you on that.

Chairman WAXMAN [presiding]. Thank you, Mr. Issa.

Ms. Watson.

Ms. WATSON. Thank you very much, Mr. Chairman, for this hearing. I want the witnesses to know we value your input. I am concerned too about the real cost of these drugs and the increases, so—I have heard you allude to a way we should really model this. Can the three of you explain more how the government can model the Part D drug program so that it really works for seniors?

A big smile there. What does that mean?

Mr. SCHONDELMEYER. Well, first, the point that was brought up by Dr. Anderson: price transparency in the marketplace. The basic issue, that we don't see how much rebates are flowing without having a congressional investigation in the Part D program, to me, tells us that is not a market. We are going to hide behind the black box and do what we want, and you guys pay the bills.

So we need to have price transparency and transparency of the flow of dollars in this marketplace. Markets work with information. When you hide information, markets cease to work properly. So one is that price transparency.

Second, I think, look to the Medicaid programs and especially what States are doing in their State supplemental rebates and obtaining these much larger discounts above the already-mandated Federal Medicaid rebate and say, How can you use those mechanisms or apply those to the Medicare Part D plans; and ask why—the Part D plans, why aren't you negotiating the same kind of rebate? If this is a market, why can't you get the same level of rebate out there?

And then look to see, are there reasons, maybe reverse, perverse incentives, that keep these Part D plans from wanting to get more rebates from the drug companies.

I would argue that no one in America is really managing or regulating prices very well, whether it is government regulated or private regulated. What we do is, we get bigger discounts and rebates, but the top keeps floating up faster than inflation by a factor of two to three times the inflation rate, every year, year after year, no matter what we do.

So prices keep going up no matter what we have done, and we fool ourselves into thinking getting more rebate dollars back is saving us money. It really isn't. It is not controlling the net we pay overall in the first place.

Rebates are simply a loan to the drug companies for 9 to 12 months, and then we collect the money back and spend a lot in administrative costs doing so.

Mr. ANDERSON. I think if are going to have a marketplace, we have to have price transparency. We don't have price transparency in the pharmaceutical market, whereas we are pushing it in the physician market, we are pushing it in the hospital market.

But I am not sure that we can ever get good prices when we have given the drug companies substantial reasons not to negotiate prices, and that would be the patents that we have given them for up to 17 years. This essentially takes away their reason for negotiation.

So I think what we have to do is take a look at what other countries are doing in this area. They are paying about half the prices that we are paying for pharmaceuticals, in other countries, and that is why Americans are going to Canada and other places for these things. So one of the things the Medicare program could do—and I know many of you voted on this a year ago—is to have the Medicare program negotiate directly with the pharmaceutical industry in order to get a best price.

The other thing that I would just add to that is, I am not sure why the VA, the Medicare program, the prisons and all the other places don't negotiate. I don't understand why the government pays

different prices for exactly the same drugs, depending on whether it is a prisoner who needs it or somebody who is part of the community health center or somebody who is the Medicaid recipient.

The government should be paying one price for drugs.

Ms. MORTON. I am a little less enthusiastic about transparency than my colleagues, because I think in the context of Medicare Part D, if I am a plan and I am negotiating hard in a particular class and I get a good deal on drug A, I don't really want to publish that for all my competing plans to see. And they might in fact be negotiating on drug B and drug C. So there is going to be differences across us, and the plans are going to be trying to get that lowest price as a way to lower their costs and attract more seniors.

So requiring manufacturers to publish that price is going to lead the manufacturers to be less willing to give those discounts and less willing to price aggressively. So I worry about transparency.

Second, I completely agree with Dr. Schondelmeyer in terms of the supplemental rebates the States are getting through Medicaid being a good model, but that actually is what Part D is doing. They are negotiating those rebates based on preferred drugs on a formulary. And what they can't do, which Medicaid can do, is get a best price or an inflation component, which are big parts of the discount that Medicaid gets.

Then, last, I would say—Dr. Schondelmeyer said, why can't Part D do some of these supplemental rebates, negotiate for lower prices? Part of the reason Part D can't is because there are protected classes, and in these protected classes, the plan is restricted from making a drug preferred and saying, You have to consume this HIV drug instead of that other one until there is a medical need for you to switch. And when you have that kind of restriction, then it is not possible for the plan to negotiate aggressively and get a discount.

Now, there are good reasons for having those restrictions, but I am just saying those restrictions are expensive.

Mr. SCHONDELMEYER. That is exactly when government needs to step in, is when you have on the one hand, the market should work by negotiating lower prices and preferring one drug over another, but on the other hand, it is clinically not appropriate.

Government has a role in that, and that is why you are here, and you do have a role in establishing a mechanism to deal with something the market can't do effectively.

Chairman WAXMAN. Thank you very much, Ms. Watson.

Mr. Shays.

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

I am struck by the fact that Medicare Part D is about \$40 billion and Medicare Part A is about \$220 billion; and we want to save money, but we are having a hearing on the Medicare Part D program. I think we should, and I think we should because I think it has worked, frankly, phenomenally well.

For years, politicians talked about having a prescription drug program, and in 2003 a Republican Congress, believe it or not, passes a prescription drug program. The program they wanted was going to cost about \$400 billion over a certain period of time, and the Democratic program was going to cost \$800 billion. I chose the less expensive plan because I thought it would cost twice as much

when we finally adopted it, because most programs that we pass under Medicare turn out to be twice as much as the estimate.

And, believe it or not, it is like one-third less than it was going to be, not twice as much.

Dr. Anderson, when you come in with a beaming face as though you have made this great discovery that those products that are controlled may be less expensive, I say, Whoopie, you are exactly right.

I would like to make a proposal. Do you ever get any Federal grants?

Mr. ANDERSON. I do.

Mr. SHAYS. I want to save the government money. How much do you get paid as a salary?

Mr. ANDERSON. \$175,000.

Mr. SHAYS. I want you to only accept \$50,000. I am going to tell you that is what you get for that grant. I want to save the Federal Government money. But we don't do that, because we want you to have your talents and we want you to have your creativity. But we don't control what you get, at least I don't think we do.

We do it with doctors. That is not negotiation; that is, take it or leave it. They are underpaid; our doctors get less for the service than it costs them, but we act like somehow this is a great program because we have price controls.

Tell me why I shouldn't be grateful that this program costs less than it was supposed to cost, that the seniors who are in it have 9 out of 10—excuse me, 85 percent satisfactory rate—and 9 out of 10 who are part of the dually eligible don't want to go back into the old system nor do the States want them to go back into the old system.

Nobody wants to go back into the old system, But you are using that as a price comparison.

Mr. ANDERSON. First of all, you said the \$400 billion. If you look at Kerry Weems' testimony that he is going to give today and you add up the numbers of the expenditures that are projected, you will see it is \$400 billion. So essentially you talk about a 30 percent reduction; but essentially when you voted on the bill, it was \$400 billion—

Mr. SHAYS. You are talking about a shifting 10-year timeframe. Let's talk about the same numbers we were using when we did it, compare apples to apples.

Mr. ANDERSON. Right, I think that is what we have.

Mr. SHAYS. Sir, you are not.

Mr. ANDERSON. We will take a look at that.

Mr. SHAYS. Dr. Morton, what is your comment?

Ms. MORTON. I just wanted to say that underlying all of this discussion, we should remember that pharmaceuticals are really unusual, because the research and development that was used to produce the drugs we are consuming today occurred 15 or 20 years ago.

So part of the problem is, if you say to a doctor, We are going to reduce your salary from \$200,000 to \$100,000, they can take it or they can drive a taxi. And if they go to drive a taxi, then we have no more doctors left. And that constrains what you do as a body for paying for physicians.

Mr. SHAYS. I know how we can build twice as many bridges. We will just pay the construction workers half the price. But I don't believe in that, and I am for the prevailing wage. But here we have a competitive model that is working.

Ms. MORTON. I am sorry. I just want to say one thing.

So the thing about the drugs is that if I say today, as Congress, I am going to pay half as much as I was paying yesterday, that drug is already invented. It costs a tiny amount to manufacture, so, of course, the drug company is going to sell it at half the price.

Mr. SHAYS. Let me ask you about price controls. I went to California about 15 years ago, and a company was developing something to slow the beginning stages of Alzheimer's. They spent \$800 million.

I checked 2 years later, they had spent about \$200 million more and it failed; they lost \$1 billion. But they told me at the time they wouldn't have spent a darn penny if they had price controls.

And it seems to me this is really a debate on whether we will have price controls or not; that is what it is really about. And I don't buy into price controls. I think what we will have is less discovery. I think we won't have the drugs that we see today.

And if you disagree, either one, tell me why.

Mr. SCHONDELMEYER. First of all, your statement, or the framing of the issue, isn't exactly correct, because price controls were in effect. If you call Medicaid rebates pricing controls, then they were in effect and they did spend the money, and VA price controls were in effect and they did spend the money.

So I find the statement that if price controls were in place, we wouldn't have spent the money to be a little bit specious of an argument, because there were price controls, by your definition.

Mr. SHAYS. Excuse me, you don't believe that when we tell doctors, this is the payment, that is not a price control? Do you really think we negotiate with our doctors?

Mr. SCHONDELMEYER. No, and the same with pharmacists and others in California. The States cut the fees.

Mr. SHAYS. Do you think we negotiate with our doctors, or do you think we basically say, this is it?

Mr. SCHONDELMEYER. No, it is take it or leave it.

Mr. SHAYS. Yes, it is price controls.

Mr. SCHONDELMEYER. But it is different. I would point out, there is not a best-price provision for doctors like there is in the Medicaid State rebate programs, and there are not State supplemental rebates like there are.

So there are some aspects of this that are market based in terms of the prices Medicaid pays. It is not all just to fix, we will only pay this.

Chairman WAXMAN. The gentleman's time has expired.

Ms. Speier.

Ms. SPEIER. Thank you, Mr. Chairman.

This lively debate is interesting to me because I believe that California is a great example. The Medicaid system in California is one in which we have historically negotiated rebates and discounts in the Medicaid system, and they have been healthy discounts. And the pharmaceutical companies have flocked to Califor-

nia because it is a great universe from which to sell their product, and there has been great competition there.

So, I guess my question is—and I would disagree a little bit with what my colleague has just said—if you look at how many dollars are actually spent on R&D, at least historically, the majority of those dollars have come from the taxpayers of this country and NIH grants, if I am not mistaken. So it is the government that funds the lion's share of this research that goes on.

All the other industrialized countries in the world have price controls in effect, and we end up subsidizing the prices of pharmaceuticals in these other countries.

So, I guess my question is, you have spoken a lot about transparency. But in trying to identify which is more important, just lifting the language in the bill that was passed by Congress, it says that the Federal Government can't negotiate.

Isn't that the most important thing we can do in terms of trying to bring the costs of these drugs down?

Mr. ANDERSON. I think it is, in fact, the most important thing, and I would strongly support that as an idea. I mean, it is very close to what the other countries are doing, as you suggest; and I don't understand why we want to be spending twice as much for drugs as other countries are spending.

Mr. SCHONDELMEYER. Also, we can look at both the market and other things that have worked. State supplemental rebates are negotiated and operated by States on behalf of the entire Medicaid program within the State.

Somebody earlier referred to General Motors or large corporations and their behaviors. I don't see General Motors turning over their drug benefit to each local plant and telling each local plant, you go out and negotiate drug prices on your own.

Hey, centralize it and do it centrally.

The equivalent of that in terms of Medicare would be for the Federal Government to use State supplemental rebate negotiation tactics on behalf of all Medicare Part D programs and then pass the benefit on to those local Part D plans out there.

So we see in the private market centralized behavior, large prudent buyer behavior and using the market to work. And I think the government can do that and be a prudent buyer and not be a price regulator, per se.

Ms. MORTON. The problem I see with that is, if Health and Human Services negotiates directly with pharmaceutical companies, it depends on your interpretation of the word "negotiate."

If you are going to say, I am a large buyer, I am the Secretary, I mandate you give me 20 percent less, of course, that is going to work. If you say, I would like you to give me 20 percent less, then the question is, why?

A regular plan says, I want you to give me 20 percent less because I am going to consume your competitor if you don't. I am going to consume drug A if you don't give me a price cut on drug B.

The Secretary presumably wants to include all drugs, doesn't want to tell American seniors, you can only have drug A and you can't have drug B. So if the Secretary can't exclude somebody, then

I don't quite understand how they negotiate a lower price. I understand how they instruct, you will give us a lower price.

Ms. SPEIER. Well, California has a MediCal medical formulary, and drugs get on or off the formulary, and, you know what? They do make those decisions.

Furthermore, these drug companies want to make sure their drug is on the formulary. So it is not like it is so much an exclusion as much as it is, we want to be on your formulary and we will give you this.

Ms. MORTON. Right.

But California Medicaid is excluding some drugs, and the people in California Medicaid are getting this benefit for free, and they don't really have the ability to complain and say, "I would like a choice of all cholesterol drugs," whereas I think seniors and employed people expect to have more choice in their formulary or choice of cost plans.

Ms. SPEIER. I have a mother on 15 drugs right now. She doesn't know which cholesterol-busting drug is the best. She is on three or four of them.

So I think it is kind of—it doesn't make a lot of sense to say that these seniors want these drugs. They tend to want the drug that they have been on, as opposed to wanting some drug. And if we didn't have direct-to-consumer marketing, we would have a whole lot better system in this country to start off with.

Mr. SCOTT MORTON. So suppose you have a national formulary. They have been on drug A all the time; they arrive at Medicare, and the Secretary has negotiated a good price on B, and that is it. The question is, what does the person do at that point?

That is a system we could have. That is what the Government of France does.

Ms. SPEIER. You know what it is called? It is called prior authorization. We have done it in California, and it has worked. For that individual who does better on the drug that is no longer on the formulary, you can still have that drug, it just needs prior authorization.

Frankly, that is what we should be doing on the Federal level. It is not like it hasn't already been done. It is done, it is done effectively, and it saves a lot of money.

Ms. MORTON. And Part D plans do that.

Chairman WAXMAN. The gentlewoman's time has expired.

Mr. Burton.

Mr. BURTON. My first wife, who died 6 years ago, was taking chemotherapy in Indianapolis. And there were two women sitting there next to her, they all had the needle in their arms taking their chemotherapy. And one of the women was saying—she was actually complaining because, she said, My Tamoxifen costs so much, I can't afford it; it is \$325 a month.

And the other lady said, I am getting mine for \$50 a month.

And she says, No, that can't be right. And I am sitting there as a legislator, and I said, No, that can't be right.

And the lady said, No, I am getting it from Canada for with about one-sixth the cost of what it was in America.

I held hearings on this when I was chairman of the committee, and I couldn't figure out why, right at the border between Canada

and the United States, you can go across the border and get the same pharmaceutical product for one-fifth, one-fourth, one-third, one-half. So I started being supportive of a process called reimportation, and that was because I couldn't figure out why Americans should pay more for pharmaceutical products than people in other parts of the world.

I found out, along with my colleagues, that in Spain, France, Germany, all over the world, the price is one-half, one-third, one-fourth, one-fifth or one-sixth of what it is in the United States.

The argument was, well, in the United States we have to do research and development, we have to do advertising and all that other sort of thing.

My problem is, why isn't the rest of the world paying for part of that? Why in the world should the American people have the burden of advertising, research and development and everything, and then pay five or six times what it costs for the same pharmaceutical product someplace else?

So we supported the reimportation program. The pharmaceutical companies went to the FDA and started talking about purity and whether or not there could be tampering and all that sort of thing, and they, in effect, have been able to block reimportation. They have been very effective, so they can protect their margins here and protect their market share. I don't understand that, and I don't think anybody in America who really thinks about it understands that.

We should not be paying more for pharmaceutical products than the rest of the world simply because, you know, we can afford the R&D, and we can afford that and load it on the back of the American people.

So we passed the prescription drug benefit, and we guaranteed in there that there would be no control whatsoever by the Federal Government in the price of the pharmaceutical products that the government is going to be involved in. So they, once again, are able to block and say, It is going to cost a lot more here in America; and they have been successful in blocking pharmaceuticals from the rest of the world.

We can, with the new technologies, guarantee that drugs coming in are the product that we say they are. We can encapsulate them in plastic. We can put microchips or those mini, very small chips in there, to make sure that the product is the same as it is here in the United States, to guarantee the purity and everything. And yet we can't do that. And we can't do that because the pharmaceutical industry wants to keep the prices at a certain level here while they are able to give discounts way, way down the line, much lower costs, in other parts of the world.

I would like for somebody to explain to me why we can't have a process where the pharmaceutical companies can say, OK, since you in the United States are going to make sure you are going to get comparable prices, we are going to go out and negotiate or tell the other countries in the world we are not going to allow you to charge this much less.

I sat down with the president of Eli Lilly, a company in my State. I sat down with people from Merck, vice presidents and presidents. And I said, why don't you come up to the Hill and sit

down with us, Members of Congress, and let's try to negotiate some type of solution to this problem so Americans aren't burdened with a huge price while the rest of the world is getting off relatively scot-free. And they wouldn't do it.

Rather than doing that, they had PhRMA, their organization here in Washington that has tons of lobbyists, some of whom I am sure are here today—they had PhRMA go to the FDA and say, Oh, my gosh, these pharmaceutical products coming in from the rest of the world may not be pure; they may be tampered with, while at the same time they knew full well there were mechanisms we could use to protect those products coming into the country.

In addition, many of the products they are talking about are made in India and other parts of the world and coming in here in bulk anyhow—Viagra being one of them, which is used very widely here in the United States and, I understand in India, which really doesn't need it. It is only costing them about 10 or 12 cents a pill, whereas here, it is costing over \$10.

Anyhow, I would like for you to give me an answer to that problem. Why do Americans pay three, four, five, six times what they are paying in Canada and elsewhere? Why can't we do something about negotiating? And why do we pass a Medicare prescription drug benefit that protects the pharmaceutical companies from negotiation with our government? I mean, it just seems to me there ought to be a question of fairness here.

I want the pharmaceutical industry to make a lot of money. I want them to be very profitable. I am for the free enterprise system. But while I say that, I say, why should Americans bear the burden of all this, while the rest of the world is, in effect, getting off scot-free?

Thank you, Mr. Chairman, for giving me the time.

Chairman WAXMAN. The gentleman's time has expired.

We will give a short opportunity for an answer. I think you answered a question there.

Ms. MORTON. I have a short answer. So, one, I like the way you phrase the question, which is, Why doesn't everybody else pay more?

I mean, we have two choices: One, there is too much R&D, we should pay less, pay the same as France, and we have a new industry that responds to that. Or we think the amount of R&D we want is good right now, or it should be more, in which case everybody else is free riding. They are as rich as we are, and they are not contributing to the cost of R&D.

I think that is a very good question. Designing a regulation to get that to happen, I have some thoughts which I would be happy to share with you. But I think it is quite tricky.

Mr. ANDERSON. Fourteen percent R&D, 30 percent marketing.

Mr. SCHONDELMEYER. And they don't spend as much on marketing in other countries because their systems aren't as open.

Others today have commented, if you do this, if you do that, it will raise prices in the rest of the market. But I would bet most of those people who made that comment weren't talking about prices in the rest of the world.

I think we need to take actions and communicate to drug companies we expect them not only to look at raising prices in the rest

of the U.S. market, but the rest of the world market; and they do need to look at other countries also to get back the money for R&D and to subsidize their development.

I would also point out that the drug that was involved in many cancer drugs was actually discovered by the National Institutes of Health. One of the leading cancer companies that has more products I think on the market than any other company, the last time I looked, 3 or 4 years ago, had about 21 cancer drug entities. And how many of those had that company discovered in their own R&D? Zero. The largest company that sells cancer drugs, at least 3 or 4 years ago, hadn't discovered a one; they had come from Federal Government funding.

Chairman WAXMAN. Thank you, Mr. Burton. Your time has expired.

Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman.

I am always amused when Mr. Burton and I come down on the same side of an issue here. I was sort of hoping that he had made that passionate plea to his caucus a few years back, and maybe we wouldn't be here discussing what we are discussing today.

Look, I think the manufacturers have a hard time justifying the high prices. I think they have gotten a bit of a windfall out of it. But I know one of the arguments we are going to hear back is just what we are talking about right there, that if you do anything about this, research is going to stop and everybody is going to go to hell and die.

So I really want to knock that out of the box right now. It is nonsense and foolishness, as far as I am concerned.

They reported, what, about \$90 billion of profits last year, up \$20 billion previous to that, or whatever, and I don't for a moment think that a change in the price situation here is going to stop them from doing research.

So let me start with Dr. Anderson, if you would. Would reducing the high prices that they are now charging on the Part D program have an impact on the industry's research and development?

Mr. ANDERSON. It is hard to answer that one analytically, but I don't think so.

Mr. TIERNEY. All right.

Dr. Schondelmeyer, what do you think? Can we reduce Part D prices without adversely impact the research?

Mr. SCHONDELMEYER. I think you can certainly go back to the Medicaid prices that you had and not affect research dramatically, because we were there and they were accepting those prices and they were living with that. So I think you can at least go back to that level, without a major effect on the market.

Mr. TIERNEY. Dr. Morton, do you want to weigh in?

Ms. MORTON. I would more or less agree with that, although I will say that a lot of these entities are discovered by venture-capital-funded small firms that are then bought by the larger firms, and anybody who is in venture capital or that kind of finance is investing because they expect a return. So anytime you alter the return, that goes into the calculation of whether they are going to spend money in the biopharma area.

So I don't think you can ever assume no effect. It is just, are we making a small shift of duals? Or are we making a big shift of everyone who's eligible for Medicare?

Mr. TIERNEY. Thank you.

Let me ask you—Dr. Schondelmeyer, you can start on this—what is the difference or what is the variation between how much research is done from government-funded projects versus what the industry does? And which drugs are involved, the more commonly used drugs or the less commonly used drugs, and all of that?

Mr. SCHONDELMEYER. I haven't examined that systematically in recent years, but the evidence seems to suggest that drugs for categories that are most critical, such as cancer, tend to come more from government-funded research, and that drugs that come from the pharmaceutical companies tend to be more the lifestyle drugs, the drugs that—you know, feel good, live-well-type drugs, come from the drug companies that have broader populations.

So the government tends to fund more critical, life-threatening drug discovery and drugs for smaller populations, while the drug companies tend to fund drugs for broader populations and maybe for more symptomatic or feel-good purposes.

Mr. TIERNEY. We have all heard the expression of “me too” drugs out there and the research on that. Do you want to comment on that a little bit?

Mr. SCHONDELMEYER. Well, I would be careful. There is an issue of “me too” drugs; I think it is often misunderstood, too, though.

I do think for a legitimate disease-state category, where there is three or four or five companies in the race to find a drug in that category, among those three, four or five, for whatever reason, whether it is regulatory or company performance, one of them is going to come out first.

I wouldn't say that the other four or five that were legitimately in the race are “me too” drugs because they were in the race. And, in fact, those other drugs could—if our market works, which it doesn't work well—could create competition.

Where “me too's” come in is when the company that first discovered it or other companies 15 years later come out with an extended release dosage form, a right-handed or left-handed molecule, those are “me too” drugs and those are kind of ways of extending patent pricing without adding a whole lot of value to the market in most cases.

Mr. ANDERSON. The NIH would suggest that more money is actually being spent by PhRMA than by NIH right now. We would have to take a look in terms of what it is spending it on.

NIH is much more basic research kinds of things. PhRMA is a lot more drug development kind of things. But I think overall, the numbers from NIH would suggest that PhRMA is spending a little more.

Ms. MORTON. I would second that.

I mean, NIH doesn't do the testing. So you can invent a molecule, but then you have to show that it is safe in thousands and thousands of people and go through the FDA. All of that is actually quite expensive, and NIH doesn't do that.

You can also see why the lifestyle drugs wouldn't be coming out of the government. I mean, I imagine the grant application to NIH for Viagra would not get funded.

Mr. TIERNEY. You have more confidence than I do. I would hope you are right on that.

Thank you, Mr. Chairman. I yield back.

Chairman WAXMAN. Thank you, Mr. Tierney.

Ms. Foxx.

Ms. FOXX. Thank you, Mr. Chairman.

I want to make one brief comment. As I have been sitting here, listening to the comments that you all have been making—and I've made this observation on a couple of other occasions—I grew up in the mountains of North Carolina in the late 1940's, early 1950's, in the poorest county in North Carolina when I was growing up.

My family was extraordinarily poor, yet we could afford health care. Everybody in our county could afford health care. In fact, I didn't know many people who had any kind of really big problems with health care. We had a hospital. We had doctors.

And I have thought a lot about why it was that we could get health care in those days, and we have such a problem now with people, who are much better well off than we were, not getting health care.

My observation is, it is two things: No. 1, government involvement, and I think any time you get the Federal Government involved in just about anything, you get more of a problem than you get a solution; and the other is third-party payer, when people are not in charge, I think you create problems.

I would just say that as a statement, because when I hear people say, get the government more involved, the Federal Government, it is just like scraping a fingernail across a blackboard for me, because I think what you are doing is simply creating more problems.

But I want to ask a question of Dr. Scott first, and then I have a general question.

Do you think that pharmacy benefit managers are sophisticated negotiators on behalf of seniors? We have heard about the problems with getting prices. Tell me what you think about that.

Ms. MORTON. Yes, I think they are sophisticated negotiators. A lot of the Part D plans that have been most successful in the sense of being taken up by many people are run by quite large and sophisticated insurance companies.

Ms. FOXX. Then the other question I have, my understanding is that under Medicare, some drugs are paid for by federally set prices. They are injectable drugs under Part B. I would ask each member of the panel—and I know we have a limited time—do we set the prices for those drugs well? What is the history of the Federal Government setting those prices? My understanding is that there is a mixed history there; sometimes we have done well, sometimes we have done poorly.

Relate that to what you are recommending now. Those are the folks on the upper end of the panel who are recommending that primarily.

Mr. SCHONDELMEYER. First, I would comment on, Are PBMs a sophisticated buyer? They are, but they don't have a fiduciary responsibility to act on behalf of the recipient. They act on behalf of

their own stockholders and corporate entities, and those are different financial decisions that they make. So they are very sophisticated at taking care of themselves and meeting the requirements that are made of them for the recipients, but not acting in the best financial interest of the recipients.

I would also bet that hospital you had in your area was government subsidized under the Phil Burton program—

Ms. FOXX. No. Well, it may have gotten some, but it was primarily supported by the people who used it.

Would you mind answering the question I asked you to answer?

Mr. SCHONDELMEYER. Yes. And what was that question? Remind me.

Mr. ANDERSON. Let me answer. I will get it.

Basically, if you take a look the Medicare program, the seniors in 1964, only about half of them had health insurance after Medicare. The other half got—

Ms. FOXX. You have just made my point.

Mr. ANDERSON. I did? I thought you said that everybody had coverage.

Ms. FOXX. I just said I think what created the problems with our not being able to get health care is third-party payer and the involvement of the government.

Mr. ANDERSON. Well, I would disagree.

Ms. FOXX. Do you mind answering the question I asked?

Mr. ANDERSON. On the Part B thing, sure, essentially there was a problem with Part B drugs, that they were essentially giving serious discounts to doctors, but the Medicare program did not know those serious discounts, did not have price transparency, did not know that.

Part of the Medicare Modernization Act of 2003, hopefully, with the average sales price, solved that problem, and now the discounts are less.

So I think the Medicare program can learn and solve the problems.

Ms. FOXX. What kind of learning curve is there for the people in the program?

Mr. SCHONDELMEYER. Well, I would answer your first question about the ASP and the government buying.

First of all, Medicare Part B is a very different market. It is primarily through physicians and a totally different distribution system, and there were incentives for doctors to actually prescribe more higher-priced drugs.

I would argue, though, similar incentives are in place in the Medicare Part D program for the very reasons I stated. There is no fiduciary responsibility on behalf of PBMs, and they can make more money by negotiating rebates from drug companies, but not passing it on in lower costs to the recipients.

So I think the problems we had and the learning curve we have hasn't really stuck in Medicare Part D.

Chairman WAXMAN. Mrs. Foxx, your time has expired.

Ms. FOXX. Thank you.

I would like to say for Federal bureaucrats, there is no fiduciary responsibility either.

Chairman WAXMAN. The last word.

I want to thank the three of you very much for your participation. I think that all the members on the committee and all the people in the audience should get college credit for this discussion. It was a very high-level one, and I think a very worthwhile one. Certainly you have been helpful to us.

Mr. DAVIS OF VIRGINIA. Let me just add to that and thank our panel. It has been very informative.

Chairman WAXMAN. Our next witness is Mr. Kerry Weems. He is Acting Administrator for the Center for Medicare and Medicaid Services, Department of Health and Human Services. I would like to ask him to come forward.

Before you even sit down, it is the policy of this committee that all witnesses testify under oath. So if you would please raise your hand.

[Witness sworn.]

Chairman WAXMAN. The record will show that the witness answered in the affirmative.

We have your prepared statement and it will be part of the record in its entirety. What we would like to ask you to do is try to stay within 5 minutes for your oral presentation.

I think you know the routine; it is green, 4 minutes; yellow for 1 minute, and when it is red, we would like you to certainly conclude.

Thank you for being here.

**STATEMENT OF KERRY WEEMS, ACTING ADMINISTRATOR,
CENTER FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. WEEMS. Thank you, Mr. Chairman, and thank you, distinguished members of the committee. It is a pleasure to appear before you today.

The success of the Medicare prescription drug benefit provides strong evidence that competition through private plans has contributed significantly to lowering costs to both the government and beneficiaries. Through Part D, Medicare beneficiaries are extremely satisfied with their current prescription drug coverage and have been given meaningful choices for drug coverage at a cost much lower than originally estimated.

Experience with Part D thus far demonstrates that competition is working for beneficiaries and taxpayers alike. According to the fiscal year 2009 President's budget, the necessary cost of the Medicare Part D program is 40 percent lower than the projections at the time the bill was passed, and beneficiaries are reaping these savings.

Independent surveys have consistently shown that more than 85 percent of Medicare beneficiaries and nearly 9 out of 10 dual eligibles are satisfied with their Part D coverage. High satisfaction rates are directly related to the other successes in the Part D program, including meaningful and affordable choices, unprecedented information and transparency for beneficiaries, lower-than-projected costs from effective private sector negotiation, and increased generic utilization.

With the overwhelming success and popularity of Medicare's Part D benefit, we should be vigilant against attempts to use govern-

ment mechanisms to intervene in the market and move to administered government pricing.

When Congress enacted Part D, the decision was made to move dual eligibles to Part D, which offered the dignity of choice and a market-based approach to the drug benefit structure and pricing. congressional research agencies like CBO and GAO widely agree that direct government negotiation of prescription drug pricing in Part D is unlikely to lead to lower costs. As the chart demonstrates, simply comparing Medicaid's rebates to Medicare does not capture all the other efficiencies and savings achieved through Part D by encouraged use of generic, lower-cost drugs, lower-cost sharing opportunities for copayments and coinsurance.

What is more, through drug utilization management, Part D has improved health outcomes by reducing the possibility of adverse drug events.

The record from implementation of mandatory price controls and rebates in Medicaid reveals that these price-setting policies have the potential to increase costs in the private sector and others not subject to the government-imposed price controls.

CBO examined the implementation of the Medicaid drug rebates on the market and found that, while access to rebates lowered Medicaid's outpatient drug expenditures, spending on prescription drugs by non-Medicaid patients may have increased as a result of the Medicaid rebate program. Further, GAO found that in the first 2 years of the Medicaid drug pricing program, the average price for medicines purchased by HMOs and Group Purchasing Organizations increased.

With Medicare beneficiaries accounting for nearly 40 percent of prescription drug spending in the United States, it is not at all unreasonable to expect that a change from market pricing in Part D to a government-mandated rebate structure could have an even stronger ripple effect on the cost of prescription drugs for those not subject to government-imposed price controls.

With a combination of more than 50 percent of the market subject to a statutorily dictated pricing structure, these two Federal programs could eliminate the potential rebates for any other purchasers. More specifically, it could lead to higher prices at the pharmacy, may compromise incentives to move enrollees toward low-cost therapeutic equivalents or generic drugs, or may undermine utilization management activities that the participating plans use for important safety protections as well as cost controls.

The Part D Program has been successful beyond expectations even in its infancy. Beneficiaries have meaningful choices for drug coverage at a cost that is much lower than estimated; and, more importantly, they are satisfied with their coverage.

Thank you for the opportunity to appear before you today. I look forward to your questions.

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

[The prepared statement of Mr. Weems follows.]

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STATEMENT OF
KERRY WEEMS
ACTING ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
ON
THE MEDICARE DRUG BENEFIT:
ARE PRIVATE INSURERS GETTING GOOD DISCOUNTS FOR
THE TAXPAYER?
BEFORE THE
HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

July 24, 2008

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

**Testimony of
Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Before the
House Committee on Oversight and Government Reform
On
“The Medicare Drug Benefit:
Are Private Insurers Getting Good Discounts for the Taxpayer?”**

July 24, 2008

Good morning Chairman Waxman and distinguished members of the Committee. I am pleased to be here today to discuss the Medicare prescription drug benefit (Part D) and in particular, how we can ensure that people with Medicare continue to get the prescription drugs they need and the choices they have come to expect at the lowest possible price. The success to date of the Medicare prescription drug benefit provides strong evidence that competition among private plans has contributed significantly to lowering both government and beneficiary costs compared to what was originally estimated. Many Part D enrollees including “dual eligibles” – those entitled to Medicare as well as full Medicaid benefits – are experiencing added value through their Part D coverage in the form of effective, safety-promoting medication management programs.

In my testimony today I will highlight the key successes to date of Medicare Part D, including taxpayer and beneficiary costs that are significantly lower than originally projected. I will also discuss some of the fundamental differences between Medicare Part D and the prescription drug coverage available through Medicaid, including the potential impact of applying Medicaid’s statutory drug rebate structure to all or a portion of the Part D benefit.

Part D Successes

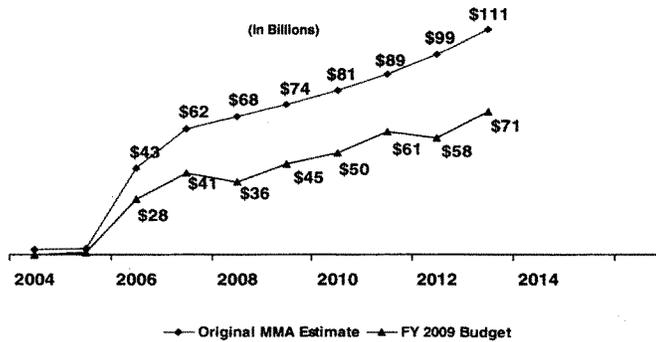
More than 25 million beneficiaries have Part D prescription drug coverage in 2008 through a Prescription Drug Plan (PDP) or a Medicare Advantage Prescription Drug Plan (MA-PD). Medicare beneficiaries are filling 100 million prescriptions a month under Part D. The program has been and continues to be a success on a variety of measures.

⇒ Lower than Projected Costs

Experience with Part D thus far demonstrates that competition is working for beneficiaries and taxpayers alike. Part D has proven to be far less costly to the government than originally projected. According to the Fiscal Year (FY) 2009 President’s Budget, the net Medicare cost of Part D is almost 40 percent (about 38.5 percent or \$243.7 billion) lower over the ten year period 2004-2013 compared to the original Medicare Prescription Drug, Improvement, and Modernization Act (MMA) projection for that same period.

**Total Projected Spending Under Part D,
A Comparison of Original MMA and FY Budget 2009 Estimates**

Total spending under Medicare Part D is projected to be 38.5 percent lower than previously estimated.



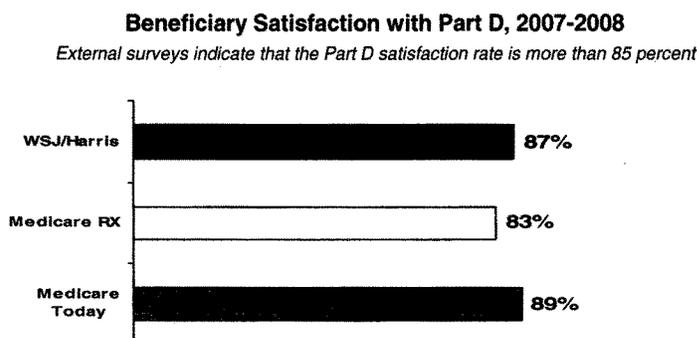
Data are from the original MMA estimate and FY 2009 President’s Budget
Source: Office of the Actuary, CMS.

Roughly 29 percent (or 11.3 percentage points) of this decrease can be attributed to greater-than-expected effects of cost management, which is largely the result of competition.

Beneficiaries also are reaping these savings. In 2008, the average monthly premium for available standard coverage is \$25.¹ While this is an increase over 2007 levels, when the average premium was \$22, it is still about 40 percent lower than was originally estimated for 2008.

⇒ High Beneficiary Satisfaction

Independent surveys have consistently shown that more than 85 percent of Medicare beneficiaries are satisfied with their Part D coverage.²



Individuals like being able to choose a plan that best meets their unique health care needs. A single, one-size-fits-all drug plan would have limited the ability of beneficiaries to address

¹ These figures are calculated based on plan bid submissions and do not reflect beneficiaries' actual enrollment choices.

² Source: Wall Street Journal/Harris Poll (January 2008), Medicare Today Survey (October 2007), Medicare Rx Network (November 2007), CMS Internal Survey (January 2008).

their own health needs. Congress did create a defined “standard plan” with the MMA; however just 15 percent of enrollees have selected that defined standard benefit for 2008. Most beneficiaries opt instead for plans with lower premiums, no deductibles, and enhancements such as coverage for generics within the coverage gap.

Enrollees are satisfied with the plans they are choosing. While Part D was already popular in its initial year with several independent surveys showing 75 percent or higher satisfaction rates,³ follow-up surveys by Medicare Today in the fall of 2007 showed growth of more than 10 percent in satisfaction rates among beneficiaries, as compared with their satisfaction at the initial implementation of the benefit.⁴ In this same survey,⁵ overwhelming majorities of enrollees gave Part D high ratings along a number of dimensions: 94 percent said the plan is convenient to use; 92 percent said they understand how the plan works; 91 percent said the plan has good customer service; and 86 percent said the co-pays are affordable. In addition, more than 9 out of 10 dual-eligible enrollees are satisfied with their coverage.⁶

⇒ *Meaningful and Affordable Choices*

In 2008, beneficiaries have continued to have meaningful and affordable prescription drug plan choices that best meet their unique health care needs. More than 90 percent of Medicare beneficiaries in a stand-alone PDP had access to at least one plan in 2008 with premiums

³ Sources: (1) J.D. Power and Associates *2006 Medicare Part D Beneficiary Satisfaction Study*, September 2006. (2) WSJ Online/Harris Interactive Health-Care Poll, conducted by Harris Interactive® between October 27 and 31, 2006 for The Wall Street Journal Online’s Health Industry Edition (www.wsj.com/health). (3) AHIP Survey: *Tracking Seniors Who Self-Enrolled in the Medicare Prescription Drug Benefit*, September 2006. (4) Kaiser Family Foundation. *Seniors’ Early Experiences with Their Medicare Drug Plans*, June 2006.

⁴ Source: *Seniors Impressions about Medicare Part Rx: Second Year Update*, Medicare Today Survey, October 2007. <http://www.medicaretoday.org/>.

⁵ Ibid.

⁶ Ibid.

equal to or lower than what they paid in 2007.⁷ In addition, in every state, beneficiaries had access to at least one PDP with premiums of less than \$20 a month, and a choice of at least five plans with premiums below \$25 a month. The total number of zero deductible plans for 2008 increased from 2,933 in 2007 to 3,308. During open-enrollment, beneficiaries in any state could have selected a plan with coverage in the gap for generic drugs for under \$50 a month.⁸ These high-value choices were offered without significant compromises to covered drugs: Part D sponsors' 2008 formularies remain relatively unchanged in comparison to 2007 formularies. In fact, on average, sponsors' 2008 formularies cover approximately 2 percent more distinct FDA-approved pharmaceuticals in comparison to 2007 formularies.

⇒ *Unprecedented Beneficiary Support Information*

With a high value placed on beneficiary choice, the Centers for Medicare & Medicaid Services (CMS) developed or enhanced an unprecedented network of support to ensure people with Medicare and their loved ones have access to the information they need to select the plan that serves their health care needs best. Information is available online, in print, via toll-free phone support, or in-person through more than 900 partners across the country including State Health Insurance Assistance Programs, local Area Agencies on Aging, pharmacies, membership organizations, and countless other community partners.

Beneficiaries have taken full advantage of these information centers. Throughout the 2008 open-enrollment period (November 15, 2007 – December 31, 2007), 1-800-MEDICARE

⁷ HHS Press Release, *HHS Announces More Than 90 Percent Of Medicare Beneficiaries Will Have Access To A Lower Premium Drug Plan in 2008*, September 27, 2007.

⁸ *Ibid.*

received roughly 4.1 million calls.⁹ More than 3,000 customer service representatives were available in seven call centers across the United States to help people in English or Spanish.

The web-based Medicare Prescription Drug Plan Finder, which offers beneficiaries comprehensive premium, pricing, benefit structure and quality information online, also has been a great success with beneficiaries. During the plan year 2008 open enrollment, the Plan Finder had more than 24 million page views. Even outside of open enrollment periods, the Plan Finder leads many other online tools available through www.medicare.gov, with a typical utilization level of 850,000 views per week. In contrast, other CMS websites like Nursing Home Compare receives 400,000 views per week and the participating physician directory receives 300,000 views per week.

⇒ *Effective Price Negotiation*

At the time of enactment, Medicare analysts thought Part D plans would take several years to attain 25 percent reductions in drug prices compared to retail price levels from price discounts, manufacturer rebates, and utilization management. Those savings in fact occurred faster than originally forecast. CMS actuaries now estimate that Part D plans are achieving 29 percent savings off of Average Wholesale Price (AWP) through a combination of price discounts (22 percent) and rebates from manufacturers (7 percent). The average 22 percent discount has been corroborated by a CMS contractor, which found that the average discount off of AWP for certain Part D plans was 15 percent for brand-name products and 45 percent

⁹ Source: CMS Press Release, *Medicare Prescription Drug Benefits Projected Costs Continue to Drop; Part D Attracts New Beneficiaries and Achieves High Rates of Satisfaction*, January 31, 2008.

for generics. These price discounts are generally deeper than the average point of sale discounts in the Medicaid program.

Moreover, prices for Part D-covered drugs have been stable. Since the beginning of 2007, CMS has been tracking price stability in Part D plans using a broad index. The number of unique drug products tracked ranges from 939 to 3,291 per plan. The results of the most recent submission from September 2007 indicate that the vast majority of enrollees (73 percent) were in plans where the price index did not increase more than 3 percent. In fact, 50 percent of enrollees were in plans where the price index did not increase more than 2 percent. Fourteen percent of enrollees were in plans where the price index actually decreased. Of course, all beneficiaries can also protect themselves under Part D from the impact of some changes in drug prices throughout the year by selecting a plan where cost-sharing is based on fixed co-payments rather than coinsurance for all preferred drugs. For 2008, 95 percent of enrollees (including LIS beneficiaries) have done exactly that.

⇒ *Increased Generic Utilization*

The Part D benefit structure is helping to drive increases in generic utilization among beneficiaries, which is an important factor contributing to the lower cost of the program. The Part D generic dispensing rate for calendar year 2007 was 64.1 percent, up from roughly 60 percent for the third quarter of 2006. Greater use of generics helps beneficiaries achieve significant savings while also maintaining high quality care and reducing health care costs overall.

Potential Impact of Importing Medicaid's Rebate Structure into Part D

Despite the overwhelming success and popularity of Medicare's Part D benefit, some continue to look for ways to re-invent the wheel. When Congress enacted Part D, the decision was made to move dual eligibles to Part D, which offered a market-based approach to drug benefit structure and pricing. As noted previously, surveys show that more than 9 out of 10 dual-eligible enrollees are satisfied with their Part D coverage.¹⁰

The Administration opposed last year's attempts to call upon the Federal government to negotiate and set the prices of Part D-covered drugs; we would be similarly concerned about suggestions that Medicaid's drug pricing system should be imported to Medicare. This proposal is based on the same misconception that government price-setting can do a better job of satisfying beneficiaries and lowering prices than a competitive marketplace.

Prescription drugs provided through fee-for-service Medicaid rely on a statutorily mandated rebate structure (drugs provided through Medicaid managed care plans do not receive these rebates). In order to have their products covered by the Medicaid program, drug manufacturers must enter into a rebate agreement with CMS. This rebate agreement requires pharmaceutical manufacturers to provide a rebate to the Federal and State governments for all drugs dispensed to Medicaid beneficiaries. For brand name drugs, the rebate program requires a base rebate that is based on a statutorily-mandated discount equal to the greater of 15.1 percent of average manufacture price (AMP) or the difference between AMP and the best price given to any other plan or pharmacy benefit manager. An additional rebate is

¹⁰ Source: *Seniors Impressions about Medicare Part Rx: Second Year Update*, Medicare Today Survey, October 2007. <http://www.medicaretoday.org/>.

required if AMP increases faster than inflation. For generic drugs dispensed to beneficiaries, Medicaid receives a mandatory rebate of 11 percent of AMP.

It is questionable whether applying Medicaid's rebates to Medicare would result in better value for Part D enrollees. In a June 2005 paper, the Congressional Budget Office (CBO) said that the average basic Medicaid rebate on brand drugs was 22 percent of AMP.¹¹ This would make the rebate larger than a Part D plan's liability in the catastrophic portion of the Part D benefit, and having a rebate larger than a plan's liability could seriously distort the incentive in the Part D benefit structure for plans to manage costs in the catastrophic portion of the benefit. Given enrollee liability for drugs in the coverage gap, plans would have perverse incentives to manage costs only in the initial coverage period.

Furthermore, simply comparing Medicaid's rebates to Medicare does not capture all of the other efficiencies and savings achieved by Part D through encouraged use of generics and lower-cost drugs, cost-sharing opportunities for co-payments and coinsurance, and improved health care outcomes. Part D and fee-for-service Medicaid are inherently different structures with different purposes and different premises.

Part D, like Medicaid managed care, places high value on beneficiary choice and variable formularies so that each individual can select from a wide range of plans and find the one best suited to his or her needs. Part D was designed to strike a balance between the need for an outpatient prescription drug benefit in Medicare and the difficult fiscal challenges presented

¹¹ Source: Congressional Budget Office: *Prices for Brand-Name Drugs Under Selected Federal Programs*, CBO Paper (June 2005), p. 19. <http://www.cbo.gov/doc.cfm?index=6481>

by financing that benefit for the long-term. Part D was deliberately designed to complement rather than crowd-out existing employer and retiree private coverage.

While focusing only on rebates at the exclusion of the core premises of Part D and other savings mechanisms may make a statutory rebate structure for Medicare seem appealing, such a structure could have far-reaching and significant impacts in both the Medicare program and the broader health care marketplace. The record from implementation of mandatory price controls and rebates in the Medicaid program reveals that these price-setting policies have the potential to disrupt the delivery of health care, increase costs in the private sector,¹² and discourage employers from continuing to provide prescription drug coverage at the levels they do today.

The Congressional Research Service and Government Accountability Office (GAO) have each concluded that artificially forcing Medicare drug prices lower -- whether through direct price negotiation or a statutorily-set rebate system such as Medicaid -- could cause manufacturers to increase prices for other payers and consumers in order to offset revenue lost from Medicare.¹³

¹² Sources: (1) Congressional Budget Office: *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, CBO Paper (January 1996), <http://www.cbo.gov/ftpdocs/47xx/doc4750/1996Doc20.pdf>; (2) Congressional Budget Office: *The Rebate Medicaid Receives on Brand-Name Prescription Drugs*, CBO Paper (June 2005).

¹³ Sources: (1) Congressional Budget Office: *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, CBO Paper (January 1996); (2) "Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals," <http://archive.gao.gov/t2pbat2/152225.pdf>; and (3) Congressional Research Service, "Federal Drug Price Negotiation: Implications for Medicare Part D" http://www.law.fsu.edu/gpc2007/CongResServCRSRL33782_MedicarePrice%20Negotiation.pdf.

Furthermore, shortly after the Medicaid drug rebate program was first implemented, CBO examined its impact on other purchasers in the health care market and found that while access to rebates lowered Medicaid's outpatient prescription drug expenditures, it may have also increased spending on prescription drugs by non-Medicaid purchasers.¹⁴ CBO also noted that Medicaid rebates could raise the launch prices of new pharmaceuticals. Additionally, GAO found that in the first two years of the Medicaid drug rebate program, the average best price for the outpatient drugs purchased by HMOs and Group Purchasing Organizations increased.¹⁵ CBO affirmed these findings again in 2005.¹⁶

As a result, the President's Budget for the last two years has included proposals to eliminate "best price" from the Medicaid rebate calculation and create a revenue-neutral rebate to encourage drug manufacturers to offer competitive drug prices. Rather than moving the Medicaid rebate's floor-setting structure to Medicare, the Administration has sought to make the Medicaid drug price structure more market-driven.

With Medicare beneficiaries accounting for nearly 40 percent of prescription drug spending in the United States¹⁷ (as compared to the 10-15 percent market share for Medicaid beneficiaries¹⁸), it is not at all unreasonable to expect that a change from market-driven pricing in Part D to a statutory rebate structure like Medicaid's could have an even stronger

¹⁴ Congressional Budget Office: *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, CBO Paper (January 1996).

¹⁵ "Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals," <http://archive.gao.gov/t2pbat2/152225.pdf>

¹⁶ Congressional Budget Office: *The Rebate Medicaid Receives on Brand-Name Prescription Drugs*, CBO Paper (June 2005).

¹⁷ Congressional Budget Office: *Issues in Designing a Prescription Drug Benefit for Medicare*, CBO Paper (October 2002), p. 11. <http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf>

¹⁸ Congressional Budget Office: *The Rebate Medicaid Receives on Brand-Name Prescription Drugs*, CBO Paper (June 2005).

ripple effect on the cost of prescription drugs for other payers and consumers. If a combined total of more than 50 percent of the market became subject to a statutorily-dictated pricing structure, these two Federal programs could eliminate the potential for rebates to any other purchaser – including those who deliver health care benefits to working Americans, veterans, and to those who pay cash at retail for their prescription needs.

This approach could also have negative consequences for Part D beneficiaries. It could lead to higher prices at the pharmacy, as manufacturers may respond by increasing prices to wholesale. These potential increases could be passed onto pharmacies and potentially beneficiaries at the point of sale. This is of particular importance to beneficiaries in the deductible and coverage gap portion of the Part D benefit. Other potential unintended impacts may compromise incentives to move enrollees toward low-cost therapeutic equivalent or generic drugs, or may undermine utilization management activities that plans use for important safety protections as well as cost control.

Conclusion

Based on a wide variety of metrics, the Part D program has been successful beyond expectations even in its infancy. Beneficiaries have meaningful choices for drug coverage at a cost that is much lower than originally estimated. CMS is concerned that efforts to adopt Medicaid's rebate structure or any other form of government price-control for Medicare Part D would undermine these important successes and could have far-reaching impacts in the health care market beyond the Federal sector.

Thank you again for the opportunity to speak with you today. I look forward to answering your questions.

Chairman WAXMAN. Without objection—I think we’ve discussed this with the minority—we want to do an initial 10 minutes on each side, 10 controlled by the Chair and 10 controlled by Mr. Davis. And without objection, that will be ordered.

I want to start off my questions with you.

Mr. Weems, we are here today because we want to know whether we can make the Part D program work better for the taxpayers. You testified that the program is highly successful. You told us that beneficiaries are satisfied with the program. They have affordable choices, and they have good information with which to make choices and that they have greater, better access to generic medicines. If that is true, it is good news. And to be honest, after we have spent almost \$100 billion on this program, I would hope that would be the case.

The issue for us is whether the taxpayers are getting the best value for their \$100 billion, and that is why the findings of the report released this morning are so troubling. The report finds that the prices paid by Part D insurers for the 100 drugs most used by dual eligibles are a lot higher than the prices Medicaid pays. On average, Medicare Part D is paying 30 percent more.

Mr. Weems, the central finding of the report is that Medicare Part D is paying significantly higher prices for drugs than Medicaid. Do you agree with this finding?

Mr. WEEMS. Mr. Chairman, I had the opportunity to be briefed on your report; and I appreciate the opportunity for that. I have not had the opportunity to examine it in depth, but I would find that, for those particular drugs, that a government-enforced price-setting system likely can produce lower prices, but that does not take into account the cost that may spread through the rest of the system. Yes, the prices may be lower in a government-administered pricing system, but, as a result, they may be higher in the Federal employees benefits. So I would say that we would need to perform the rest of the analysis to see where those costs flow to.

Chairman WAXMAN. Well, we had the Medicaid system in place for 10 years with pharmaceutical rebates. Do you know that—if there is any evidence to show that there was a flow throughout the whole system of higher drug prices?

Mr. WEEMS. Yes. We have evidence that suggests that, yes, costs were higher in the private sector as a result and also that there was a—

Chairman WAXMAN. Can you say that those higher prices were attributed to the Medicaid payment? Or are drugs getting higher every year?

Mr. WEEMS. Well, I believe there is research that attributes to that, and it is also no accident that the amount of rebates that were available under the best price began to go away under under the—in the private sector.

Chairman WAXMAN. We have looked at all the research on this subject, and we can’t find any studies that substantiate your position. So we would like you to submit that to us for the record.

You’re in charge of Part D; and what we see is that, according to this report, taxpayers paid more than \$3.7 billion over the first 2 years of the program as a result of the dual eligibles not being

given the Medicaid price and now going to the Medicare price. Does that concern you?

Mr. WEEMS. Again, I think the analysis may be incomplete. It may be that the prices were—you know, there could be a lower price there, but it is also likely that those prices would have shown up higher someplace else, probably in the non-dual part of the Part D program.

Chairman WAXMAN. You have emphasized that Medicare Part D is costing less than projected—

Mr. WEEMS. Yes.

Chairman WAXMAN [continuing]. And that is true. But the biggest reason the costs are less is that fewer seniors have enrolled than projected. It is obvious that if Part D is serving fewer seniors, it's costs are going to be lower.

On the central issue of drug prices, Part D is overpaying. Before January 2006, the 6 million dual-eligible beneficiaries were getting their drugs through Medicaid. After January 1, 2006, they started getting their drugs through Medicare Part D. The only thing that changed is how much the taxpayers have to pay for these drugs. The cost for just 100 popular drugs increased by \$3.7 billion. That is indisputable.

Are you putting the interest of the big drug companies ahead of the interests of the taxpayers when your concern is not for the extra costs that we are actually paying for these very same beneficiaries?

Mr. WEEMS. Let me dispute one of your premises, if I might, that the only thing that changed was that the price changed. No, something else changed; and that is that the beneficiaries were moved from a State-run, price-fixing program—in some cases, of States with restricted quantities—into a risk-based insurance product, where they have in many cases, even for the low income, the dignity of choice, which they didn't have in Medicaid, broader access to more drugs and no limits on the—

Chairman WAXMAN. That depends on what plan they joined. Because the plans could restrict the drugs' formulary.

But the Medicaid rebate program, which I helped design—I was around when we adopted it. It is all voluntary. The drug company didn't have to participate. And the drug companies participated on the basis that we would demand the best price for them that they were charging others in exchange for adding all their drugs on the formulary. So the companies benefited by making sure that all their drugs could be available to Medicaid patients.

This wasn't a fixed price or price fixing. It was a negotiation by the government for a lower price for that population. Now we have no negotiation; and, as a result, I believe, we are seeing higher prices. We are definitely paying higher prices. Would you say it is because we don't negotiate it any longer? Is it because we don't have the Medicaid reimbursement formulary that—for that same population for those same drugs?

Mr. WEEMS. Again, I would say there is only half the analysis; and that is the analysis that, you know, the States pay. You can look at the—you know, the price that is mandated by the rebate. The analysis that needs to be complete is what happens on the other side of the equation, the market equation, when—press down

prices here, they are going to go up someplace else. The Federal employees benefit program, private insurer, we've seen it happen.

Chairman WAXMAN. We'd have to see if that is the case. I'm looking forward to see what documentation you have for that.

If we had lower prices in the United States, it would probably lead to higher prices in the other countries. Should we worry about that?

It just seems to me that for the dual eligibles that we actually provided drugs to under the Medicaid program at a lower cost and we are now paying for that same population at a much higher cost and for that group we are paying a lot more money. I don't think—I don't see what we're getting for that extra money.

Mr. WEEMS. If we were to—let's take one of the suggestions that one of the academics made here. And that is if we were to take that dual-eligible population and apply the rebate, the Medicaid rebate, to that population, the most likely initial result would be an increase in Part D for everybody else who is not dually insured. Is that, you know, the consequence that we would like to have? Is, you know, a secular increase in Part D that then spread beyond Part D and other parts of private market?

Chairman WAXMAN. I don't believe that would be an accurate statement of what would happen. I think the drug companies are trying to maximize the amount they can get for their drugs; and if you provide more money for their drugs, they are going to be happy to take it. So I don't see evidence for that statement.

I'm going to reserve the balance of my time, which is 1 minute and 37 seconds and yield to—now 10 minutes to Mr. Davis.

Mr. DAVIS OF VIRGINIA. We just have a fundamental disagreement between us over if you reduce costs in one area, does it raise costs in other areas. Somehow I think the chairman and advocates on that side think that this just comes out of the drug companies' hides and that is the end of it and it has no effect on research and development or anything else. And I don't think that is borne out.

The majority staff report found that Part D rebates are smaller than Medicaid rebates. You're not surprised by that finding, are you?

Mr. WEEMS. Not at all.

Mr. DAVIS OF VIRGINIA. Is this new information?

Mr. WEEMS. No.

Mr. DAVIS OF VIRGINIA. In Congress, we often lobby to change reimbursement for different services covered by Medicare or to expand those services all from political perspectives. The drug company or somebody could be—or a manufacturer could be from your district and there is pressure to slip this in here or slip this in there or expand services to one needy group over another.

At CMS, we are tasked with creating a national formulary or setting prices. Do you think the process would be open to meddling by Congress by disease advocates and drug manufacturers?

Mr. WEEMS. Absolutely. And, you know, we can see the evidence of this. You know, if you look at the mail that CMS receives, we receive virtually no mail—I don't think I'm in a position to say zero—but virtually no mail about the price of specific drugs under Part D. We receive huge volumes of mail about those drugs for

which we do administer pricing under Part D. A lot of mail, a lot of pressure and, in some cases, there is even legislated prices—

Mr. DAVIS OF VIRGINIA. When you say mail, are you talking about mail from Members of Congress?

Mr. WEEMS. Members of Congress, manufacturers, lobbying organizations, you name it. We receive virtually none of that under Part D. One of the great success stories of Part D is it has depoliticized the price of individual drugs.

Mr. DAVIS OF VIRGINIA. What would be—is that one of the reasons, you think, that the costs that were projected originally are far and above what has actually taken place?

Mr. WEEMS. That and the effects of competition.

Mr. DAVIS OF VIRGINIA. I mean, there is a fundamental difference, that some of us believe competition brings down costs, some of us think that the government is smart enough to be able to just negotiate the best cost because of our buying power. In fact, there are some formularies that have greater potential buying power than the Federal Government.

Mr. WEEMS. The PBMs, the prescription benefit managers, the ones that the Part D program use, represent about 240 lives across the Nation. So that is real buying power.

Mr. DAVIS OF VIRGINIA. If CMS—we talk about we are tasked with creating a national formulary, setting prices. What impact could that have on seniors in Part D?

Mr. WEEMS. If it is a highly restrictive formulary, it might mean that they don't get the drugs that they need.

Mr. DAVIS OF VIRGINIA. Mr. Weems, you have been a career employee, haven't you?

Mr. WEEMS. I am a career employee, sir.

Mr. DAVIS. So you are a career employee on there. You weren't some administration lackey or anything else that they were able to take because you had given contributions to a campaign or been active in political causes, right? You're a career employee, and you have worked at this all your life?

Mr. WEEMS. I started my career in 1983 as a junior budget analyst with the Social Security Administration.

Mr. DAVIS OF VIRGINIA. How does the financial outlook for Medicare Part D compare to the Part A program which covers hospital care?

Mr. WEEMS. They are financed entirely differently. Part A is financed by FICA taxes. Part D is financed by premiums and by general fund transfers. So the financing schemes are different.

Part A, because of its financing schemes and because of the rising costs in Part A, is going to go broke in 11 years, according to the trustee's report.

Mr. DAVIS OF VIRGINIA. And you concur with that from your observations?

Mr. WEEMS. I do.

Mr. DAVIS OF VIRGINIA. And Part D?

Mr. WEEMS. Part D is financed, as I said, from—it is financed entirely differently, and so it is not subject to the same sort of constraint that the Part A is.

Mr. DAVIS OF VIRGINIA. But, in fact, the projections on Part D, are they greater or less than were projected in terms of the costs to the government?

Mr. WEEMS. In fact, you can see the original cost estimate is the upper line.

Mr. DAVIS OF VIRGINIA. That is the third chart over?

Mr. WEEMS. That is the third chart over. The lower line is the most recent cost from the President's budget, most recent cost estimates.

Mr. DAVIS OF VIRGINIA. So Part A has basically been overruns and Part D has been underruns in terms of—

Mr. WEEMS. Again, Part A—in fact, this year in Part A, the expenditures of—in Part A will exceed what we take in in taxes for Part A.

Mr. DAVIS OF VIRGINIA. Now, in the previous panel we heard—I think it was Dr. Anderson testified that all Federal prices for prescription drugs should be uniform. Outside of prescription drugs, does Medicare, Medicaid, the VA and FEHBP pay uniform prices for health care services?

Mr. WEEMS. No, they don't. Not as a matter of policy. There might be times when they—

Mr. DAVIS OF VIRGINIA. Coincidentally.

Mr. WEEMS. Yeah, by coincidence.

Mr. DAVIS OF VIRGINIA. How do you think an effort to make prices uniform across these programs to the lowest denominator would be received by physicians or hospitals?

Mr. WEEMS. Well, you know, Mr. Davis, it is an interesting question. And the question—the answer to that question depends on your philosophy.

If you were to do it through competitive means, you would allocate resources correctly. If you were to turn it over to CMS with my very well-meaning Federal employees who fix prices every day for A and B, we likely would not get it right.

Mr. DAVIS OF VIRGINIA. There is sufficient evidence that Medicaid price controls increase prescription drug prices to private payers, which in the United States are generally employers. These are like GM and Ford who are competing in a global marketplace. Although we may get a reduction for Medicaid recipients, in effect, I think there is evidence that drives up the costs to these companies that has an effect downstream in terms of their ability to compete.

GM and Ford have both cited higher health care costs as one of the factors affecting their decline in global competitiveness. What do you think would be the impact of requiring Medicaid prices in Part D on Ford or GM?

Mr. WEEMS. For the entirety of Part D?

Mr. DAVIS OF VIRGINIA. And union pension plans I guess you could throw into that as well.

Mr. WEEMS. Sure, sure. So Part D, together with Medicaid, represents over half of the pharmaceutical market in the United States. Applying government cost controls to more than half the market and pushing down that half of the market to some specified pricing scheme would definitely—and I say this without reservation—cause cost increases in the rest of the market, which specifi-

cally would be the private sector. And, you know, for companies like Ford and GM, it would substantially increase the pharmaceutical costs in every vehicle.

Mr. DAVIS OF VIRGINIA. You don't think the pharmaceutical companies would just say, we're going to continue the same amount on research and development anyway. We're just going to take this out of our bottom line, reduce advertising costs and the like?

Mr. WEEMS. I think that is unlikely, but the next panel will have somebody from pharmaceutical companies on it, and I would invite you to ask them.

Mr. DAVIS OF VIRGINIA. OK. I happen to agree with you.

Much has been made about the Medicaid coverage of prescription drugs, but prices are only one factor in determining the success of any new benefit. How do you think seniors' access to drugs in Part D compares with Medicaid recipients' access to drugs?

Mr. WEEMS. They have more access and more choices. The main feature of Part D is the ability to choose a plan that works best for the individual.

Mr. DAVIS OF VIRGINIA. You may have a rare disease or something that is not covered, for example, by Medicaid—

Mr. WEEMS. Correct.

Mr. DAVIS OF VIRGINIA [continuing]. That is covered by Part D, and you can choose that particular—

Mr. WEEMS. A lot of it just has to do with choice. You know, what is the level of premium that I want to pay each month? What is the amount of co-pay that I want to be exposed to? Do I want to use my neighborhood pharmacy?

Those are the kinds of things that seniors find extremely agreeable about this program, that it is not a government one-size-fits-all, the government picks winners and losers. It is that there is choice and a lot of choice, and their drugs are available to them in a very convenient way that—where they can get what they want.

When I talk to seniors around this Nation—and I spend a lot of time talking to them—we hear great satisfaction with Part D. And what they say over and over again is don't take this benefit away from us. Make sure you keep this benefit. This benefit is working for us.

Mr. DAVIS OF VIRGINIA. I think that is why you don't hear the majority saying let us move these dual eligibles back to Medicaid. Because it would be politically very, very unpopular with these groups. And now they'd like to have a hybrid, it seems to me, of—well, we are going to have Medicaid pricing in Part D for some items and the like.

Mr. WEEMS. In fact, satisfaction rates for the duals are higher than those even of the regular population. For one of the first times, they have been given the dignity of choice from a government program.

Mr. DAVIS OF VIRGINIA. As opposed to a one-size-fits-all, take-it-or-leave-it?

Mr. WEEMS. That's correct.

Mr. DAVIS OF VIRGINIA. The purpose of the Medicaid price regulations was to control the cost to States and the Federal Government. That is why they put the price controls in. Since implementing price controls 18 years ago, do you have any observations on

the cost of prescription drugs in Medicaid? Have they remained flat? Have they gone up? Have they gone down?

Mr. WEEMS. Well, you know, the best price provisions, the provisions with respect to rebates, are fixed from a price. So drug prices continue to go up. You know, they have been effective in reducing the liability for drugs in the Medicaid program while increasing the liabilities in other places and causing market distortions in other places on the market.

Mr. DAVIS OF VIRGINIA. OK. My time is up. Thank you.

Mr. YARMUTH [presiding]. We have a series of votes, as you might have noticed. So we'll at this point recess the hearing and reconvene at 1.

[Recess.]

Chairman WAXMAN [presiding]. The meeting of the committee will come to order.

The Chair recognizes Mr. Murphy to pursue questions.

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

I wanted to make a brief comment off of the chairman's concern, Mr. Weems, over the terminology you used regarding the Medicaid rebate program and that is peppered in your testimony, both written and oral, is the idea that this is price control, that this is price fixing. When it seems to us that it is merely using the market leverage and market power of the Federal Government to do exactly what private industry does, what the HMOs do in negotiating these prices, which is to say, through a choice of a particular pharmaceutical company, that this is the price that we're willing to pay. And if you don't pay it, then you're not going to be part of our plan, which is essentially what the Medicaid rebate program does.

Price control strikes me as something very different. I mean, that is a statutorily imposed price that everyone has to accept for their product.

This is a voluntary program. I would hope that we'd be a little careful in mixing what is a voluntary rebate program that the pharmaceutical companies pay as a means of selling their drug in a particular plan, the Medicaid plans versus what is traditionally thought of as price controls.

But my question is a little bit different, and that is—your testimony, Mr. Weems, as to the disruption in the delivery of health care that would result from imposing Medicaid rebates on the dually eligible population. And I want to just ask you to elaborate a little bit on that as to what evidence you have that gaining these discounts for taxpayers would lead to this potentially troublesome disruption of the health care delivery system.

Mr. WEEMS. Thank you for the question.

And, you know, I don't mean to get into a semantic battle. But, in my view, a system which fixes a specific rebate amount and fixes it through statute is very different than a negotiation. And the 15.1 percent rebate in Medicaid is fixed and fixed in statute. So I would stand by my terms, sir.

You know, as for the disruptions—I mean, we can—we can see this. You know, it was the GAO report that found that, in the 2 years following the implementation of the Medicaid best price rebate program, the best price discount for outpatient drugs pur-

chased by HMOs and PPOs decreased to about 14 or 15 percent, which is approximately the minimum required by the statute.

CBO found that the best price rebate program, found that drug purchasers in the private sector, their discounts weren't as good. Between 1991 and 1994, the best price discounts that pharmaceutical manufacturers gave off of wholesale prices fell from 36 percent to 19 percent.

Mr. MURPHY. For private insurers?

Mr. WEEMS. That's correct.

Mr. MURPHY. So you're suggesting that there is a movement—there is also testimony that you give about we would have a discouraging of employers from continuing to provide prescription drug coverage at the same level they do today. Is that—

Mr. WEEMS. If it is more costly, we can expect less of it, yes.

Mr. MURPHY. I guess it strikes me as strange that the testimony here is that we are essentially going to be—that today we are, in essence, subsidizing privately held plans purchased through employers?

Mr. WEEMS. No, not at all.

Mr. MURPHY. Wouldn't that be the converse of suggesting that—if your suggestion is that by the taxpayers paying less that you're essentially pushing the bubble in somewhere and it comes out somewhere else, that private employers are going to pay more, wouldn't the suggestion be currently today then we are subsidizing private employers' purchase of—

Mr. WEEMS. Not at all. You need to compare the two systems. If, in fact—if you had a competitive pricing system on both sides, then you can make a direct comparison. But, in fact, on the Medicaid side, there are mandatory rebates. The simple hydraulics of supply and demand means that, as you force down those prices, they are going to go up someplace else. That, in fact, means that the private sector currently is subsidizing Medicaid.

Mr. MURPHY. And currently, though, how does that not lead to an argument that we are currently, through our inflated prices that we are paying—and you admit that the prices we are paying today are not commensurate with what Medicaid is paying—isn't providing a subsidy on the other side to the private insurers?

Mr. WEEMS. No. The market—the market prices—you're asking to compare a risk-based market price to a government-imposed price. They don't compare. Because you have the cross subsidy and you're not able to capture the cost of forcing down the lower price and the cost that imposes on the rest of the nongovernment cost-controlled part of that sector.

Mr. MURPHY. And I know my time has expired, Mr. Chairman. But to get back to, I think, a fundamental disagreement, I think that the government rebate program is not completely risk independent. I mean, we obviously are setting a price at which we believe that the drug provider will continue to provide the pharmaceutical product. We are incorporating risk because we know if we set the rebate price too high that pharmaceutical company will no longer sell the product. So it may be different than the negotiation in the back and forth that occurs in the private sector, but it is completely interdependent upon risk. Wouldn't you agree that is part of the—

Mr. WEEMS. No. I think we're talking about risk in two different ways. When I refer to a risk-based insurance product, that is what we have in Part D where the—the profit, the equity of the firm is in fact at risk for achieving a good bid, for lowering drug prices and for bringing in recipients into their plan. That's the risk. That's a much different kind of risk than the kind you're describing.

Mr. MURPHY. You're right. I am mixing terms.

I guess what I'm suggesting is that the fundamentals of supply and demand that underlie a negotiation between an HMO and a pharmaceutical company are not absent from the determination of what the rebate will be under the Medicaid program. Because if the rebate again is set too high, then that drug will not be provided as part of the Medicaid program. So many of the same economic factors that underlie those negotiations are present in the determination of the—

Chairman WAXMAN. Your time has expired.

If you want to make a comment. Otherwise, we can move on.

Mr. WEEMS. We can move on, sir.

Chairman WAXMAN. OK. Mr. Issa.

Mr. ISSA. Thank you.

Are you aware of the history of this best price practice that Medicaid has where, a year after its implementation, the Department of Veteran Affairs asked Congress to exempt it from the calculation of Medicaid's best price because in fact it was raising their prices? Isn't that true?

Mr. WEEMS. To the best of my knowledge, yes.

Mr. ISSA. So here we have the gold standard to a certain extent. The Veterans Administration buys selected drugs at the best possible price, makes decisions, including formulary decisions, based on the best value for our veterans and then makes it available to other—certain limited other government agencies such as Bureau of Indian Affairs and so on for Indian health, and they choose to always take advantage of it because the prices are good. And they are saying, when you mandate a discount, you distort the market and you distort the likely retail price. Now, isn't that really what we're really talking about?

Mr. WEEMS. Sure. And we've seen that, since the best price mandate, that best prices have gone up, unsurprisingly, I would say.

Mr. ISSA. So a question I asked the economist earlier today—and I will challenge you on this side some—isn't our gold standard—the Veterans Administration, it backs up a truck, takes a whole truckload, reduces reliability, administration, takes the drugs and makes a good price. Isn't that the gold standard for pretty much as good as you would do, assuming you don't simply distort the market and demand a lower price, regardless of merit?

Mr. WEEMS. Well, I might disagree with that characterization, because I think it—first of all—and we are probably trying to get to the same place here. But, first of all, the Veterans Administration is a government agency that actually takes custody—

Mr. ISSA. And maybe I can clarify. What I'm saying is, when you do all of those things, you get the price maybe lower than any other plan.

Mr. WEEMS. Quite possibly.

Mr. ISSA. But when we're looking for the lowest possible price, we should not look to Medicaid with a mandated price, we should look to a bulk buyer buying by reducing administration and risk to these companies. When they make a buy, they make a big buy; and you just ship it.

Mr. WEEMS. That's right.

Mr. ISSA. OK. So, earlier today, I said, when we want to evaluate Medicare Part D's performance, shouldn't it be taking, if you will, if possible arithmetically, take the VA, put back in the administrative cost of not buying from a single payer but rather allowing people to get drugs where they want to be, where their doctors and their pharmacies are, rather than going to a VA facility to pick them up. Recognizing there is distribution costs, administrative costs, but that convenience is something our seniors demand because they want that capability. They're not asking us to please have 35 locations around the country they can drive to to get their drugs.

If you add back in those reasonable costs and so on, isn't that the standard where we would like to see Medicare Part D close to? And in your estimation are we, when you add back in those costs, somewhat close?

Because here today it seems like everybody wants to use Medicaid, which is an artificial mandated price, as the gold standard, rather than any other comparison. Or they want to use Canada, where they say if you don't give us a lower price, we'll simply void your patent and knock it off. So that is my real question. Can you progress on how you see it should—

Mr. WEEMS. Sure. That makes the comparison more fair. But the thing that—that Part D offers that—you know, is that you need to layer in again here is the choice of plans, you know, the many, many choices that are available to seniors and the way that they can, you know, structure their payments. They can choose, you know, a higher premium level in return for lower structured copayments, those kinds of things. All of that adds to the value of Part D. And, you know, once you step up from a highly restricted—all the way up to a program that offers considerable choice—

Mr. ISSA. Right. And, look, I have no question at all that my seniors want the features of being able to choose between formularies, to have some choices, to decide sort of good, better and best.

One of the controversial things by some here on the dais is, well, why don't we just have one formulary? Why don't we just have one solution? In a sense, the price that Medicare Part D gets, which is better than originally forecasted, isn't one of the most important parts of that. The fact that independent companies compete based on their formulary and features and by the way offered to pharmaceuticals, do you want to be with us, and will you give you a better price for it, because they are not necessarily taking every therapeutic solution.

Mr. WEEMS. That's absolutely true.

Mr. ISSA. If we come up with one mandated solution, although we might get a lower price on that, don't we distort the market for what the seniors want?

Mr. WEEMS. Yes. And I would say that there are two aspects to that. First of all, that a restricted formulary may mean that some

people don't get the drugs they need; and, second, it puts the government in the position of choosing winners and losers in the marketplace.

Chairman WAXMAN. The gentleman's time has expired.

Ms. Foxx, do you have questions?

Ms. FOXX. Thank you, Mr. Chairman.

I think that last point was really important, that we should not be putting the government in charge of picking winners and losers, especially when it comes to health care.

I have a couple of questions that I'd like to ask you, Mr. Weems; and I would say that I'm not always happy with the way CMS operates. There are things that I disagree with that you all have done, and so there are lots of things that I think could be done better over there, and we'll have another conversation about that sometime after this.

But let me ask you a question. According to the material that you all have produced, Medicare Part D enrollees continue to save about—excuse me. I'm asking the wrong question. You show that Part D costs are lower than the initial estimates. Can you tell us what accounts for that?

Mr. WEEMS. Sure. There are a number of things. First of all, that the degree of competition that occurred in the system was more robust than originally estimated; second, the price of drugs has not risen as fast as originally estimated; then, last, the total population enrolled is somewhat lower than originally estimated.

Ms. FOXX. The second question has three parts to it.

You have been around the Department for a long time, and you probably will remember during the debate about Part D there were a lot of doomsday predictions. I was not here during that debate. I didn't vote on Medicare Part D. But tell me in your opinion which—how these doomsday predictions have worked out.

No. 1, did plans refuse to offer drug-only insurance? I'll ask all three of the questions, and then you can respond. Did plans cherry-pick only the healthiest seniors? And you've already mentioned this about drug prices not rising exponentially. If we have time, I would like you to also say something about the price of drugs holding down the cost of health care in other areas.

Mr. WEEMS. You know, clearly, there was a lot of concern at the beginning that there wouldn't be marketplace entry. There has been robust and substantial marketplace entry. In fact, the complaints are reversed, from nobody is going to get into this to aren't there too many.

As for cherry-picking, that is something that we still remain very, very vigilant about in CMS. Every year when the bids come in, we examine the bids, we examine the formularies to make sure that there are not discriminatory bids as part of that.

You know, as for pricing, you know, if you—73 percent of our enrollees are in plans where the price index did not increase by more than 3 percent; 50 percent are in plans where the price index did not increase more than 2; and 14 percent are in plans where the price actually fell. So we not only see good price stability, we also see that our seniors are able to protect themselves against the risk of higher prices in the plans and also during the plan year by choosing tiered co-payments. Ninety-five percent of our bene-

ficiaries buffer themselves against the risk of payment increases by having set co-payments, rather than percentage co-payments.

Ms. FOXX. Thank you.

Mr. Chairman, I would just like to make a brief comment.

I find it so interesting that, in matters of choice, the majority party here wants choice when it comes to destroying life but not choice for citizens when they have the opportunity to save money and have better health care. Because it seems to me that one of the things that drives the majority party so crazy about Medicare Part D is that people do have choice. We don't want people to have choice about where to go to school, but, again, we do want them to have choice to kill babies.

The other thing that I think is not recognized that Mr. Shays said earlier is Medicare is in deep trouble; and there is material out all over the place today that the majority party is going to avoid dealing with the trigger, going to sweep that under the rug. We don't want to deal with the big issue of Medicare, but because there is this animus toward the drug companies, it is easy to pick on drug companies and pick on the private sector whenever we possibly can and make them look bad.

So I think we need to be dealing with the real problems that we have, which is the major Medicare program and what has come to be called an entitlement, because that is where our real problems are.

Chairman WAXMAN. The gentlelady's time has expired.

Mr. Weems, I want to ask you some questions. Under Medicare Part D, people can choose a plan that will offer them some drugs. It doesn't have to be every choice of drugs, but they have their formulary or they can join another plan that will have its formulary. Isn't that the way it works?

Mr. WEEMS. That's correct, yes, sir.

Chairman WAXMAN. So they have a choice, but they may find one drug on one plan but not on that same plan for another drug so they have to—they really can't pick and choose. They can't belong to two plans. They can only belong to one. So they don't really get the choices of all the drugs they need.

Under the old Medicaid, they had all the drugs on the list. So I just say that rhetorically when we talk about how much choice we are actually giving people.

Second, I want to point out you said with pride that a lot of insurance companies are out there competing and that just shows us it is wonderful and really working. But it also might show that they are making a lot of money; and if they're making a lot of money, why not go into that business? I just say that rhetorically as well.

Then the other thing I want to ask you is, we had 6 million people on Medicaid, and we paid less for them. Now they are on Medicare Part D, and we pay more for them. It is your premise that, if we paid less, the prices would go up in other areas where government spends on drugs; is that right?

Mr. WEEMS. That's correct. Or in the private sector. I wouldn't just limit it to government, sir.

Chairman WAXMAN. OK. Now that we've taken 6 million people and we have paid less for them, are we seeing a drop in what is being paid in other government programs or in the private sector?

Mr. WEEMS. Again, I think that is a question that bears examination. The question may be—

Chairman WAXMAN. It goes to your argument.

Mr. WEEMS. It bears examination, sir.

Chairman WAXMAN. Have you seen any evidence of the prices dropping for other government programs?

Mr. WEEMS. One of the reasons that we did not see the top line on that is prices have not increased in the way or at the speed that was originally estimated. So I would point to that as evidence, sir.

Chairman WAXMAN. What prices haven't increased at the speed of—

Mr. WEEMS. Drug prices.

Chairman WAXMAN. Who estimated them?

Mr. WEEMS. The original estimate from the Office of the Actuary for the—

Chairman WAXMAN. Is that the one we were never allowed to see? We still haven't gotten that one, as I understand. That was—the actuary's life—no, not his life, his job was threatened if he shared with Congress the cost.

Well, let me go into another question. Let us say we spent \$3.7 billion for 6 million beneficiaries when they're under Medicaid—\$3.7 billion less, now we're paying \$3.7 billion more. Is that the best use of our \$3.7 billion? The drug companies like it, but couldn't we use that for other purposes when we have so many uninsured?

For example, one of the reasons the President said he vetoed the SCHIP bill was because it cost so much money. Well, that \$3.7 billion would have covered 3.3 million uninsured children. Which is a better use of that money, paying it to the drug companies or paying less to the drug companies and using it for children?

Mr. WEEMS. Again, sir, I think that analysis ignores—is only half the equation. It ignores the distortions that the price setting creates in other parts of the market. You may—

Chairman WAXMAN. We can't be responsible for every distortion—you have never given us any evidence of that. But even if you do, there are always distortions.

I want to ask you one question about this issue of distortion. Do you think if we charge less—let me put it this way—if we charge more for drugs that the drug companies say, well, since I'm making so much money under this Medicare Part D, I'm going to give a break to these other payers of the private sector?

I can't believe that is the case. They are in business to make money. If they can sell their drugs at a certain price to the private sector, they'll do it. If they can sell their drugs to the government at a higher price, they'll do it. It is when somebody says, no, we're not going to pay the higher price that they have to realize that they're not going to make the money they were making before and then make their business calculations.

Mr. WEEMS. And I think you perfectly encapsulated the problem with government-administered pricing. We know that in Part A and B we overpay in some areas and underpay in others, and it

creates distortions and costs that, frankly, we're not able to measure.

Chairman WAXMAN. In Part D?

Mr. WEEMS. A and B. In Part A and B. It is a government-administered prices program. We know that we overpay.

Chairman WAXMAN. Would you be surprised if you found that one plan was paying more for the same drug than another plan under Part D?

Mr. WEEMS. For the same drug, no.

Chairman WAXMAN. You wouldn't be surprised?

Mr. WEEMS. No.

Chairman WAXMAN. Would you be surprised if one plan was bargaining for lower prices and didn't pass it onto the consumer but increased their profits?

Mr. WEEMS. If it is a rebate, they have to pass it on in their premiums, sir.

Chairman WAXMAN. Well, it may not be a rebate. They just negotiated a better price because they did some deals. That's what we want in the market, right?

Mr. WEEMS. That's correct.

Chairman WAXMAN. Pass on the lower prices to the Medicare system or beneficiary or does it just simply make all those companies that to our surprise decided to go into the business richer?

Mr. WEEMS. If they are going to compete for beneficiaries, they're going to have lower premiums, and that drives down their profits.

Chairman WAXMAN. Do you think that's the only reason signs up on one plan as opposed to another, the price?

Mr. WEEMS. The price and the coverage of the drugs.

Chairman WAXMAN. Yeah. OK. Thanks.

The gentleman from North Carolina, Mr. McHenry is recognized.

Mr. MCHENRY. I appreciate it, and I hope we will still have the same liberal time policies for me as for you. I know being chairman has its privileges.

Chairman WAXMAN. I went over 30 seconds. If you want an extra 30 seconds, I'll give you—

Mr. MCHENRY. That would be great, but I think you probably just burned it.

So anyway—

Chairman WAXMAN. I can't make you happy any way, huh?

Mr. MCHENRY. Well, actually, you know, your philosophy is very different and your focus is different here because—based on the studies—

Chairman WAXMAN. The gentleman's time is just beginning at 5 minutes.

Mr. MCHENRY. OK.

Chairman WAXMAN. Take my generosity.

Mr. MCHENRY. I appreciate your generosity.

But in this particular case, I think we do have some disagreements. Because, based on the studies I have seen, Mr. Weems—now, you know, Medicare Part D has cost both less for consumers that are using the program and for the taxpayers than the original cost estimate; is that correct?

Mr. WEEMS. Forty percent less, yes.

Mr. MCHENRY. Forty percent less?

Mr. WEEMS. Yes, sir.

Mr. MCHENRY. So market forces are—have been much more powerful in bringing down the cost than the government setting an arbitrary dollar amount that they will pay for an arbitrary drug?

Mr. WEEMS. The power of Part D has been to use market forces to bring prices down well below those that were originally estimated.

Mr. MCHENRY. OK. There is an IMS health report in 2007. Generics—and it said, generics account for 13 of the 15 drugs most prescribed by Medicare Part D. All right? And also according to this study, generics accounted for 68 percent of all medicines prescribed in Part D.

Mr. WEEMS. Generic usage is in the 60 percentile. My number is about 64 percent.

Mr. MCHENRY. So can you comment on the effect that has on the cost for the consumer, the senior and for taxpayers?

Mr. WEEMS. Sure. And that was one of the points that I was making earlier. It is not an exact comparison to compare somebody who is in a price-fixed indemnity program to a risk-based program that has some additional benefits to it, you know, such as therapy management, such as therapeutic interchange. I mean, there can be and, you know, we have seen scenarios where somebody who was in Medicaid came over to Medicare, was able to get more of the drugs, would be able to get more drugs, the ones that they needed and, in many cases, to be able to get those at a lower price and have better health outcomes and avoid costs in the A and B part of the Medicare program.

Mr. MCHENRY. I have four questions here in succession. You can answer them just briefly.

Do Medicare and Medicaid programs generally serve the same type of beneficiaries? Yes or no?

Mr. WEEMS. No.

Mr. MCHENRY. OK. Are Medicare and Medicaid programs financed the same way?

Mr. WEEMS. No, they're financed very differently.

Mr. MCHENRY. OK. So then is it fair to say that Medicare and Medicaid are two fundamentally different programs?

Mr. WEEMS. They are.

Mr. MCHENRY. They serve different beneficiaries and have different benefit structures and are financed in different ways?

Mr. WEEMS. Yes.

Mr. MCHENRY. So if you and I understand this correctly—I mean, obviously, by overseeing the program, you know, you have a depth of knowledge. Do you believe that the price structure of one program would work for the other program?

Mr. WEEMS. Well, clearly, it would not be wise to move the price structure of the Medicaid program into the Medicare program where there would essentially be an administered price-fixing arrangement for, you know, more than half of the pharmaceutical market in the United States. That would have, at least in my estimation, you know, considerable effects that would spill over into the private sector in terms of higher costs. So I would say that would not be particularly wise.

Mr. MCHENRY. There are some shortcomings with the program. It is a government program. It is what government does very well. Inefficiency is what government does very well. However, because market forces are involved, it has been better in terms of the cost and the benefits to consumers.

So we have talked about the negative aspects of the program. That's what this whole hearing is about, after all. That is why you have a crowd behind you and the reason why the chairman had it. But can we talk about some successes, and, you know, and answer one general question? Has Medicare Part D shown to improve beneficiary access at a less-than-expected cost?

Mr. WEEMS. Certainly. And beneficiaries are getting the drugs that they need. They are getting it in a way that is convenient to them. It is a real challenge to find any program that has a satisfaction rate of 85 percent on the part of the beneficiaries, and that's what the Medicare Part D program has. Among the low-income beneficiaries, it is 90 percent.

Mr. MCHENRY. Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. McHenry.

Mr. Weems, thank you very much for your participation. I know you're anxious to get back to the work that the government bureaucracies do so poorly, according to my friends on the other side of the aisle. But I salute you for the work that you do, and we want to make laws that will make sure that we protect the taxpayers and the beneficiaries.

Mr. WEEMS. Thank you for the opportunity to appear, sir.

Chairman WAXMAN. For our next panel, we want to call forward Mr. Mark Merritt, president and chief executive officer of the Pharmaceutical Care Management Association; Mr. Rick Smith, senior vice president for policy, Pharmaceutical Research Manufacturers Association [PhRMA]; Mr. Paul Precht, director of policy and communications, Medicare Rights Center; and Ms. Judith Stein, executive director of the Center for Medicare Advocacy.

We are very grateful for all of you coming to our hearing today, and we thank you for being here. And I want to make mention of the fact that we're particularly grateful that you allow us to share Mr. Merritt's birthday with him and to have him here on this special occasion. You wouldn't have wanted to be anywhere else on your birthday.

Mr. MERRITT. It really is a dream come true. Thank you.

Chairman WAXMAN. OK. Well, you said that without being under oath, but the rest of the testimony you all be asked to give—it is the practice of this committee that it be done under oath. So I'd like to ask you to all stand.

[Witnesses sworn.]

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

Mr. Merritt, as a birthday gift to you, we are going to let you start.

I think you all know the rules. Your prepared statements will be in the record in their entirety. We would like to ask you to try to limit the oral presentation to 5 minutes. We have the clock.

STATEMENTS OF MARK MERRITT, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION; RICK SMITH, SENIOR VICE PRESIDENT FOR POLICY, PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATION [PhRMA]; PAUL PRECHT, DIRECTOR OF POLICY AND COMMUNICATIONS, MEDICARE RIGHTS CENTER; AND JUDITH STEIN, EXECUTIVE DIRECTOR, CENTER FOR MEDICARE ADVOCACY

STATEMENT OF MARK MERRITT

Mr. MERRITT. Thank you, Mr. Chairman and Ranking Member Davis, the rest of the Members who will be in and out throughout.

My name is Mark Merritt. I am president of the Pharmaceutical Care Management Association. PCMA is a national association representing America's pharmacy benefit managers. PBMs administer prescription drug benefits for more than 200 million Americans with health coverage. Our clients include the Nation's largest public and private purchasers, including labor unions, Fortune 500 companies, FEHBP plans, and, of course, Medicare.

First, I would like to thank you, Chairman Waxman, for your leadership on health care issues. PCMA is appreciative of the opportunity to work with your staff on generic biologics legislation and on ensuring generic competition in the marketplace, and I am pleased to be here today to testify about Medicare Part D and what we do in it.

To begin, PBMs use a number of tools and strategies to maximize value in terms of quality, access and convenience and overall drug spending. First, let's talk about PBMs and discounts and rebates regarding manufacturers. There, PBMs pool the purchasing ability of all our clients and consumers and encourage certain kinds of utilization to obtain discounts and rebates from brand-name manufacturers.

First, our panels of independent clinical experts, called P&T committees, or pharmacy and therapeutic committees, comprised of independent doctors, pharmacists, academics and others, inform us of which drugs are appropriate for certain therapeutic classes which address particular medical conditions. Then we negotiate with manufacturers who make competing products within that class.

The manufacturer which offers the best discounts and rebates typically has their drugs placed on formularies at lower copays than their competitors. That encourages consumers to choose the more affordable drug, although their physician can, of course, direct them to another, if clinically appropriate.

While discounts on individual drugs can vary widely, overall, manufacturer rebates have decreased drug spending by up to 9 percent in FEHBP, according to their report. And I believe your new report, if I read it correctly—and I just got it, of course—says we save about 14 percent in Part D. But I am not sure about that.

Extracting manufacturer discounts, however, is only one way PBMs deliver savings. The majority of our savings that we generate results from innovative and aggressive management of other components of drug spending.

First, we create more affordable delivery options, such as mail service pharmacy, which can save 10 percent for payors and patients alike. Second, we aggressively negotiate more economical reimbursement and dispensing fees with drugstores in our pharmacy networks. Third, we use formularies, medication, therapy management and other tools to increase generic utilization and create a more affordable and often safer drug mix for patients. Four, we employ drug utilization review programs [DUR], to inform patients and doctors when we identify unsafe or unnecessarily expensive prescribing patterns. And, five, we are constantly developing new innovative tools, like electronic prescribing, which improve efficiency, safety and savings across the whole system.

Today, we are proud of our accomplishments in Part D. Costs are lower than expected, premiums are as well, generic utilization is higher and getting better, beneficiaries have broad access to formularies and drugs and have access to over 60,000 pharmacies.

Overall, our savings are comparable to those we generate in the private sector and for FEHBP plans. Most importantly, of course, beneficiaries themselves are highly satisfied with the program; and, of course, that is our marketplace.

There are, however, additional policy options that would further enhance our ability to generate savings that I would offer for the committee's consideration, some of which have been mentioned already today.

First, we desperately need to create competition among biologics by pursuing legislation such as your proposal, Mr. Chairman, the Access to Lifesaving Medicines Act. This is the fastest-growing component of drug spend and will reach \$100 billion sometime in the next 10 years. We need more competition in that space.

Second, we would ask policymakers to build on the groundbreaking new e-prescribing incentives that were just passed as part of the physician pay package.

Third, we would ask you to take a closer look at the six classes of clinical concern that have been mentioned earlier in which all drugs from all drug makers are mandated for coverage in certain classes, therapeutic classes. These are specifically important regarding dual eligibles, who are heavy utilizers of these drugs.

And this policy of mandating coverage, again, for all drug companies, all drugs in a certain class, we don't believe it improves access, but it does make it difficult, more difficult, for PBMs to negotiate rebates for drugs in those classes. And, again, they account for about 40 percent or more of the spending of dual-related spending.

In fact, the rebates in the six protected classes, we are only able to generate about half as much—or half of significant rebates as we are in other classes. Because when that leverage is taken away from us, it inhibits our ability to get the right discounts from the pharmaceutical manufacturers.

In conclusion, though, I appreciate the opportunity to share with you our progress on my birthday and also look forward to answering any questions you might have and any concerns you might have.

Chairman WAXMAN. Thank very much, Mr. Merritt.
[The prepared statement of Mr. Merritt follows:]



Testimony of Mark Merritt

President & Chief Executive Officer

Pharmaceutical Care Management Association

Before the

**UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM**

*The Medicare Drug Benefit:
Are Private Insurers Getting Good Discounts for the Taxpayer?*

July 24, 2008

Introduction

Good Morning Chairman Waxman, Ranking Member Davis, and Members of the House Committee on Oversight and Government Reform.

I am Mark Merritt, President of the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP).

Managing prescription drug benefits – in either the private or public sectors – PBMs utilize a number of tools and strategies to maximize value for their clients, the payors. A common thread connecting all programs administered by PBMs is that success depends on saving their clients money and offering the best overall value in terms of cost, quality, access, and convenience. To stay in business, PBMs must deliver high quality prescription drug benefits at highly competitive prices.

Today, PBMs manage most Medicare Part D drug benefits, either as stand-alone Prescription Drug Plans (PDPs) or as contractual service providers to PDPs and MA-PDPs. Within the competitive Part D framework established by Congress and implemented by CMS, PBMs have worked hard to meet the justifiably high expectations of seniors and policymakers alike and have successfully achieved savings comparable to union plans, State employee health plans, FEHBP, and other commercial payors.

In addition to drug rebates, there are several other key reference points for measuring Part D cost trends, including: pharmacy discounts, dispensing fees, generic substitution rates, formulary compliance rates, use of low-cost delivery channels, and the number and type of prescriptions used by beneficiaries.

While there is always room for improvement, PBMs are proud of their performance in Part D. PBMs and Part D sponsors have reduced overall program costs by 30 percent below original government projections, offered beneficiaries lower than expected premiums, generated high levels of generic utilization while providing broad choice of drugs and access to over 60,000 pharmacies, all while attaining a continually high rate of beneficiary satisfaction.

The Role of PBMs in Medicare Part D

In many respects, the role of a PBM in Medicare Part D is that of a federal contractor competing to provide services to the program. PBMs work with Part D plans to submit competitive bids which are either approved or rejected by CMS. Competition is further enhanced as each Medicare beneficiary then compares plans and chooses to enroll in the plan that best meets their needs. Finally, plans are subject to rigorous oversight by CMS and Congress.

Working within the competitive Part D framework, PBMs offer Medicare and its beneficiaries the best overall value by using proven tools and strategies that both control costs and provide the highest quality prescription drug benefits.

In addition to reviewing PBMs performance in Part D, I would like to discuss ways in which we believe additional savings are possible for the Medicare Program using common-sense measures that can be implemented by Congress. These include: establishing a clean pathway for biogenerics, reducing regulatory barriers to generics entering the market, implementing e-prescribing effectively, and enhancing mail service pharmacy options. PCMA and the PBM industry look forward to working with you on this and other measures that provide high levels of access, improve efficiency, and save money for the Medicare program and its beneficiaries.

PBMs Help Medicare Program and Seniors Save Money

PBMs have played a major role in creating broad access to prescriptions drugs while generating significant savings for Part D and its beneficiaries.

- **Part D Savings:** Part D expenditures over the 2008–2018 period are now projected to save more than \$117 billion than estimated last July.
- **Premiums:** At about \$25, the average monthly Part D plan premium paid by beneficiaries is far below the CBO estimate of \$35 and CMS estimate of \$37 for average premiums during the first year of Part D.

As a result of better-than-expected plan savings and lower-than-expected premiums, the Part D program will be 30 percent less expensive for the first 10 years than originally estimated.¹ According to analysis conducted by PricewaterhouseCoopers, overall savings of PDPs in Part D are also comparable to levels achieved by PBMs in the Federal Employees Health Benefits Program (FEHBP).

In addition, Part D has helped many beneficiaries obtain drug coverage and save money, as high satisfaction levels with the program attest:

- **Coverage:** The percent of seniors with prescription drug coverage has increased from 75 percent prior to Part D, to more than 90 percent in 2007. Surveys have shown that those few remaining seniors without drug coverage are those that don't want it because they take few or no prescriptions.²
- **Drug costs:** According to CMS, Medicare seniors today are saving an average of \$1,200 a year versus those who previously had no drug coverage.

¹ According to the CMS actuaries, projected Part D spending over 2008-18 will be \$117 billion lower than projected in OMB's Mid-Session Review released in last July.

² Swanbrow, Diane. "Most seniors now have drug coverage, study shows" *The University Record* University of Michigan News Service. August 13, 2007. Available at http://www.ur.umich.edu/0607/Aug13_07/18.shtml

- **Satisfaction:** A variety of surveys from sources such as AARP, J.D. Power and Associates, and the Kaiser Family Foundation show that more than three quarters of seniors are satisfied with their Part D drug benefit.

PBMs Encourage Generic Drug Use in Part D

One of the most important ways that PBMs help the Medicare program and its beneficiaries save money is by encouraging the use of generic drugs whenever clinically appropriate. Generic drugs cost on average, 71 percent less than brand drugs.³ For each percentage point increase in the generic utilization rate, Part D drug spending falls by an estimated \$12 billion.⁴ In addition to substituting for their brand equivalents, generic drugs are also frequently effective therapeutic alternatives to similar branded products within the same class.

As they do in the private sector, PBMs encourage generics in Part D through lower or waived copayments and formulary compliance programs such as step therapy. To make sure that generic substitution occurs as soon as generics come to market, PBMs educate physicians and patients beforehand. In addition, Part D plans encourage generics by ensuring that pharmacies make the prices of both generics and brands available for comparison by beneficiaries. According to the MMA, each Part D plan should ensure that its network pharmacies inform beneficiaries of the cost differential between the price of the prescribed drug and the lowest cost generic drug equivalent.

Generic drug utilization in the Part D program averages 56 percent, as compared with 54 percent in Medicaid.⁵ Among some Part D sponsors, utilization of generics exceeds 80 percent.⁶ More recent evidence suggests that generics have reached 63 percent of Part D prescriptions in

³ Office of the Inspector General, Department of Health and Human Services. "Generic Drug Utilization in the Part D Program" November, 2007. OEI-05-07-005130 Available at <http://www.oig.hhs.gov/oei/reports/oei-05-07-00130.pdf>

⁴ PriceWaterhouseCoopers. "Medicare Part D: An Assessment of Plan Performance and Potential Savings" A Report Prepared for the Pharmaceutical Care Management Association. January 2007

⁵ OIG. "Generic Drug Utilization in the Part D Program"

⁶ Ibid

2008, up dramatically from just 50 percent when the program began in 2006.⁷ We believe this substantial increase in generic drug use among Medicare seniors attests to the effectiveness of Part D plans.

By encouraging generics, PBMs help many seniors avoid the statutorily created coverage gap or “doughnut hole.” According to a PCMA analysis, beneficiaries can avoid their entry into the doughnut hole by an average of 74 days by utilizing of generic drugs and mail-service pharmacies.

Some Part D plans also cover generics in the coverage gap, and while we believe it would be preferable for Congress to eliminate the doughnut hole entirely, a recent study suggests that it does encourage seniors to switch to generics. For those beneficiaries that do switch to generics to save money in the gap, just 6 percent return to using brands after coverage resumes.⁸

Getting more generic drugs to market sooner would also further reduce Part D costs. PCMA is pleased that steps were taken in this year’s Food and Drug Administration Authorization Act to reduce frivolous citizens petitions that delay market entry for generic drugs. We support removing loopholes that prevent generics from entering the market, and fully support establishing a regulatory pathway for approval of generic biologic drugs.

With spending on biologics expected to double from \$54 billion to \$99 billion by 2010, creating an effective regulatory pathway to approve generic biologics would save Medicare billions of dollars. PCMA looks forward to working with you to help pass the Access to Life Saving Medicines Act. This legislation meets what we believe to be the most important criteria for any biologics legislation Congress considers by:

- Empowering the FDA to use its expertise to determine on a case-by-case basis what scientific data they need to approve comparable and interchangeable products;

⁷ Wolters Kluwer Health. “New Study Says Generic Drugs Now Own 63% of Medicare Part D Market — Up from 50% Less Than Three Years Ago” Press Release. June 23, 2008. Available at http://www.wolterskluwer.com/WK/Press/Product+Press+Releases/2008/Jun/pr_23Jun08b.htm

⁸ Ibid

- Being free of administrative barriers that impede the FDA's ability to approve safe and effective biogenerics; and
- Providing a clear and timely resolution to patent disputes and prohibits frivolous suits that restrict access and delay competition.

Thank you for your leadership on this important initiative.

Unit Price Discounts Just One Component of Total Value

Just as they do in the private sector, PBMs play a key role in negotiating price discounts from manufacturers and pharmacies in order to lower unit drug prices in Medicare Part D. Unit price is one of many components of overall program costs, with the amount and type of drugs used being of at least equal importance. Encouraging higher generic utilization, employing more affordable delivery vehicles such as mail-service pharmacy, negotiating aggressively with retail pharmacies, and helping doctors and patients understand when safer, more affordable options are available all have a profound influence on overall costs to the program and its beneficiaries. The added value of these services to the Medicare program includes choice of formularies, broad access to medications, convenient pharmacy options, effective medication therapy management, and other benefits for Part D enrollees.

PBMs Negotiate Price Discounts in Part D Comparable to FEHBP

Lower-than-expected program costs and high beneficiary satisfaction indicate that PBMs have provided the Part D program and its beneficiaries strong overall value. According to PricewaterhouseCoopers, PBMs are achieving overall savings in Part D of about 29 percent relative to unmanaged drug expenditures, taking into account both prices and utilization. This is a figure comparable to FEHBP.

Manufacturer rebates negotiated by PBMs in Part D are similar to those attained under FEHBP. According to this Committee's October 2007 report, rebates reduced Part D plans expenses by 8.1 percent.⁹ According GAO, in FEHBP, manufacturer rebates negotiated by PBMs reduce total annual drug spending by 3 to 9 percent.¹⁰

How Coverage Mandates Help Manufacturers and Hurt Part D

While Part D savings to date have been comparable to FEHBP, we remained concerned with successive regulatory and statutory measures that erode the ability of PDPs to develop formularies consistent with best practices in the commercial sector. Of particular concern is the recent codification of CMS regulations requiring that "all or substantially all" drugs be covered in certain drug classes of clinical concern.¹¹ While there is little evidence that this requirement improves access to appropriate medications, it does reduce the ability of Part D plans to negotiate discounts with drug manufacturers. The upward cost implications of such measures are clear. As CBO explained in its original cost estimates for Part D:

"How effectively PDPs could control Medicare drug costs would also depend on whether and to what extent they were allowed to use the various tools at their disposal, such as enforceable limits on the number and types of drugs included in their 'formulary,' or list of covered drugs."¹²

Alternatively, PCMA supports using an evidence-based approach to Part D formularies. Allowing for more clinical input through refining the two-drugs-per-class rule and the set of

⁹ U.S. House of Representatives, Committee on Oversight and Government Reform, Majority Staff. "Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage," October, 2007.

¹⁰ Government Accountability Office. "Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," GAO-03-196, January 2003.

¹¹ Public Law 110-275, as enacted by Congress, includes a section (176) on formulary requirements with respect to certain categories or classes of drugs

¹² Congressional Budget Office, "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit," July 2004.

protected classes would better help to ensure that formularies are able to accommodate for differences across drug classes.¹³

Use of PBM Tools in Part D Guided by Congress, CMS, and Beneficiary Choice

Unlike the way PBMs manage benefits in the commercial market, under Part D they must work with plan sponsors to provide PDP offerings that both comply with Medicare's unique program requirements and also attract individual beneficiaries to enroll. While the tools and strategies available to PDPs are similar to those used by PBMs in the commercial sector, their use in Medicare is guided by statute, regulation, and beneficiary plan choice. This framework, as established by Congress, relies on a delicate balance between ensuring beneficiary access and utilizing tools (such as those of PBMs) to control costs. Moving further in one direction or the other would result in either decreased quality and access or increased costs.

For example, the pharmacy contracting and formulary requirements of Part D ensure access and a higher quality benefit for enrollees, but the Program's unique features (stand-alone nature of its drug plans, insurance risk, and extensive regulatory reporting and compliance costs) mean that its administrative costs are often higher than in commercial sector or government fee-for-service plans. The trade-off is that beneficiaries can keep traditional Medicare A and B and add drug coverage by selecting from a wide range of drug plans based on their individual needs and preferences. It is the competition among Part D plans that ensures plans strive to keep administrative costs as low as possible by achieving ever-greater efficiencies.

Regardless of the size of its enrolled population, the ability of any plan to negotiate substantial rebates with drug manufacturers depends on the extent to which it can implement an effective formulary and management strategies to encourage compliance with that formulary. PBMs negotiate the highest rebates from manufacturers of brand medicines that face competition from several similar brand products within the same therapeutic class. If competing brand drugs

¹³ This idea has been outlined by Jack Hoadley of the Commonwealth fund. Hoadley, J., "Medicare Part D: Simplifying the Program and Improving the Value of Information for Beneficiaries," Commonwealth Fund, May 2008.

are judged to be close therapeutic substitutes, as determined by third party experts,¹⁴ the PBM will then negotiate price concessions from a manufacturer in return for a preferred formulary tier position. Typically, the actual manufacturer rebate amount will be calculated at the end of the benefit year when sales figures are available to show how successful these strategies were in increasing the market share of the preferred brand product relative to its competitors. PBMs will also utilize other strategies, such as educating both prescribing physicians and patients about more affordable alternatives. High formulary compliance results in increased market share for the preferred product and higher rebate savings.

How PDPs Use Rebates to Lower Costs for Medicare and Beneficiaries

Questions have been raised as to how much of the manufacturer rebate is “retained” by the PDP, particularly in the context of beneficiary spending in the coverage gap. PDPs are required to pass “some or all” of these rebates back to the program and the beneficiaries it serves. Rebates may be used to expand coverage or to reduce any combination of premiums, negotiated prices, deductibles, copays, or other cost sharing. Rebates lead to lower bids, result in lower premiums and lower plan costs while allowing PDPs to better attract enrollees. Likewise lower premiums reduce costs for *all* of a plan’s enrollees rather than only those beneficiaries with high utilization. Although PDPs are allowed to retain a portion of rebates to cover administrative costs, competition forces each PDP to allocate rebates efficiently in order to assure their bids are approved by CMS and to attract and retain enrollees.

Comparing Manufacturer Rebates in Part D to Medicaid and VA

When comparing unit price discounts achieved by PBMs in Part D to the discounts of other government administered programs such as Medicaid and the VA, it is important to remember that drug manufacturers are required by law to provide these programs with discounts equal to the best price concessions they offer to large buyers in the commercial sector:

¹⁴ PBMs rely on panels of third-party experts known as Pharmacy and Therapeutics (P&T) Committees. P&T Committees are made up of physicians, pharmacists, and individuals with specialized clinical expertise. Typically, to avoid conflict of interest, P&T Committee members are not employed by drug manufacturers or PBMs and are not involved in rebate negotiations with manufacturers.

- The Medicaid program receives a legally required unit price discount from drug manufacturers that is tied to the best prices manufacturers provide to their commercial sector clients or a statutory minimum discount.
- The VA program receives unit price discounts based on Federal Supply Schedule (FSS) drug prices which, like Medicaid, are statutorily tied to the best discounts manufacturers provide large private-sector clients. In addition, the VA is a closed system that purchases, takes possession of, and dispenses drugs itself.

The linkage of manufacturer price discounts in federal programs to the best discounts received in the commercial sector has had the effect of shifting costs from government to private purchasers. Research suggests that Medicaid rules substantially increase prices for non-Medicaid consumers:

- When Federal Supply Schedule (FSS) prices were included in the calculation of the Medicaid best price in the early 1990s, the VA experienced related price increases on brand name drugs.¹⁵ Congress subsequently passed legislation to exempt FSS from the Medicaid best price formula.
- CBO estimates that a Medicaid-style “best price” system in Part D “would put upward pressure on prices paid by the VA, Medicaid, and private purchasers” and “would encourage drug manufacturers to reduce private-sector discounts.”¹⁶
- One study found that a ten percentage-point increase in the market share of the Medicaid program was associated with a 10 percent increase in the average price of a prescription.¹⁷

¹⁵ Congressional Budget Office. “Pricing for Brand-Name Drugs Under Selected Federal Programs,” June 2005.

¹⁶ Congressional Budget Office. Letter to the Honorable Debbie Stabenow, April 16, 2007.

¹⁷ Duggan, Mark G. and Scott Morton, Fiona M., “The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing” (November 2004). NBER Working Paper No. W10930. Available at SSRN: <http://ssrn.com/abstract=622874>

Based on this experience, Congress exempted Medicare Part D from the calculation of Medicaid best price. CBO estimated that this exemption reduced spending in the Part D program by 1.6 percent.¹⁸

According to CBO, “For HHS to use the greater market share of the entire Medicare population as a source of leverage to secure deeper price discounts and greater cost savings, it would probably have to threaten similar exclusions and limitations on coverage for that entire population,”¹⁹ or, in other words, institute a national formulary for Medicare beneficiaries. Likewise, CBO notes that “under current law... PDPs have both the incentives and the tools to negotiate drug prices that the government [does not currently have].”²⁰

Unique Features of Part D Determine Administrative Costs

In addition to processing claims, PDPs actively manage prescription drug benefits, using tools and strategies to encourage greater utilization of generics, preferred brands, and low cost pharmacy options. They also implement medication therapy management, physician and consumer education, and e-prescribing programs that enhance the safety, quality, and affordability of Medicare’s prescription drug benefit.

These PBM administered programs add up to significant savings for the Part D program. For example, an analysis of costs in commercial plans sponsored by large employers finds that PBMs accounted for 3 cents of each prescription dollar.²¹ In return for that investment, PBMs

¹⁸ Avalere Health. “Follow the Dollar: Understanding Drug Prices and Beneficiary Choices Under Medicare Part D.” April 2006.

¹⁹ Congressional Budget Office. “A Detailed Description of CBO’s Cost Estimate for the Medicare Prescription Drug Benefit,” July 2004.

²⁰ Congressional Budget Office. Letter to the Honorable John D. Dingell, Chairman of the House Energy and Commerce Committee, January 10, 2007.

²¹ Bain and Company. “Pharmaceutical Benefit Channel: Economics, Fulfillment Models,” presented at the PCMA Annual Meeting, October 2005.

reduce overall costs by 29 percent relative to an unmanaged benefit.²² While administrative costs may be higher in Part D due to its unique features, the overall cost reductions are comparable.

Mail-Service Pharmacies Provide Additional Savings Opportunity

Mail-service pharmacies provide the Medicare program and its beneficiaries with another opportunity to achieve greater overall savings. While seniors with short-term acute needs must obtain their prescriptions from local pharmacies, those with chronic conditions such as high-blood pressure can be more affordably served by mail-service pharmacies.

As a result of high levels of automation and efficiency, prescriptions filled through a mail-service facility cost approximately 10 percent less than equivalent retail pharmacy prescriptions.²³ Today, about 20 percent of prescription volume flows through mail-service pharmacies. If this were to increase to 50 percent, the Medicare program and its beneficiaries could save more than \$40 billion over the next ten years.²⁴

We commend CMS for enabling Medicare beneficiaries to compare their drug costs through local vs. mail-service pharmacies on the Plan Finder website. We also look forward to exploring with Congress how the use of mail-service pharmacies can be encouraged in Medicare.

E-Prescribing Implementation

Another way to not only increase savings in the prescription drug market, but also increase safety, is to continue to increase adoption of electronic prescribing (E-Prescribing). E-prescribing allows doctors to access formulary information and patient drug history, ensuring the most affordable drug treatment and protecting against harmful drug-drug interactions.

²² PriceWaterhouseCoopers. "Medicare Part D: An Assessment of Plan Performance and Potential Savings" A Report Prepared for the Pharmaceutical Care Management Association, January 2007.

²³ The Lewin Group. "Mail-Service Pharmacy Savings: A Ten Year Outlook for Public and Private Purchasers", report prepared for the Pharmaceutical Care Management Association, August 2005.

²⁴ Ibid.

Earlier this month, Congress enacted critical legislation that will for the first time require physicians to e-prescribe under Medicare. We thank you for your support of this important initiative. The inclusion of an e-prescribing requirement in Medicare is a major victory for America's seniors. From a patient's perspective, e-prescribing is the most important issue in the Medicare bill because it saves lives and saves money. This is a historic step forward for e-prescribing as the new requirement in Medicare will now lead to broader adoption of overall health care information technology.

Conclusion

By using PBMs' proven strategies within the competitive Part D framework, the Medicare Program has achieved better-than-expected savings and a majority of beneficiaries are extremely satisfied with their plans, which provide wide access to medications and pharmacies at affordable monthly premiums.

As the Part D program continues to grow and succeed, PCMA looks forward to working with this Committee and Congress to find additional ways to promote savings while continuing to deliver the highest quality prescription drug benefits for America's seniors and Medicare's beneficiaries.

Mr. Chairman, this concludes my testimony. Once again I appreciate the opportunity to appear before this panel today. I am happy to answer any questions that you may have. Thank you.

Chairman WAXMAN. Mr. Smith.

STATEMENT OF RICK SMITH

Mr. SMITH. Thank you, Mr. Chairman and members of the committee. Thank you for the invitation to participate in today's hearing.

My name is Richard Smith. I am senior vice president for policy and research at PhRMA, which represents pharmaceutical research companies.

Medicare Part D has greatly improved beneficiaries' access to needed medicines, reduced out-of-pocket costs and retained broad choice among medicines. This has been accomplished at much lower than anticipated cost to beneficiaries and taxpayers, and data show that Part D enrollees are highly satisfied and they are saving money.

Last week, Congress adopted an important PhRMA support improvement allowing more low-income beneficiaries to qualify for enhanced assistance.

The committee requested that I provide information on the nature of financial arrangements between pharmaceutical manufacturers and Part D plans, along with the extent of discounts. As a trade association, PhRMA maintains a strict antitrust compliance policy, so I can neither obtain nor discuss our members' proprietary information related to prices, negotiations or discount strategies. As a result, my testimony reflects only publicly available information.

Part D was designed to achieve a range of objectives by carefully balancing affordability, access choice and improved use of medicines. This careful balance requires assessing the program on an overall basis, recognizing that its objectives are interrelated.

Part D saves beneficiaries money. Peer-reviewed research and government studies report sizable reductions in seniors' monthly out-of-pocket costs, and premiums in 2008 are actually below the level initially projected for 2006.

Part D's competitive structure saves taxpayers money. Both CBO and the Medicare Trustees report costs are far less than anticipated, largely because of vigorous competition. CBO concludes plans have "secured rebates somewhat larger than the average rebates observed in commercial health plans." And the Trustees report states many brand-name prescription drugs carry substantial rebates, often as much as 20 to 30 percent.

I would also note, in the six classes, plans have an array of tools used to negotiate savings. In these classes, plans have tiers, utilization management and many generics.

Comparing CBO's 2008 and 2006 baseline shows that projected total cost for 2007 through 2016 has dropped by \$438 billion, or 37 percent. Actual plan bids, the best measure of the program's per person cost, are 12.8 percent lower than they were 2 years ago.

Part D offers beneficiaries choice of medicines through the medicines covered by individual plans and through choice among plans. In fact, two of the largest Part D plans report covering all 100 of the most commonly used drugs; and beneficiaries are picking plans that combine no deductible, lower-than-average premium, and a broad choice of medicines.

While access to medicines has improved as intended under Part D, IMS Health estimates that the program's impact on retail pharmaceutical sales was an increase of about 1 percent in 2006. And a recent academic study reports that, overall, Part D reduced average drug prices, and the trustees have reported that rebates increased in 2008. Moreover, drug costs growth has slowed since Part D's enactment to 3.8 percent in 2007, the lowest rate since 1961.

In assessing the program's cost savings, it is important to consider the full range of populations covered and the full range of cost-saving tools used. For instance, 14 million uninsured or underinsured beneficiaries before Part D did not have discounts and rebates routinely negotiated on their behalf. Now, powerful purchasers representing millions of covered lives each negotiate savings on their behalf.

And plans use a variety of tools, among them discounts, rebates and incentives, to increase generic use to achieve savings. As was mentioned previously, 13 of the 15 most commonly prescribed drugs in Part D are generic. These tools have produced affordable premiums and are largely responsible for the overall \$438 billion reduction in the program's total projected cost.

In conclusion, Part D has achieved its objectives for beneficiaries who clearly recognize its value. Vigorous competition has driven down costs, both for beneficiaries and taxpayers. Changing Part D's market-based structure would undermine the balanced approach which has produced sizable cost savings and greatly improved access to needed medicines.

We look forward to working with the committee to enhance the program by building on its successful foundation, and I appreciate the opportunity to testify.

Chairman WAXMAN. Thank you very much.

[The prepared statement of Mr. Smith follows:]

**RICHARD I. SMITH
SENIOR VICE PRESIDENT, POLICY AND RESEARCH
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

**BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON
OVERSIGHT AND GOVERNMENT REFORM**

JULY 24, 2008

Mr. Chairman, Ranking Member Davis, and Members of the Committee, thank you for the invitation to participate in today's hearing on the Medicare prescription drug insurance program. My name is Richard I. Smith and I am Senior Vice President for Policy and Research of the Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA represents the pharmaceutical and biotechnology research sector, which the Congressional Budget Office (CBO) identifies as "one of the most research-intensive industries in the United States."¹ This research investment is yielding results for patients. As summarized by CBO, "Many examples exist of major therapeutic gains achieved by the industry in recent years...anecdotal and statistical evidence suggests that the rapid increases that have been observed in drug-related R&D spending have been accompanied by major therapeutic gains in available drug treatments."² For instance:

- The Centers for Disease Control and Prevention has identified "new drugs and expanded uses for existing drugs" as contributing to the decline in heart disease and stroke mortality.³
- Academic researchers have associated new medicines with declines in mortality for breast cancer⁴ and other cancers,⁵ reduced disability rates among elderly persons,⁶ and increased productivity among workers with conditions like rheumatoid arthritis.⁷

The continuing development of new medicines has a key role in improving health and health care. For instance, the prevalence of Alzheimer's Disease will increase sharply in coming years, imposing large human and economic costs. A report for the Alzheimer's Association projects that new treatments that delay the onset or slow the progression of Alzheimer's by five years could save \$100 billion annually in Medicare and Medicaid costs by 2020.⁸ Likewise, researchers project a doubling of the prevalence of Parkinson's Disease.⁹ The authors of this projection note that the answer "will come from more research and new treatments that protect against Parkinson's, or slow its course."¹⁰

The Medicare Prescription Drug Program (Part D) has greatly improved seniors' and disabled beneficiaries' access to needed medicines, offering improved health outcomes. While improving access, it has also offered beneficiaries low premiums, reduced out-of-pocket expenditures on medicines, and provided choice among medicines. Last week, Congress enacted an important

improvement to the program for beneficiaries, by redefining the income and asset tests in a manner that will allow a greater number of beneficiaries with limited means to qualify for additional assistance.

Part D is a program with many elements balanced to best achieve the range of objectives, including choice, affordability, access, improved use of medicines, and maintaining a competitive and innovative pharmaceutical sector. This range of objectives calls for assessing the program on an overall basis, recognizing that its objectives are interrelated. The remainder of my testimony addresses these issues.

The Committee has requested that I provide information on the nature of financial arrangements between pharmaceutical manufacturers and Part D plans, along with the extent of discounts. As a trade association, PhRMA maintains a strict antitrust compliance policy, which prohibits us from obtaining or discussing our members' proprietary information about the prices or discounts each individual company negotiates with its customers or the ways in which each company determines the prices or discounts it will offer. Therefore, I do not have information concerning any individual company's pricing or discounting policies or practices, and my testimony can address overall trends regarding the Part D program based solely on publicly available information.

Part D and Affordability

Part D was structured to achieve substantial cost containment, along with its other goals. To achieve this full range of goals, Part D structured a highly competitive market among private prescription drug insurance plans. Among the approaches to a Medicare prescription drug benefit considered by Congress, the approach eventually adopted in Part D was scored by CBO as having the highest "cost management factor."¹¹

Cost containment in Part D is generated by competing private plans seeking to offer affordable coverage to beneficiaries. One of many strategies that plans use to generate savings is to negotiate with manufacturers for discounts and rebates. Generally, plans offer more favorable coverage of a drug (e.g., listing on the formulary and its preferred tier, fewer utilization management restrictions) in exchange for discounts and rebates. Plans' effectiveness at steering patients to the medicines that receive favorable coverage¹² give plans considerable leverage in negotiations. In Part D, the resulting formularies appropriately need to meet the statute's requirement that they not discriminate against certain beneficiaries and discourage enrollment, among other standards. Prior to the implementation of Part D, CBO noted expectations "that substantial savings will be obtained by the private plans"¹³ and economists have subsequently shown this is the case. A recent study reported that due to Part D plans' ability to "negotiate price discounts through their ability to influence the market share of specific

treatments...Part D substantially lowered the average price and increased the total utilization of prescription drugs by Medicare recipients.”¹⁴

With this and other cost saving strategies, Part D has produced a strong track record of affordability for beneficiaries and taxpayers, while simultaneously enhancing beneficiaries’ access to medicines and maintaining choice among medicines.

Part D Has Reduced Beneficiary Cost—The Medicare Prescription Drug Program is saving beneficiaries money. According to HHS, “The average Part D premium for 2008 is approximately \$25, 40 percent below the original estimate of \$41,” and “Savings to beneficiaries have been significant as well, averaging \$1,200 annually.”¹⁵

Additionally, peer-reviewed research analyzing prescription claims data from Part D enrollees has reported sizable reductions in seniors’ monthly out-of-pocket costs, even when combining results from populations that were both with and without coverage previously.¹⁶ Research also points to even larger reductions in out-of-pocket costs by beneficiaries who were previously without drug coverage. For example, a PhRMA-sponsored study by the Amundsen Group based on prescription claims data since the introduction of the program found that average monthly out-of-pocket spending on medicines has been cut by over 40 percent, from \$73 to \$42, for beneficiaries who were without drug coverage in 2005. Out-of-pocket costs declined even though these beneficiaries are using more medicines than before implementation of Part D.¹⁷

Part D is Costing Taxpayers Far Less than Previously Projected by Independent Government Agencies—Both CBO and the Medicare Trustees have stated that the Part D program is costing far less than anticipated because plans have been able to negotiate better discounts from prescription drug manufacturers than expected.¹⁸ For instance, comparing CBO’s March 2008 10-year projections to its March 2006 projections, the program’s total projected cost for FY2007-FY2016 has dropped by \$438 billion, or 37 percent.¹⁹ These savings are so large that, if the program were being designed today, the revised estimates would allow for a program with no or a greatly reduced coverage gap within the amount of money originally allocated to the program. Notably, plan bids, the best measure of the program’s per capita costs, have markedly declined since 2006—in 2008, they were 12.8 percent lower than in 2006.²⁰

While a number of factors have gone into these revised estimates, CBO continues to attribute the bulk of these reductions to competition among private insurers. Speaking last year, CBO Director Orszag said, “...the ‘primary cause’ of the reduced cost estimate is lower-than-expected bids submitted by prescription drug plans to provide coverage, which were on average 15 percent less than last year... ‘The bids are coming in, and the pricing is coming in better

than anticipated, and that is likely a reflection of the competition that's occurring in the private market."²¹

Regarding discounts and rebates under Part D, publicly available information includes useful information. According to the Medicare Trustees, savings off retail price from discounts, rebates, and utilization management on all drugs are about double those previously projected—an increase from 15 percent estimated in 2006 to “about 30 percent” in 2008.²² The Trustees Report also notes, “Many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent.”²³ Medicare’s Office of the Actuary reports that prescription drug price growth was 0.8 percentage points lower than that reported by the 2006 Consumer Price Index, “which did not reflect the movement to Medicare Part D coverage of beneficiaries who previously lacked drug coverage or were only partially insured.”²⁴ And according to CBO, Part D plans have “secured rebates somewhat larger than the average rebates observed in commercial health plans.”²⁵

Part D and Beneficiary Access to and Choice among Medicines

Insurance is key to good access to care, whether such care be hospitals, physicians, or medicines. Part D has greatly expanded seniors’ and disabled persons’ access to needed prescription medicines. According to a Lewin Group analysis commissioned by PhRMA, in 2006 approximately 14 million senior and disabled Medicare beneficiaries first gained access to comprehensive drug coverage through Part D and the percent of beneficiaries with comprehensive coverage increased from 59 percent to 90 percent.²⁶ Peer-reviewed literature estimates a 6 percent to 12 percent average increase in the utilization of prescription medicines by Part D enrollees, including both those who were previously with and without coverage.²⁷ Other research indicates that those who enrolled in Part D and were without prior coverage, experienced better adherence to prescribed therapies.^{28, 29}

In addition to offering beneficiaries coverage improving their access to medicines, Part D has offered beneficiaries choice of medicines, through the medicines covered by individual plans and through choice among plans. Two of the largest Part D plans advertise that they offer coverage of all 100 drugs most commonly used by beneficiaries.³⁰ Clearly, then, offering choice of medicines is compatible with offering an affordable insurance plan.

Beneficiary choice among plans and the availability of a range of affordable options are key components of the program, promoting both affordability and access to medicines. According to CMS, in every state this year, beneficiaries have access to at least five freestanding plans with premiums of less than \$25 a month.³¹ All enrollees can change plans on an annual basis in order to maintain prescription drug coverage that fits their cost and coverage needs. Those who qualify for the low income subsidy (LIS) may change plans at any time

throughout the year. The Lewin Group in a study commissioned by PhRMA found that in both 2006 and 2007, a very large majority of beneficiaries picked plans that combined no deductible, lower-than-average premiums, and a broad choice of medicines, which adds up to high value.³²

Research conducted prior to Part D on the impact of drug coverage and use of medicines on the elderly indicates there is strong potential for drug coverage to reduce avoidable hospitalizations paid for by Medicare as health outcomes improve.³³

Medicare Beneficiaries Report That They Are Satisfied With Their Part D Coverage and Are Saving Money—Surveys conducted within the last nine months by AARP and The Wall Street Journal Online/Harris Interactive report that Medicare Part D enrollees are highly satisfied with their Part D coverage and are saving money. In these two surveys, 85 percent and 87 percent of Part D enrollees reported being either “satisfied” or “very satisfied” with their coverage. Additionally, 67 percent and 75 percent of respondents in the two polls indicated that they were saving money.³⁴

Medicare Part D’s Impact on the Pharmaceutical Innovator Sector

As mentioned above, Part D has cost far less than CBO or the Medicare Trustees had anticipated for both beneficiaries and taxpayers. At the same time, a substantial amount of publicly reported information indicates that since Part D’s enactment and implementation, drug cost growth has slowed. While this likely is related to a variety of factors, taken as a whole, these data indicate that even as coverage greatly expanded for Medicare beneficiaries, based on publicly available data discussed below, Part D has had limited impact on pharmaceutical innovators’ sales.

Drug Spending Growth Has Slowed Since Part D Was Implemented—Notwithstanding the large-scale expansion of coverage that came with Part D in 2006, when approximately 14 million seniors and disabled Medicare beneficiaries first gained comprehensive prescription drug coverage,³⁵ IMS Health reported that drug spending increased that year at the second lowest rate of growth since 1995 (8.3 percent).³⁶ IMS Health also reported that retail drug spending in 2007, the second year of Part D’s operation, grew by the lowest rate in 47 years, (since 1961—3.8 percent) and 15 percentage points below the peak growth rate in 1999.³⁷ Notably, the slowdown in prescription drug cost growth has continued. IMS Health reported earlier this week that total U.S. spending of prescription medicines through retail pharmacies (which includes mail order pharmacies) grew by just 1 percent for the twelve months ending in May 2008.³⁸

Part D Has Increased Pharmaceutical Sales by Just Under 1 Percentage Point—According to IMS Health, in its first year of operation, the Medicare Part D program had only “lifted retail prescription volume by an estimated 1 to 2

percentage points and pharmaceutical sales by just under 1 percentage point.³⁹ The sales figure includes both brand and generic drugs and both manufacturer and pharmacy costs.

Generics Fill Over Two-Thirds of Part D Prescriptions and the Rate Is Increasing—IMS Health reports that in 2007, generics accounted for 13 of the 15 drugs most prescribed to Medicare Part D beneficiaries,⁴⁰ and generics accounted for 68 percent of all medicines prescribed in Part D,⁴¹ up from 65 percent in 2006,⁴² when the Medicaid program had a 60 percent generic prescribing rate.⁴³

The Medicare Trustees and Others Note that Part D Plans Have Put Cost Pressure on the Pharmaceutical Research Sector—As discussed above, the Medicare Trustees have roughly doubled their estimate of the savings off retail price from discounts, rebates, and utilization management achieved by Part D plans—from 15 percent in 2006 to “about 30 percent” in 2008.⁴⁴ Additionally, according to the Trustees Report, “Many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent.”⁴⁵

Cost Savings for Those Who Previously Paid Full Retail Prices— It seems likely that Part D plans negotiate rebates for drugs on behalf of their entire covered population.⁴⁶ In examining the costs of a program such as Part D, a key factor to consider is aggregate cost savings (including but not limited to discounts and rebates) for the entire Medicare population.

An important aspect of this issue is that a full assessment of Part D’s impact on pharmaceutical innovators would include the roughly 14 million seniors and disabled persons who previously were uninsured or lacked comprehensive prescription drug insurance and who have now gained coverage through Part D.⁴⁷ Previously, this group typically paid prices that did not reflect negotiated discounts and rebates. Now, discounts and rebates are negotiated on their behalf by powerful purchasers, representing millions of covered lives. As noted above, the Medicare Trustees have reported that rebates on brand drugs often are substantial and CBO has reported, based on preliminary data, that beneficiaries are in plans that have “secured rebates somewhat larger than the average rebates observed in commercial health plans.”⁴⁸

We also note that for several reasons rebates alone are not the full measure of cost savings achieved in Part D. First, as the Medicare Trustees have made clear, generic manufacturers typically do not pay rebates to Part D plans⁴⁹ (though publicly available information suggests generic manufacturers may pay rebates to pharmacies⁵⁰). With generic prescribing rates at an unprecedented high level, overall rebates may diminish even though drug spending is constrained. Similarly, rebates are only one type of price concession; the mix of rebates and discounts may vary from one setting (such as Medicaid) to another (such as Part D) based on many differences in program structure.⁵¹

Government Price Controls Should Not Be Added to Medicare Part D

Part D includes vigorous cost containment which has produced real cost savings while offering increased beneficiary access to needed medicines. The alternative approach of government price controls and/or access restrictions would not meet the program's objectives.

A study of foreign government price controls by the U.S. Department of Commerce found, "[s]uch controls can also delay or reduce the availability of some innovative medicines in foreign countries, with the effect of limiting competition and requiring national health systems to forego the benefits of these innovations in reducing health care costs."⁵² According to the findings, "[t]hese strategies tend to have the most significant impact on the newest and most innovative medicines..." Jack Calfee, resident scholar at the American Enterprise Institute, notes "[o]ther than the dismantling of intellectual property, no policy would be more destructive to innovation than price controls."⁵³

A review of empirical literature on government price controls, supported by PhRMA, addresses the negative effects of government price regulation. According to this review, "[t]he adverse effects of price regulation occur through two channels. First, price regulation depresses firms' market performance, thereby depressing R&D and the discovery of new drugs. Declines in the number and innovativeness of new drugs, in turn, lead to decreased longevity and higher expenditures on other forms of medical care. Second, price regulation delays drug launches, distorts consumers' choices toward less innovative drugs, and in some cases actually leads to increases in prices. These effects lead to decreased longevity as well."⁵⁴

Additionally, independent analysts have indicated that price controls inside one payer can have an adverse effect on other payers. According to CBO, "[s]ome private-sector purchasers pay higher prices as a result of the best-price provision in Medicaid's rebate program."⁵⁵

The Competitive, Market-Based Medicare Part D Program Is Working

In conclusion, CBO and the Medicare Trustees have reported that it is primarily the effective operation of the competitive market that has driven down Part D costs for beneficiaries and taxpayers compared to previous estimates. Government negotiation of Part D prices will achieve "negligible" savings according to CBO unless the government restricts access or sets prices.⁵⁶ Changing Part D's competitive, market-based structure would undermine the carefully balanced approach that has produced sizable cost savings for Medicare beneficiaries and taxpayers and greatly improved access to needed medicines for seniors and disabled persons. Like any program, Part D may benefit from improvements, as it did last week. We believe improvements should proceed

from and maintain the successful foundation that the program has established to date, along with recognition of its aggregate impact and multiple policy objectives.

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- ⁵ Lichtenberg, FR. "The Expanding Pharmaceutical Arsenal in the War on Cancer." National Bureau of Economic Research Working Paper 10328, February 2004.
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- ¹³ CBO Letter to the Hon. Bill Frist, January 23, 2004
- ¹⁴ Mark Duggan and Fiona Scott Morton, "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization" NBER Working Paper No. 13917, April 2008.
- ¹⁵ The U.S. Department of Health and Human Services, "FY 2009 Budget in Brief," page 53, available at: www.hhs.gov/budget/09budget/2009BudgetInBrief.pdf
- ¹⁶ Lichtenberg and Sun, "The Impact of Medicare Part D on Prescription Drug Use by the Elderly," *Health Affairs*, Nov/Dec 2007 and Yin, et al., "The Effect of the Medicare Part D Prescription Drug Benefit on Drug Utilization and Expenditures," *Annals of Internal Medicine*, February 2008.
- ¹⁷ Verispan Longitudinal Data, Amundsen Group analysis for PhRMA, May 2008. This analysis does not include Medicare-Medicaid dual eligible population, which had drug coverage in 2005 under Medicaid.
- ¹⁸ Remarks by Richard Foster, CMS Chief Actuary, in John Reichard, "Foster Offers Little Comfort to Medicare Funding Combatants" CQ HEALTHBEAT NEWS, April 1, 2008; 2008 Medicare Trustees Report, p. 160; See also: Bloomberg News, January 26, 2007; See also: CBO, "The Budget and Economic Outlook: FY 2008-18," January 2008, pp. 58-59; See also: CBO, "The Budget and Economic Outlook: FY 2008-17," January 2007, pp. 58-59.
- ¹⁹ CBO Medicare Baseline Spending Estimates for March 2006 and March 2008, available at www.cbo.gov
- ²⁰ August 13, 2007 CMS Office of the Actuary Memo, "Release of the 2008 Part D National Average Monthly Bid Amount." The CMS/OACT memos for 2006, 2007, and 2008 are available at www.cms.hhs.gov. See also CMS Press release; Strong Competition And Beneficiary Choices Contribute To Medicare Drug Coverage With Lower Costs Than Predicted, August 13, 2007.
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- ²⁵ March 12, 2007 CBO letter to the Honorable Joe Barton and the Honorable Jim McCrery, page 3.
- ²⁶ Lewin Group analysis for PhRMA "Beneficiary Choices in Medicare Part D and Plan Features," <http://www.lewin.com/PublicationsInsights/Publications.aspx>, September 2006.
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- ²⁹ Madden et al., "Cost-Related Medication Nonadherence and Spending on Basic Needs Following Implementation of Medicare Part D," *JAMA*, April 23/30 2008.
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- ³¹ CMS Press Release, August 13, 2007, *Op. cit.*
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- ⁴² IMS Health, "IMS Medicare Watch: Medicare Part D: The First Year," August 9, 2007.
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- ⁴⁵ 2008 Medicare Trustees Report, p. 160.
- ⁴⁶ Consistent with long-standing Medicare policy and practice. many groups worked to integrate the dual eligible population into Part D, so that they would be treated as part of rather than differently than the full Medicare population. Notably, dually eligible beneficiaries also are integrated into Parts A and B, with Medicare coverage and payment policies prevailing for the services covered by Parts A and B.
- ⁴⁷ Lewin Group analysis for PhRMA "Beneficiary Choices in Medicare Part D and Plan Features," <http://www.lewin.com/PublicationsInsights/Publications.aspx>, September 2006.
- ⁴⁸ March 12, 2007 CBO letter to the Honorable Joe Barton and the Honorable Jim McCrery, page 3.
- ⁴⁹ 2008 Medicare Trustees Report, p. 160.
- ⁵⁰ CBO, "Prescription Drug Pricing in the Private Sector," January 2007, p. 1
- ⁵¹ See, for example, "Medicare Part D Reporting Requirements: Contract Year 2008" which instructs plans to report a variety of cost saving measures such as, "rebates... non-rebate discounts, price concessions, or other [items]...Available at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_NextYear.pdf
- ⁵² Source: Pharmaceutical Price Controls in OECD Countries, Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, U.S. Department of Commerce, International Trade Administration, Washington, D.C., December 2004.
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- ⁵⁴ Source: Daniel P. Kessler, "The Effects of Pharmaceutical Price Controls on the Cost and Quality of Medical Care: A Review of Empirical Literature," Annex C, PhRMA Submission to the U.S. Department of Commerce, July 1, 2004
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- ⁵⁶ CBO Score of S.3, The Medicare Prescription Drug Price Negotiation Act of 2007, April 16, 2007

Chairman WAXMAN. Mr. Precht.

STATEMENT OF PAUL PRECHT

Mr. PRECHT. Thank you, Chairman Waxman, members of this committee, for this opportunity to testify.

I am Paul Precht, director of policy and communications for the Medicare Rights Center.

The Medicare Rights Center is a national consumer service organization with offices in New York and Washington. Our hotline volunteers and caseworkers help older and disabled Americans deal with every conceivable type of problem standing between them and the health care they need.

Before the Part D benefit started in 2006, the most frequent call came from people with Medicare who could not afford to buy the medicines they were prescribed. Today, despite the billions in subsidies provided to the insurance companies and pharmacy benefit managers running Part D, it remains the No. 1 problem we hear.

A typical call comes from someone making less than \$20,000 a year. More than half of the people with Medicare earn less than that amount. They don't have much to live on, but it is still too much to qualify for extra help with their prescription drug costs.

Multiple drugs to treat multiple chronic conditions put this person in the Part D coverage gap, the donut hole, where she—and it is often a widow living alone who calls—must pay both the premiums for her Part D drug coverage and the full price of her drugs. With a drug bill in excess of \$500 per month for months on end, on top of medical and other bills, the options are few. She can try to get free samples from her doctor. She can head for the emergency room. When these strategies fail, too often, she may go without the medicine she needs.

Prescription drug prices are just too high, and Part D plans are not delivering the lower prices that were promised when this benefit was created. They certainly are not providing discounts on par with the prices the VA, State Medicaid programs, or our neighbors in Canada have secured. That is widely acknowledged.

What is less well-known, however, is that the rebates and discounts that the Part D plans have been able to obtain are not passed through to consumers in the form of lower prices. That means each time a diabetic person with Medicare scrapes together the money to buy a \$400 specialty drug, the Part D plan pockets a \$30 or \$40 rebate, based on the averages that this committee has uncovered. That rebate is not used to lower the \$100 coinsurance she paid during the initial benefit period, and it does not bring down the \$400 price she pays during the donut hole.

Plans argue that rebate revenue is used to keep premiums down. In effect, under this system, sick people who need expensive medicine pay a surcharge to keep costs down for their healthier neighbors. It is the opposite of the way insurance is supposed to work.

It is not just brand-name drugs that are too expensive under Part D. People with Medicare are also being overcharged for generics under some plan D plans. This scheme was described in the Wall Street Journal this week. This is how it works.

The Part D plan, an insurance company, pays its pharmacy benefits manager \$60, for example, for each prescription of generic

Zocor that it covers. But the drug really costs only \$20. The pharmacy receives \$15 from the PBM and \$5 from the consumer. At the end of the month, the consumer gets a statement from the PBM saying it spent \$55 for the prescription, and the customer is \$60 closer to the donut hole.

Consumers who take a few generic drugs that are subject to these inflated prices can be pushed into the donut hole 2 or 3 months earlier in the year. What happens when consumers hit the donut hole? Do they pay the \$20, the reimbursement rate for the pharmacy? They do not. They pay \$60, and the pharmacy is forced to kick back \$40 to the PBM.

PBMs argue this pricing scheme keeps administrative costs down for the insurance companies. But here is the twist: Sometimes the Part D plan and the PBM running this pricing scheme are part of the same company. In our view, prices are being manipulated to gouge both the consumer and Medicare, which pays more for the dual eligibles, since they pay the cost sharing.

We are 2½ years into the Part D drug benefit, and even if the administration follows through on its promise to end this scheme—and they backed off last time they proposed to end it—it will continue through the end of 2009.

When the insurance industry and the PBMs talk about how Part D has marshaled market forces to lower costs, this is the market they are talking about. It is untransparent, it is rigged against consumers, particularly when they fall sick, and it does not deliver the prices consumers could receive if Medicare was negotiating with manufacturers and running the benefit.

People with Medicare should have the choice to receive drug coverage directly through Medicare. A Medicare plan that, for example, could encompass the duals, as a start, would be a good way to deal with these overcharges that we are facing.

Just one last remark. Everybody talks about the satisfaction rates with Part D. But those same polls also show similar percentages of people want a simpler benefit, they would like the option to have coverage under Medicare, and they want the government to be able to negotiate lower prices.

Thank you.

[The prepared statement of Mr. Precht follows:]



Medicare Rights Center

Medicare Part D Drug Benefit

Testimony before the U.S. House of Representatives

Committee on Oversight and Government Reform

**Paul Precht, Director of Policy and Communications
Medicare Rights Center**

July 24, 2008

Thank you Chairman Waxman, Ranking Member Davis, distinguished members of the House Committee on Oversight and Government Reform for this opportunity to testify about the Medicare Part D Prescription Drug Benefit. I am Paul Precht, Director of Policy and Communications for the Medicare Rights Center.

The Medicare Rights Center is a national consumer service organization, with offices in New York and Washington, working to ensure that older and disabled Americans get good, affordable health care. Every year the Medicare Rights Center hears from more than 60,000 Americans with Medicare, who have questions about their Medicare benefits, rights and options and problems accessing critical care. Their greatest problem by far is securing affordable prescription drugs. We thank you for inviting MRC to share with you the consumer perspective on the issue of prescription drug costs for people with Medicare.

Medicare Rights Center caseworkers and hotline volunteers handle a wide variety of consumer complaints related to the Part D drug benefit. Some of the issues include:

- Consumers find that medicines they need are not covered by their Part D plan and the plan is unresponsive to their efforts, or the efforts of their doctor, to obtain coverage on the basis of medical necessity.
- Consumers find themselves in the Part D coverage gap, and are unable to afford the cost of their prescriptions.
- Low-income people with Medicare cannot afford the cost sharing under Part D, but are just above the income or asset levels that would qualify them for premium and cost sharing assistance under the Extra Help program.

- Low income people with Medicare who receive Extra Help find their coverage is unstable and unpredictable, as they are abruptly shifted from a plan with a premium that is too high to qualify for a full subsidy to a plan that is cheaper but has new coverage restrictions.
- Consumers find the annual changes in premiums and coverage, and the more frequent changes in prices, confusing and frustrating and the process of selecting a Part D plan daunting.

Too often the result of these problems is that people stop taking their medicines, skip or split doses, or delay filling prescriptions. When these medicines are used to treat conditions such as heart disease, diabetes, mental illness or HIV-related illnesses, the impact on consumers' health can be serious, even life-threatening.

If I was filling all of my prescriptions monthly perhaps I would be able to better control my multiple health issues. As it is, I have hit the coverage gap early on and have had to stop taking some of the meds because I just cannot afford them. I am one month behind in my premium payments because if I get medicine I can't pay the premium. I never have anything left to help with medical copays so now I owe quite a bit of money to my doctors and have stopped calling and going unless I absolutely must. It is a nightmare for the doctors trying to help me fight these illnesses and for me. When I am not in the coverage gap, I pay my premium and roughly \$800 for medication and copays. My disability check is only \$1250. In my state the amount of the check disqualifies me from receiving help from the senior food program. I have no family to help. I have a Master's Degree in Education and thought I would always be able to work—an illusion. No savings, no retirement—all long gone trying to stay alive. I am living now in HUD project that takes my medical into consideration and adjusts my monthly rental. Were it not for that I would be homeless.

Person with Medicare, Baton Rouge, LA

All of these consumer problems are rooted in the continuing high cost of prescription drugs under a benefit run exclusively by insurance companies and pharmacy benefit

managers (PBMs). There is no option to obtain coverage through Original Medicare and the administration is barred from any role in negotiating lower drug prices.

The high drug prices consumers pay at the pharmacy counter are a direct consequence of the decision by Congress to turn administration of the benefit over to private companies. These prices are also symptomatic of an opaque, unfair, unstable and inefficient pricing system that exists in the private market and that has been adopted with all its flaws by Part D.

Part D plans have been unable to negotiate discounts from drug manufacturers on par with the prices that the Veterans Administration, state Medicaid programs or the Canadian government have been able to secure.¹ Plans have also failed to pass through, in the form of lower prices, the manufacturer rebates they do receive. The failure to deliver lower prices impacts consumers in four principal ways:

- Consumers pay higher prices during the deductible and coverage gap, the phases of the benefit when they pay the full price of the drug.
- More consumers fall into the coverage gap, or are pushed into the gap earlier in the year, because the spending that determines the start of the coverage gap, and the end of the initial benefit period, is based on these high drug prices.
- Copayments and coinsurance rates during the initial benefit period are higher, since these payments must, on average, equal 25 percent of the price of covered drugs. The higher the price, the more money it takes to equal an average coinsurance rate of 25 percent.

¹ See *The Best Medicine: A Drug Coverage Option under Original Medicare*, Medicare Rights Center, October 2007, available at <http://www.medicarerights.org/TheBestMedicine.pdf>

- Coverage is more restricted, since plans want to discourage use of high-cost medicines.

Basic Part D Plan in 2008:

- The first \$275 of their drug costs for covered drugs each year (deductible);
 - Coinsurance or copayments worth on average 25% of the cost of covered drugs between \$276 and \$2,510;
 - 100% of the cost of covered drugs between \$2,511 and \$5,726.25 (coverage gap or doughnut hole); and
 - 5% of the cost of covered drugs above \$5,726.25—catastrophic coverage (or a copayment of \$2.25 for covered generics/preferred drugs and \$5.60 for covered brand name drugs, whichever is greater).
- Under this plan, consumers will have to reach \$4,050 in out-of-pocket costs in 2008 before you can receive catastrophic coverage.

Policy Implications

The high prices also impact people with Medicare because they constrain the policy options available to Congress to improve coverage.

The very existence of the doughnut hole under Part D is attributable to the high prices paid under the benefit. Congress could not provide a benefit without a coverage gap for the \$400 billion budgeted for a Medicare drug coverage. If the Part D plans could secure prices similar to those provided by the health systems in other industrialized countries, the savings would be sufficient to eliminate the doughnut hole.² The high prices under Part D make it expensive to enact even incremental improvements to the drug benefit, such as expanding access to Extra Help by removing the asset test. This would allow low income older adults and people with disabilities with modest nest eggs to qualify for lower copayments and coverage through the doughnut hole.

² See *The Best Medicine: A Drug Coverage Option under Original Medicare*, Medicare Rights Center, October 2007, available at <http://www.medicarerights.org/TheBestMedicine.pdf>

A System Without Transparency

The prices charged by Part D plans are available to the public on medicare.gov, the on-line plan finder developed by the Centers for Medicare & Medicaid Services (CMS). The availability of these prices, however, provides only the illusion of transparency.

The retail price used by Part D plans is typically based on a percentage of the list price set by the manufacturer, known as the Average Wholesale Price. As a result, consumer prices rise whenever the manufacturers raise the list price. The price that is listed one month, when a consumer consults the plan finder to select the plan, may be completely different the following month, after they have chosen their plan and are locked in for the year.

My 91 year old mother-in-law hit donut hole last year so I went to Medicare drug plan website to use drug plan finder (I have power of attorney). Switched plans and realized in January that the drug pricing information placed on website by insurance company was erroneous and therefore the drug plan finder recommended the wrong plan. This plan will cost several thousand dollars more than plans we could have switched to. It is also amazing to realize how different the price is that these big insurance companies pay for the same drug.

Caretaker for person with Medicare, Atlanta, GA

Lock-In Pricing Model

The price listed on the plan finder, and the monthly Explanation of Benefits received by Part D enrollees, may, or may not reflect the price received by the pharmacy. A number of the major Part D and Medicare Advantage plans, with over 3.5 million enrollees, charge their members prices that are well above the prices received by the

pharmacy. The difference, known as the spread, is pocketed by the pharmacy benefit manager (PBM) administering the benefit for the Part D plan, or, in cases where the PBM and the Part D plan are the same, by the Part D plan itself. Part D plans who adopt this pricing scheme, which is common also in the private market, are said to use a “lock-in” pricing model.

In our experience, the use of the so-called “lock-in” pricing model, in which the prices plan sponsors pay the PBMs are used to calculate spending and coinsurance rates, results in substantially higher prices for consumers, particularly for many widely prescribed generic drugs. These prices are substantially higher than the reimbursement rates established for network pharmacies and often higher than widely available retail prices, indicating that the PBM is keeping the “spread” between the price it receives from the Part D sponsor and what it pays network pharmacies. Whether this spread is a disguised payment for administrative services, or simply a hidden revenue source for the PBM is irrelevant. It is a cost shift to the consumer that is not related to the cost of the drug.

These higher prices can have the effect of pushing consumers into the coverage gap earlier in the year than would occur if drug spending were calculated on the basis of the price negotiated with the pharmacy. These higher “lock-in” prices are used to calculate coinsurance rates as well as to calculate copayment rates. In effect, plans that use these inflated prices do not provide the minimum standard benefit required under the statute. Average beneficiary cost-sharing between the deductible and the initial coverage limit is no longer equivalent to 25 percent of the cost of drugs, the cost sharing established by statute for a standard benefit. By inflating the drug price to include the

“spread” retained by the PBM, the benefit is diluted and consumers effectively pay more than an average of 25 percent.

Similarly, because the initial coverage limit is based on prices that are inflated to include the PBM spread, enrollees in plans using this pricing model have an initial coverage limit that is based not only on total drug spending, but on total drug spending plus PBM “spread” revenue. Once the PBM spread is subtracted from total drug spending, the initial coverage limit can be substantially lower than the amount established by statute.

It is deeply troubling that the lock-in pricing model tends to substantially raise prices for commonly prescribed generics. Consumers generally have switched to a generic because of coverage restrictions imposed on brand name drugs in the same therapeutic class, to reduce out-of-pocket spending and to avoid falling in the Part D coverage gap. It is unfair that these consumers, after taking action they thought would lower their costs, should be subject to a pricing model that not only fails to deliver the full savings benefit of generic substitution but could also push them into the coverage gap earlier in the year.

The lack of transparency in the “lock-in” pricing model puts consumers at a disadvantage. In our experience, consumers selecting Part D plans tend to focus primarily on the monthly premium and, to a lesser extent, the coverage and copayments associated with classes of drugs, such as generics. Consumers may be attracted to a Part D plan because it offers low premiums, low copayments and/or gap coverage for generic drugs, yet be unaware that these lower costs are financed by the use of inflated prices for these generics. Moreover, these inflated prices can push them into the coverage gap earlier in

the year and raise their costs once they are in the gap. Our comparison of Part D plans on the plan finder shows that plans charging the highest prices for generic drugs most subject to a “spread” between pharmacy and PBM reimbursement can cost consumers hundreds of dollars more per year, even though they charge premiums and provide coverage and copayments for generics that would seem to provide consumers with a cost advantage.

The “lock-in” pricing model also results in higher prices for consumers when they are in the deductible or coverage gap phases of the benefit. Sometimes, these prices are higher than what pharmacies charge their uninsured customers. Congress’ intent in guaranteeing access to negotiated prices in all phases of the benefit was surely meant to ensure access to prices that are lower than those charged uninsured consumers. As presently construed, however, a Part D plan can meet the requirement to provide access to negotiated prices by charging prices that are higher than the price paid by consumers with no drug coverage.

Besides consumers, state pharmaceutical assistance programs (SPAPs) that coordinate with Part D also pay higher prices when pick up cost-sharing for SPAP members enrolled in Part D plans that use “lock-in” pricing. This makes it more expensive for states to provide wrap-around coverage for Part D and more expensive to extend such coverage to other people in need not currently eligible for SPAP coverage, such as people with disabilities. Similarly, the use of inflated “lock-in” prices raises the cost to the government of paying cost-sharing for low income recipients of Extra Help. The government also pays more in reinsurance subsidies when plans use lock-in pricing.

CMS has proposed new regulations that would eventually bar Part D plans from using “lock-in” prices under Part D. We support those regulations and trust that the administration will stick to its proposal, notwithstanding pressure from the PBM lobby to weaken it. It is a shame that this anti-consumer practice has been allowed to continue for this long.

Even if CMS follows through on its proposed regulation, however, we are concerned that it will not prevent consumers from being charged inflated prices because the negotiation between the Part sponsor (or its PBM) allows certain network pharmacies, including mail order pharmacies, to pocket the “spread” on certain generic drugs. This practice is especially pernicious when Part D plans use lower copayments to steer beneficiaries to pharmacies that use higher drug prices than other network pharmacies.

There is at least one major Part D plan which sets substantially higher prices for certain generic drugs purchased through a mail order service offered by a national pharmacy chain than it charges to enrollees who use “brick-and-mortar” pharmacies. This national pharmacy chain has substantially more market leverage to secure lower prices for generics than independent pharmacies and there are no higher dispensing costs associated with these particular drugs. It appears the Part D plan, and its mail-order pharmacy, are colluding to disadvantage both consumers and the Medicare program through the use of inflated prices. Beneficiaries who use the mail order service during the initial phase of the benefit are likely unaware that they are being pushed into the coverage gap more quickly because higher prices are being used to calculate total drug spending.

Similarly, there is one Part D plan where the plan sponsor, its PBM and a national pharmacy chain, are all related entities. Under the lock-in pricing model, this plan

charges among the highest prices for commonly used generics, according to data on medicare.gov. Under CMS' proposed regulation, such inflated prices could not be used when plan enrollees used a network pharmacy that received a lesser rate as reimbursement. But, the plan sponsor may still be allowed to use these higher prices to calculate the benefit if its in-house mail-order pharmacy, or the pharmacy chain that is part of the PBM, is the entity that is allowed to pocket the spread. This plan still could use lower copayments for mail-order or for "preferred" network pharmacies in the national pharmacy chain to steer enrollees to pharmacies that allow the parent company to benefit from the spread, even as the customer is pushed closer to the coverage gap because these inflated prices are used to calculate drug spending.

Rebates

As research by this committee and others demonstrates, Part D plans do not use the rebates and other price concessions they receive from brand name drug manufacturers to lower prices for consumers. As a result, consumers paying prices for brand name drugs that are higher than the net prices actually paid by Part D plans.

Research conducted for the Medicare Payment Advisory Commission shows that the prices charged by Part D plans for drugs that may also be covered under Part B are usually higher than the Part B reimbursement rate. The Part B reimbursement rate is itself 6 percent higher than the Average Sales Prices, a measure which is meant to reflect the price, net of manufacturer rebates, actually received by PBMs, insurers and other providers. The B-D price differential indicates that these manufacturer rebates are not passed through as lower the prices for consumers. Since these drugs are primarily high-cost specialty drugs, and the price differential between Parts B and D is substantial, this

means that beneficiaries who need these medicines to treat cancer or other serious and life-threatening diseases or prevent rejection of transplanted organs, often pay thousands of dollars more per year because of Part D plans failure to use the rebates they receive to lower consumers prices.

Instead of lowering the consumer prices, manufacturer rebates are used to lower premiums, pay administrative costs or increase the profits or Part D plans. Using higher drug prices to pay costs that should be derived from premiums dilutes the insurance principle. Under the insurance principle, the premiums paid by sick and healthy plan members are used to defray the cost of care when a plan member falls ill. Under the Part D pricing system, the reverse occurs. In effect, beneficiaries who purchase brand name drugs generate rebate revenue that Part D plans use to subsidize coverage (through lower premiums) for beneficiaries who do not take these drugs.

Last year I fell into the donut hole in early May. I then had to pay full price for all my medicines. My total prescription bill for 2007 was \$4688.91. That is an average of \$390.74 a month. This year I am getting my name brand medicines from out of the country and only using my Medicare D plan for my generic medicines. I think I will be cutting my average monthly cost down to \$200 a month; a 50 percent savings.

Person with Medicare, Marquette, MI

This effect is particularly pernicious in the case of high cost specialty drugs— medicines that are generally not “discretionary” but, instead provide the only hope for the beneficiary's survival. Already burdened with the high out-of-pocket costs associated with a serious illness like cancer, these patients must pay prices that are higher, because they are not reflective of the price, net of rebates received by the Part D plans. The sickest plan enrollees pay both premiums and the inflated prices of their medicines,

bearing a disproportionate share of the administrative costs and profits of their Part D plan.

A Better Option

The pricing schemes employed by Part D plans—the use of “lock-in” pricing to inflate the cost of generics and the failure to have consumer prices reflect the manufacturer rebates for brand name drugs—mean that consumers pay higher copayments during the initial and catastrophic phases of the benefit and higher prices during the coverage gap. The coverage paid for by premiums and taxpayer subsidies is devalued by prices that are inflated to allow Part D plans and their subcontractors to pocket the “spread” on generics and the rebates on brand name drugs.

Consumers and taxpayers would be better served by a transparent, stable drug pricing system. The system that exists today, however, with its secret rebates and hidden “spreads,” is reflective of the larger marketplace for prescription drugs. When the architects of the Part D benefit decided to use the “power of the marketplace” to control costs under Part D, it is *this marketplace*, with all its instability, perverse incentives and lack of transparency that they decided to employ. The result for consumers is drug prices that continue to spiral higher. The result for taxpayers is a \$1 trillion benefit that fails to provide people with Medicare with the affordable medicines they need.

We have seen how a privatized Part D benefit works and the prices it delivers. Taxpayers and people with Medicare deserve better. Congress should allow people with Medicare the option to obtain drug coverage directly through Original Medicare. That will provide consumers with stable coverage, lower prices, and with the one choice they

now cannot have. It will save taxpayers money and inject price discipline and transparency into a drug marketplace that now has neither.

Chairman WAXMAN. Ms. Stein.

STATEMENT OF JUDITH STEIN

Ms. STEIN. Good afternoon and thank you, Chairman Waxman. Thank you for being here, Mr. McHenry and Congressman Murphy.

I am Judy Stein. I am testifying today on behalf of the Center for Medicare Advocacy, of which I am the founder and executive director.

Since 1977, first at Connecticut Legal Services and then when I founded the Center in 1986, I have dedicated my legal career to representing Medicare beneficiaries. At the Center for Medicare Advocacy, we have represented thousands of Medicare beneficiaries and their helpers in Connecticut and across the country to understand and utilize Part D. We hear repeatedly from them about problems that arise from the complexity of the program and its ever-increasing costs. Unfortunately, problems go beyond just the dually eligible population.

There are a myriad of plans, each with varying benefit structures, formularies, out-of-pocket costs, and it makes comparisons all but impossible. Beneficiaries have insufficient information to understand formularies, coinsurance, copayments and coverage gaps. They lack sufficient information to make sound choices. Indeed, the Center has hired an experienced advocate who dedicates all of her time just to handle the Part D problems just in Connecticut.

I thank you very much, Chairman Waxman for your leadership in investigating prescription drugs and Part D in general and Congressman Murphy for all the work he has done in our home State and now very happily here in Washington to help Medicare beneficiaries across the country.

Over the past several years, the Center has written extensively about the effects on our clients of increased reliance on private insurance plans to provide Medicare coverage. Those plans lack the stability and uniformity of the Medicare program, and they have often decreased, not increased, access to care and increased costs.

Unfortunately, the only way to get Medicare coverage for outpatient prescription drugs is through private plans. Our clients must decide each year which plan to choose from among dozens and dozens with varied cost sharing and coverage rules.

This is the packet my mother had to look through, and she is a relatively well woman who takes only three drugs. It took us hours to go through the decisions for her.

If beneficiaries seek assistance, and if it is available, they must divulge private information about their health and medications. I don't think this has been thought of at all as one the personal expenses of the program. This information is something that many beneficiaries do not even want to share with their families. And, frankly, I was not aware of the drugs my mother took until I had to help her with Part D; and she would have preferred I didn't. It is also a step beyond to divulge this information to 1-800-MEDICARE representatives or a plan operator, and many people don't want to do that.

As a consequence, the vast majority of beneficiaries, because of these problems and others, do not in fact change plans from year

to year, so the whole issue of choice is increasingly becoming a red herring. In fact, 17 percent—only 17 percent of people chose to switch plans this last year, even though it would have been in their best interests oftentimes to do so.

Our clients are subject to the whims of the companies that decide to offer drugs to the Medicare program. They must either bear the increased costs and reduced access to drugs or go through one or another an onerous process, either to choose to appeal a decision or to wait until next year when they may be able to get a better plan. Because if your health changes or the plan changes the drug's pricing or the drugs on its formulary, all of which can happen, you cannot get into a different Part D plan.

According to an ongoing study by AARP, any savings in drug costs achieved by Part D were achieved through a reduction in the cost of generic drugs. However, the prices for 169 brand-name drugs went up 50.4 percent between 2001, when the first AARP study happened, and 2007.

Higher drug costs mean that beneficiaries reach the coverage gap, or donut hole, sooner. Increased costs are causing a terrible impact on our beneficiaries, especially those who cannot take a generic equivalent, and that includes people with cancer, cardiac problems and other very significant illnesses. No stand-alone drug program offers brand-name drug coverage during the gap.

This week, a woman from California e-mailed us telling us, "I am having terrible problems trying to find a way to pick the medication for my father's chronic illness. He is diabetic, needs chemotherapy for bladder cancer, and has cardiac arrhythmia. Between him and my mother, they have only \$1,900 per month, and my father is already in the donut hole." That was in July. There are 6 more months ahead.

One of our clients in Connecticut, a 52-year-old woman, pays \$6,000 a month for her medications, if she could afford them, which she cannot. She is on Social Security Disability because of her sickle cell anemia. Her prescription drug plan refused to provide coverage for the dose needed by this woman, even though it was ordered by her physicians, who referred her to the Center, and we appealed outside the plan finally and got coverage.

One woman in Tennessee wrote she can't afford and is therefore not taking her drugs.

In conclusion, the program has untold expenses for beneficiaries, for States who, like Connecticut, are wrapping around and paying for Medicaid beneficiaries and people on their State pharmaceutical assistance plans, and are putting ever-increasing costs of prescription drugs into the prices that taxpayers must pay for Medicare in general.

In summary, we urge the Congress to take the following steps: Include a prescription drug benefit in the traditional Medicare program and authorize the Secretary to negotiate the cost of drugs within that program at least; require drug plans to pass along the fullest extent of their rebates and include beneficiaries while they are—and include those rebates when beneficiaries are paying themselves in the gap; increase transparency by requiring drug plans to make available information about their pricing and rebates; increase oversight of the Medicare Web page, which is often

very different from the information given on the plan's Web pages themselves; and require CMS to provide greater oversight of the Part D plans in their oversight.

Chairman WAXMAN. Thank you very much, Ms. Stein. We are going to put that whole statement in the record and all of those recommendations, which we very much appreciate.

[The prepared statement of Ms. Stein follows:]



STATEMENT OF

Judith A. Stein, Esq.
Executive Director
Center for Medicare Advocacy, Inc.

BEFORE THE

United States House of Representatives
Committee on Oversight and Government Reform

CONCERNING

**“The Medicare Drug Benefit:
Are Private Insurers Getting Good Discounts for the Taxpayer?”**

July 24, 2008

Chairman Waxman, Ranking Member Davis, distinguished members of the Committee, thank you for the opportunity to testify today on behalf of Medicare beneficiaries concerning prescription drug pricing under Medicare Part D. I am Judith Stein, Executive Director and Founder of the Center for Medicare Advocacy, a national, non-profit, non-partisan organization that works to ensure fair access to Medicare and quality health care.

Since 2006, the Center has assisted tens of thousands of Medicare beneficiaries and their helpers in Connecticut and across the country to understand and utilize Part D. We hear repeatedly from them about problems that arise from the complexity of the program and about its ever-increasing costs to them. There are myriad plans, each with varying benefit structures, formularies, and out-of-pocket costs, making meaningful comparisons impossible. Beneficiaries have insufficient information to understand formularies, co-insurance, co-payments, and coverage gaps; they lack sufficient information to make sound choices. Indeed the Center has hired an experienced advocate who dedicates all of her time just to handling Part D problems for people in Connecticut.

We thank Chairman Waxman for his leadership in investigating prescription drug costs under Part D and in his continued oversight of the Part D program as a whole. We also thank committee member Congressman Murphy, from the Center's home state of Connecticut, for his efforts to ensure that Medicare beneficiaries in Connecticut and across the country have access to affordable prescription drugs.

Over the past several years, the Center has written extensively about the negative effect on our clients of the increased reliance on private insurance plans to provide Medicare coverage and benefits. Private plans lack the stability and uniformity of the Medicare program as originally designed. This often results in decreased access to care and increased costs to the older people and people with disabilities who are enrolled in these private plans. Unfortunately for our clients, the

only way to get Medicare coverage for outpatient prescription drugs is through private insurance plans. Our clients must decide each year which plan to choose from among dozens of plans, with varied cost-sharing and coverage rules. If beneficiaries seek assistance—and if it is available—they must divulge private information about their health and medications. This is information many beneficiaries do not even want to share with their family let alone with an unknown helper, a 1-800-MEDICARE representative, or a plan operator. Experience now shows that, as a consequence, the vast majority of beneficiaries do not change plans from year to year even though staying with the same plan is often not in their best interest. And, as the Committee knows, there is no option to obtain drug coverage through the Medicare program itself.

Thus, our clients are subject to the whims of the companies that decide to offer drug benefits through the Medicare program. They cannot petition their Members of Congress, as they can when changes to coverage under Parts A and B of the Medicare program are proposed, to say that they disagree with their drug plan's latest change to tiered benefit structure, to formulary choices, to premiums, and to coverage of drugs in the so-called doughnut hole. Instead, they must either bear the increased costs and/or reduced access to prescriptions, or go through one or another onerous process—either to seek an exception to their plan's structure for the drug in question or wait and choose a new drug plan for the following year—with no guarantee that their new drug plan will not change its benefit package in the future.

As this Committee found in its report of October 2007, *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, "...use of private insurers to deliver Medicare drug coverage is driving up costs and producing only limited savings on drug prices." According to on-going studies by AARP, any savings in drug costs achieved by Part D

were achieved through a reduction in the cost of generic drugs.¹ However, the prices for 169 brand name drugs have gone up 50.4% between 2001, when AARP first began studying drug prices, and 2007. The general inflation rate for that time period was 19%.²

High costs of brand name drugs can be particularly difficult for people who depend on the highest cost drugs, often referred to as “specialty drugs.” The Centers for Medicare & Medicaid Services (CMS) allows drug plans to place drugs that cost more than \$600 in a specialty tier. Even if the plans have flat co-payments for drugs in other tiers, they generally charge a percentage, or co-insurance, for specialty drugs. Thus, the more a drug costs, the larger the out-of-pocket cost for the plan enrollee. About twice as many of the national prescription drug plans (PDPs) (now 41 of 47) include a specialty tier in their benefit structure in 2008 as did in 2006. Twenty-one of these plans charge a co-insurance of 33% for specialty tier drugs, up from four plans in 2006.³

Higher drug costs mean that beneficiaries reach the coverage gap, or doughnut hole, sooner. Once in the doughnut hole, when they are paying the full cost of their drugs, they are paying more than they should. And, increased costs can have a significant impact on beneficiaries with chronic conditions for which there are no generic equivalents. Coverage of brand-name drugs in the doughnut hole is virtually non-existent. No national stand-alone PDP offers gap coverage for brand name drugs in 2008. Humana offered such coverage in 2006 and Sierra Rx offered such coverage in

¹ AARP, *Rx Watchdog Report Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries 2003 to 2007* (May 2008), http://assets.aarp.org/rgcenter/health/2008_08_generic_q407.pdf.

² AARP, *Rx Watchdog Report Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries 2000 to 2007* (March 2008), http://assets.aarp.org/rgcenter/health/2008_05_watchdog_q407.pdf.

³ Hoadley, J., et al., “Medicare Prescription Drug Plans in 2008 and key Changes since 2006: Summary of Findings.” Kaiser Family Foundation (April 2008), www.kff.org/medicare/upload/7762.pdf. The number of national PDPs charging 33 percent co-insurance for specialty tier drugs has increased more than five-fold since 2006, from 4 to 21 national PDPs in 2008. Cost-sharing for drugs placed on a specialty tier is generally limited to 25 percent coinsurance, although CMS allows plans to have higher cost-sharing for drugs on the specialty tier if offset by a lower deductible.

2007, but each eliminated that option after offering it for one year. Additionally, plans are providing less extensive gap coverage of generic drugs in 2008 than they did in previous years.⁴

The Center hears frequently from beneficiaries and their families who find themselves without any way to pay for needed medications. A woman in California recently e-mailed us:

I am particularly troubled because I am actually a social worker in California, and I am having a horrible time trying to find a way to pay for medication for my father's chronic illnesses! He is diabetic (Type II), is receiving ongoing chemotherapy for bladder cancer, and has recently been diagnosed with cardiac arrhythmia and now has a blood clot. He and my mother are both retired (ages 68 and 70) with a meager income of about \$1900 per month. As you know, this is NOT ENOUGH to survive, especially in California. My father is currently in the "doughnut hole" in Medicare and has NO WAY to pay for his medication for the rest of the year. I have had no help from local agencies. They have even told us to go to Mexico for medications.

A client from Connecticut contacted the Center for help on the advice of her physician. This 52-year-old woman has sickle-cell anemia. Her PDP refused coverage for a \$6,000-per-month medication which she had been taking, as ordered by two of her physicians. The plan did not cover the dose needed by our client and refused coverage despite the fact that her doctor wrote that she would have excruciating pain if she did not continue on the medication as prescribed. The Center had to appeal this case to the Independent Review Entity—outside the plan—in order to get coverage. What would have happened to our client if she did not have a dedicated doctor who brought the case to our attention? What do other beneficiaries without such physicians and advocates do?

A beneficiary from Tennessee wrote:

I am diabetic and mentally [sic] ill. I went into the doughnut hole quickly. I need drug coverage desperately [sic]!!! I am not taking all the drugs I need because I can't afford them. I am having to beg my Drs. to give me samples of what I just have to have. This is degrading as some of us still have a little pride left. Where is the help we need? I worked and paid my dues and look where I am. Can't someone help us?

⁴ *Id.*

Beneficiaries who want to try to find the best prices for their medication are stymied by the system. CMS tells beneficiaries to go to the Medicare plan finder to find the best drug plan for them, but the plan finder does not include information about the actual cost to the drug plan of their drugs. Nor does it provide information about manufacturer rebates negotiated with the plan. Beneficiaries can find information about the projected cost of the drugs, but even that information may not be accurate. As one beneficiary explained in an e-mail to the Center:

Assume one uses the Medicare Prescription Drug Finder and comes up with two or three plans that seem right for them. Since information [in] this tool are only estimates it makes sense to check with the companies. But trying to get through to a company can involve a long wait. (I waited over 40 minutes today to speak to a Humana representative.) When I asked the representative to review my Drug Finder results her figures were not even close to those quoted in the Drug Finder...I'm assuming [the] Medicare Drug Finder will be generally accurate, but I really don't have a way to check their estimates with the company if I can't get through to them or if the information they give me differs significantly from the Plan Finders results. I also tried to use Humana's website to get Rx prices. But the site was not operational. So where does that leave one in trying to review their 2008 options?

Beneficiary advocates also found that the information on the Medicare plan finder about prescription drug prices did not always comport with the information they received from the plans themselves. CMS was very responsive to complaints about this concern filed by the Center, the State Health Insurance Assistance Programs (SHIPs), and the advocates with whom we work, especially when we could provide specific information about discrepancies between the plan finder and the information provided by the plans. However, CMS did remind one national organization with which we partner that discrepancies between the plan finder and the plans over pricing are harder to resolve because plans can change prices on a weekly basis. How are beneficiaries supposed to choose when the cost of the drugs presented to them in December are not the cost they will pay in July when they reach the doughnut hole?

The burden of unnecessarily high drug costs is borne not only by Medicare beneficiaries, but also by the Medicare program itself. Many of the Center's clients who are dually eligible for Medicare and Medicaid automatically qualify for the low-income subsidy (LIS), often referred to as "extra help." We also represent clients who receive LIS because they are eligible for one of the Medicare Savings Programs, or because they applied for LIS through the Social Security Administration. Receipt of the LIS immunizes our clients and individuals like them from the effect of overpriced prescriptions. Eligible beneficiaries pay no deductible, pay low, flat rates for their prescriptions, and have no gap in coverage. Because Medicare subsidizes these beneficiaries by paying the difference between what they pay and what other, non-LIS eligible enrollees in the same plan would pay, Medicare pays more when Part D plans do not get the best prices or do not pass along the full savings to their enrollees.

And, when Medicare has to expend more than it should to cover the cost of drugs, all Medicare beneficiaries, as well as all taxpayers in general, lose out. We do not have to remind this Committee of the budgetary shortfalls facing the Medicare trust fund, shortfalls grievously exacerbated by payments to private insurance plans. But, we would like to point out that when funds go to pay private drug plans more than necessary, there is less money for other Medicare items and services. While we are pleased and thankful that Congress included beneficiary improvements in the law passed last week, those improvements—including improved access to preventive benefits and mental health services—were less generous than improvements included in legislation passed by the House of Representatives last summer, partly because of the lack of resources to pay for them.

States also end up paying more to make sure that their citizens can access affordable drugs when private drug plans do not negotiate the best prices or do not pass on savings from rebates by

reducing drug costs. The State of Connecticut, where the Center is headquartered, is one of about two dozen states that offers a State Pharmaceutical Assistance Program (SPAP).

Our Connecticut program, called ConnPACE, helps eligible Connecticut residents pay for certain prescription drugs, insulin, insulin syringes, and needles. To qualify, the individual must have resided in Connecticut for at least 183 days and must be at least 65 years old, or at least 18 years old and disabled. The annual income levels for an individual and for a married couple are higher than the income eligibility levels for LIS; there are no asset restrictions. There is an annual ConnPACE fee of \$30.00. All enrollees must pay a maximum of \$16.25 toward the cost of approved drugs each time a prescription is filled. For those with Part D coverage, the state of Connecticut pays the actual cost of prescribed drugs above ConnPACE's \$16.25 co-payment.

Needless to say, when Part D prescription drug prices are inflated, Connecticut must expend more to meet its obligations under the ConnPACE program. This unnecessary expense comes at a time when states are experiencing their own economic downturns, with more residents becoming eligible for needs-based programs as their own incomes decline. Expenditures under the ConnPACE program must be authorized every year. The ever-increasing costs of prescription drugs, exacerbated by Part D, puts ConnPACE at risk.

Further, in order to continue to provide the same prescription drug coverage for Connecticut's dually eligible residents as that provided for non-dually eligible Medicaid participants, Connecticut "wraps around Part D" to cover the co-payments and other payment gaps in Part D that are covered by Connecticut Medicaid. Here too, as drug prices increase, so do costs to the state. It would be very unfortunate if, as a result of these higher expenses, Connecticut or other states that provide some assistance with Part D costs decide to eliminate or reduce the assistance they provide.

Congress can take steps to reduce the cost of the Part D program to beneficiaries, to Medicare, and to the states while also making the benefit more responsive to the needs of Medicare's older and disabled beneficiaries:

1. Include a prescription drug benefit in the traditional Medicare program and authorize the Secretary of Health and Human Services to negotiate the cost of prescription drugs.
2. Require drug plans to pass along the full extent of the rebates they receive, including to beneficiaries while they are in the coverage gap.
3. Increase transparency by requiring drug plans to make available information about their pricing and rebates.
4. Increase oversight of the Medicare web page, including the plan finder and drug pricing tools, to monitor for quality control.
5. Require CMS to provide greater oversight of Part D plan websites and customer service representatives in regard to pricing information.

When PDPs fail to negotiate the best price for their formulary drugs, or fail to pass along to their enrollees the manufacturer rebates they receive, Medicare beneficiaries and taxpayers are not getting what Congress promised—access to *low-cost* prescription drugs. As a beneficiary from Oregon wrote to the Center during the annual enrollment period in November 2007:

So did the “market place” work for us as Secretary Leavitt exclaimed in 2005. [sic] Did “choice” work for us. [sic] No. The premiums are higher. The donut hole coverage is gone. The brand name drug prices are higher. The company making the main drug my wife takes charges \$430 retail for a months [sic] supply, up from \$383 in early 2006. That company, Bristol-Myers Squibb had a 34% increase in that drug's revenue in the third quarter of 2007. This due to higher demand and higher net prices. (It's on their own website in their investor section).

Medicare beneficiaries, and taxpayers, are paying more than they should for the drugs people with Medicare need. The Part D program is simply too expensive, too unresponsive, and too resource-intensive. It is not the best way to provide this much needed drug coverage.

Thank you for the opportunity to testify today.

Chairman WAXMAN. I am going to start off the questions.

Our committee for the first time was able to analyze the drug and insurance company proprietary data on drug pricing and compare the prices charged to the Medicare Part D program and the prices charged to Medicaid, and the findings reveal that the private Medicare Part D insurers are paying 30 percent more for drugs than the Medicaid program. This has resulted in a windfall of over \$3.7 billion for the drug manufacturers on the sale of drugs to dual-eligible enrollees.

These elderly and disabled individuals used to get their drugs from Medicaid. They have switched to Medicare Part D, and now their higher drug prices are costing taxpayers billions of dollars.

Mr. Weems argued that if Medicare Part D got the same discounts for drugs that the dual eligibles that Medicaid gets, there would be a negative consequence for other Medicare beneficiaries. Specifically, he said this could lead to higher prices at the pharmacy, compromised incentives to move enrollees to generic drugs, undermine utilization management activities that plans for important safety protections as well as cost controls.

Ms. Stein, what do you think about what Mr. Weems' concerns are that he expressed to us about this issue?

Ms. STEIN. Thank you, Chairman.

Well, one of the things I think is that I added one of the economists who spoke this morning, the figures on the bottom line on Mr. Weems' chart, and they came to, I believe, \$400 billion, which I believe was also the original estimate of what the program would cost. So it seems to me that I don't understand where the savings are in that explanation that was given. I think one of the things we often find is that one has to add up the numbers and question where they are coming from.

What I know is that we have 6,500 calls and thousands of e-mails every year at this Center. I sit in the real world listening to real people. They cannot afford these drugs. They are in the donut hole way earlier than was anticipated, and it is a problem with them. They cannot afford the drugs, and they are not getting the rebate in price when they are in the donut hole. Also, the plans don't cover their drugs, more often than not.

Chairman WAXMAN. Thank you very much.

Mr. Precht, what do you think of the argument that we are really doing a favor for the rest of the Medicare beneficiaries by paying a higher price for the dual eligibles?

Mr. PRECHT. I am not an economist, but it doesn't make any sense to me. It seems that there is money that is going into the pharmaceutical manufacturers, rather than into providing coverage for people with Medicare; and it certainly seems we could use that money to get more people into the extra health program, for example, so they wouldn't have to pay full price in the donut hole.

It seems to me that if there were competition between the private plans and a Medicare option that negotiated its rates that would provide some price discipline and it could result in lower prices, both in the Medicare option as well as the private option.

Chairman WAXMAN. Mr. Merritt and Mr. Smith, do you disagree with the report's findings that the manufacturers are charging

more for drugs under Medicare Part D for dual eligibles than they are under Medicaid?

Mr. SMITH. Mr. Chairman, I haven't had an opportunity to review the report. It certainly wouldn't surprise me if the type of market-based system we have, with very powerful large purchasers, lots of tools at their disposal—Mr. Merritt described those—negotiated a price that was different than the price that was previously set through the administered pricing system of Medicaid.

I think it is important to recognize that the—

Chairman WAXMAN. You say because of all the strong tools they have they negotiated a price that is higher than Medicaid?

Mr. SMITH. I am saying there might be a valuation in the marketplace that is different than the valuation through the administered pricing system of Medicaid.

Chairman WAXMAN. So you think Medicaid is lower priced, and we have moved to a higher price system under Part D through the private plans?

Mr. SMITH. Mr. Chairman, without having had an opportunity to review the report, I am simply saying that I can imagine that private purchasers with lots of tools negotiating come up with different valuations than does an administered pricing system.

And when we look at the entire population, including the 14 million individuals who previously weren't typically having discounts and rebates negotiated on their behalf, I think that we see that there is considerable price pressure.

Chairman WAXMAN. How about just the 6 million that are dual eligibles? With all these tools that the private plans have for negotiating better prices, why are we paying more for that distinct population for their drugs than we were under Medicaid?

Mr. SMITH. Well, I believe, first, that private plans negotiate for entire populations, so average rebates for entire populations may differ than average rebates for a segment of the population. They may also use a different mix of savings mechanisms. They may use more than rebates of savings mechanisms. And, ultimately, I think it is difficult to pull the one population out, look at it separately from the entirety the population being covered and for which savings is being negotiated.

Chairman WAXMAN. Would you include the private-sector coverage for non-Medicare? Would you put them in the overall picture?

Mr. SMITH. I am not quite sure I understand the question, Mr. Chairman.

Chairman WAXMAN. I will send you a letter about it afterwards.

Mr. McHenry.

Mr. MCHENRY. Thank you, Mr. Chairman.

You know, this committee is trying to find efficiency in government, and I appreciate it. It has taken us a while to actually get to hearings that get to that during this Congress, but I am glad that we can actually have this discussion.

I do have a question. Mr. Precht, we are speaking about Medicare Part D today. But, admittedly, Medicare is a larger issue that we are concerned about.

Ms. Stein, I appreciate your advocacy and help in this process and helping American seniors get the information they need to

make good decisions about this. But, you know, I would like to know, because you are concerned about Medicare rights, Mr. Precht, are you concerned about the financial adequacy of Medicare Part A?

Mr. PRECHT. Yes, sir, very much.

Mr. MCHENRY. In terms of the amount of money the government spends, isn't it far greater in Medicare Part A?

Mr. PRECHT. That is correct. There is more money spent on hospital care than on prescription drugs.

Mr. MCHENRY. Do you think we should be looking at that as a Congress?

Mr. PRECHT. Absolutely.

Mr. MCHENRY. OK. I mean, the price differential between the two is significant. It is—what—about \$200 billion—\$220 billion for Medicare Part A and about \$50 billion for Medicare Part D. Is that roughly correct? I am not trying to put you on the spot.

Mr. PRECHT. I will take your word for it.

I mean, there is certainly more spending. I guess I don't know. I am not as familiar as I should be with research that looks at the spending under Part A and whether we could be saving money. But I think probably there are ways to save money there as well.

Mr. MCHENRY. Ms. Stein, to your comment that beneficiaries are struggling with ever-increasing prices—and, generally speaking, in this time right now of inflation, we are all struggling with high prices—gas prices, food prices and everything else. It is putting a pinch on seniors, especially. But in terms of the Medicare Part D beneficiaries and what they pay in premiums, has that gone up?

Ms. STEIN. Yes, sir. In fact, my—for instance, Humana has gone up three times what it was in the first year of the program.

And, by the way, with regard to Part A, the Center for Medicare Advocacy is extremely concerned about the cost of Medicare in general, and we do a great deal of work with regard to those issues.

Mr. MCHENRY. Sure. Back to the point of what the beneficiaries are paying, according to the CBO, the cost estimate at the beginning of this program was, I believe, \$37 or \$35, and CMS estimated about the same at the beginning of the program. I think CMS estimated \$37. CBO said \$35. In fact, the Democrats had an amendment in committee to set the price of premiums for seniors at \$35. Well, premiums are under \$25 right now across the population for all beneficiaries, is that not correct?

Ms. STEIN. For all beneficiaries, the premiums went down. For plans that people were in, they often went up, and they didn't switch. So that people were in a plan in the first year, their premium went up three times in the second year for one of the entities that has the largest population.

Mr. MCHENRY. Sure. But there are other entities by which they can say, I am done with Humana. I am going over here. There are enough forces out there—

Ms. STEIN. Because of the structure of the program—

Mr. MCHENRY. Ma'am, let me finish asking the question.

There are enough in the way of choices out there that seniors can make an informed decision; and if on average the premiums have gone down, isn't that a good thing?

Ms. STEIN. It depends, sir. In my mother's case, for instance, yes, she takes two drugs. She decided to stay in her plan because it was a lower premium, she thought. But it didn't cover one of her drugs. So you could choose a premium that is lower this year but not get your drug coverage. It is as not as simple as that.

Mr. MCHENRY. Because an individual makes a mistake doesn't mean it is a bad policy or bad program. Mistakes are made every day. After all, look at the U.S. Congress. We have made mistakes. We are all human.

Ms. STEIN. With all due respect, sir, just let me say this. There is only 17 percent of people that switched plans. So the fact is that people, for whatever reason—I believe the design of the program—are not utilizing the choice option because it is so complex. And the fact is that, if they do choose based on the lowest-cost premium, they may well find themselves in the wrong plan.

Mr. MCHENRY. OK. Thank you. I appreciate your testimony.

I have one final question for Mr. Smith, if I may, Mr. Chairman.

Overall, we are talking about price negotiation. That is a part of this. And the majority report, the Democrat report from this committee, expresses that there will be a "windfall" to the pharmaceutical industry unless government negotiated the price. Even though what they failed to mention is that private entities, all these different insurers, are negotiating for the price of drugs. So, therefore, they want the government to step in and say all these different insurers have to accept this price.

OK. If there is a windfall for the pharmaceutical industry, how much has your business gone up? Because the statistic I have, in your testimony, is that prescription drug sales have increased by only 1 percent since Medicare Part D was implemented. Where is the windfall?

Mr. SMITH. Yes, sir. I would, of course, view prices that are set by very powerful purchasers negotiating very aggressively for prices and the resulting prices as not generating a windfall. The basic result has been that, in 2008, prescription drug costs in the United States went up by the lowest rate since 1961, 3.8 percent, and the slowdown in growth continues. IMS Health reports, for the 12 months ended May of this year, the growth rate for prescription medicines in the United States, the entire cost for the whole country, was 1 percent.

Mr. MCHENRY. Thank you, Mr. Chairman.

Mr. MURPHY [presiding]. Thank you, Mr. McHenry.

Mr. Smith, I want to get back to followup on a few of Chairman Waxman's questions. I know he may followup with you in written correspondence.

But with regard to the differences between the negotiations that happened with private plans and the Medicaid rebate system, your ultimate leverage in a negotiation with a particular health care plan is to not sell that drug to that plan, to not be part of their formulary, is that correct?

Mr. SMITH. Without suggesting proprietary information about business practices, I think that would generally accurately characterize the market.

Mr. MURPHY. With regard to the Medicare rebate system, your ultimate leverage with the Medicaid rebate system is to voluntarily not sell your drug as a part of the Medicaid system?

Mr. SMITH. That is correct. On a one-size-fits-all basis, you are really excluded from a very large portion of the market entirely, very different from the private sector.

Mr. MURPHY. Because the purchasing pool is so large from the Medicaid side, because, as you say, it is a one-size-fits-all, the decision is much harder to not sell the drug to the Medicaid system.

Mr. SMITH. Well, there is no real opportunity to reflect value, because there is that statutory formula that sets the price. So I think that one of the challenges is that there really is no negotiation in that respect because it is a decision that is generated by a statutory pricing formula.

Mr. MURPHY. But you are not compelled to sell the drug?

Mr. SMITH. It is either sell at that statutory formula or be excluded from the entire Medicaid market.

Mr. MURPHY. Ms. Stein, the report that is released today details a 6.6 percent increase in the average cost of a drug from 2006 to 2007, which is about twice the rate of inflation. You suggested some of the impacts of this in your testimony.

But I just wanted to ask you, what is the impact of that 6.6 percent increase in the price of the drug to an average health care consumer in the Part D system, given I think the testimony that you have given about the number of people falling into the donut hole earlier than expected or earlier than people had hoped for?

Ms. STEIN. Sir, they are very often in the donut hole earlier. Once they are there, they are paying the full cost of the drug, not with the rebate. People, as you will see in my written testimony, are taking less than the full prescription which has been given by their physician, as someone is quoted in my testimony. Particularly people on psychotropic drugs we find are not taking their medications. Many of them don't like to take them in the first place.

So we have a lot of problems with the fact that people aren't taking the medications or taking less than has been prescribed, and they are falling into the donut hole earlier.

I would also like to suggest there are tremendous costs to the States as a consequence, which, as you know in Connecticut, we are also paying—when the people fall into the donut hole, we are paying those coinsurances. And on specialty drugs that can be for the individual as well as for the State up to 33 percent of the cost of that special brand-name drug.

Mr. MURPHY. The last question, just to make this point clear, when an individual falls into the donut hole, when they come to pay for the price at the retail pharmacy, they are not getting the benefit, certainly not of Medicaid, but they are not getting the benefit of the potential discount negotiated by the HMO they were covered which?

Ms. STEIN. That is correct. That is included and helps them get into the donut hole sooner. Once they are in the donut hole, they don't have the benefit of that; and they pay more.

Mr. MURPHY. Thank you, Ms. Stein.

Thank you very much to the entire panel. We will keep the record open for further comments and statements.

I would like to add without objection for the record a statement for today's hearing submitted by America's Health Insurance Plans. Without objection, that is entered into the record.
[The information referred to follows:]



FOR THE RECORD

**Statement
on
The Medicare Part D Prescription Drug Program**

**America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, DC 20004**

**Submitted to the
U.S. House Committee on Oversight and Government Reform**

July 24, 2008

I. Introduction

America's Health Insurance Plans (AHIP) and our member companies are strongly committed to the long-term success of the Medicare Part D prescription drug program. Our membership includes most sponsors of both stand-alone prescription drug plans (PDPs) and Medicare Advantage plans that combine drug benefits with comprehensive health coverage (MA-PDs). These companies have a long history of participation in Medicare and other public programs.

Today, approximately 39.5 million Medicare beneficiaries – representing approximately 90 percent of the Medicare population – have prescription drug coverage either through Part D plans directly, employer plans that are partially supported by Part D, or other sources. On a daily basis, these beneficiaries are personally experiencing the early success of the Part D program and the role that competition, choice, and innovation have played in providing them with high quality, affordable prescription drug coverage.

We appreciate the committee's interest in examining the Part D program's role in meeting the prescription drug needs of Medicare beneficiaries. In an effort to contribute to this dialogue, we will address the following topics in our statement:

- The track record of the Part D program in delivering savings and value to beneficiaries;
- Survey data showing that Medicare beneficiaries are highly satisfied with the Part D program;
- Factors that have contributed to the success of the Part D program;
- Our perspectives on the government's role in the Part D program; and
- Our views on legislative proposals addressing Part D issues.

II. Savings and Value for Beneficiaries

Part D prescription drug plans are exceeding expectations by offering more comprehensive benefits and lower premiums than originally were anticipated. Plan sponsors have accomplished this by using tools and techniques to promote quality while holding down costs for beneficiaries, reducing medication errors, and promoting clinically sound drug usage.

According to the Centers for Medicare & Medicaid Services (CMS)¹, Part D enrollees who previously did not have drug coverage saved an average of \$1,200 in the first year the program was implemented. For millions of Medicare beneficiaries, the savings available through the Part D program are enabling them to receive the medications they need at an affordable price.

While beneficiaries of all income levels can save money by choosing Part D plans, financially vulnerable beneficiaries can expect to receive exceptionally large savings because of the low-income subsidies the program provides. More than 10 million Medicare beneficiaries currently are receiving this additional assistance. On average, Medicare will pay more than 95 percent of prescription drug costs for these low-income beneficiaries. To ensure that eligible beneficiaries apply for and receive this assistance, plan sponsors have supported outreach efforts through a variety of partnerships while also organizing community events across the nation to raise awareness among beneficiaries.

Plan sponsors are offering a range of prescription drug plans with high quality coverage, many of which go well beyond the minimum requirements of the Medicare Modernization Act of 2003 (MMA). Rather than establishing a one-size-fits-all benefits package, the Part D program creates incentives for plan sponsors to design different benefit packages that address beneficiaries' needs in three key areas – cost, coverage, and convenience.

As a result, 66 percent of PDPs and 86 percent of MA-PDs offer zero or reduced deductibles, instead of requiring beneficiaries to pay the \$275 deductible that is part of the standard benefit. Additionally, 29 percent of PDPs and 44 percent of MA-PDs provide additional coverage in the “coverage gap” for beneficiaries who have exhausted the initial coverage limit and are not yet eligible for the catastrophic benefit. All beneficiaries nationwide have access to plans offering benefits in the “coverage gap.”

For the small percentage of enrollees who are affected by the “coverage gap,” Part D plans provide significant discounts off their prescription drug prices. According to one study², these savings total more than 35 percent relative to retail prices. Moreover, plan sponsors are helping many beneficiaries delay reaching the “coverage gap” – or, in some cases, avoid the gap altogether – by using innovative tools and techniques that promote the use of cost-effective medications.

¹ CMS, *Part D Medicare Prescription Drug Benefit Fact Sheet*, January 2007

² Pharmaceutical Care Management Association, press release, March 15, 2006

The value offered by Part D plans also can be seen in the lower-than-expected premiums that beneficiaries are paying. CMS has estimated that the average monthly premium paid by Part D enrollees in 2008 is \$25. This figure is nearly 40 percent lower than the \$41 monthly premiums that originally were projected for 2008. According to CMS, the lower-than-expected premiums “reflect the effects of aggressive competition as well as lower costs resulting from better care coordination and drug benefit management techniques.”³

Taxpayers also are benefiting from plans’ success in delivering quality prescription drug coverage at an affordable price. CMS announced⁴ in January 2008 that the projected costs of the Part D program are \$117 billion lower over the next ten years than was estimated only a year ago. CMS also noted that program costs over the ten-year period of 2004-2013 are now projected to be 38.5 percent lower than the original cost projections at the time the MMA was enacted. In an earlier announcement in January 2007, CMS⁵ reported that competition was a major factor contributing to lower-than-expected costs in the Part D program.

Finally, a new study published earlier this year in the *Annals of Internal Medicine*⁶ reaffirms that Part D enrollees are now taking more of the medications they need while spending less out-of-pocket than before the program was established. These results demonstrate that the Part D program is fulfilling its goal of extending valuable prescription drug benefits to Medicare beneficiaries.

III. Beneficiaries Are Highly Satisfied With the Part D Program

Numerous surveys show that a large percentage of the Medicare population is pleased with the new Part D program and the benefits it is delivering. The positive attitudes of Medicare beneficiaries toward the Part D program are reflected in surveys sponsored by AHIP, the Medicare Rx Education Network, the *Washington Post*/ABC News, AARP, Medicare Today, JD Power and Associates, the *Wall Street Journal*, and the Kaiser Family Foundation.

Each of these surveys confirm that a significant majority of Medicare Part D enrollees are having a positive experience with their new prescription drug benefits. These surveys clearly show that

³ CMS, *Medicare Part D Plan Premiums for 2008 Show Continued Impact of Strong Competition*, August 13, 2007

⁴ CMS, *Medicare Prescription Drug Benefit’s Projected Costs Continue to Drop*, January 31, 2008

⁵ CMS, *Projected Net Medicare Drug Costs Drop by Another Ten Percent*, January 8, 2007

⁶ *Annals of Internal Medicine*, *The Effect of the Medicare Part D Prescription Benefit on Drug Utilization and Expenditures*, February 5, 2008

most beneficiaries are satisfied with the program, are saving money on their prescription drugs, are not experiencing problems, and would recommend the program to others.

The most recent survey conducted by Harris Interactive continues to corroborate these findings:

- 87 percent of beneficiaries enrolled in a Part D plan reported they were satisfied with their plan;
- 83 percent said their Part D plan was easy to use; and
- 75 percent said their plan has saved them money on prescription drugs.⁷

IV. Factors Contributing to the Success of the Part D Program

A major factor contributing to the success of the Part D program is the fact that plan sponsors are working aggressively to negotiate lower prescription drug prices for beneficiaries. The 2008 report of the Medicare Board of Trustees⁸ found that Part D plan sponsors were able to negotiate substantial rebates on many brand-name prescription drugs, as much as 20-30 percent of the cost of the drug for some products. The Trustees report that drug manufacturer rebates negotiated by Part D plans continue to increase, reflecting the growing impact of the competitive market forces put in place by Congress.

Another important feature of the Part D program is its emphasis on choice and competition. Because beneficiaries can choose from a wide range of plans, plan sponsors are forced to compete based on their ability to design benefit packages that are most appealing to beneficiaries. This competition plays an important role in encouraging innovation and sustaining high quality coverage options in the Medicare Part D program. This innovation is evidenced by the assortment of tools and techniques plans have developed to limit out-of-pocket costs for beneficiaries and, at the same time, improve quality by reducing medication errors and promoting clinically sound drug use.

Formularies are an important tool that help control prescription drug costs. Medical professionals play a central role in developing formularies, which must comply with stringent

⁷ *Wall Street Journal*, "Poll Shows Growing Satisfaction with Medicare Drug Benefit" (December 12, 2007)

⁸ *2008 Annual Report of The Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, March 25, 2008, p. 160

standards to ensure that they include drugs necessary to treat all major diseases. To ensure that formulary decisions are clinically appropriate, health plan Pharmacy & Therapeutics Committees – composed principally of physicians and pharmacists – identify drugs for inclusion on health plan formularies based on documented safety, efficacy, and therapeutic benefit.

Generic substitution programs are another tool that encourage beneficiaries to use lower-cost prescription drugs when clinically appropriate. Part D plan formulary management techniques such as step therapy and prior authorization also are working to reduce out-of-pocket costs for beneficiaries.

A number of studies demonstrate that these tools and techniques are highly effective in making prescription drugs more affordable for consumers. For example:

- CMS has estimated that the tools and techniques used by plan sponsors – including retail pharmacy network negotiation and activities to manage drug utilization – will save beneficiaries and taxpayers 22 percent⁹ on average, relative to the expenditures the program otherwise would incur without these strategies.
- Part D sponsors' generic substitution programs encourage beneficiaries to use lower-cost prescription drugs when clinically appropriate. In 2007, 63 percent of prescriptions dispensed through Medicare Part D plans were for generic drugs.¹⁰ The generic dispensing rate is higher in the Part D program than in Medicaid.¹¹
- Another study¹², published in *Health Affairs* last year, found that one in four Part D enrollees reported switching to a less expensive medication after they enrolled in a Part D plan (i.e., switching from a high-cost to lower-cost brand-name drug or from a brand-name to a generic drug). This finding demonstrates the effectiveness of strategies used by plan sponsors to encourage beneficiaries to use lower cost medications when clinically appropriate.

⁹ 2007 Medicare Trustees Report, page 155

¹⁰ Wolters Kluwer Health, June 2008

¹¹ Committee on Oversight and Government Reform Majority Staff, "Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage." (October 2007)

¹² "Medicare Prescription Drug Benefit Progress Report: Findings From A 2006 National Survey of Seniors" by Patricia Neuman, Michelle Kitchman Strollo, Stuart Guterman, William H Rogers, Angela Li, Angie Mae C. Rodday and Dana Gelb Safran, Health Affairs, 2007 available at <http://content.healthaffairs.org/cgi/content/full/26/5/w630>.

- Prior to the implementation of the Medicare Part D program, the Congressional Budget Office (CBO) estimated¹³ that the private sector management techniques employed by plan sponsors would save individuals 20-25 percent off retail prices for prescription drugs.
- The Government Accountability Office (GAO) has reported¹⁴ that management techniques used by health plans in FEHBP resulted in savings of 18 percent for brand-name drugs and 47 percent for generic drugs, compared to the average cash price customers would pay at retail pharmacies.
- A PricewaterhouseCoopers study¹⁵ concluded that the tools and techniques used by plan sponsors and PBMs are estimated to save Medicare beneficiaries \$693 billion over ten years.

These findings clearly demonstrate that the private sector has a strong track record of using its experience and capabilities to deliver affordable prescription drug benefits. At a time when federal resources are severely strained, it is important for policymakers to recognize the ability of health insurance plans to implement strategies that are enabling Medicare beneficiaries to receive the greatest possible value for the dollars the Medicare program is spending on their prescription drug coverage.

Additionally, we urge Congress to recognize that innovation will continue to flourish as long as plans are competing based on their ability to design benefits that are appealing to beneficiaries. This element of competition is critically important in sustaining the high quality, comprehensive, affordable options that beneficiaries are seeing in the Part D program.

V. Understanding the Government's Role in the Part D Program

Medicare beneficiaries are receiving significant savings through the Part D program and plan sponsors are offering coverage that exceeds original expectations. These savings can be found primarily in the reduced cost-sharing and reduced premiums that plans are able to offer as a result of their success in negotiating rebates with drug manufacturers.

¹³ CBO, *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit*, July 2004

¹⁴ Government Accountability Office, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefits Managers on Health Plans, Enrollees, and Pharmacies* (GAO-03-196), January 2003

¹⁵ PricewaterhouseCoopers, *Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation*, March 2007

Despite this record of success, some observers have suggested that the program should be restructured to establish a larger government role in the negotiation of rebates, the setting of prices, and perhaps even the establishment of a federal government plan that would either compete with or take the place of the private plans that have successfully administered the Part D program.

While the federal government already has a significant role in shaping the administration of the Part D program – which we believe is appropriate for ensuring healthy competition and consumer protection – we are concerned that an expansion of the government’s role would be problematic. CBO’s evaluation of legislation considered by Congress last year indicates that the value of creating a larger government role in the negotiation of drug prices may be overstated. CBO reported¹⁶ that this legislation, H.R. 4, passed by the House last year “would have a negligible effect on federal spending.” CBO said it anticipates 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.” CBO further stated that Medicare Part D plans “have both the incentives and the tools” to negotiate with drug manufacturers to generate savings for beneficiaries and taxpayers.

CBO’s analysis suggests that the only way a government-run system could achieve savings comparable to those private plans have achieved in Part D is through the establishment of a national formulary akin to a VA-style system. Yet establishing a national formulary is problematic. The existing Part D system allows beneficiaries to choose a private plan that is appropriate for them by determining which offer their prescription medications on their formulary with the lowest available cost-sharing. A national formulary would not provide this opportunity. Moreover, by adopting a “winner-take-all” approach, a national formulary could stifle innovation in the pharmaceutical marketplace to the disadvantage of Part D enrollees and others who rely upon the private marketplace to create competitive incentives for pharmaceutical manufacturers to research and develop new medications that meet beneficiary needs.

By contrast, Part D plans are able to generate savings for beneficiaries and taxpayers while preserving choices and without imposing a one-size-fits-all approach that is found in government-run programs. One of the defining characteristics of the Medicare Part D program is its strong emphasis on beneficiary choice. Rather than establishing a uniform benefits package or relying on a national formulary, the program creates incentives for plan sponsors to design different benefit packages and formularies that address beneficiaries’ needs in three key areas – cost, coverage, and convenience.

¹⁶ CBO Cost Estimate for H.R. 4, Medicare Prescription Drug Price Negotiation Act of 2007, January 10, 2007

This approach recognizes that Medicare beneficiaries themselves are best served by a program that allows them to select the prescription drug plans that will be most effective in meeting their unique needs and circumstances. Plan sponsors have responded by offering a range of prescription drug plans with high quality coverage. Part D plans also are negotiating significant rebates and discounts with manufacturers. These negotiations – paired with management techniques that encourage utilization of the most clinically appropriate, cost effective medications – are reducing costs for beneficiaries.

Some have suggested that comparisons of rebates collected by Part D plans to those available in the Medicaid rebate program demonstrate the savings that would be available from a larger government role in the program. These analyses fail to consider the value of the tools and techniques used by private plans that are described above and encourage beneficiaries to use the most clinically appropriate cost-effective medications. Moreover, the experience of the Medicaid rebate program offers other important lessons about the consequences of legislating or administratively setting prices. A January 2007 report by CBO¹⁷ points out that drug prices for non-Medicaid payers increased relative to the average manufacturer price (AMP) following the implementation in 1991 of the Medicaid rebate program, which requires pharmaceutical manufacturers to provide rebates to state Medicaid programs based on the lowest prices they charged other purchasers. An earlier GAO report¹⁸ reached a similar conclusion about the impact of the Medicaid rebate program, noting that the discounts available to large private purchasers “dropped substantially” for many outpatient drugs.

Future improvements to Medicare Part D should build upon the choice, competition, and innovation that have played a central role in the program’s strong record of success. Early experience in this program demonstrates that enrollees and taxpayers are paying less than initially projected and beneficiaries are very satisfied with the choices available to them. A larger government role in the Part D program would undo these successes.

VI. Our Views on Legislative Issues

We also want to highlight our views about other legislative proposals that could have an effect on the Part D program.

¹⁷ CBO, *Prescription Drug Pricing in the Private Sector*, January 2007

¹⁸ GAO, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, August 2000

The Part D program would be strengthened by proposals to accelerate the availability of safe and effective generic biopharmaceuticals. In February 2007, AHIP's Board of Directors approved a statement expressing support for legislation that would provide an expedited means of bringing safe and effective generic biologics to the market. Our statement outlines three key principles to guide these legislative efforts: (1) promoting the timely market entry of generic biologics; (2) ensuring that generic biologics are comparable to brand-name products in safety, quality, and efficacy; and (3) providing a mechanism to allow the review criteria to keep pace with innovation in biologics. We applaud Chairman Waxman for introducing bipartisan legislation, H.R. 1038, that would accelerate approval by the Food and Drug Administration (FDA) of generic versions of life-saving biological products. For millions of Medicare beneficiaries and other health care consumers, this legislation offers the hope of significant cost savings and greater access to advances in biotechnology.

Additionally, we want to emphasize the importance of maintaining the confidentiality of competitively sensitive information pertaining to the Part D program. The public release of highly sensitive proprietary information has the potential to fundamentally undermine the ability of Part D plans to negotiate favorable terms with manufacturers. Economists have long agreed that keeping pricing information confidential is integral to the performance of a competitive marketplace. For example, the U.S. Federal Trade Commission has written that "knowledge of rivals' prices can dilute incentives to bid aggressively and facilitate tacit collusion, which increases prices."¹⁹ The underlying bidding process in the Part D program was designed as a blind process to ensure vigorous competition, and the existing structure – in which such information is held confidential – has contributed to a competitive marketplace which has kept beneficiary premiums far below initial expectations. We urge Congress to be mindful of these concerns as it considers further legislation that would provide other parties with access to such sensitive information.

Over the past 18 months, the committee has expressed considerable interest in obtaining and reviewing data on rebates, price concessions, administrative costs, and other proprietary information from sponsors of Part D plans. We thank the committee for scrupulously honoring its commitment to protect the confidentiality of the information it has collected from plan sponsors.

¹⁹ Federal Trade Commission Letter to the Honorable Terry Kilgore (October 2, 2006).

VII. Conclusion

The Medicare Part D prescription drug program is delivering significant value to beneficiaries, including millions of low-income seniors who are receiving additional assistance with their premiums and cost-sharing. The availability of high quality choices – spurred by vigorous competition among plan sponsors – has played a pivotal role in generating these savings. We urge the committee to continue to support the competition, choice, and innovation that have played such an important role in delivering savings and value to our nation’s Medicare beneficiaries.

Mr. MURPHY. Again, thank you to this panel. Thank you to our previous two panels.

This hearing is adjourned.

[Whereupon, at 2:26 p.m., the committee was adjourned.]

