

SENIORS FEELING THE SQUEEZE: RISING DRUG PRICES AND THE PART D PROGRAM

HEARING BEFORE THE SPECIAL COMMITTEE ON AGING UNITED STATES SENATE ONE HUNDRED ELEVENTH CONGRESS SECOND SESSION

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SENIORS FEELING THE SQUEEZE: RISING DRUG PRICES AND THE PART D PROGRAM

WEDNESDAY, MARCH 17, 2010

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:49 p.m. in room SD-562, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl, Nelson, McCaskill, Corker, and LeMieux.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon to one and all, and we thank the witnesses who are with us today.

We are pleased to have Senator Bill Nelson chair today's hearing on the effect of high drug prices on America's seniors and the Medicare Part D program.

Senator Nelson is a most valuable member of this committee, who hails from a State that understands very well the unique challenges and opportunities posed by an aging population. He has been a leader on this issue, and we are very happy to have him leading the charge for the Aging Committee.

Before I turn over the gavel to Senator Nelson, I want to make sure we all understand that prices for brand-name drugs are higher in this country than anywhere else in the world. This affects seniors severely, both because they tend to need more medications and because of the doughnut hole in Medicare Part D, which can cost individuals up to \$4,400 out-of-pocket every year.

But ultimately, the high price of drugs does affect each and every one of us. Americans pay as much as two to three times as much for the same medications as people in other industrialized countries. This is one of the reasons healthcare costs so much more in this country.

I have written letters to the top six drug makers to find out why. Why must American consumers pay so much more, when the bulk of drug research and innovation happens right here in the United States, and much of it is subsidized by our Federal Government? The Aging Committee looks forward to taking a look at the answers to these questions later on this spring.

In the meantime, today's hearing is getting at an ongoing issue that is crucial to our seniors. I would like again to thank Senator Nelson for all his work on closing the doughnut hole and will now turn over the gavel and the remainder of the hearing to Senator Bill Nelson from Florida.

[The prepared statement of Senator Kohl]

**Opening Statement of Senator Herb Kohl
Special Committee on Aging Hearing
Seniors Feeling the Squeeze:
Rising Drug Prices and the Part D Program
March 17, 2010**

Good afternoon, and thank you to all the witnesses for joining us. I'm pleased to have Senator Bill Nelson chair today's hearing on the effect of high drug prices on America's seniors and the Medicare Part D program. Senator Nelson is a valuable member of the Aging Committee, who hails from a state that understands very well the unique challenges and opportunities posed by an aging population. He has been a leader on this issue and we're very happy to have him leading the charge for the Aging Committee.

Before I turn over the gavel, I want to make sure we all understand that prices for brand name drugs are higher in this country than anywhere else in the world. This affects seniors severely, both because they tend to need more medications, and because of the doughnut hole in Medicare Part D, which can cost individuals up to \$4400 out of pocket every year.

But ultimately, the high price of drugs affects us all. Americans pay as much as two to three times as much for the same medications as people in other industrialized countries. This is one of the reasons health care costs are so much higher in America.

I've written letters to the top six drug makers to find out why. Why must American consumers pay so much more, when the bulk of drug research and innovation happens here in the U.S and much of it is subsidized by the federal government? The Aging Committee looks forward to taking a look at the answers to these questions later this spring.

In the meantime, today's hearing is getting at an ongoing issue that is crucial to our seniors. I would like to thank Senator Nelson for all his work on closing the doughnut hole. I'll now turn over the gavel.

OPENING STATEMENT OF SENATOR BILL NELSON

Senator NELSON. Thank you, Mr. Chairman.

Late last year, the AARP released a report that showed that while the Nation was in a recession and the overall inflation rate was negative, brand-name drugs were seeing some of their highest price increases in years. According to the report, the price of brand-name drugs most commonly used by Medicare beneficiaries increased 9.3 percent in 2009, a much higher increase than any of the previous 7 years.

For some drugs, their price increase was markedly higher. Aricept, a drug that treats dementia, saw a 17 percent increase. Ambien, a sleep aid, 19 percent increase. The price of Flomax, a drug used by men with enlarged prostates, increased 20 percent.

Just yesterday, the Kaiser Family Foundation released a report confirming these trends. According to their report, 9 of the top 10 drugs in Medicare Part D saw an increase between 2009 and 2010, and for half of those drugs, the increase was 5 percent or more.

Kaiser also highlights some particularly egregious cases. Between 2006 and 2010, for Medicare Part D beneficiaries in the so-called doughnut hole, they paid 20 percent to 25 percent more for Lipitor, Plavix, Nexium, Lexapro, and paid 39 percent or more for Actonel, and paid 41 percent more for Aricept.

In comparison, the Consumer Price Index, which is the general price increase of consumer goods, increased by 9 percent between 2006 and 2010. Even the price of most medical care, which we call the health inflation—and of course, we know that that is increasing rapidly—well, that grew by 16 percent. So you can see the comparisons.

Now these reports show us that a time when people's pocket-books are getting squeezed, seniors are being asked to pay more and more for their prescription drugs. So, in this hearing, which you have given me, Mr. Chairman, the graciousness of planning the hearing and chairing it—and I thank you. In this hearing, I hope that our witnesses are going to be able to help us look at these drug price increases, try to understand what is happening, and consider how they affect seniors in Medicare prescription drug Part D plans, and then discuss policy options for addressing these high and increasing costs.

In order to understand how increasing drug prices affect seniors, it is important to understand the standard Part D prescription drug plan and how it works. Now a standard Part D plan in 2010—can you hold that up a little higher—starts with a \$310 deductible, which the senior pays right at the outset. This then is followed up to an amount of total cost of drugs of \$2,830 in total spending, where the senior pays an average of 25 percent, and the prescription drug Part D plan pays 75 percent up to that level.

All right. Then this is known as the doughnut hole. Because under what was passed back in 2003 in order to establish a new prescription drug plan and for it not to cost the Federal Government more than a certain amount, someone devised this crazy plan that then has the doughnut hole all the way up to \$6,440 in total drug costs that the senior citizen is paying 100 percent of that hole, known as the doughnut.

I suppose they call it a doughnut, although it is not closed on all sides, because you have got some coverage down here on this side of the doughnut and then up there on the doughnut. That is what is basically the catastrophic coverage, of which the senior citizen pays 5 percent, the prescription drug Part D plan pays 15 percent, and Medicare pays 80 percent. Now that is the doughnut, and that is the hole.

So, you can see on out-of-pocket costs, the senior is paying \$310 right off the bat on the bottom. By the time they get to where they are paying 100 percent of the drug cost in the doughnut hole, they have expended \$940 out-of-pocket costs. By the time they got through the doughnut hole, they are now out of pocket \$4,550 out-of-pocket costs.

Over in the House, Congressman Pete Stark requested a report from the Government Accountability Office on the prescription drug program drug price increases, and we are going to discuss that today. This report gives us an example of a cancer drug called Gleevec, and the price was increased by 46 percent between 2006 and 2009, from about \$31,200 per year to about \$45,500 per year.

Average out-of-pocket cost for this drug per year increased for a senior citizen of \$4,900 back in 2006 to more than \$6,300 in 2009. That, over 3 years, is not a trivial amount of increase.

If drug prices were increasing for some underlying necessary reason, such as scarcity of resources or excessive increase in demand, then we would be able to understand the increases a lot better. But these very same drugs are sold all over the world, and they are sold for far less than they cost here in the United States.

The 30 most commonly prescribed drugs cost 27 percent less in Canada and 66 percent less in New Zealand, the 30 most commonly prescribed drugs. The drugs are approximately 50 percent less in the United Kingdom, the Netherlands, and France.

So, while pharmaceutical companies are giving other countries deep discounts, they are still able to maintain a tidy profit due to their high prices in the U.S. Let us go to Chart 3. Between 2006 and 2009, the profits of the top drug makers grew by up to 201 percent. Between 2006 and 2009, the top drug makers, and there they are listed, and here their profits grew over that period of time, starting at 96 percent here up to 201 percent.

Now health reform legislation provided unprecedented opportunity to control prescription drug prices, and the House of Representatives is going to get a chance to vote on what we provided in the Senate. What came out in the Senate-passed bill was something that was agreed to early on between the White House and some of the leadership in the Congress and the drug companies. In the Senate-passed bill, the doughnut hole is not eliminated.

Let us go back to that chart with the doughnut hole. Instead, the brand-name drug manufacturers are mandated to give seniors a 50 percent discount on drugs when they are in the doughnut hole. Remember, the senior pays 100 percent here. In the Senate-passed bill, if you thought the doughnut hole was closed, it wasn't.

The drug companies will give a 50 percent discount for the brand-name drugs to seniors. It doesn't say what the price is. It says that they will give a 50 percent discount to the seniors.

Now there is talk, and it is supposed to be published on the Internet tonight, this additional proposal, and we will see once it gets up on the Internet, for a bill that would come to the Senate from the House next week, after the Senate bill is signed into law. That is that the Federal Government kicks in an additional 25 percent to expand the discount to 75 percent for brand-name drugs, as well as a 75 percent discount on generics. It is not the drug companies that are kicking in the additional 25 percent for the doughnut hole. It is the Federal Government.

Proponents of the plan argue that this achieves full coverage since seniors are paying 25 percent co-insurance, but when the drug manufacturers are required to give a discount, what happens? Do they raise their prices? By basing this doughnut hole policy on a discount, beneficiaries and the Federal Government are still going to be subject to working off the base price of whatever the pharmaceutical company has established as the price of the brand-name drug.

So, is this policy going to prevent manufacturers from raising their prices? Well, I certainly would encourage them to do so, but there is no guarantee.

Now, since this whole thing was created back in 2003, and the prescription drug benefit, been a lot of folks talking about eliminating the doughnut hole. While this proposal that is coming back to the Senate next week is not going to stop manufacturers from raising their prices, it will provide additional protection to seniors that would otherwise experience having to pay the whole freight in the doughnut hole.

Why do I get exercised about this? Because back in the Finance Committee, I offered an amendment that was not accepted on a 10 to 13 vote, 13 votes against and 10 for, that would have caused there to be a rebate for only dual eligibles, those people who were eligible for Medicaid because either they were poor or disabled, and they were eligible also dually because they were of Medicare age.

Back in the old days before the prescription drug benefit, the dual eligibles got the same rebate that is in law from drug manufacturers for Medicaid recipients because they qualified for Medicaid, even though they were of retirement age for Medicare. Uh-uh, not after the 2003 prescription drug benefit. If you went and got your drugs through Medicare in the new plan, prescription drug benefit D, you didn't get a rebate to the Federal Government. You had to go through this scheme.

So, today, taxpayers pay higher cost for the same drugs for the same seniors that they used not to do before the prescription drug benefit. So, we want our panel to discuss all of this. We want you to tell us your personal experiences.

I am sorry to have taken as long as I have, but we needed to get into the technicalities on this to set the table for this discussion. We have a distinguished panel.

Dr. Gerard Anderson is an expert on healthcare payment policy. He is currently a Professor of Johns Hopkins. Dr. Anderson also directs Johns Hopkins Center for Hospital Finance and Management. He co-directs the Program for Medical Technology and Practice Assessment, and previously, he was the National Program Director

for the Robert Wood Foundation-sponsored program Partnership for Solutions. I could go on and on.

I will finish introducing the panel, and then I am going to turn to you, Senator Corker, as the ranking member? Let me finish introducing the panel.

John Dicken is the Director for healthcare issues at the U.S. Government Accountability Office, where he directs evaluations of private health insurance, long-term care quality and financing, and prescription drug pricing issues. Prior to working at the GAO, Mr. Dicken was a Senior Analyst for the Presidential Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. I could go on and on with his lengthy resume.

Greg Hamilton has worked in the pharmaceutical industry for 31 years. Mr. Hamilton's areas of expertise include product reimbursement, as well as pharmaceutical issues in Medicaid and Medicare. Mr. Hamilton worked for major drug manufacturers as a pharmaceutical, nutritional, and biological account executive for 20 years. He has experience in marketing, sales, business development, and Government contracting. He was a Senior Product Manager for Bayer, and I could go on and on with his resume.

Ms. Willafay McKenna is a Medicare beneficiary all too familiar with the challenges of what we have been talking about. Ms. McKenna has diabetes, and she controls that with insulin. Every year, her insulin costs push her into the Medicare Part D doughnut hole that we described where she has to pay 100 percent of those medications out of her pocket. She is from Williamsburg, VA.

Finally, John Calfee, listed here as Jack Calfee. He is a resident scholar and Economist at American Enterprise Institute, where he studies the pharmaceutical industry and the Food and Drug Administration, along with the economics of tobacco tort liability and patents. He was previously a visiting senior fellow at Brookings, previously worked at the Federal Trade Commission's Bureau of Economics. He has taught marketing and consumer business behavior at a number of schools and has a very lengthy resume.

So, Mr. Chairman, with those introductions, if you want me to chair the meeting or throw it back to you, I would like to call on Senator Corker for his opening comments.

[The prepared statement of Senator Nelson follows:]

Senator Bill Nelson
 Opening Statement
 United States Senate Special Committee on Aging
 "Seniors Feeling the Squeeze: Rising Drug Prices and the Part D Program"
 March 17, 2009

Late last year, the AARP released a report that showed that while the nation was in a recession and the overall inflation rate was negative, brand name drugs were seeing some of their highest price increases in years. According to their report, the price of the brand name drugs most commonly used by Medicare beneficiaries increased by 9.3 percent in the 2009 – a much higher increase than any of the previous seven years. [Chart #1]

For some drugs, their price increase was markedly higher. Aricept, a drug that treats dementia, saw a 17 percent increase. Ambien, a sleep aid, saw a 19 percent increase. The price of Flomax, a drug used in men with enlarged prostates, increased by 20 percent.

Just yesterday, the Kaiser Family Foundation released a report confirming these trends. According to their report, 9 of the top 10 drugs in Medicare Part D drug plans saw a price increase between 2009 and 2010; for half of these drugs, the increase was 5 percent or more. Kaiser also highlights some particularly egregious cases. Between 2006 and 2010, for Medicare Part D beneficiaries in the so-called doughnut hole paid 20 percent to 25 percent more for Lipitor, Plavix, Nexium, and Lexapro, paid 39 percent more for Actonel, and paid 41 percent more for Aricept.

In comparison, the consumer price index – meaning the price of general consumer goods – increased by just 9 percent between 2006 and 2010. Even the price of most medical care, which we all know is increasing rapidly, grew by just 16 percent. These reports show us that a time when peoples' pocketbooks are getting squeezed, seniors are being asked to pay more than ever for their prescription drugs.

In this hearing, I hope our witnesses can help us look at these drug price increases, try to understand why they are happening, consider how they affect seniors in their Part D plans, and discuss policy options for addressing these high and increasing costs.

In order to understand how increasing drug prices affect seniors, it's important to understand how the standard Part D prescription drug plan works. [Chart #2] A standard Part D plan in 2010 starts with a \$310 deductible, where a senior pays the full cost of any drugs. This is followed by a period of coverage up to \$2,830 in total spending, where the senior pays on average 25 percent of drug costs. After this point, the senior reaches the coverage gap, known as the 'doughnut hole.' Here seniors experience the full brunt of high and rising prescription drug prices, as they are paying 100 percent of their prescription drug costs. Let's be clear – while seniors are paying monthly premiums to their Part D plans, they are on the hook for paying \$3,610 out-of-pocket on their medications. No wonder 15 percent of seniors who have reached the doughnut hole end up stopping their medications. Once seniors have spent the full \$3,610 in the doughnut hole, they reach catastrophic coverage, where the plan pays 15 percent of total costs, Medicare pays 80 percent, and the beneficiary pays 5 percent.

Altogether, beneficiaries are responsible for paying \$4,550 in drug costs out-of-pocket before they reach catastrophic coverage. As you can imagine, a senior will spend \$4,550 a lot quicker with drug prices increasing as fast as they are. That will push more seniors into catastrophic coverage, putting taxpayers on the hook for the increasing drug prices as well.

Congressman Pete Stark requested a report from the Government Accountability Office on prescription drug price increases in the Part D program, which we will discuss today. This report gives an example of a cancer drug called Gleevec. The price of Gleevec increased by 46% between 2006 and 2009, from about \$31,200 per year to about \$45,500 per year. Average out-of-pocket costs for this drug per year increased from about \$4,900 in 2006 to more than \$6,300 in 2009. A \$1,400 dollar difference over 3 years is hardly a trivial increase.

If drug prices were increasing for some underlying necessary reason – scarcity of resources, or excessive increase in demand – these drug price increases would be understandable. Problem is, they're not.

The very same drugs are sold all over the world for far less than they cost here in the United States. The 30 most commonly prescribed drugs cost 27 percent less in Canada and 66 percent less in New Zealand. The drugs are approximately 50 percent less in the United Kingdom, the Netherlands and France.

While pharmaceutical companies are giving other countries deep discounts, they're still able to maintain a tidy profit due to their high prices in the U.S. [Chart 3] Between 2006 and 2009, the profits of top drug makers grew by up to 201%. I'm afraid that the drug companies are laughing all the way to the bank, while seniors and taxpayers are picking up the tab.

I think one important way to insulate seniors from rising drug prices is by filling in the doughnut hole. It is there that they experience the full brunt of high and increasing drug prices. I have introduced a number of measures to achieve this aim. One bill, the Medicare Prescription Drug Gap Reduction Act, would require the Secretary to negotiate prescription drug prices with manufacturers, and the savings would be used to fill the doughnut hole for beneficiaries. I've also proposed requiring pharmaceutical manufacturers to pay a rebate to the government for so-called dual-eligible beneficiaries—those that are eligible for both Medicare and Medicaid. Prior to passage of the *Medicare Modernization Act*, which created the Part D program, these beneficiaries were covered under Medicaid, and the government received rebates to lower the cost of providing drugs to low-income seniors. Today, taxpayers pay higher costs for the same drugs for the same seniors for no good reason.

These provisions can lower costs for taxpayers and for seniors. If we can force drug companies to provide negotiated or mandated rebates by using the full weight of the Part D program, we will see prescription drug prices that are fair to both beneficiaries and to taxpayers.

I look forward to discussing these ideas and others with our distinguished panel of witnesses.

OPENING STATEMENT OF SENATOR BOB CORKER

Senator CORKER. Thank you, Mr. Chairman.

I typically don't give opening comments. However, our staff had written such an outstanding one, I was going to give one today. I am not going to do that because of the time. I respect the witnesses too much and want to hear from them.

I know we have a vote at 3:30 p.m. So let me just say, though, I, too, have been concerned about the cost of brand drugs. We met with the Obama administration's trade representative just recently to see if there are ways of getting at the fact that Americans pay so much more for brand name drugs than other folks. With that, I will stop.

I look forward to hearing the testimony, Mr. Chairman. Thank you for calling this.

[The prepared statement of Senator Corker follows:]

U.S. Senate Special Committee on Aging

UNITED STATES SENATOR BOB CORKER
RANKING MEMBER



Hearing on Rising Drug Prices and the Medicare Part D Program

Opening Statement of U.S. Senator Bob Corker, R-Tenn., Ranking Member

Wednesday, March 17, 2010

****Remarks As Prepared for Delivery****

Thank you, Chairman Kohl and Senator Nelson for calling today's hearing. Prescription drug prices have been a top concern of mine. Now that Medicare covers prescription drugs through the Part D benefit, the government is on the hook for paying high and increasing drug costs along with the high and increasing costs of all health care.

According to the Congressional Budget Office, Medicare spending will grow by 7 percent per year for the next 10 years. The federal spending per beneficiary for Parts A and B will grow close to 50 percent, and per capita benefits for Part D will more than double. As a result, Medicare spending under CBO's projections will rise as a percentage of GDP, from 3.5 percent in 2009 to 4.6 percent by 2020.

But there's a catch, these CBO projections take into account a very steep payment cut to doctors called the Sustainable Growth Rate or SGR or "doc fix." But, Congress never actually allows these cuts. Instead, Congress votes every so often to stop these cuts, which means Medicare spending ends up even higher than CBO projections. CBO cannot calculate the actual percentage of GDP that Medicare will be in the future because Congress only patches the doc fix and has not come up with a long-term solution.

On top of all this, the Medicare trustees have stated that in 2017 Medicare will be insolvent.

The health reform legislation the Senate will debate soon is supposed to help contain Medicare spending and help preserve the trust fund. But, according to CBO, it will not. In reality, the bill takes money from Medicare and leverages it into a new entitlement for younger Americans.

Americans across the country are closely watching the health reform debate and are wary of the bill emerging from Congress. It will be irresponsible for us to pass a bill which further adds to the deficit, especially by taking money from Medicare.

Older Americans rely on Medicare today and baby boomers count on Medicare being there for them tomorrow. We were elected in part to make sure this government health insurance program runs well. Of course, one aspect of running a program well means making sure we are getting the best prices.

Americans do not get the best prices for prescription drugs. This is true for all Americans, not just those enrolled in the Part D program.

Indeed, most countries' citizens get much better deals on prescription drugs. Foreign countries directly set prices for drugs and devices which they see as a part of their internal health systems, not a normal market subject to international trade rules.

These countries typically have some form of socialized medicine, and they require artificially low prices on drugs and devices to balance their budgets. So, Americans subsidize other nations' "free" or "inexpensive" health care. Many of these countries like Canada, Australia, the European countries and Japan have the resources to pay market price, but refuse.

I have met with the U.S. trade representative under both President Obama and President Bush and consulted with numerous trade experts about what we can do to end this unfair practice. I still have not found an answer.

I look forward to hearing the witnesses today explain the rising costs of prescription drugs, why Americans pay so much more than the rest of the world, and any ideas to solve this disparity, not just for Medicare beneficiaries, but for all Americans.

###

Senator NELSON. OK. All of the witnesses have been briefed ahead of time. We want to really dig into some questions. So we have asked each of you to keep your comments to 5 minutes. That will take some time, and I would encourage you to talk to us instead of reading a statement.

Of course, your full statement will be entered as a part of the record, and we will start just in the order that I introduced you.

So, Dr. Anderson?

STATEMENT OF GERARD ANDERSON, M.D., DIRECTOR, CENTER FOR HOSPITAL FINANCE AND MANAGEMENT, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, BALTIMORE, MD

Dr. ANDERSON. Thank you, Mr. Chairman and members of the committee—

Senator NELSON. Make sure your microphone is on.

Dr. ANDERSON. OK. The rising prices of prescription drugs, especially brand-name drugs, is an important issue for America's seniors and for the Medicare program. Let me begin by following up with Senator Kohl and Senator Nelson on the price, the international perspective.

In 2007, the prices for brand-name drugs in the United States were about double the prices in other industrialized countries. For example, the average price of one dose of Lipitor in the United States was \$2.82. The U.S. was paying 54 percent more than Canada, more than twice as much as most other industrialized countries, and four times the price for Lipitor in New Zealand.

The story, however, is quite different for generic drugs. Most other countries pay two to three times what we pay for generic drugs. Countries have devised a whole variety of different ways to try to control drug prices, and some of them seem to be much more effective price negotiators than other countries. The U.S. seems to be not very good at brand-name drugs and very good on generic drugs.

These price differentials have very important public policy implications. In 2006, I coauthored an article, which said if the United States was paying the same prices as these other countries, we could completely eliminate the doughnut hole.

Ms. McKenna, who you are going to hear from in a moment, is typical of the about 4 million Medicare beneficiaries that enter the doughnut hole each and every year. The Kaiser Family Foundation, looking at this data, found that once people entered the doughnut hole, about 10 percent of the diabetics stopped taking their medications and about 18 percent of people with osteoporosis stopped taking their medications.

In 2008, I coauthored an article in JAMA discussing how Medicare beneficiaries could respond to the financial incentives created by the doughnut hole. We did not recommend that they stop taking their medications. Changing medications or eliminating medications for financial reasons can lead to very severe adverse outcomes, higher emergency rooms, more preventable hospitalizations, a whole series of things.

Between 2007 and 2017, the size of the doughnut hole is projected to double, exposing more beneficiaries to even higher out-of-

pocket expenditures and increasing the costs of cost-related non-compliance. It is now virtually impossible to get insurance coverage that fills in the doughnut hole.

There is basically two categories of drugs, brands and generics. On average, brand-name drugs are about four times as expensive as generic drugs. Brand-name drugs are the ones that are most likely to push people into the doughnut hole. Beneficiaries who enter the doughnut hole are the ones who are most likely to be using these brand-name drugs.

According to the—and it was already talked about, according to a report by AARP, overall drug prices increased about 9 percent in 2008 and 2009. What this means is that about 300,000 Medicare beneficiaries are added to the doughnut hole each time drug prices go up by about 9 percent.

According to the GAO, the prices for the most expensive brand-name drugs increased an average of 12 percent between 2006 and 2009. MedPAC has found that Part D plans were unable to negotiate significant drug prices with drug companies for brand-name drugs. GAO found pretty much the same thing for specialty drugs.

One reason the drug companies argue that they need more money is to do more research and development. But what you have got to recognize is they only spend about 15 percent of their resources on research and development. They spend 30 percent on marketing.

The 50 percent deal, or now maybe 75 percent deal, is to get the prices down. If beneficiaries enter the doughnut hole and they can leave, they will have a benefit. They will probably save about \$522 under this. Over the course of the 10 years, that is a savings of about \$17 billion, but not the \$80 billion promised.

If, however, you enter the doughnut hole, it is very important that you get full credit for all the expenditures, not the 25 percent that you pay. Otherwise, you are going to remain in the doughnut hole forever.

So what are the implications of rising drug prices for Medicare beneficiaries? Between 2006 and 2010, their premiums increased 10 percent per year. The beneficiaries that used brand-name drugs are the ones most likely to enter the doughnut hole quickly and to stay in the doughnut hole.

What are the implications for the Medicare program? Between 2006 and 2009, the cost of reinsurance—that is what happens when you enter the doughnut hole and where the Medicare program pays 80 percent of the bill—increased an average of 22 percent per year. For low-income beneficiaries, the Medicare program pays almost all of the bill, and therefore, all of the costs for brand-name drugs basically is paid for by the Medicare program.

Thank you for your time.

[The prepared statement of Dr. Anderson follows:]



**The Center for Hospital
Finance and Management**

624 North Broadway/Third Floor

Baltimore MD 21205

410-955-3241/FAX 410-955-2301

Mr. Chairman, and members of the Aging Committee, thank you for inviting me this afternoon. I am Gerard Anderson, PhD, a professor of public health and medicine at Johns Hopkins University. It is a pleasure to discuss Medicare Part D, the doughnut hole, and escalating drug prices today.

The first time I ever testified to Congress was before the Aging Committee in 1983 on the topic of the Medicare prospective payment system and my most recent testimonies at the Aging Committee have focused on the millions of Medicare beneficiaries with multiple chronic conditions. It is always a pleasure to testify before the Aging Committee.

International Drug Price Comparisons

Let me begin by comparing average drug prices in the US to the average drug prices in other industrialized countries. In figure 1, I compare the prices for the 30 most commonly prescribed drugs in the US to the prices for these same 30 drugs in eight other high income countries (Australia, Canada, France, Germany, Netherlands, New Zealand, Switzerland, and United Kingdom).

Figure 1 shows that in 2006/7, ***the prices for brand name drugs in the US were often double the prices in these other countries.***

There was considerable price variation across the countries. For example, Canada paid an average of 64 cents for a brand name drug that cost \$1.00 in the US while France and New Zealand were paying only 32 and 33 cents respectively.

Countries have developed a variety of ways to control drug prices and some of the countries appear to be more effective price negotiators than other countries. If the US is going to import drugs from other countries, then France or New Zealand may be a better choice than Canada.

I also examined the prices for specific brand name drugs and found the same story. For example, the average price for one dose of Lipitor in the US was \$2.82 (figure 2). In 2007, the US was paying 54 percent more than Canada (\$1.83) , twice as much as several other countries and almost four times the price for Lipitor (\$0. 71) in New Zealand. The average price of Nexium was \$3.91 in the US (figure 3). The US price was 80 percent above the price in Switzerland (\$2.15), more than double the price in most other countries and over three times the price for Nexium in Germany (\$0.88). These are identical drugs - the only difference is price.

The story is quite different for generic drugs. ***The US pays significantly lower prices for generic drugs compared to all these other countries*** except for New Zealand (Figure 1). Many of the other countries pay two to three times what the US pays for generic drugs.

Figure 4 compares the overall level of spending on pharmaceuticals per capita across industrialized countries. In 2007, the US spent the most per capita on pharmaceuticals (\$878). Canada spends the second highest amount per capita (\$691) followed by France (\$588). New Zealand spends only \$241 per capita.

The price differential shown in Figure 1 on brand name drugs goes a long way to explain why Americans spend so much more on prescription drugs compared to these other countries. ***In general, the US is not utilizing more drugs. The US is paying much higher prices for brand name drugs.*** While the US uses more generic drugs than brand name drugs, it spends considerably more per capita on brand name drugs than generic drugs. ***"Its Prices Stupid"*** is a simple way of expressing why Americans spend so much more on prescription drugs than the other industrialized countries.

These price differentials have important policy implications. In 2006, I coauthored an article in Health Affairs (attached) showing that ***if the US paid the same prices for drugs as these other countries; it would be possible to completely close the "doughnut hole" in Medicare Part D.***

Who Enrolled in Part D

We now have data to see what happens as Medicare beneficiaries faced the doughnut hole in 2007. We can see who enrolled; how much they spent; how they changed their behavior while they were in the

doughnut hole; what happened once they exited the doughnut hole; and how high prices for brand name drugs affected the pocketbooks and the health of Medicare beneficiaries.

A high percentage of Medicare beneficiaries (88%) had prescription drug coverage in the first year of the program (2007). The most common sources of coverage were standalone Part D plans (38%), Medicare Advantage Plans (19%) and employer-sponsored drug coverage (30%). It must be noted that 12% of beneficiaries did not have prescription drug coverage in 2007. By 2009, there were still 10% of Medicare beneficiaries without Part D coverage.

In 2007, there were 26.7 million Medicare beneficiaries enrolled in Part D of which 17.6 million were in standalone Part D plans. Of these beneficiaries, 9.6 million were dual eligibles (eligible for both Medicare and Medicaid) and beneficiaries eligible for low income subsidies.

These low income individuals had comprehensive drug coverage that filled in the doughnut hole paid for by the government. In other words, public sector paid the full cost of filling in the doughnut hole. While I excluded them from the analysis since they would not be affected by the doughnut hole, their expenditures come directly from public funds and so the Congress should pay special attention to their costs. They are also very expensive for the Medicare program because many of them have poor health status.

I obtained data from CMS on the experience of over 1.5 million Medicare beneficiaries enrolled in Medicare Part D in 2007. The data is a nationally random representative sample of Medicare beneficiaries. I will present results on the beneficiaries over age 65 that enrolled in standalone Part D plans (not Medicare Advantage) that did not qualify

for dual eligible or low income status for all 12 months in 2007. Many Medicare beneficiaries in Medicare Advantage plans also faced the doughnut hole, but in this testimony we did not examine them. There is simply less data about their health status.

First, it is interesting to see the characteristics of these beneficiaries who enrolled in a Part D plan. Approximately 11 million Medicare beneficiaries over the age of 65 enrolled in a standalone Part D plan (no duals and no low income).

Compared to the overall Medicare population, beneficiaries with the following characteristics are more likely to enroll in a standalone Part D plan.

- Women
- Blacks and Hispanics
- Beneficiaries located in rural communities
- Beneficiaries with multiple chronic conditions

The Kaiser Family Foundation used a different data set (MCBS) to analyze the characteristics of Medicare beneficiaries enrolled in Medicare Part D and found a similar set of characteristics. In addition, they also found that the disabled under age 65, low income beneficiaries, the oldest old (85+), and people living in long term care facilities were more likely to be enrolled in Medicare Part D.

Although the data does not say why they are more likely to enroll in standalone Part D plans, the most likely explanation is that these beneficiaries were less likely to have access to retiree health benefits and used the opportunity to obtain prescription drug coverage.

Who Entered The Doughnut Hole

The next question was how many of these beneficiaries entered the doughnut hole. I was also interested in who exited the doughnut hole in 2007.

Of the approximately 11 million Medicare beneficiaries over age 65 who enrolled in a standalone Part D plan in 2007, almost 7 million (63%), never reached the doughnut hole, ***about 3 million (27%), entered the doughnut hole and never left, and over 1 million (10%), entered and exited from the doughnut hole.***

Compared to beneficiaries in standalone Part D plans whose expenditures never reached the doughnut hole, beneficiaries with the following characteristics were more likely to enter and never leave the doughnut hole.

- Women
- Older beneficiaries
- Beneficiaries with multiple chronic conditions
- Beneficiaries with hypertension, high cholesterol, heart disease, diabetes, arthritis, thyroid disorders, COPD, cognitive impairments, and several others

Who Left the Doughnut Hole

Compared to beneficiaries in standalone Part D plans whose expenditures never reached the doughnut hole, the following types of people were more likely to enter and then exit the doughnut hole.

- Women
- Older beneficiaries
- Blacks, Asians and Hispanics
- Beneficiaries with five or more chronic conditions
- Beneficiaries with hypertension, heart disease, diabetes, arthritis, thyroid disorders, COPD, cognitive impairments and several others

The characteristics of beneficiaries who entered and those who exited the doughnut hole are not especially surprising. They are often the individuals with the poorest health, who see the most doctors, are most likely to be hospitalized and fill the most prescriptions.

They are also the beneficiaries with the most chronic conditions. Chronic conditions have been defined as medical conditions that last a year or longer, limit what you can do and require ongoing care. The key fact to remember is that chronic conditions are long lasting and so these beneficiaries who enter the doughnut hole are likely to enter the doughnut hole each and every year.

Entering the doughnut hole can represent a continuing significant financial burden for beneficiaries with multiple chronic conditions each and every year.

Life in the Doughnut Hole

In 2007, the doughnut hole began when a beneficiary incurred \$2,400 in total drug spending and ended after out-of-pocket spending reached \$3,850. This is equivalent to \$5,451 in total drug spending. Once

through the doughnut hole, beneficiaries become eligible for catastrophic coverage where most of the costs of drugs are covered.

Between 2007 and 2017, the dollar value of the doughnut hole is projected to double, exposing some beneficiaries to potentially higher out-of-pocket costs and increasing the risk of cost-related non-compliance. If the beneficiaries' use of drugs changes, or they stop taking their medication altogether, while they are in the doughnut hole, expenditures for hospital and physician services can increase because they did not get the appropriate drugs while in the doughnut hole.

In the standard Part D plan, the beneficiary pays 25% of the cost and the Part D plan pays 75% of the cost before the beneficiary enters the doughnut hole. Once in the doughnut hole (a \$3051 coverage gap in 2007) the beneficiary pays the full cost of the drugs. Once the beneficiary exits the doughnut hole the beneficiary pays 5%, the plan 15% and the Medicare program 80%.

Part D plans are not required to follow the standard Part D plan but they are required to be actuarially equivalent to the standard plan or provide a richer benefit package. In 2007, approximately 8 percent of plans had coverage that filled in the doughnut hole. However, these plans were generally not available in subsequent years as these plans experienced adverse selection, lost money and did not reissue the plan in the following year. ***It is now virtually impossible to obtain Part D coverage that fills in the doughnut hole*** in a standalone plan.

The Medicare program has a strong financial interest in making sure that beneficiaries get the correct medications while they are in the doughnut hole. Some of them will exit the doughnut hole and some of them will require additional medical care if they do not take their prescriptions or alter their prescriptions because of cost considerations.

Medical Implications

In 2008, I coauthored an article in JAMA (attached) discussing how Medicare beneficiaries could respond to the financial incentives created by the doughnut hole. It was written to help doctors and their patients navigate the doughnut hole and made clinical and financial suggestions. It was written in response to stories of patients discontinuing medications because they could not afford them while they were in the doughnut hole.

The Kaiser Family Foundation has already analyzed ***what happens to beneficiaries when they enter the doughnut hole***. The found that:

- ***15 percent stopped taking their medication***
- 5 percent switched to an alternative drug in the same class
- ***Among diabetics, 10 percent stopped taking their diabetes medication***, 8 percent switched to an alternative and 5 percent reduced their medication use
- ***Among beneficiaries with osteoporosis, 18 percent stopped taking their medication for osteoporosis*** once they reached the doughnut hole, 3 percent switched and 1 percent reduced their medication use.

The Kaiser Family Foundation study also found that some beneficiaries changed their prescriptions once they exited the doughnut hole and they did not have to pay the full amount any longer. Across all patients:

- 57% remained off the medication
- 36% resumed taking their medication

- 7% switched medications

We do not know why the beneficiaries did not resume taking their medications. It could be that their health status improved or they saw that they were doing well without the medications. Alternatively, it is possible that they did not want to start taking medications only to stop in the following year when they entered the doughnut hole again.

In our JAMA article we did not recommend that beneficiaries stop taking their medications. ***Changing medications or eliminating medications for financial reasons can lead to adverse health outcomes for the patient.*** It can also lead to higher emergency room use and more preventable hospitalizations. Changing to generics can be acceptable assuming there is a generic substitute. However, if a generic substitute is available then it makes sense to use the generic from the beginning of the year and not change medications during the year for financial reasons.

When Did They Enter the Doughnut Hole?

Some beneficiaries entered the doughnut hole as early as January and some as late as December. It all depends on their health status, utilization of drugs, especially the more expensive brand name drugs, monthly spending, and when the spending began. It also matters if their health status deteriorates during the year.

Beneficiaries who entered and exited the doughnut hole tended to enter the doughnut hole earlier than those who entered but did not exit. The median (50% before and 50% after) beneficiary who entered, and never left, the doughnut hole entered the doughnut hole in August. The median beneficiary that entered and exited the doughnut

hole entered in April. This is because the beneficiary that exited the doughnut hole typically had higher monthly expenses.

We also examined when the beneficiaries left the doughnut hole. The median beneficiary that exited the doughnut hole left in August although there were some that left as early as January and some who left as late as December.

We also examined the mean number of months a beneficiary was in the doughnut hole. For beneficiaries who entered and never left the doughnut hole it took them an average of 7.8 months to enter the doughnut hole and they were in the doughnut hole an average of 4.2 months. For beneficiaries who entered and exited the doughnut hole, it took them an average of 3.5 months to enter the doughnut hole; they remained in the doughnut hole an average of 4.6 months and were beyond the doughnut hole for an average of 3.9 months.

Prices of Generic Versus Brand Name Drugs

In 2007 beneficiaries entered the doughnut hole once \$2400 had been spent to purchase drugs in the calendar year. We are interested in knowing what types of drugs are responsible for the beneficiary entering the doughnut hole.

There are two basic categories of drugs: brands and generics. On average, ***brand name drugs are almost four times more expensive as generic drugs***. In 2007, the average amount paid for a brand name drug was \$94.68 with the beneficiary paying \$22.44 and the Part D plan paying \$72.44. The average amount paid for a generic drug was \$20.34 with the beneficiary paying \$4.40 and the Part D plan paying \$15.94.

These numbers probably over estimate the amounts paid by the Part D plans because the Part D plan may receive rebates, charge backs, and other discounts that are not reflected in the amount the Part D plan paid the pharmacy. This would increase the percentage of the total bill that the beneficiary pays and lower the percentage paid by the Part D plan. The Medicare program should begin to report the amount the Part D plan is actually paid so the beneficiary can know what percentage of the total bill they are actually paying.

It is also interesting to note that the percentage of the total bill the Medicare beneficiary pays varies substantially by drug. We examined the 200 most commonly prescribed drugs (using national drug codes or NDCs). For some drugs the beneficiary paid less than 10 percent of the total cost and the Part D plans paid over 90 percent. For example, the beneficiary paid the lowest percentage of the total bill for a lidoderm patch (9.5 percent). On the other hand ***there were some drugs where the beneficiary paid over 60 percent of the total cost out-of-pocket***. For example, beneficiaries paid 62.1 percent of the cost of amoxicillin capsules. Clearly not all drugs are treated equally by the Part D plans. In the 200 most commonly prescribed drugs (NDCs), the beneficiary is paying more than 40 percent of the total cost for 41 out of 200 drugs.

Clearly beneficiaries need to know whether they are taking brand name or generic drugs. The cost is likely to be much higher for brand name drugs. They also need to know what percent of the total bill the Part D plan pays for the drugs that they take. It varies widely from drug to drug.

Brand Versus Generic Drug Use In and Out of the Doughnut Hole

Beneficiaries who entered and exited the doughnut hole were more likely to use more brand name drugs than beneficiaries who never entered the doughnut hole. Likewise beneficiaries who entered but never left the doughnut hole were more likely to use more brand name drugs than beneficiaries who never entered the doughnut hole.

Beneficiaries who never entered the doughnut hole used an equal mix of brand and generic drugs. Because the brands are more expensive they spent an average of \$239 in generic drugs and \$773 in brand name drugs. On average, they filled a total of 24 prescriptions.

Beneficiaries who entered but never exited the doughnut hole used a higher percentage of brand name drugs (59%) than generics (41%). Again, because brands are more expensive, these beneficiaries spent an average of \$542 on generic drugs and \$2,888 on brand name drugs. They reduced the use of brand name drugs once they entered the doughnut hole. While they were in the doughnut hole the percentage of them taking at least one brand name drug declined from 99.9 % to 94.1%.

Beneficiaries who entered and exited the doughnut hole had the highest percentage of brand name drug use (63%). The beneficiary who exited the doughnut hole had \$1012 in generic drug spending and \$7729 in brand name drug spending.

When Drug Companies Raise Their Prices For Brand Name Drugs

Unfortunately, the 2008 Part D data has not been released yet and so I cannot examine the levels or impact of price increases on the utilization of brand and generic drugs in the Medicare Part D program.

According to a report by AARP, **overall drug prices increased by 8.7% between 2007 and 2008 and 9.3% between 2008 and 2009.**

According to the General Accountability Office, **the prices for the most expensive brand name drugs (specialty tier drugs) increased an average of 12% per year between 2006 and 2009.**

Some drug prices increased even faster. For example the price of a one year supply of Gleevec went from \$31,200 in 2006 to \$45,500 in 2009 – an average increase of over 15% per year according to the GAO.

The General Accountability Office interviewed the Part D plans and found that had “limited ability to negotiate price concessions with manufacturers of specialty tier-eligible drugs.” The GAO then listed a number of reasons for this including a “lack of competitors for many of these drugs.”

I used these figures to estimate how many Medicare beneficiaries would enter the doughnut hole as a result of a 9 percent increase in drug prices. **A 9 percent increase in drug prices pushes an additional 300,000 Medicare beneficiaries into the doughnut hole each year.** This assumes that the beneficiaries do not reduce their use of drugs or change their mix of drugs as the prices are raised.

Drug Price Increases

One reason that brand name pharmaceutical companies argue that they need to charge high prices is in order to conduct research and development. Once these expenditures occur; however, there are no additional research and development costs for that drug. In economics, these are called fixed or sunk costs.

One possible reason for increasing prices for one drug is to have the resources to develop other drugs. However, it must also be noted that ***the percentage spent on research and development by the overall pharmaceutical industry is less than 15 percent. Marketing represents 30 percent or double the expenditures for research and development.***

Another possible reason is that the cost of producing the drugs is increasing. However, ***most drugs can be produced for pennies per pill.*** Overall inflation has been relatively low and so it is difficult to see why the production costs in the pharmaceutical industry are increasing enough to justify the 9 percent annual increases in prices.

One reason that brand name drug companies need to increase prices is that they need to generate significant profits from the increasingly smaller number of new drugs and blockbuster drugs. In the last 20 years both the number of new compounds that lead to new drugs and the number of blockbuster drugs that generate over \$1 billion dollars in annual sales has been declining. There are simply fewer and fewer drugs that can generate substantial profits and therefore the drug companies need to increase prices.

The 50% Deal With PhARMA

Various groups of providers were asked to make financial concessions in order to reduce the cost of health care reform. The pharmaceutical industry promised to reduce the prices for brand name drugs by 50 percent while the beneficiary is in the doughnut hole.

This deal will affect beneficiaries who remain in the doughnut hole and beneficiaries who exit the doughnut hole very differently.

Beneficiaries that enter the doughnut hole and who never leave will benefit from this deal. An average of \$1043 per beneficiary is spent on brand name drugs while they are in the doughnut hole. If the price that they pay is reduced by 50% then they will save an average of \$522 per person. Multiplying this times the approximately three million beneficiaries who enter but never leave the doughnut hole provides an annual savings of \$1.53 billion. Assuming a 5% growth in brand name prices this represents a benefit to these beneficiaries of \$16.9 billion over the period from 2011 to 2019.

For those beneficiaries who now enter and leave the doughnut hole, they will remain in the doughnut hole much longer because of the lower prices on brand name drugs. Their cost will not decline at all if they leave the doughnut hole. Some of them that exit the doughnut hole now may never reach the point when coverage resumes unless they get credit for the full cost of the drugs. The Medicare program has the most to gain from the deal since Medicare pays 80% of the cost once the beneficiary exits the doughnut hole. The Part D plans pay 15%. These two entities will receive the greatest benefit from this change since fewer beneficiaries will exit the doughnut hole unless they get credit for the full cost of the drugs not the 50% reduction.

The Aging Committee should ask the General Accountability Office to determine who benefits from the 50% reduction in prices for brand name drugs. My preliminary estimates suggest that most of the benefit will accrue to the Medicare program because fewer beneficiaries will exit the doughnut hole and enter the period of coverage when the Medicare program pays 80% of the cost. The other group that will benefit are the approximately 3 million Medicare beneficiaries who enter but never exit the doughnut hole.

It must be noted that the pharmaceutical companies stand to benefit substantially from health reform if the millions of currently uninsured now have prescription drug coverage. The cost of producing an additional pill is often only pennies.

Implications for Beneficiaries

- *Between 2006 and 2010, premiums increased 43% or more than 10% per year. Premiums increased 10% from 2009/10 in the 10 plans with the most subscribers.*
- *Beneficiaries that use expensive brand name drugs are most likely drugs to experience high levels of cost sharing, to enter and exit the doughnut hole rather quickly.*

Implications for Medicare

- *For low income beneficiaries the Medicare program pays most of the cost sharing (except for a small copayment), the full cost while the beneficiary is in the doughnut hole and 85% of the cost once the beneficiary leaves the doughnut hole. Nearly all of the price increases are paid by the Medicare program.*
- *Low income beneficiaries are more likely to use high cost specialty drugs*
- *Between 2006 and 2009, the cost of reinsurance (the 80% of the cost the Medicare program pays once the person exits the doughnut hole) increased 82% or 22% per year.*
- *Most of the cost of expensive drugs is paid for by the Medicare program since the beneficiary quickly exits the doughnut hole where the Medicare program pays 80% of the cost.*

I would be happy to answer any questions.

Read a related paper by [Patricia M. Danzon](#)

HEALTH TRACKING

MARKET WATCH

Doughnut Holes And Price Controls

If Medicare could meet the benchmark drug prices of three other countries, Congress could eliminate the “doughnut hole”—but with a trade-off in R&D.

by Gerard F. Anderson, Dennis G. Shea, Peter S. Hussey, Salomeh Keyhani, and Laurie Zephyrin

ABSTRACT: In 2003 citizens of Canada, the United Kingdom, and France paid an average of 34–59 percent of what Americans paid for a similar market basket of pharmaceuticals. If the Medicare program were to pay comparable prices for pharmaceuticals, it would be possible to eliminate the “doughnut hole” in its prescription drug benefit and keep Medicare drug spending within the overall limits established by Congress. This provides Congress with a clear choice: reduce the level of cost sharing and improve beneficiaries’ access to pharmaceuticals, or allow the pharmaceutical industry to use the higher prices to fund research and development and to engage in other activities.

PREFACE: On 8 December 2003 President George W. Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. The landmark legislation was designed partly to provide Medicare beneficiaries with an entitlement to outpatient prescription drug coverage for the first time in Medicare’s history, an issue that had become increasingly important to American seniors. In spite of the significance of this law, many details and even major turns remain murky to the lay public and analysts alike—in-
deed, an April 2004 survey by the Henry J. Kaiser Family Foundation revealed that 60 percent of seniors did not even know that MMA had been passed by Congress and signed into law.

In an effort to bridge this information gap, Health Affairs has encouraged the nation’s leading Medicare analysts, whose views range along the political spectrum, to examine the new law and write their findings in papers that we could consider for publication. The

best of these papers will be published as Health Affairs Web Exclusives over the coming months; also, under the aegis of a collaboration with the National Academy of Social Insurance, some of the papers will be considered for presentation at NASI’s January 2005 meeting, which will focus on MMA implementation.

The current paper by Gerard Anderson and colleagues explores some issues surrounding the infamous “doughnut hole” in the new Medicare drug benefit, which leaves a considerable coverage gap. Specifically, the authors examine whether the adoption of some mechanism to control pharmaceutical spending such as price controls would allow for the elimination of the “doughnut hole.” The paper by Anderson and colleagues will certainly provoke controversy, given the industry’s vigorous efforts to avoid price controls. Without question, there will be many efforts to close the “doughnut hole,” and Anderson’s proposal is only one of the first. A perspective by Patricia Danzon follows Anderson’s paper.

Gerard Anderson (ganderse@jhsp.h.edu) is a professor at the Bloomberg School of Public Health at the Johns Hopkins University in Baltimore, Maryland. Dennis Shea is a professor at Pennsylvania State University in University Park. Peter Hussey is a doctoral candidate at Johns Hopkins. Salomeh Keyhani and Laurie Zephyrin are fellows in the Robert Wood Johnson Clinical Scholars Program at Johns Hopkins.

THE RECENTLY PASSED Medicare prescription drug legislation contains two provisions that when considered together offer a difficult policy choice for Congress. The first provision is an elaborate cost-sharing arrangement that includes a gap in coverage commonly known as the "doughnut hole." A second provision restricts the federal government from directly negotiating with drug companies over price. This paper examines whether the adoption of some mechanism such as price controls to contain drug spending would allow Medicare to eliminate the doughnut hole.

■ Cost sharing. In the recently passed legislation, most Medicare beneficiaries will pay \$35 per month for prescription drug coverage.¹ The coverage will pay 75 percent of a beneficiary's prescription drug expenses up to \$2,250; then there is a gap in coverage from \$2,250 to \$5,100 (the "doughnut hole"). Then coverage resumes, with Medicare paying 95 percent of a beneficiary's prescription drug expenses above \$5,100.²

While most other public and private drug insurance programs use some type of cost sharing, a gap in coverage such as the doughnut hole is extremely rare. It was developed as a way to hold Medicare drug spending below a previously agreed-upon target of \$400 billion over a ten-year period.³ It was also designed to encourage beneficiaries to sign up if they were likely to have small drug bills while still protecting those likely to have large ones.

This elaborate system of cost sharing will make it difficult for many beneficiaries to know when they are paying 25 percent of expenses out of pocket, when they are in the doughnut hole paying 100 percent, and when they are paying only 5 percent out of pocket. This cost sharing may be particularly onerous for beneficiaries with multiple chronic conditions—the heaviest users of prescription drugs.

■ Negotiation restriction. Most other industrialized countries have instituted a variety of mechanisms to limit drug spending, including formularies, reference pricing, and price controls.⁴ If the Medicare drug bill did not pre-

clude Medicare from directly negotiating with drug companies, Medicare could probably obtain prices similar to those in other industrialized countries. At a minimum, these international prices could be used as a benchmark for Congress to evaluate U.S. prices that are obtained through drug discount cards or some other mechanism.

■ Can Medicare eliminate the gap? The key question addressed here is whether Medicare could eliminate the doughnut hole if it paid the same prices for pharmaceuticals as other countries pay. To answer this question it is important to know the following: (1) a reasonable international benchmark for pharmaceutical prices, and (2) what level of price discount would be necessary to eliminate the doughnut hole and still keep Medicare spending at the same level?

Price Comparison

■ Data. We obtained data on the prices of drugs in Canada, France, the United Kingdom, and the United States for January–September 2003 from IMS Health. These countries were chosen because they are similar in economic development but different in their approaches to regulating drug prices.

We compared the prices of a market basket of the thirty drugs with the highest total spending (including both brand-name and generic drugs) in the United States that are also sold in the other countries.⁵ Each of the thirty items used to construct the index represents a specific manufacturer, compound, and form. For example, the top selling pharmaceutical product in the United States was Lipitor, manufactured by Pfizer in tablet form. In 2003 the price of a 10 mg tablet of Lipitor was \$1.81 in the United States, \$0.99 in Canada, \$0.67 in France, and \$0.90 in the United Kingdom.⁶

■ Methods. We first determined the price of each of the thirty specific products for all available dosage strengths for each country. We then calculated a Laspeyres price index, using the quantity sold in the United States as the base.⁷ The prices compared are the average wholesale prices (AWP)—those faced by major U.S. purchasers, not individual consumers

at pharmacies—because these are the prices that Medicare and other large purchasers would pay. However, since these purchasers rarely pay the full AWP, we also calculated the price index assuming a 20 percent discount. This figure is at the upper end of the discounts that the private insurers administering the Medicare drug benefit are reported to have negotiated with pharmaceutical companies.⁶

These methods differ slightly from those used recently by Patricia Danzon and Michael Furukawa.⁹ They opted for greater representativeness, while we opted for greater standardization.¹⁰ We chose this approach to simulate the prices that would be paid in the United States for the most commonly used products if U.S. usage were fixed but prices were the same as those in other countries.

■ **Comparison results.** Averaged over the market basket of thirty drugs and compared with U.S. prices, prices were 52 percent lower in Canada, 59 percent lower in France, and 47 percent lower in the United Kingdom (Exhibit 1). Assuming a 20 percent discount for U.S. purchasers, prices were 40 percent lower in Canada, 48 percent lower in France, and 34 percent lower in the United Kingdom.¹¹ These differences are greater than those reported by Danzon and Furukawa. One reason for this may be the methodological differences described above; another may be our use of more

recent data (2003 versus 1999). U.S. pharmaceutical prices rose more rapidly during 1999–2003 than prices in other countries.¹²

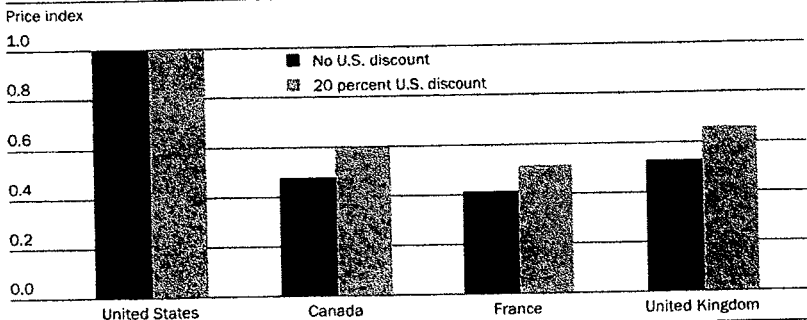
■ **Caveats.** The price differences noted above should be interpreted with several caveats in mind. First, since the market basket used for comparison was chosen to maximize standardization, it may not accurately reflect the average prices across the entire range of prescribed products in each country.¹³ Second, our comparison is based on the assumption that the number of units in the United States is fixed. In reality, however, changes in prices would likely be accompanied by changes in the quantity prescribed. Third, the political and regulatory environment in each country may influence the results: for example, the French government may be more likely to pay higher prices to French manufacturers.

We now turn to our main question: If Medicare could regulate prices and obtain prices similar to those in Canada, France, and the United Kingdom, would this be sufficient to eliminate the doughnut hole?

Eliminating The Doughnut Hole

■ **A microeconomic simulation.** To determine the effects of eliminating the doughnut hole on drug spending, we developed a microeconomic simulation of the effects of Medicare Part D on beneficiaries' behavior.¹⁴

EXHIBIT 1
Relative Prices Of Thirty Pharmaceuticals In Four Countries, 2003



SOURCE: Authors' analysis of IMS Health data.

NOTE: Prices shown are relative to U.S. prices.

The model uses data from the 1999 Medicare Current Beneficiary Survey (MCBS) to simulate a scenario for 2006 by adjusting income, population weights, and drug spending based on data from the Medicare trustees' reports, the U.S. Census Bureau, and the National Health Accounts (NHA) from the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary.¹⁴ The model simulates the choices by Medicare beneficiaries whether to accept a drug plan of the type described in the Medicare prescription drug legislation. The choice is based upon whether the new plan offers net benefits to the beneficiary in the form of reduced premiums, reduced out-of-pocket drug costs, or greater protection from risk compared with existing coverage. Once a person chooses a plan, the effects on spending are estimated based upon an assumed spending elasticity of -0.3, with adjustments for the effects of deductibles, the doughnut hole, and stop-loss protection.¹⁵

The model was run using alternative assumptions about price discounts on prescription drugs and elimination of the doughnut hole. The current Medicare plan (referred to here as the "current legislation") was simulated with a coinsurance rate of 25 percent, a deductible of \$250, and a doughnut hole beginning at \$2,250 and ending at \$5,100, with 5 percent coinsurance after that point. A premium subsidy of 74.5 percent was assumed for all Medicare beneficiaries.¹⁶ Deductibles, coinsurance, and premium subsidies were adjusted for low-income beneficiaries to match

as closely as possible the features of the bill passed.¹⁷ It was assumed that drug purchasers would achieve a 20 percent price discount under the current legislation. An alternative (referred to here as "alternative benefit") was then modeled, with the doughnut hole eliminated and assuming a 45 percent price discount, with all other features identical to the current legislation.

■ Overall effects. The model indicates that under current legislation, Medicare beneficiaries' total drug spending in 2006 would be \$101.9 billion, \$44.5 billion of which would be financed by Medicare. Under the alternative benefit, drug prices were reduced 45 percent, and the doughnut hole was closed. Under this benefit, total spending in 2006 would be \$73.6 billion (Exhibit 2). Medicare spending would be the same as under the current legislation in 2006, at \$44.5 billion. The major reductions would be in out-of-pocket and other spending.

Our model is for 2006 only. Using estimated growth in per capita drug spending from the NHA and estimated growth in the Medicare population from the Medicare trustees' reports, we estimate that total Medicare drug spending during 2006–2013 would equal \$667 billion under the current legislation. This is higher than the initial projections of the Congressional Budget Office (CBO, \$408 billion) and the Bush administration (\$534 billion).¹⁸ Our out-year projections for Medicare spending for 2006–2013 would decline to \$537 billion under the alternative benefit. The CBO and the administration have incorporated as-

EXHIBIT 2
Spending On Medicare Prescription Drug Benefits In 2006

Model version	Model assumptions		Drug spending by Medicare beneficiaries in 2006 (billions of dollars)			
	Stop-loss level (\$)	Price discount (%)	Total drug spending	Medicare	Out of pocket	Third-party payers
Current legislation	5,100	20	101.9	44.5	31.0	26.4
Alternative benefit	2,250	45	73.6	44.5	19.1	9.9

SOURCE: Authors' simulation using data from the Medicare Current Beneficiary Survey (MCBS).

NOTE: "Current legislation" refers to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; "alternative benefit" is authors' simulation as described in text.

sumptions about beneficiaries' behavior that are more complex than our simple extrapolation of the Medicare actuaries' spending and population projections. This could explain their lower estimates.

■ Impact on beneficiaries with chronic conditions. Elimination of the doughnut hole would affect Medicare beneficiaries in different ways. Here we highlight one group that would most likely benefit from the elimination of the doughnut hole: beneficiaries with multiple chronic conditions. These beneficiaries are the heaviest users of prescription drugs, and we assume for our analysis that all of them will enroll. In 1999 beneficiaries with five or more chronic conditions (15 percent of beneficiaries) filled an average of fifty prescriptions per year—almost one per week.²⁰ Also, these beneficiaries often forgo needed medications because the out-of-pocket costs are too high.²¹

We examined the effect of the Medicare drug benefit, with and without the doughnut hole, on people with ten specific chronic conditions. We compared the difference for each person in out-of-pocket drug spending between the current legislation and the alterna-

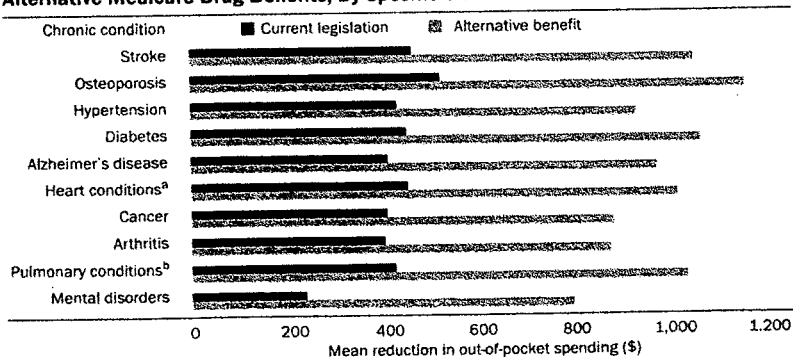
tive benefit.²² Our calculations include all Medicare beneficiaries reporting one of these ten chronic conditions, whether or not they choose to accept the new drug benefit or stay with existing coverage.

Under current legislation. The typical savings under the current legislation for beneficiaries with one of the selected conditions is about \$425, with a range of \$235 for those with a mental disorder to \$519 for those with osteoporosis (Exhibit 3). In general, the current legislation provides savings in out-of-pocket drug spending of more than \$1,000 for 15–20 percent of people with one of these conditions, and savings of more than \$500 for 25–30 percent of these beneficiaries (data not shown).

Under the alternative benefit. The alternative benefit would lead to much larger reductions in out-of-pocket spending—from \$794 to \$1,153—and 25 percent or more beneficiaries would reduce their out-of-pocket spending by at least \$1,000 (Exhibit 3). The alternative benefit would reduce out-of-pocket spending for beneficiaries with no chronic conditions by \$159, while for those with four or more chronic conditions, it would reduce out-of-pocket

EXHIBIT 3

Reduction in Beneficiaries' Annual Out-Of-Pocket Spending Under Current And Alternative Medicare Drug Benefits, By Specific Chronic Conditions



SOURCE: Authors' simulation using data from the Medicare Current Beneficiary Survey (MCBS).

NOTE: "Current legislation" refers to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; "alternative benefit" is authors' simulation as described in text.

^a Includes hardening of the arteries, myocardial infarction, angina pectoris, congestive heart disease, and other heart conditions.

^b Includes emphysema, asthma, and chronic obstructive pulmonary disease.

spending by \$1,034 (Exhibit 4).

Impact on the drug industry. As we have shown, to eliminate the doughnut hole, drug prices for Medicare beneficiaries would have to be 45 percent lower than they are now. But what impact would lower U.S. prices likely have on the industry?

Lower U.S. prices might result in a loss in pharmaceutical research and development (R&D). U.S. manufacturers account for nearly half of the major drugs marketed worldwide.²³ At the same time, the United States constitutes 41 percent of the worldwide pharmaceutical market, followed by Europe (23.5 percent) and Japan (15.9 percent).²⁴ Any attempt to control U.S. prices, given the large percentage of international consumption, may affect investment in the industry and consequently pharmaceutical innovation.

Higher prices, especially for brand-name drugs, allow the industry to sponsor high levels of R&D investment in the United States. In 1999, 60 percent of domestic investment in R&D was made by the pharmaceutical industry (\$33.9 billion), 34 percent was made by the National Institutes of Health (\$18.9 billion), and the remaining 6 percent (\$3.6 billion) was made by other entities such as universities and

foundations.²⁵ This investment has resulted in considerable innovation. Between 1993 and 2003 more than 300 new medicines, biologics, and vaccines were approved by the U.S. Food and Drug Administration (FDA).²⁶

There has been a wide range of estimates using vastly different methodologies to estimate the cost of bringing new drugs to market. Public Citizen, an advocacy organization, estimates the cost of drug development to be around \$57–\$71 million.²⁷ The Tufts Center for the Study of Drug Development has estimated the cost to be around \$802 million.²⁸ Considerable investment in pharmaceutical R&D is necessary given the uncertainty in drug development.²⁹ Of every 5,000 medicines tested, only five on average are tested in clinical trials, and only one is approved for patient use. In addition, only three of ten marketed drugs produce revenues that exceed average R&D costs.³⁰ This pipeline of innovation is what may be jeopardized if U.S. drug prices are lowered.

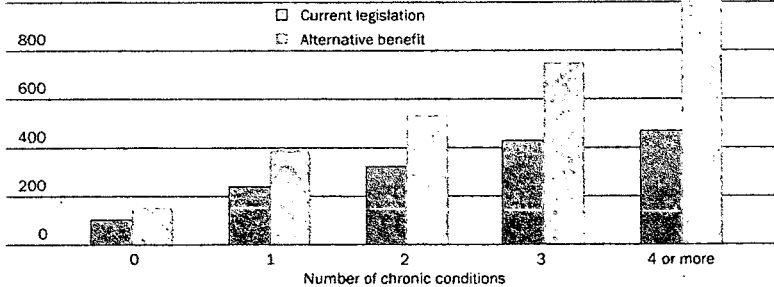
Others have questioned the industry's record on innovation. The National Institute for Health Care Management (NIHCM) reports that from 1989 to 2000 the FDA approved 1,035 new drug applications. Of the drugs approved, 361 had new active ingredients, 558 were

EXHIBIT 4

Reduction in Beneficiaries' Annual Out-Of-Pocket Costs Under Current And Alternative Medicare Drug Benefits, By Number Of Chronic Conditions

Mean reduction in out-of-pocket spending (\$)

1,000



SOURCE: Authors' simulation using data from the Medicare Current Beneficiary Survey (MCBS).

NOTE: "Current legislation" refers to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; "alternative benefit" is authors' simulation as described in text.

incrementally modified drugs, and 116 were identical to drugs already on the market. Of the 361 drugs with new active ingredients, 42 percent provided real clinical improvement over existing drugs. Of the 558 incrementally modified drugs, only 15 percent offered clinical improvement over existing drugs. Therefore, only 24 percent of these drugs offered clinical improvement over existing drugs. NIHCMI concluded that a large proportion of R&D investment is spent developing drugs similar to those already on the market.³¹

Concluding Comments

Drug prices are 34–59 percent lower in Canada, France, and the United Kingdom than they are in the United States. These countries provide a benchmark for the drug prices Medicare could achieve. This should be a feasible benchmark considering that other large purchasers, notably the Department of Veterans Affairs (VA), have come close to international prices.³² If Medicare could also meet this benchmark, then Congress could eliminate the doughnut hole in the Medicare drug benefit.

Several methods could be used to lower drug prices. One option is for Medicare to use a method similar to the approach it already uses to set prices for physician and hospital services. Another is for Medicare to set prices with pharmacy benefit managers (PBMs) for all covered drugs as it now sets prices with health plans for all covered services.³³ Under the current Medicare legislation, insurers or PBMs act as intermediaries between government and beneficiaries. The insurers or PBMs bid for Medicare business.³⁴

Demand controls, such as cost sharing, are yet another method for controlling drug costs. A three-tier copayment system is the most common type of cost sharing in the United States. Reference pricing—requiring beneficiaries to pay the difference between a “reference price” set for drugs in a therapeutic class and a brand-name drug—is another type of cost sharing.³⁵ There is some evidence that reference pricing has lowered drug spending in some countries.³⁶ In addition to cost-sharing mechanisms, collection of better pharmaco-

economic information would allow the development of formularies that exclude drugs that are overpriced for their relative effectiveness and benefits.

POLICYMAKERS IN THE United States have a choice. It is possible to eliminate the doughnut hole if Medicare pays drug prices that are similar to the prices of Canada, the United Kingdom, and France. The trade-off is less pharmaceutical R&D.

The authors thank the Commonwealth Fund and the Robert Wood Johnson Foundation for support. The views expressed here are the authors' own.

NOTES

1. Beneficiaries who are dual eligibles (eligible for both Medicare and Medicaid) and those meeting income and asset requirements receive a full subsidy for the premium. Additional beneficiaries meeting income and asset requirements will receive partial premium subsidies.
2. In addition, the standard drug package has an annual deductible of \$250 in 2006, rising in later years proportionally to Medicare spending.
3. The Congressional Budget Office has estimated that the prescription drug benefit will add \$409.8 billion in spending during 2004–2013. However, the other provisions of the bill will lead to some savings, resulting in a total estimate of \$394.8 billion in increased spending for the entire bill over this time period. Congressional Budget Office, “CBO Estimate of Effect on Direct Spending and Revenues of Conference Agreement on H.R. 1,” Letter to the Honorable William Thomas, 20 November 2003, www.cbo.gov/showdoc.cfm?id=4808&sequence=0 (21 June 2004). The administration has projected much higher costs, however, due mainly to different assumptions about enrollment and spending growth. CBO, Letter to the Honorable Jim Nussle, 2 February 2004, www.cbo.gov/showdoc.cfm?id=4995&sequence=0 (21 June 2004).
4. J.P. Newhouse, “How Much Should Medicare Pay for Drugs?” *Health Affairs* 23, no. 1 (2004): 89–102.
5. We examined the top fifty U.S. products; twenty of these products were not sold in any of the other three countries in 2003.
6. Prices were adjusted from each country's currency units to U.S. dollars using 1 January 2003 exchange rates. Exchange rates were 0.6361 Ca-

nadian dollars per U.S. dollar, 10501 Euros per U.S. dollar, and 1,6114 pounds per U.S. dollar.

7. The units are generally tablets or some other form of pill, although sometimes doses of nasal spray.
8. Our analysis assumes that Canada, France, and the United Kingdom pay the full average wholesale price. Estimates of the potential U.S. discount vary widely. Danzon and Furukawa assumed an 8 percent discount from average manufacturers' price. P.M. Danzon and M.F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs*, 29 October 2003, content.healthaffairs.org/cgi/content/abstract/hltaff.w3.521 (21 June 2004). The CMS estimates that Medicare beneficiaries will be able to achieve a 10-15 percent average discount from retail price using discount drug cards. CMS, "Overview: Medicare Prescription Drug Discount Card and Transitional Assistance Program," www.cms.hhs.gov/discountdrugs/overview.asp (21 June 2004).
9. Danzon and Furukawa, "Prices and Availability of Pharmaceuticals."
10. Danzon and Furukawa averaged the prices for each pharmaceutical compound over the various available dosage strengths and forms, whereas we matched each dosage strength and form. Since there are some differences in the availability of dosages and forms sold in the four countries, our methodology leads to fewer product matches, but our matched products are standardized more closely. The thirty products were sold in a total of 105 dosage forms in the United States. Of these 105, 75 products matched in Canada, 52 matched in France, and 59 matched in the United Kingdom.
11. The 20 percent discount off U.S. prices only translates into an approximately 5 percent reduction in the ratio between the United States and other countries. For example, if a U.S. drug cost \$1.00 and a Canadian drug cost \$0.50 (that is, Canadian prices were 50 percent lower than U.S. prices), a 20 percent discount in the U.S. price would still lead to Canadian prices that are 37.5 percent lower than U.S. prices.
12. There were also new drugs introduced, changes in patent protection, and exchange rate fluctuations between 1999 and 2003.
13. Our sample represented 30 percent of total U.S. pharmaceutical sales in 2003.
14. For details, see D. Shea, B. Stuart, and B. Briesacher, "Participation and Crowd-Out in a Medicare Drug Benefit: Simulation Estimates," *Health Care Financing Review* 23, no. 2 (2003/2004): 47-61.
15. The simulations are run using the community-residing population in the MCBS, excluding approximately 5 percent of the sample residing in institutions. In addition, the results focus on changes in out-of-pocket drug spending, ignoring changes in premium costs.
16. The MCBS does not have information about the premium cost of existing prescription drug plans held by individuals. To assess the net value of a person's drug plan, we estimated the existing premiums paid using information on whether the person paid some, none, or all of their current premium; the type of plan; and what the person's drug costs are. The premium cost of the new Medicare benefit, however, is estimated by the simulation model. This is done recursively, by identifying who enrolls and what the premiums would have to be to break even. The recursion continues until the costs stabilize, and that provides an estimate of the Medicare premium cost. In addition, the changes in insurance coverage that a Medicare beneficiary might make in response to the new plan could have effects on premiums paid through employer plans, Medicare health maintenance organizations (HMOs), Medigap plans, and others. These changes, while important in assessing benefits, are difficult to forecast at this time. The elasticity estimate is based on M.V. Pauly, "Medicare Drug Coverage and Moral Hazard," *Health Affairs* 23, no. 1 (2004): 113-122.
17. Henry J. Kaiser Family Foundation, "Prescription Drug Coverage for Medicare Beneficiaries: A Summary of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," 10 December 2003, www.kff.org/medicare/upload/28710.Lpdf (30 June 2004).
18. The simulation does not try to estimate the effect of nominal dollar copays on spending, for example.
19. R. Pear, "Bush Aides Put Higher Price Tag on Medicare Law," *New York Times*, 30 January 2004.
20. Partnership for Solutions, *Chronic Conditions: Making the Case for Ongoing Care* (Baltimore: Johns Hopkins University, 2002).
21. W. Hwang et al., "Out-of-Pocket Medical Spending for Care of Chronic Conditions," *Health Affairs* 20, no. 6 (2001): 267-278; and S.B. Soumerai et al., "Effects of Medicaid Drug Payment Limits on Admission to Hospitals and Nursing Homes," *New England Journal of Medicine* 323, no. 15 (1991): 1072-1077.
22. As noted above, these estimates do not include the premium costs. The MCBS does not have an accurate estimate of these costs, so the benefit here is based solely on the out-of-pocket drug costs.
23. Hilly Moore and Associates, "Pharmaceutical In

- dustry—Segment Profile," 3 October 2002, www.hiltymore.com/pdf_elements/Pharma.pdf (21 June 2004).
24. P. Feldstein, *Health Policy Issues, An Economic Perspective*, 3d ed. (Washington: Association of University Programs in Health Administration, 2003).
 25. M. Gluck, *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals* (Washington: Kaiser Family Foundation, July 2002).
 26. Pharmaceutical Research and Manufacturers of America, "A Decade of Innovation," 2003, www.phrma.org/publications/publications/2003-10-16.855.pdf (21 June 2004).
 27. Public Citizen, *Rx Re/D Myths: The Case Against the Drug Industry's Re/D "Scare Card"*, July 2001, www.citizen.org/documents/rdmyths.pdf (24 June 2004).
 28. J. DiMasi, "The Price Of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (2003): 151-185.
 29. PhRMA, "Why Do Prescription Drugs Cost So Much?" www.phrma.org/publications/publications/brochure/questions (24 June 2004).
 30. *Ibid.*
 31. National Institute for Health Care Management, "Changing Pattern of Pharmaceutical Innovation," May 2002, www.nihcm.org/innovations.pdf (24 June 2004).
 32. W.H. von Oetson III, *Pharmaceutical Discounts under Federal Law: State Program Opportunities*, May 2001, www.ppsv.com/issues/pharm_discounts.pdf (24 June 2004).
 33. Newhouse, "How Much Should Medicare Pay for Drugs?"
 34. *Ibid.*
 35. U.E. Reinhardt, "Perspectives on the Pharmaceutical Industry," *Health Affairs* 20, no. 5 (2001): 136-149.
 36. *Ibid.*

Senator NELSON. Thank you, Dr. Anderson.
Mr. Dicken.

**STATEMENT OF JOHN DICKEN, DIRECTOR, HEALTHCARE,
GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC**

Mr. DICKEN. Mr. Chairman and members of the committee, I am pleased to be here today to provide highlights from GAO's recent report entitled, "Medicare Part D: Spending, Beneficiary Cost-Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier."

This report focuses on drugs covered by Medicare Part D that have particularly high costs, sometimes exceeding tens of thousands of dollars per year, and how beneficiaries who take these drugs often face high out-of-pocket costs.

Part D plans can assign covered drugs to special distinct tiers with different levels of cost-sharing, such as separate tiers for generic and brand-name drugs. CMS also allows Part D plans to establish a specialty tier when the total cost for a drug exceeds a certain threshold, set at \$600 per month for 2010.

Drugs eligible to be placed on specialty tiers are among the most expensive drugs on the market and are used by a small proportion of Medicare beneficiaries. Examples include immunosuppressant drugs, such as CellCept for transplant recipients; those used to treat cancer, such as Gleevec for leukemia; and antiviral drugs, such as Truvada for HIV. We found that specialty tier eligible drugs account for \$5.6 billion, or about 10 percent of Medicare Part D spending in 2007.

Medicare beneficiaries who received a low-income subsidy account for about 70 percent of this total spending. This is noteworthy because the cost-sharing for these beneficiaries is largely paid by Medicare.

While most of the spending for these drugs was for beneficiaries who received a low-income subsidy, most Medicare beneficiaries are responsible for paying the full cost-sharing amounts required by their plans. Given the high costs, most Medicare beneficiaries taking a specialty tier eligible drug are likely to reach the catastrophic coverage threshold by spending at least \$4,550 in out-of-pocket costs in 2010.

Over half of all beneficiaries who used at least one specialty tier eligible drug reached the catastrophic coverage threshold in 2007, compared to only 8 percent of Part D beneficiaries who filed claims but did not use any specialty tier eligible drugs.

Let me walk through an example of a beneficiary's expected out-of-pocket cost for a specialty tier eligible drug costing \$1,100 per month, the median cost in 2007 for these drugs. Initially, out-of-pocket costs are likely to vary because some Part D plans may place the drug on a tier with a flat copayment while other plans may require co-insurance.

In this example, excluding any deductibles, out-of-pocket costs during this initial coverage period could range from a flat \$25 monthly copayment to \$363 per month for a plan with a 33 percent co-insurance. Under either cost-sharing approach, within 3 months, the beneficiary will typically reach the 2010 coverage gap threshold of \$2,830 in total drug costs and be responsible for paying 100 per-

cent of the drug's costs. This is commonly referred to as the doughnut hole.

Once out-of-pocket costs reach \$4,550 in 2010, in about 6 months for this example, most beneficiaries will pay 5 percent of the drug's negotiated price for the remainder of the calendar year. At this point, beneficiaries' out-of-pocket costs will be similar, regardless of the plan's initial requirement for a flat copayment or for co-insurance.

Variations in negotiated prices between drugs across plans for the same drug and from year-to-year can also affect out-of-pocket costs for beneficiaries. As Senator Nelson noted, for example, for seven plans we reviewed, the average negotiated price for the cancer drug Gleevec increased by 46 percent from about \$31,000 in 2006 to more than \$45,000 in 2009.

Correspondingly, the average out-of-pocket cost for a beneficiary taking Gleevec for the entire year will have risen from about \$4,900 in 2006 to more than \$6,300 in 2009.

Finally, let me close by noting that Part D plan sponsors report having little leverage to negotiate price concessions, such as rebates from manufacturers, for most specialty tier eligible drugs. All 7 of the plan sponsors we surveyed reported they were unable to obtain price concessions from manufacturers on 8 of the 20 drugs in our sample.

For most of the other 12 drugs, plan sponsors report that they were able to obtain price concessions that averaged 10 percent or less. Reasons plan officials cited for limited leverage include the lack of market competitors, CMS formulary requirements, and very low utilization.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions that you or other members may have.

[The prepared statement of Mr. Dicken follows:]

United States Government Accountability Office

GAO

Testimony

**Before the Special Committee on Aging,
U.S. Senate**

For Release on Delivery
Expected at 2:30 p.m. EDT
Wednesday, March 17, 2010

MEDICARE PART D

Spending, Beneficiary Out- of-Pocket Costs, and Efforts to Obtain Price Concessions for Certain High-Cost Drugs

**Statement of John E. Dicken
Director, Health Care**



GAO

Accountability • Integrity • Reliability

GAO-10-529T

March 17, 2010



Highlights of GAO-10-529T, a testimony before the Special Committee on Aging, U.S. Senate

MEDICARE PART D

Spending, Beneficiary Out-of-Pocket Costs, and Efforts to Obtain Price Concessions for Certain High-Cost Drugs

Why GAO Did This Study

The Centers for Medicare & Medicaid Services (CMS) allows Part D plans to utilize different tiers with different levels of cost sharing as a way of managing drug utilization and spending. One such tier, the specialty tier, is designed for high-cost drugs whose prices exceed a certain threshold set by CMS. Beneficiaries who use these drugs typically face higher out-of-pocket costs than beneficiaries who use only lower-cost drugs.

This testimony is based on GAO's January 2010 report entitled *Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier* (GAO-10-242) in which GAO examined, among other things, (1) Part D spending on these drugs in 2007, the most recent year for which claims data were available; (2) how different cost-sharing structures could be expected to affect beneficiary out-of-pocket costs; (3) how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs; and (4) information Part D plan sponsors reported on their ability to negotiate price concessions. For the second and third of these objectives, this testimony focuses on out-of-pocket costs for beneficiaries responsible for paying the full cost-sharing amounts required by their plans. GAO examined CMS data and interviewed officials from CMS and 8 of the 11 largest plan sponsors, based on enrollment in 2008. Seven of the 11 plan sponsors provided price concession data for a sample of 20 drugs for 2006 through 2008.

View GAO-10-529T or key components. For more information, contact John E. Dicken at (202) 512-7114 or DickenJ@gao.gov.

What GAO Found

High-cost drugs eligible for a specialty tier commonly include immunosuppressant drugs, those used to treat cancer, and antiviral drugs. Specialty tier-eligible drugs accounted for 10 percent, or \$5.6 billion, of the \$54.4 billion in total prescription drug spending under Medicare Part D plans in 2007. Medicare beneficiaries who received a low-income subsidy (LIS) accounted for most of the spending on specialty tier-eligible drugs—\$4.0 billion, or 70 percent of the total. Among all beneficiaries who used at least one specialty tier-eligible drug in 2007, 55 percent reached the catastrophic coverage threshold, after which Medicare pays at least 80 percent of all drug costs. In contrast, only 8 percent of all Part D beneficiaries who filed claims but did not use any specialty tier-eligible drugs reached this threshold in 2007.

Most beneficiaries are responsible for paying the full cost-sharing amounts required by their plans. For such beneficiaries who use a given specialty tier-eligible drug, different cost-sharing structures result in varying out-of-pocket costs only until they reach the catastrophic coverage threshold, which 31 percent of these beneficiaries did in 2007. After that point, beneficiaries' annual out-of-pocket costs for a given drug are likely to be similar regardless of their plans' cost-sharing structures.

Variations in negotiated drug prices can also affect out-of-pocket costs for beneficiaries who are responsible for paying the full cost-sharing amounts required by their plans. Variations in negotiated prices can occur between drugs, across plans for the same drug, and from year to year. For example, the average negotiated price for the cancer drug Gleevec across our sample of plans increased by 46 percent between 2006 and 2009, from about \$31,200 per year to about \$45,500 per year. Correspondingly, the average out-of-pocket cost for a beneficiary taking Gleevec for the entire year could have been expected to rise from about \$4,900 in 2006 to more than \$6,300 in 2009.

Plan sponsors reported having little leverage to negotiate price concessions from manufacturers for most specialty tier-eligible drugs. One reason for this limited leverage was that many of these drugs have few competitors on the market. Plan sponsors reported that they were more often able to negotiate price concessions for drugs with more competitors on the market—such as for drugs used to treat rheumatoid arthritis. Two additional reasons cited for limited negotiating leverage were CMS requirements that plans include all or most drugs from certain therapeutic classes on their formularies, limiting sponsors' ability to exclude drugs from their formularies in favor of competing drugs; and that the relatively limited share of total prescription drug utilization among Part D beneficiaries for some specialty tier-eligible drugs was insufficient to entice manufacturers to offer price concessions.

CMS provided GAO with comments on a draft of the January 2010 report. CMS agreed with portions of GAO's findings and suggested additional information for GAO to include in the report, which GAO incorporated as appropriate.

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss high-cost drugs covered under Medicare Part D and to provide highlights from our January 2010 report entitled *Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier*.¹ Medicare Part D is the outpatient prescription drug benefit offered by Medicare, the federal health insurance program which serves about 45 million elderly and disabled individuals. Some drugs covered by Part D have particularly high costs—sometimes exceeding tens of thousands of dollars per year—and beneficiaries who take these drugs often face high annual out-of-pocket costs.

Under Part D, coverage and beneficiary cost sharing can vary. Medicare beneficiaries obtain Part D drug coverage by choosing from multiple competing plans offered by plan sponsors—often private insurers—that contract with the Centers for Medicare & Medicaid Services (CMS) in order to offer the prescription drug benefit. As of February 2010, CMS reported that 27.6 million beneficiaries were enrolled in Part D plans. Part D plan sponsors can offer a range of plans with either a defined standard benefit or an actuarially equivalent alternative, or plans with enhanced benefits. Plans can vary in the coverage provided, monthly premiums, and cost-sharing structure such as copayments and coinsurance.² Most Part D beneficiaries—approximately 18 million—are responsible for paying the full premium and cost-sharing amounts required by their plans. Part D provides premium and cost-sharing assistance through its low-income subsidy (LIS) for other beneficiaries who meet certain income and asset requirements.

Plan sponsors can assign covered drugs to distinct tiers, such as separate tiers for generic and brand-name drugs. These tiers often have increasing levels of cost sharing in order to encourage beneficiaries to utilize less costly drugs such as generics. CMS also allows Part D plans to establish a “specialty tier” for high-cost drugs when the total cost for a drug—as determined through negotiations between the plan and pharmacies—

¹GAO, *Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier*, GAO-10-242 (Washington, D.C.: Jan. 29, 2010).

²A copayment is usually a fixed dollar amount paid by the beneficiary, while coinsurance is a percentage of the cost.

exceeds a certain threshold, set by CMS at \$500 per month for 2007 and \$600 per month for 2008 through 2010. Drugs eligible to be placed on specialty tiers are among the most expensive drugs on the market. They are used by a small proportion of beneficiaries and commonly include immunosuppressant drugs, those used to treat cancer, and antiviral drugs. Plan sponsors may be able to manage spending on these high-cost drugs by negotiating price concessions with manufacturers or price discounts with pharmacies.³

My statement today is based upon our January 2010 report, in which we examined, among other things, (1) spending under Medicare Part D on specialty tier-eligible drugs covered in 2007, the most recent year for which claims data were available when we conducted our study; (2) how the different cost-sharing structures used by Part D plans for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs; (3) how prices negotiated with pharmacies for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs; and (4) the ability of Part D plans to negotiate price concessions from manufacturers for specialty tier-eligible drugs. For the second and third of these objectives, my statement today focuses primarily on out-of-pocket costs for most beneficiaries—those who are responsible for paying the full cost-sharing amounts required by their plans. Details on out-of-pocket costs for LIS beneficiaries, which are subsidized by Medicare, can be found in our January 2010 report.

To do the work for our report, we examined CMS's Prescription Drug Event (PDE) claims data from 2007 for Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDP) to determine spending on drugs eligible to be placed on a Part D plan's specialty tier. For our purposes, we considered specialty tier-eligible drugs to be all drugs with claims reimbursed under Part D with a median negotiated cost of at least \$500 for a 30-day supply (i.e., where at least half of the claims for these drugs in 2007 met or exceeded the CMS cost threshold of \$500 per month). We analyzed the effect of typical cost-sharing structures on beneficiary out-of-pocket costs. We also chose a judgmental sample of 20 specialty tier-eligible drugs and a sample of 36 high-enrollment MA-PD and PDP plans from six counties based on

³Sponsors must pass price concessions on to the program. See the Social Security Act §§ 1860 D-2(d)(1)(A), -15(b)(2), and -15(e)(1)(B) (as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)) (codified at 42 U.S.C. §§ 1395w-102(d)(1)(A), -115(b)(2), and -115(e)(1)(B)).

enrollment as of March 2008. We used CMS negotiated price data³ and CMS estimates of beneficiary out-of-pocket costs for our sample of drugs in 35 of the 36 selected plans⁴ to analyze how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs from 2006 through 2009. The results of this analysis cannot be generalized beyond our judgmental sample of drugs and selected plans. We conducted interviews with representatives from 8 of the 11 largest MA-PD and PDP plan sponsors based on 2008 enrollment data from CMS. In addition, 7 of the plan sponsors we interviewed provided price concession data for our sample of 20 specialty tier-eligible drugs for 2006 through 2008. These 7 plan sponsors represented 51 percent of all MA-PD enrollment and 67 percent of all PDP enrollment in 2008. We determined that the data we used for our report were sufficiently reliable for our purposes. We conducted the work for our report from March 2009 through December 2009 in accordance with all sections of GAO's quality assurance framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product. A detailed explanation of our methodology is included in our January 2010 report.

Background

Under the defined standard benefit in 2009, beneficiaries subject to full cost-sharing amounts paid out-of-pocket costs during the initial coverage period that included a deductible equal to the first \$295 in drug costs, followed by 25 percent coinsurance for all drugs until total drug costs reached \$2,700, with beneficiary out-of-pocket costs accounting for \$896.25 of that total. (See fig. 1.) This initial coverage period is followed by a coverage gap—the so-called doughnut hole—in which these

³Negotiated drug prices are prices negotiated between pharmacies and plan sponsors for drugs dispensed by a pharmacy to plan beneficiaries and are reported by plan sponsors to CMS. CMS negotiated price data, which reflect average prices reported by plans across pharmacies available to beneficiaries, can be used only to estimate average beneficiary out-of-pocket costs, and may not reflect actual out-of-pocket costs paid by beneficiaries. The latter are influenced by factors—such as the extent of price concessions negotiated between plans and pharmacies—that vary by pharmacy and region.

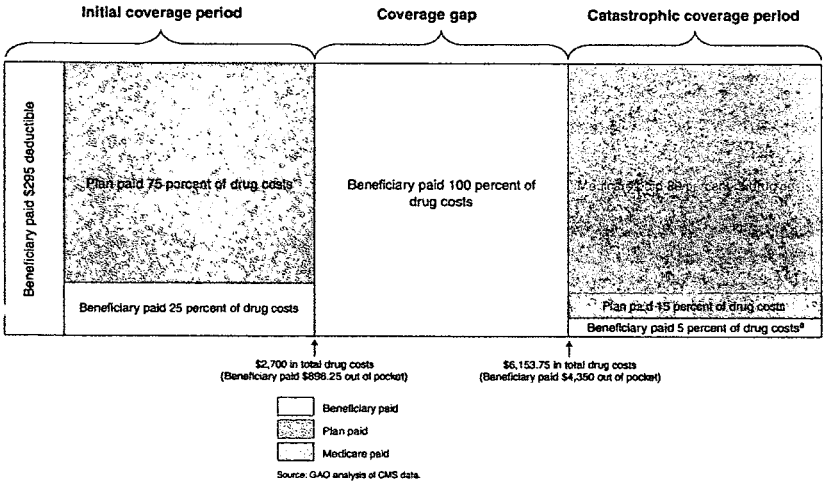
⁴CMS was unable to provide negotiated drug price data and estimated out-of-pocket costs for all 4 years—2006 through 2009—for one plan in our sample. Therefore, we excluded this plan from our analyses.

beneficiaries paid 100 percent of their drug costs. In 2009, the coverage gap lasted until total drug costs—including the costs accrued during the initial coverage period—reached \$6,153.75, with beneficiary out-of-pocket drug costs accounting for \$4,350 of that total. This point is referred to as the catastrophic coverage threshold.⁶ After reaching the catastrophic coverage threshold, beneficiaries taking a specialty tier-eligible drug paid 5 percent of total drug costs for each prescription for the remainder of the year.⁷

⁶In designing an actuarially equivalent alternative plan, plan sponsors must maintain the catastrophic coverage threshold set by CMS pursuant to law (\$4,350 in 2009). See the Social Security Act §1860D-2(b)(4)(B) (as added by the MMA) (codified at 42 U.S.C. §1395w-102(b)(4)(B)).

⁷For 2010, the standard benefit amounts set by CMS are as follows: a \$310 deductible, a \$2,830 initial coverage limit, and a catastrophic coverage threshold of \$4,550.

Figure 1: Medicare Part D Cost-Sharing Structure for Specialty Tier-Eligible Drugs under the Defined Standard Benefit, 2009



Note: LIS beneficiaries paid lower amounts in all phases of the benefit, while Medicare paid the remainder of beneficiaries' out-of-pocket costs.
*Because of the high cost of specialty tier-eligible drugs, the beneficiary always paid 5 percent of drug costs during the catastrophic coverage period.

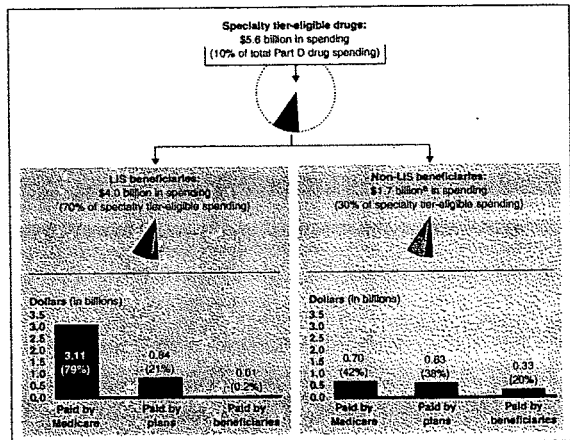
In addition to cost sharing for prescription drugs, many Part D plans also charge a monthly premium. In 2009, premiums across all Part D plans averaged about \$31 per month, an increase of 24 percent from 2008.⁴ Beneficiaries are responsible for paying these premiums except in the case of LIS beneficiaries, whose premiums are subsidized by Medicare.

⁴A Status Report on Part D for 2009, "Report to the Congress: Medicare Payment Policy" (Washington, D.C.: Medicare Payment Advisory Commission [MedPAC], March 2009), http://www.medpac.gov/document_search.cfm (accessed Aug. 13, 2009).

In 2007, Specialty Tier-Eligible Drugs Accounted for 10 Percent of Part D Spending

We found that specialty tier-eligible drugs accounted for about 10 percent, or \$5.6 billion, of the \$54.4 billion in total prescription drug spending under Part D MA-PD and PDP plans in 2007.^a Prescriptions for LIS beneficiaries accounted for about 70 percent, or about \$4.0 billion, of the \$5.6 billion spent on specialty tier-eligible drugs under MA-PD and PDP plans that year. (See fig. 2.) The fact that spending on specialty tier-eligible drugs in 2007 was largely accounted for by LIS beneficiaries is noteworthy because their cost sharing is largely paid by Medicare.

Figure 2: Spending on Specialty Tier-Eligible Drugs under Part D MA-PD and PDP Plans, 2007



Source: GAO analysis of CMS data.

^aTotals do not add to \$5.6 billion due to rounding.

^aThese amounts include spending by Medicare, the plans, and beneficiaries.

While only 8 percent of Part D beneficiaries in MA-PD and PDP plans who filed claims but did not use any specialty tier-eligible drugs reached the catastrophic coverage threshold of the Part D benefit in 2007, 55 percent of beneficiaries who used at least one specialty tier-eligible drug reached the threshold. Specifically, among those beneficiaries who used at least one specialty tier-eligible drug in 2007, 31 percent of beneficiaries responsible for paying the full cost sharing required by their plans and 67 percent of beneficiaries whose costs were subsidized by Medicare through the LIS reached the catastrophic coverage threshold. Most (62 percent) of the \$5.6 billion in total Part D spending on specialty tier-eligible drugs under MA-PD and PDP plans occurred after beneficiaries reached the catastrophic coverage phase of the Part D benefit.

Differences in Plans' Cost-Sharing Structures Result in Out-of-Pocket Costs for Most Beneficiaries That Vary Initially and Then Become Similar

For most beneficiaries—those who are responsible for paying the full cost-sharing amounts required by their plans—who use a given specialty tier-eligible drug, different cost-sharing structures can be expected to result in varying out-of-pocket costs during the benefit's initial coverage period.¹⁵ However, as long as beneficiaries reach the catastrophic coverage threshold in a calendar year—as 31 percent of beneficiaries who used at least one specialty tier-eligible drug and who were responsible for the full cost-sharing amounts did in 2007—their annual out-of-pocket costs for that drug are likely to be similar regardless of their plans' cost-sharing structures.¹⁶

During the initial coverage period, the estimated out-of-pocket costs for these beneficiaries for a given specialty tier-eligible drug are likely to vary, because some Part D plans may place the drug on a tier with coinsurance while other plans may require a flat copayment for the drug. For example, estimated 2009 out-of-pocket costs during the initial coverage period, excluding any deductibles, for a drug with a monthly negotiated price of \$1,100 would range from \$25 per month for a plan with a flat \$25 monthly copayment to \$363 per month for a plan with a 33 percent coinsurance rate.¹⁷

¹⁵LIS beneficiaries' out-of-pocket costs for all drugs, including specialty tier-eligible drugs, are not significantly affected by different plans' cost-sharing structures because Medicare has established fixed cost-sharing levels for all LIS beneficiaries, regardless of the plans in which they are enrolled.

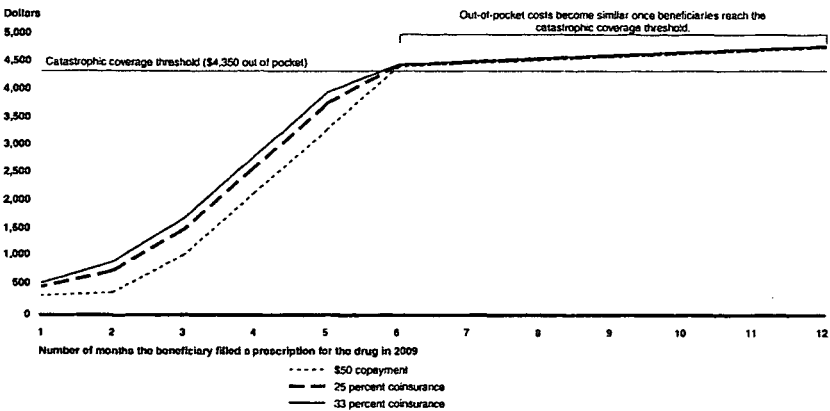
¹⁶\$1,100 per month was the utilization-weighted average of the median negotiated price of all specialty tier-eligible drugs in 2007 based on PDE claims data.

However, even if beneficiaries pay different out-of-pocket costs during the initial coverage period, their out-of-pocket costs become similar due to the coverage gap and the fixed catastrophic coverage threshold (\$4,350 in out-of-pocket costs in 2009). (See fig. 3.) There are several reasons for this. First, beneficiaries taking equally priced drugs will reach the coverage gap at the same time—even with different cost-sharing structures—because entry into the coverage gap is based on total drug costs paid by the beneficiary and the plan, rather than on out-of-pocket costs paid by the beneficiary. Since specialty tier-eligible drugs have high total drug costs, beneficiaries will typically reach the coverage gap within 3 months in the same calendar year. Second, during the coverage gap, beneficiaries typically pay 100 percent of their total drug costs until they reach the catastrophic coverage threshold. This threshold (\$4,350 in out-of-pocket costs) includes costs paid by the beneficiary during the initial coverage period. Therefore, beneficiaries who paid higher out-of-pocket costs in the initial coverage period had less to pay in the coverage gap before they reached the threshold. Conversely, beneficiaries who paid lower out-of-pocket costs in the initial coverage period had more to pay in the coverage gap before they reached the same threshold of \$4,350 in out-of-pocket costs. Third, after reaching the threshold, beneficiaries' out-of-pocket costs become similar because they typically pay 5 percent of the drug's negotiated price for the remainder of the calendar year.¹²

o

¹² While not common, some plan sponsors offer MA-PD plans with lower cost sharing than the usual 100 percent during the coverage gap or the usual 5 percent during the catastrophic coverage period. In these rare cases, beneficiaries would have lower out-of-pocket costs for specialty tier-eligible drugs over the course of the calendar year.

Figure 3: Cumulative Beneficiary Out-of-Pocket Costs under Different Cost-Sharing Structures for a Drug with a Negotiated Price of \$1,100 per Month, for Beneficiaries Responsible for Full Cost-Sharing Amounts



Note: All scenarios include a \$295 annual deductible paid by the beneficiary, \$2,700 initial coverage limit, and \$4,350 catastrophic coverage threshold.

Variations in Negotiated Drug Prices Affect Out-of-Pocket Costs for Most Beneficiaries

For most beneficiaries—those who are responsible for paying the full cost-sharing amounts required by their plans—variations in negotiated drug prices affect out-of-pocket costs during the initial coverage phase if their plans require them to pay coinsurance.¹³ All 35 of our selected plans required beneficiaries to pay coinsurance in 2009 for at least some of the 20 specialty tier-eligible drugs in our sample. Additionally, negotiated drug prices will affect these beneficiaries' out-of-pocket costs during the coverage gap and the catastrophic coverage phase because beneficiaries generally pay the entire negotiated price of a drug during the coverage gap and pay 5 percent of a drug's negotiated price during the catastrophic

¹³ Out-of-pocket costs for LIS beneficiaries are generally not affected by variations in negotiated drug prices because most LIS beneficiaries pay a flat monthly copayment for all drugs regardless of the drug's price.

coverage phase. As the following examples illustrate, there are variations in negotiated prices between drugs, across plans for the same drug, and from year to year.

- **Variations between drugs:** In 2009—across our sample of 35 plans—beneficiaries who took the cancer drug Gleevec for the entire year could have been expected to pay about \$6,300 out of pocket because Gleevec had an average negotiated price of about \$45,500 per year, while beneficiaries could have been expected to pay about \$10,500 out of pocket over the entire year if they took the Gaucher disease drug Zavesca, which had an average negotiated price of about \$130,000 per year.¹⁴
- **Variations across plans:** In 2009, the negotiated price for the human immunodeficiency virus (HIV) drug Truvada varied from about \$10,900 to about \$11,400 per year across different plans with a 33 percent coinsurance rate, resulting in out-of-pocket costs that could be expected to range from about \$4,600 to \$4,850 for beneficiaries taking the drug over the entire year.
- **Variations over time:** Since 2006, average negotiated prices for the specialty tier-eligible drugs in our sample have risen across our sample of plans; the increases averaged 36 percent over the 3-year period.¹⁵ These increases, in turn, led to higher estimated beneficiary out-of-pocket costs for these drugs in 2009 compared to 2006. For example, the average negotiated price for a 1-year supply of Gleevec across our sample of plans increased by 46 percent, from about \$31,200 in 2006 to about \$45,500 in 2009. Correspondingly, the average out-of-pocket cost for a beneficiary taking Gleevec for an entire year could have been expected to rise from about \$4,900 in 2006 to more than \$6,300 in 2009.

¹⁴Values reported are averages in 2009 across the 35 selected plans used in our analysis.

¹⁵We calculated average negotiated drug prices separately for 2006 and 2009 across all plans that covered a given drug for each year and then compared the two average prices to determine the percent increase. CMS did not provide negotiated prices or estimated out-of-pocket costs for four drugs in our sample—Aranesp, Intron-A, Kaletra, and Letairis—for 2006. Therefore, these drugs are excluded from this calculation.

Plan Sponsors Report Three Main Reasons Why They Have a Limited Ability to Negotiate Price Concessions for Specialty Tier-Eligible Drugs

The eight Part D plan sponsors we interviewed told us that they have little leverage in negotiating price concessions for most specialty tier-eligible drugs. Additionally, all seven of the plan sponsors we surveyed reported that they were unable to obtain price concessions from manufacturers on 8 of the 20 specialty tier-eligible drugs in our sample between 2006 and 2008.¹⁸ For most of the remaining 12 drugs in our sample, plan sponsors who were able to negotiate price concessions reported that they were only able to obtain price concessions that averaged 10 percent or less, when weighted by utilization, between 2006 and 2008. (See app. I for an excerpt of the price concession data presented in our January 2010 report.)

The plan sponsors we interviewed cited three main reasons why they have typically had a limited ability to negotiate price concessions for specialty tier-eligible drugs. First, they stated that pharmaceutical manufacturers have little incentive to offer price concessions when a given drug has few competitors on the market, as is the case for drugs used to treat cancer. For Gleevec and Tarceva, two drugs in our sample that are used to treat certain types of cancer, plan sponsors reported that they were not able to negotiate any price concessions between 2006 and 2008. In contrast, plan sponsors told us that they were more often able to negotiate price concessions for drugs in classes where there are more competing drugs on the market—such as for drugs used to treat rheumatoid arthritis, multiple sclerosis, and anemia. The anemia drug Procrit was the only drug in our sample for which all of the plan sponsors we surveyed reported that they were able to obtain price concessions each year between 2006 and 2008.

Second, plan sponsors told us that even when there are competing drugs, CMS may require plans to include all or most drugs in a therapeutic class on their formularies, and such requirements limit the leverage a plan sponsor has when negotiating price concessions. When negotiating price concessions with pharmaceutical manufacturers, the ability to exclude a drug from a plan's formulary in favor of a therapeutic alternative is often a significant source of leverage available to a plan sponsor. However, many specialty tier-eligible drugs belong to one of the six classes of clinical concern for which CMS requires Part D plan sponsors to include all or substantially all drugs on their formularies, eliminating formulary

¹⁸One of the plan sponsors we interviewed declined to provide price concession data through our survey.

exclusion as a source of negotiating leverage.¹⁷ We found that specialty tier-eligible drugs were more than twice as likely to be in one of the six classes of clinical concern compared with lower-cost drugs in 2009.¹⁸ Additionally, among the 8 drugs in our sample of 20 specialty tier-eligible drugs for which the plan sponsors we surveyed reported they were unable to obtain price concessions between 2006 and 2008, 4 drugs were in one of the six classes of clinical concern. Plan sponsors are also required to include at least two therapeutic alternatives from each of the other therapeutic classes on their formularies.

Third, plan sponsors told us that they have limited ability to negotiate price concessions for certain specialty tier-eligible drugs because they account for a relatively limited share of total prescription drug utilization among Part D beneficiaries. For some drugs in our sample, such as Zavesca, a drug used to treat a rare enzyme disorder called Gaucher disease, the plan sponsors we surveyed had very few beneficiary claims between 2006 and 2008. None of the plan sponsors we surveyed reported price concessions for this drug during this period. Plan sponsors told us that utilization volume is usually a source of leverage when negotiating price concessions with manufacturers for Part D drugs. For some specialty tier-eligible drugs like Zavesca, however, the total number of individuals using the drug may be so limited that plans are not able to enroll a significant enough share of the total users to entice the manufacturer to offer a price concession.

Agency Comments and Our Evaluation

The Department of Health and Human Services (HHS) provided us with CMS's written comments on a draft version of our January 2010 report. CMS agreed with portions of our findings and suggested additional information for us to include in our report. We also provided excerpts of the draft report to the eight plan sponsors who were interviewed for this

¹⁷ A therapeutic class or category of drugs is generally based on an indication approved by the Food and Drug Administration. Part D sponsor formularies must include all or substantially all drugs in the following six classes of clinical concern as identified by CMS: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. Examples of other therapeutic classes include analgesics, blood glucose regulators, cardiovascular agents, dermatological agents, respiratory tract agents, and sedatives.

¹⁸ This analysis was conducted by comparing specialty tier-eligible and nonspecialty tier-eligible drugs at the drug (ingredient) level with a list of drugs in the six classes of clinical concern provided by CMS.

study and they provided technical comments. We incorporated comments from CMS and the plan sponsors as appropriate in our January 2010 report.

Mr. Chairman, this completes my prepared remarks. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

GAO Contact and Staff

Acknowledgements

For further information about this statement, please contact John E. Dicken at (202) 512-7114 or DickenJ@gao.gov.

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Key contributors to this statement in addition to the contact listed above were Will Simerl, Assistant Director; Krister Friday; Karen Howard; Gay Hee Lee; and Alexis MacDonald.

Appendix I: Comparison of Price Concessions Negotiated by Seven Plan Sponsors for a Sample of 20 Drugs in 2008

Drugs (including strength and dosage form), by indication	Number of plan sponsors that obtained price concessions	Average negotiated price per 30-day supply, before price concessions, weighted by utilization (dollars)	Average negotiated price per 30-day supply, after price concessions, weighted by utilization (dollars)
Multiple sclerosis			
Glatiramer acetate (Copaxone) 20 mg/ml injection	7	1,867	1,732
Interferon beta-1a (Avonex) 30 mcg intramuscular injection	5	1,935	1,884
Inflammatory conditions (e.g., rheumatoid arthritis, psoriasis, Crohn's disease)^a			
Adalimumab (Humira) 40 mg/0.8 ml injection	7	1,600	1,469
Anakinra (Kineret) 100 mg injection	— ^b	1,424	1,423
Etanercept (Enbrel) 50 mg/ml injection	6	1,527	1,470
Human immunodeficiency virus (HIV)			
Atazanavir sulfate (Reyataz) 150 mg tablet	6	853	810
Emtricitabine and tenofovir disoproxil fumarate (Truvada) 200 mg/300 mg tablet	0	881	881
Lamivudine and zidovudine (Combivir) 150 mg/300 mg tablet	6	741	714
Lopinavir and ritonavir (Kaletra) 200 mg/50 mg tablet	0	745	745
Cancer			
Erlotinib (Tarceva) ^c 150 mg tablet	0	3,393	3,393
Imatinib mesylate (Gleevec) 400 mg tablet	0	3,389	3,389
Hepatitis C			
Interferon alfa-2b (Intron-A) 3 million IU injection	0	580	580
Peginterferon alfa 2a (Pegasys) ^c 180 mcg/0.5 ml injection	6	1,817	1,561

Drugs (including strength and dosage form), by indication	Number of plan sponsors that obtained price concessions	Average negotiated price per 30-day supply, before price concessions, weighted by utilization (dollars)	Average negotiated price per 30-day supply, after price concessions, weighted by utilization (dollars)
Anemia			
Darbepoetin alfa (Aranesp) 100 mcg/0.5 ml injection	4	1,128	994
Epoetin alfa (Procrit) 40,000 units/ml injection	7	1,593	1,420
Enzyme disorders (e.g., Gaucher disease)			
Miglustat (Zavesca) 100 mg capsule	0	8,344	8,344
Pulmonary arterial hypertension			
Ambrisentan (Letairis) 10 mg tablet	0	4,416	4,416
Bosentan (Tracleer) 125 mg tablet	0	4,423	4,423
Other (selected based on high utilization)			
Mycophenolate mofetil (CellCept)— immune suppressant 500 mg tablet	7	681	652
Teriparatide (Forteo) ¹ —osteoporosis 250 mcg/ml injection	4	748	641

Source: GAO analysis of price concessions data provided by seven plan sponsors GAO surveyed.

¹These three distinct diseases (rheumatoid arthritis, psoriasis, and Crohn's disease) may be treated using some of the same drugs. We selected three of those drugs for our sample.

²The total number of plan sponsors who reported receiving price concessions for this drug was too small to allow us to report this value while maintaining confidentiality.

³One of the seven plan sponsors we surveyed did not submit any data for this drug. Therefore, values listed for this drug are based on data submitted by six plan sponsors, rather than seven plan sponsors.

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Senator NELSON. Thank you, Mr. Dicken.
Mr. Hamilton.

**STATEMENT OF GREGORY HAMILTON, MBA, CONSULTANT,
ALGONQUIN, IL**

Mr. HAMILTON. I remembered to turn my mike on.

Mr. Chairman and members of the Aging Committee, thank you for inviting me here this afternoon. My name is Greg Hamilton, and I am a consultant in the healthcare industry in which I have been working for over 35 years.

Most of my clients are Qui Tam attorneys working with whistleblowers, the DOJ, and States to recover monies lost through fraud. I have been asked here today to discuss with you the effect on seniors of the 2008 and 2009 drug price increases, which you have described quite well.

A couple quick points, the Wall Street Journal article on April 15 quoted one of my former employers, Express Scripts, saying it saw prices rise more than 10 to 15 percent over the past 12 months. The New York Times reported that wholesale prices for brand-name drugs rose about 9 percent last year, and this was all in the face of, as you noted, the Consumer Price Index decrease by 1.3 percent.

Analysts in these articles believe these unusual increases were preemptive attacks on anticipated cost containment under healthcare reform, coupled with a drive to maintain profits as patients on many popular brand drugs are set to expire soon.

These price increases will harm seniors—seniors in Part D, seniors in retirement plans, seniors paying cash. Pretty much anybody that goes to buy a prescription is going to be affected by these price increases. Here is why. It all has to do with the system in which they get paid.

Pharmacies are not paid by the insurance companies. Almost all pharmacy claims are paid by a middleman called a pharmacy benefit manager, or PBM, as in one of my former employers. Insurance companies, unions, and other payers hire PBMs to maintain networks of retail pharmacies, create formularies, configure copay tiers, collect rebates, and adjudicate claims.

PBMs begin this process by contracting with retail pharmacies. They negotiate reimbursement rates for prescription drugs at some discount off of average wholesale price, otherwise known as AWP, also commonly called “ain’t right price.” Many of you here might be familiar with all the Federal and State lawsuits revolving around AWP. There have been many multimillion dollar settlements.

The problem is that our industry continues to use that system, and it is that system that will continue to pass these price increases along to the consumer. We should also note that all the Medicaid programs predominantly use AWP for their own reimbursement also. The typical reimbursement, by the way, just for on average for State Medicaid and for what the PBMs negotiate, is about 14 percent as a discount off of AWP that they actually pay the pharmacy.

AWP is directly related to wholesale price. It is typically 20 percent or 25 percent above wholesale price. So when wholesale price

increase, so does AWP, which, in turn, drives up the reimbursement to the pharmacy and, consequently, the patients' copay.

Price increases to both patients and payers, can, theoretically, be offset through rebates. PBMs combine AWP's with rebates to determine the total cost of a drug to the payer. Lower-cost drugs are sometimes placed in a lower copay category to encourage patient selection and thus reduce their cost and the cost to the payer.

The New York Times article cites analysts and a 2007 congressional study as saying these rebates often accrue to the middlemen and not to consumer. My experience in the industry supports this claim.

Although PhRMA Senior Vice President Ken Johnson has claimed that the pricing studies were incomplete because they did not consider the rebates, he is wrong. He forgets the basic nature of rebates. These rebates are not paid out of generosity or altruism. They are negotiated vigorously on relative prices for drugs within specific therapeutic categories.

The eight largest pharmaceutical companies all had comparable increases. So if all the prices went up at about the same rate in the same time period, there would be no rationale for new or additional rebates as the relative prices would remain constant. Payers would have no leverage with which to pit one company against another in order to derive new rebates.

Under this regime and with the system that we use, the payers and the patients will just have to pay more for the drugs, seniors included.

Thank you.

[The prepared statement of Mr. Hamilton follows:]

Mr. Chairman, and members of the aging committee, thank you for inviting me here this afternoon. My name is Greg Hamilton and I am a consultant in the healthcare industry in which I have worked for over 35 years. Most of my clients are Qui Tam attorneys working with relators, the DOJ and the States to recover monies lost through fraud. I've been asked to discuss with you the affect on Seniors of the 2008 and 2009 drug price increases as described in articles by the Wall Street Journal and the New York Times.

The WSJ's article on April 15, 2009 quoted one of my former employers, Express Scripts, saying it saw prices rise more than 10-15% over the past 12 months. The NYT article in November 2009 stated that Wholesale Prices for brand name drugs rose by about 9% in the last year. They further noted that this increase was in contrast to a reduction in the Consumer Price Index which had fallen by 1.3%.

Both articles quote Catherine Arnold, a drug industry analyst at Credit Suisse, who said her study of the nations eight biggest pharmaceutical companies showed list prices rising an average of 8.7% in the 12 months ending September 30, 2009.

Contributors to both articles believe these unusual increases were the result of anticipated cost containment under healthcare reform and/or a need to maintain profits as patents on many popular brand drugs are set to expire over the next few years. I suspect it is a combination of the two.

In order to see why these price increases will impact seniors (both Part D and others) we need to understand the way in which drug claims are adjudicated i.e. paid. Pharmacies are not paid by insurance companies. Almost all pharmacy claims are paid by a middleman called a Pharmacy Benefit Manager (PBM). Insurance companies, Unions, and other payors hire PBM's to maintain networks of retail pharmacies, create formularies, configure co pay tiers, collect rebates, and adjudicate claims.

PBM's begin the process by first contracting with retail pharmacies. They negotiate reimbursement rates for prescription drugs at some discount off of Average Wholesale Price (AWP). NOTE: Most Medicaid drug reimbursement is also calculated at a discount off of AWP. I'm sure many of us here are familiar with the numerous state and federal lawsuits concerning AWP, but we will have to save that issue for another day.

AWP is directly related to Wholesale Price. It is typically 20% or 25% above Wholesale Price. So when Wholesale Price increases so does the AWP, which in turn drives up the reimbursement to the pharmacy and consequently the patients' co pay.

Price increases, to both Patients and Payors, can, theoretically, be offset through rebates. PBM's combine AWP's with rebates to determine the total cost of a drug to the payor. Lower cost drugs are sometimes placed in a lower co pay category to encourage patient selection and thus reduce their cost and the cost to the payor. The NYT article cites analysts and a 2007 Congressional study as saying these rebates often accrue to the middlemen and not to consumers. My experience in the industry supports this claim.

The NYT article cites PHARMA Senior Vice President Ken Johnson as saying the pricing studies were incomplete by failing to include rebates. I believe he is implying that rebates may erase or mitigate the price increases mentioned. Such an inference is flawed in that it forgets the basic nature of rebates. These rebates are not paid out of generosity or altruism. They are negotiated based on relative prices for drugs within specified therapeutic categories. In this case the articles report that the eight largest pharmaceutical companies had comparable increases. So if all the prices went up at about the same rate there would be no rationale for new or additional rebates as the relative prices would remain constant. Payors would have no leverage with which to pit one company against another in order to derive new rebates. The Payors and the patients will just have to pay more for the drugs, seniors included.

THANK YOU.

Senator NELSON. Thank you, Mr. Hamilton.
Ms. McKenna.

**STATEMENT OF WILLAFAY MCKENNA, MEDICARE PART D
PARTICIPANT, WILLIAMSBURG, VA**

Ms. MCKENNA. I want to thank each of you for allowing me to speak this afternoon very briefly on what my experience with Medicare Part D has been.

I anticipated this program with a great deal of hope as it was debated in Congress in the months before it passed. I was pretty horrified at the thought of the doughnut hole, but one thing that saved me in the first year was that I found or I misunderstood the bill and thought that the out-of-pocket expenses that would take me to the doughnut hole were my own expenses.

But of course, they include the insurance company payments. So when I went into it, it was a big shock. That was my first year.

Just before I went into the Part D program, I purchased one of my prescriptions for insulin, and I paid a total of \$77. That was \$44 for the drug and a modest copay under the plan that I had at the time. As you will see from the information I submitted, at this time, the drug that I paid \$44 and a copay for in 2005 is now selling for \$239.99.

I have also experienced the doughnut hole in each year that I have been with the program. Each year, as the doughnut hole has changed in its breadth and its range, even though the drug prices may have stayed the same or if they go up a little, they never quite match what the doughnut hole has done. So it has been a constant problem.

I have insulin-dependent diabetes. I am on two different insulins, which I take several times a day. In addition, I am on three other medications that are used generally with diabetics for the maintenance or prevention of the typical kinds of side effects and other complications that you can have with the disease.

There is no generic insulin, and that is a definite criticism. Surely the copyrights or the patents or whatever controls the drug manufacturers has run out now. Here we are in 2010 with what is basically a simple drug that is made up of some kind of RNA or DNA, but there is no protocol to allow a drug company to come in and know how to get approval through the FDA. That is part of the problem.

Also I would say that the transparency that has not been available to seniors in examining the plans each year, that is being addressed now. The first year that they were included on the Medicare website, they were quite inaccurate. This year, they were much better, and I think that Medicare has done a marvelous job with its Plan Finder. It is very, very helpful, and I do have some suggestions about that later.

The one last thing I would like to address with you is that this year because something happened with one of my drug manufacturers, I am now purchasing one of my drugs from Canada. The manufacturer of one of the cartridges that I use for insulin discontinued those as of December 31st. They are sold all over the country, but they are no longer available in the United States.

I was switched to a different insulin by my endocrinologist, and as with a series of insulins before that, I developed an injection site reaction that was a horrible thing, and I was taken off that drug. I contacted the drug manufacturer, the FDA, Medicare, everybody else, and I kept sending letters. Finally, in late December, I received a letter from the FDA, which did not guide me and direct me but let me discover for myself that it would be legal for me to purchase this drug in Canada.

Even though I went through the process with fear that it would never arrive because it would be confiscated and within a very, very uneasy feeling when I had to go to the post office to pick it up, absolutely certain that out of the door with the package would come a bunch of Federal agents and spirit me away. I got through that, and I am now using it. The packaging is exactly the same. The only difference is that it is printed in English on one side and French on the other.

The information contained within the package, it is the same writing. It says the same thing. It is all the same, but the price—\$65 is the full price for the Canadian prescription. Then I paid \$10 for insulated packaging to get it here, and that is remarkable to me. That expense that I will bear myself will probably keep me out of the doughnut hole this year.

I very quickly want to go through, as somebody who deals with the program but is not professionally involved in it, some suggestions that I have. I really think this is a laudable thing to do. Medicare people being the senior citizens of this country, many of them on a limited income, particularly with the people who are now experiencing it because they grew up in a time when Social Security was offered as the way to retire. Remember the old ad? Retire on \$300 a month in Florida?

Well, anyway, the first thing is I think that allowing Medicare to negotiate with the pharmaceutical companies for the drug costs is just about the only way that may give some relief in this thing, in this whole program. Permitting Medicare, and if you want to keep the private drug companies involved or the insurance companies involved, let Medicare contract with them to process the claims, but not to run the program.

I would also note that Medicare pays faster on its medical bills and provides more information to the Medicare participants than any of the insurance companies do. We may get a statement once a quarter from the private insurance company, but we get them constantly from Medicare.

Encourage the FDA to issue rules for development of generic biologics like insulin. It is absolutely ridiculous that a simple drug, a basic, simple, biologic drug could undoubtedly be put on the market here for a very minimal price. It was a low price even 10 years ago, and it has gone sky high and it hasn't changed.

Consider a modest increase in the withholding tax for Medicare. Obviously, when Medicare was made available decades ago, the anticipated costs could never—didn't anticipate pharmaceuticals. It didn't anticipate the higher cost. But like for my secretary, I think I deduct like \$6.08 out of a pay period. I would go to \$7 at least without—I wouldn't think twice about that.

Finally, consider a grading part for Part D programs, a grading similar to what Medicare used to do when it did the A to F groupings for the Medigap insurance that was sold some time ago. But that way, if the participant could identify the specific health problems they are having and get those programs that are graded for them, that might be helpful.

I would just say one more thing, and that is Mr. Dicken, I think, mentioned the big tier of the drugs. One of the years, my insulin was in that tier, and I certainly can't understand that. It never costs \$600 a month. It is not a rare drug. It is not a controlled substance. But it was in Tier 4. Of course, that upped the price.

Senator NELSON. Yes.

Ms. McKENNA. Thank you very much, and I appreciate the opportunity again.

[The prepared statement of Ms. McKenna follows:]

UNITED STATE SENATE SPECIAL COMMITTEE ON AGING
"Seniors Feeling the Squeeze: Rising Drug Prices and the Part D Program"
March 17th, 2010

Statement by Willafay H. McKenna, J.D.
Medicare Part D Participant

Thank you for the opportunity to speak about my experience with Medicare Part D. My interest and familiarity with this program began as I watched the hearings aired by C-Span in the months before its passage. My participation in and conversance with Part D began in the program's first year when my health insurance plan discontinued prescription drug coverage and continues to the present time.

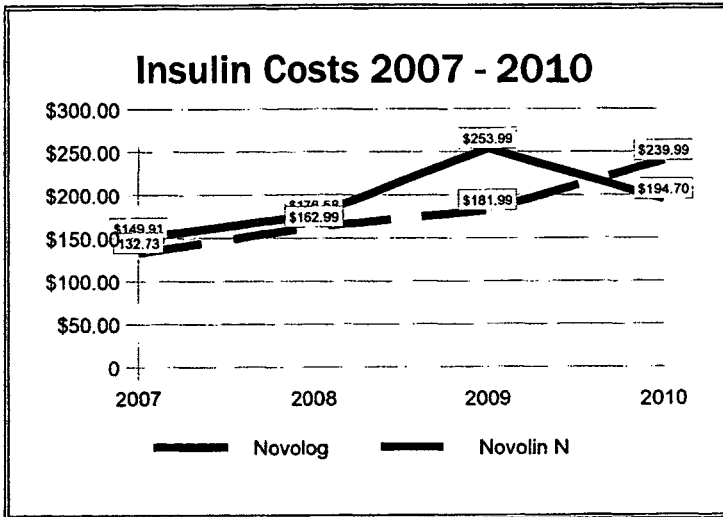
During the first year of my enrollment, I quickly learned that my previous private plan had been far more generous in providing prescription drugs than my new PDP. This fact was painfully underscored in September of that year when I reached the coverage gap. Each year since 2006, as monthly premiums, deductibles and drug costs have increased and the range and size of the coverage gap has grown, the "doughnut hole" has swallowed me sooner only to present its threat when the cycle begins again with each new year.

I have insulin dependent diabetes and take two different insulins several times each day. In addition, I take several drugs commonly prescribed for diabetics to prevent and control the complications frequently associated with this disease. There are no generic insulins and only one of the three additional drugs I take is available as a generic. While in the coverage gap, the average monthly cost of my prescription medications is \$700. I have come close but have never reached the catastrophic level which is set higher each year and always seems to be set at a figure above the amount by which drug costs have increased. Since my initial enrollment in 2006, the catastrophic level has risen from \$5,100 to \$6,440. The costs a Participant would be required to exit the coverage gap to the relief of the catastrophic level has risen from \$2,850 to \$3,610.

With little transparency in drug prices until recently, seniors evaluating plan options or checking a chosen plan's performance worked without prices which are a required element in their quests. For 2008 plans, Medicare's PlanFinder incorporated drug prices for the first time allowing one to see monthly premiums along with out-of-pocket expenses and to know if or when the dreaded coverage gap would be reached. Evaluations undertaken after the enrollment period had ended found substantial inaccuracies in the prices provided.¹ Efforts undertaken before the 2010 enrollment period began appear to improved the reliability of this data. PlanFinder's inclusion of accurate drug price information makes this Medicare site invaluable for Part D participants and Medicare should be applauded for the organization and depth of information it has made usable through its website.

¹ *Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder*, July 2009, OEI-03-07-00600.

My personal drug costs have risen substantially since I originally enrolled in Part D. The full price of the insulin I purchased at the end of 2005 before my enrollment in Part D was \$77. Although the cost of all of my prescribed medications has increased, only the changes in insulin costs are summarized in the following chart.



This year will be different for me because Novo Nordisk discontinued its Novolin N PenFill cartridges at the end of December 2009. The discontinued cartridges were made for reusable insulin pens which can dispense half-unit doses. I have relied on these pens for nearly a decade because insulin sensitivity makes half-unit dosing a necessary part of my disease management.

When I first learned that these cartridges would no longer be available, I contacted Novo Nordisk about my concern. Their response was "sorry but we did give you notice." They did assure me that the FDA would be notified and would, in all likelihood, contact me directly. When I heard nothing, I began sending letters to Novo Nordisk, the FDA and to other agencies which might deal with this problem.

By early December, I was in a near panic. My endocrinologist switched me to a long-acting insulin from another drug company. It came in disposable pens dispensing only whole unit doses. After several days of unpredictable and unmanageable blood glucose highs and lows, I developed a putrid, festering injection site reaction which precluded its further use. Hope came just before Christmas in a letter from the FDA suggesting that it could be legal for me to order Novolin N from Canada where its sale has not been

discontinued. After checking the references cited in the letter, I researched Canadian pharmacies and chose one based on its credentials. My physician approved and wrote the prescription and a letter outlining my need and a prescription. These were faxed to the Canadian pharmacy along with an affidavit I had prepared stating that the drug was approved in this country but unavailable in the cartridges I require.

Five days later, a notice from the post office let me know that my order had not been confiscated but was waiting for me to appear in person to pick it up. I waited in line at the post office with an uneasy feeling that I would be grabbed and spirited away by federal agents as soon as the package was placed in my hands. Nothing like that happened and I left with a great sense of relief and my Canadian drugs in hand.

What is most remarkable to me is the cost that I paid for my order from Canada: \$65.00 for one 5-cartridge box of Novolin N insulin and \$10.00 for shipping in a large insulated box. My co-pay for the same insulin at my local pharmacy would be at least \$88.00 for the same 5-cartridge box which it sells for \$239.99. Although I will pay \$75.00 monthly for this medication, \$239.99 monthly will not be included in my TrOOP which pushes me toward the dreaded "doughnut hole."

In addition to the rising costs of Part D plans, the complexity of the program is daunting. Between November 15th and the end of December in each of the last several years, I have spent countless hours on the computer and printed reams of information in my efforts to find the best plan for my circumstances. I have become almost comfortable with tiers, formularies, quantity limitations, TrOOPs, etc.—the correlates of making an informed decision between plans. Each year is different as monthly premiums, deductibles and the size and range of the coverage gap increase annually. I have spoken with many Medicare seniors who have relied, to their sorrow, on television or mail ads put out by the major plans. The goal of providing prescription drugs to seniors at reasonable costs is laudable. I believe it is a goal that can be achieved faster and at less cost if some changes are made to the present system. In that light, I make the following modest suggestions for your consideration:

- Allow Medicare to negotiate with the drug companies for lower costs to Medicare recipients;
- Permit Medicare to contract with private insurance companies to process prescription drug claims for Medicare D participants or arrange for Medicare to assume these processes itself;
- If private insurance plans continue to offer these plans, encourage them to provide their negotiated drug costs to their subscribers and to those who are choosing between plans;
- Encourage the FDA to issue rules for development of generic biologics like insulin;
- Consider a modest increase in the tax withholding for Medicare; and

- Consider “grading” Part D programs in a manner similar to the A-F groupings used years ago for Medi-Gap policies.

Respectfully submitted,

Willafay H. McKenna

Senator NELSON. Thank you, Ms. McKenna.

Before you go, Senator, what we will do, we have got about 6½ minutes to get over to the floor to vote. We will recess right now. We will pick up with Mr. Calfee, and then I am going to flip it to you for questions first, Senator Corker.

Thank you. We will stand in recess.

[Recessed.]

Senator NELSON. Good afternoon. The committee will resume, and sorry for the interruption. But when it is time to vote, it is time to vote.

Mr. Calfee, you are recognized.

**STATEMENT OF JACK CALFEE, PH.D., RESIDENT SCHOLAR,
THE AMERICAN ENTERPRISE INSTITUTE, WASHINGTON, DC**

Dr. CALFEE. Thank you, Mr. Chairman.

I would like to thank you and the committee for inviting me to testify. The views I present are my own, not those of the American Enterprise Institute, which does not take institutional positions on specific legislation, litigation, or regulatory proceedings.

My testimony focuses on three topics—price trends for the most-used drugs among the elderly, the influence of the Medicaid drug price rebate program, and international patterns in drug pricing.

A series of reports from AARP on price changes for the most-used drugs for the elderly has attracted considerable attention, including in these hearings. These reports find that branded drugs typically have annual price increases substantially greater than increases in the Consumer Price Index.

For example, the April 2009 report said that during years 2002 through 2008, price increases for branded drugs ranged from 5.3 percent to 8.7 percent. These results are very misleading. The AARP reports failed to describe the impact of the ongoing wave of patent expirations and generic entry for many blockbuster drugs. These reports disguise the dramatic price declines that have occurred for such widely prescribed molecules as Ambien, Aricept, Flomax, Fosamax, Neurontin, Norvasc, Pravachol, Prevacid, Protonix, and Zocor.

Instead, the AARP tables track prices for the branded versions of these drugs, even though the market has shifted dramatically to generic versions. Notwithstanding the AARP reports, which seem to show steadily increasing drug costs for seniors, actual events demonstrate a central characteristic of the pharmaceutical market, which is that a period of profitable prices for drugs under patent is followed by dramatic price reductions that permit patients to obtain some of the best drugs we have at very low prices for years to come.

So-called specialty drugs are also important. These are usually, although not always, biologics rather than chemical compounds. Created through biotechnology methods, they are often very expensive. Although they are presently not subject to generic competition, through application of the Hatch-Waxman Act, a regulatory pathway for post-patent competition may well be created soon by new legislation.

The price effects would come relatively slowly, however, because of the complex nature of these products. On the other hand, spe-

cialty drugs typically address longstanding unmet therapeutic needs. They have revolutionized the treatment of, to cite a few examples, MS, rheumatoid arthritis, some forms of cancer, and the leading cause of blindness in the elderly. Despite their costs, specialty drugs remain an example of how the competitive marketplace creates previously unobtainable medical solutions despite the tremendous costs and uncertainties of the R&D process.

A very different set of economic issues is raised by a proposal introduced in the Medicaid drug rebate, which pertains the dual eligibles who qualify for both Medicaid and Medicare Part D. Research has demonstrated that the Medicaid rebate has tended to increase prices in the private sector. An expansion of the scope of the Medicaid rebate seems likely to reinforce a tendency to bring higher drug prices in the private sector even as the Medicaid system gets lower prices.

Finally, there is the matter of international disparities in patented drug prices. Research has consistently found large differences, sometimes more than twofold, although this is usually not true for specialty drugs. These disparities arise from three factors—the tendency to charge higher prices in wealthier nations, and the United States is the wealthiest nation; the fact that some drugs save money in healthcare services, which cost more in the U.S., making these drugs more valuable here than elsewhere; and most important, Government price controls that have been implemented in all rich nations other than the United States.

The result is that the U.S. market provides a disproportionate share of worldwide pharmaceutical profits. This means that other wealthy nations are, to a significant extent, free riding on U.S. R&D investment that is motivated by the search for profits and which remains a dominant source of valuable new treatments. Unfortunately, there is no easy solution to this problem, although there are some measures that could provide some help.

Mr. Chairman, that concludes my oral testimony. Additional details are provided in my written testimony.

[The prepared statement of Dr. Calfee follows:]

John E. Calfee
American Enterprise Institute
1150 17th St., NW, Washington, D.C.
tel: 202-862-7175 -- fax: 202-862-7177 -- email: calfeej@aei.org

Written testimony
Before the
United States Senate Special Committee on Aging
Public Hearings on
“Seniors Feeling the Squeeze: Rising Drug Prices and the Part D Program”

March 17, 2010

I would like to thank the Committee for inviting me to testify in these hearings. I am a Resident Scholar at the American Enterprise Institute for Public Policy Research, where I have conducted research on pharmaceutical and health care markets. I have also occasionally consulted for firms in the pharmaceutical and related industries. The views I present are my own, not those of any organization including the American Enterprise Institute, which does not take institutional positions on specific legislation, litigation, or regulatory proceedings.

My testimony focuses on three topics: (1) Price trends for the most-used drugs among the elderly; (2) The influence of the Medicaid drug price rebate; and (3) International patterns in drug prices.

Recent Trends in Drug Prices for the Elderly

In April 2009, the advocacy and marketing organization AARP published one of its regular reviews of price trends for the most-used drugs purchased by the elderly (AARP 2009). The report contained separate sections on branded drugs, generic drugs, and so-called “specialty”

drugs. The specialty drug category consists mainly of expensive “biologics” (giant molecules that are grown rather than synthesized the way traditional “small-molecule” drugs are). Many of them are relatively new and were designed and often manufactured using biotechnology methods.

Focusing on branded Part D drugs, the AARP report concludes that during 2002-2008, annual price increases ranged from 5.3% to 8.7% (p. 2). This is a very misleading conclusion, however. In the AARP reports, branded and generic drugs are separated into different tables and calculations. Recent years have seen an extraordinary and unprecedented surge of patent expirations and subsequent generic entry among the most popular drugs including many that are heavily used by the elderly. The problem with how the AARP reports deal with price changes and generic entry is evident from looking only at the top-selling drugs. Table 1 in both the 2005 and 2006 year-end updates (p. 11 and p. 10, respectively) provide a list of the top 25 branded drugs for 2005 and 2006 (some of the items are different doses or package sizes of the same drug). The two lists are identical, because they are actually compiled from 2003 sales and prescribing data (see AARP 2006, p. 15). Fifteen of these 25 drugs are now available as generics. (The affected brands are Actonel, Ambien, Aricept, Flomax, Fosamax, Levaquin, Neurontin, Norvasc, Pravachol, Prevacid, Protonix, Toprol, and Zocor.) Although a few of these may have been generics in 2005, most were not. Hence most of these drugs are now far less expensive than they were in 2005, often qualifying for Wal-Mart’s special \$4 price for a 30-day prescription. In the AARP top-25 list of branded drugs for the year 2007 (AARP 2008, Table 2, p. 13), 12 of the 25 listed drug items are available as generics, usually at very low prices. Because these tables track prices of only the branded versions of those drugs, which are prescribed far less often than generics, the tables provide rather little information about the most relevant changes in drug prices.

The AARP reports simply fail to track prices as drugs go off patent and become available at generic prices. (The greatest price drops come after the first six months, during which the first generic entry has a temporary monopoly among generic versions of the brand in question.) Readers of the reports can see how prices change among brands, and among generics, but they do not see the sharp drop in prices that occur when patients switch from brands to generics. Because Medicare Part D has an extraordinary record of taking up generics soon after they appear, this is a serious omission. Notwithstanding the summaries of the various AARP reports,

the general trend in recent years has been toward far less expensive versions of the most popular drugs.

Specialty Drugs:

Quite aside from the AARP reports on drug pricing, specialty drugs are of great interest. I noted that most of these are relatively new and that most were created through biotechnology methods. Specialty drugs typically address previously untreatable or poorly treated conditions. They have, for example, revolutionized the treatment of rheumatoid arthritis, multiple sclerosis, and certain types of cancer. Most of these drugs are not eligible for the regulatory pathway toward generic substitutes created by the 1984 Hatch-Waxman Act. Although the complex nature of these drugs and their manufacturing processes preclude a simple generic approval process, several proposals have been introduced to create a regulatory pathway for “biosimilars” or “follow-on biologics.” Even with such legislation, however, substitutes would be slow to appear, so that prices are unlikely to fall dramatically in the near future, even for drugs near or beyond the end of the patent life (which is itself a complicated matter) (Grabowski 2008; Calfee 2008).

Many specialty drugs cost thousands or tens of thousands of dollars annually. According to a January 2010 GAO report, they account for only about 10% of Medicare Part D expenses, but that proportion is growing. In general, this market is characterized by three factors (cf. Calfee and DuPré 2006 and Grabowski 2008). First, drug development is very expensive and tends to be targeted at previously unsolved medical problems, so that the few drugs that make it through the lengthy and uncertain development process are of great value. Second, R&D continues long after initial drug approval. The extraordinary cancer drug Avastin, for example, has been involved in hundreds of clinical trials as scientists explore the full therapeutic potential of a product that could be effective against a very diverse range of cancers. This is far from unusual among biotech drugs. And third, these drugs often prove effective against illnesses that are quite different from the ones they originally addressed, so that “cross-over” competition occurs among drugs that started out treating completely different conditions. The cancer drug Rituxan, for example, is also widely used to treat rheumatoid arthritis.

Thus the kind of drugs known as specialty drugs differ from traditional drugs in their costs, their benefits, their research agendas (although some older drugs such as the cholesterol-

reducing statins have also undergone many years of post-approval research), and the nature of competition. So far, they stand as examples of advances in medical technology that are expensive but bring even greater value. On the whole, this kind of research should be encouraged.

The Influence of the Medicaid Drug Price Rebate

Pharmaceutical manufacturers are required to pay an annual rebate to the Center for Medicare and Medicaid Services (CMS) sufficient to reduce the prices of drugs purchased through Medicaid to what is usually 15.1% less than the lowest price paid in the private sector. A recent proposal is that this rebate be applied to Medicare Part D purchases by “dual eligible” Medicare beneficiaries who qualify for Medicaid but receive their drugs through Part D (<http://billnelson.senate.gov/news/details.cfm?id=318232&>). This would expand the effects of the current Medicaid drug rebate plan. Economic reasoning suggests that pharmaceutical manufacturers take this requirement into account when negotiating sales in the private sector. They know that providing a deeper discount to a private purchaser would also reduce Medicaid prices because of the annual rebates. This would discourage discounting and therefore induce higher prices in the private sector. Scott Morton and Duggan (2006) examined this question using econometric methods. They found that a 10% increase in Medicaid’s share of the market for individual drugs was associated with a 7%-10% increase in the drug’s average price. This strongly suggests that the effect of expanding the Medicaid drug rebate would mainly be to shift expenses to the private sector rather than reduce drug costs. A second effect, however, would simply be to exercise more stringent control over drug pricing generally. This would be unwise because it would tend to weaken incentives to develop useful new drugs and new uses for existing drugs.

International Patterns in Drug Prices

International disparities in drug prices among advanced nations have three causes. One is that manufacturers naturally tend to charge more in wealthier nations, and the United States is the richest nation. Another is that some drugs save on costs elsewhere in the health care system,

and those costs are typically much higher in the U.S., making cost-saving drugs more valuable here. The most potent cause of international price disparities, however, is national price controls. Several studies have found persistent gaps between prices here and in Canada, the European Union, Australia, New Zealand, and, sometimes, Japan. Recent studies include International Trade Administration (2004); Danzon and Furukawa (2008); and Calfee and DuPré (2006). In our study, we found almost no international differences for unique biotech drugs (most of them so-called “specialty drugs”) but very large differences for drugs in competitive therapeutic classes. Earlier studies were generally similar, although ours was the only one to separate out the most innovative drugs.

These disparities have economic implications. Pharmaceutical research and development is motivated and funded by profits. Wealthy nations other than the U.S. enact price ceilings in the expectation that the drugs will continue to be sold because they are cheap to manufacture, leaving plenty of room for profit even at controlled prices. Brands that compete with one or a few others, which include almost all the most-used drugs, usually suffer the largest discounts because price controllers can play the manufacturers against each other. The net effect is lower profits abroad, sometimes cutting out half or more of profits, leaving the United States as the prime source of profits and therefore of R&D funds (cf. the 2004 ITA report). One might think that this does not matter very much for therapeutic classes that have several competing entries, such as the statins (Zocor, Lipitor, Crestor, and others). But history has shown that the arrival of a new brand in a therapeutic class (a “follow-on” drug) tends to generate a new wave of research (Wertheimer and Santella 2005; Calfee 2007). In the case of the statins, for example, it was research on Lipitor and other follow-ons, most recently Crestor, that greatly expanded the patient population known to benefit from statin therapy, while also transforming scientific understanding of heart attacks (Topol 2004; O’Riordan 2008).

The result is that wealthy foreign nations have essentially been free-riding on drug development disproportionately supported by profits in the American market, as pointed out by among others, then-FDA Commissioner Mark McClellan in 2003 and the ITA report of 2004. The solution to the problem is unclear, however.

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Senator NELSON. Thank you, Mr. Calfee.

Senator Corker?

Senator CORKER. Thank you. I want to thank each of you for your testimony, and I have a—like we always do, I have got a conflict. I am going to leave very briefly, but I think your testimony has been outstanding.

Senator Nelson, I appreciate you calling this hearing and for the explanation you gave on the front end.

Let me say, generally speaking, I have concerns, as I mentioned on the front end, about the high cost of brand name drugs here. We have talked to trade representatives from both administrations, explored things like “most favored nations” clauses and those kind of things to deal with it.

But I am going to ask some questions to sort of look at the other side of this, not that I am in any way debunking what is before us today. But when I was in Tennessee as commissioner of finance, we had a program called TennCare, and in that program, we did not have things like the doughnut hole or appropriate copays. What we found was that drug utilization just went through the roof, OK?

While I have—my heart goes out to Ms. McKenna and the issues that she is dealing with, sometimes we have unintended consequences with policies like this. I wondered if you might comment as to the effect, if you will, of not having some of the financial constraints that exist, which are very difficult for some people, but what the unintended consequences might be as it relates to actual drug utilization?

Mr. Anderson.

Dr. ANDERSON. Sure. Thank you.

What I am really concerned about is that I think you definitely need to have co-insurance, and at the beginning of the doughnut hole, you have 25 percent co-insurance, which I think is quite high compared to what we have from other goods and services. But essentially, that is the co-insurance.

The problem is, obviously, the doughnut hole, and what happens when you enter the doughnut hole is that your incentives change dramatically. As I said, 10 percent of the diabetics stop taking their medications when they entered the doughnut hole. Eighteen percent of the people with osteoporosis stop taking their thing, and that leads to further expenditures in the Medicare program because now they are going to be hospitalized. They are going to need emergency room care. They are going to need a whole set of things.

So it is really penny wise and pound foolish in a number of instances to have this doughnut hole and have these people paying so much, and they can't afford it. I mean, \$5,000 for a Medicare beneficiary making \$20,000 a year is a quarter of their income. That is an awful lot of money to pay just on prescription drugs.

Senator CORKER. You know, we hear a lot about the fact that the reason drug prices are so high here is that we do so much research and development in this country of new drugs, and we get them to the markets quicker here. Our seniors actually take advantage of them more quickly.

At the same time, you look around the world in other places where prices are negotiated and set, and there is a lot of research and development that is taking place in those other places. Is that

because they are able to still sell into the U.S. market, or is the whole issue that we talk about as far as research and development one that is a myth?

I guess I will ask whoever is most qualified to answer that.

Dr. ANDERSON. Well, let me try again. Basically, what we are spending is 15 percent of our drug budgets in most pharmaceutical companies on research and development. We are spending 30 percent of our budgets on marketing.

So I am all for more research, and I think we really need to change the incentives for pharmaceutical industries to spend more than 15 percent. If we had higher drug prices and they were spending 50 percent of their things on new research and development, I think that would be great. But at 15 percent on research and development, I just don't think we are getting value. The other countries are just getting all that.

So if we had unlimited money, if we didn't have a deficit in the Federal Government, a trade deficit with the rest of the world, I think that would be fine. But we do.

Senator CORKER. Mr. Dicken, I read a report, CBO report, I guess, talking about the fact that if we had actually negotiated—if we negotiated prices for our brand drugs, that at the end of the day, which seemed like it was counterintuitive to what much has been said about the actual negotiation for brand drug prices. But I read a report that said there would actually be very little saved if we did that, and I wondered if you might respond to that?

Mr. DICKEN. Well, I think part of what CBO's analysis was, was that one of the things that will drive how much plans or in this case the Government, could negotiate in savings, is dependent on the formularies and to what extent they can steer particular utilization to particular manufacturers. I think CBO's estimate was based on an assumption that it would not be within the Medicare program's ability for the Government to negotiate with having restrictive limited formularies.

Senator CORKER. Mr. Chairman, I have a number of questions I want to submit for the record. I have got to go on. I know that these witnesses have been waiting a long time, but I thank you for the hearing and look forward to the results.

Senator NELSON. Thank you, Senator Corker.

Mr. Chairman Kohl?

The CHAIRMAN. Thank you very much, Mr. Chairman.

I would like to ask each and every one, or one or two on the panel, is there any justification in your mind, in terms of the people of our country, for Americans to be paying twice as much for the same product as is sold in other countries when particularly we manufacture the product here? In many cases, the costs of a product's development is paid for by tax dollars through the NIH? Is there any justification for that?

How we get to an answer might be another question, but is there any way that you can justify that in terms of the American consumer? Anybody think that there is a justification for it? We should pay twice or three times as much?

Yes, Mr. Calfee?

Dr. CALFEE. Well, I guess it depends partly upon what you mean by "a justification." I mean, the reason those prices are so low is

because of price controls that are implemented by those nations. In most cases, the manufacturers would like very much to charge higher prices in some developed nations but are prohibited from doing so.

I think it is worth bearing in mind that in a normal world in which you didn't have any kind of price controls at all, prices in the U.S. would be higher than they are in those countries for a couple of different reasons, which I mentioned earlier. Some of these drugs are just worth a lot more in the U.S. than they are in France or Switzerland or Germany because when they save days of healthcare here, which they often do, the cost of the healthcare services they save is much higher here than it is over there. So, the drugs are more valuable here than they are there.

The Nation is wealthier, wealthier people tend to pay more for products generally. There would be a disparity, but it wouldn't be as big as it is now. There are some elements of unfairness, just as you suggest.

I think one thing is worth paying attention to, and Gerry Anderson mentioned this in his remarks, and that is that the U.S. market for generics is extremely competitive and extremely efficient. It is that way because we have a very open market.

There are a number of European nations which make it rather difficult for generic manufacturers to enter into the market. They tend to favor their domestic generic manufacturers, and in fact, several years ago, Mark McClellan, who was then the Commissioner of the FDA, gave a speech in which he pointed out that for many European nations, if they were to open up their generic market to competition instead of favoring their domestic manufacturers, generic prices would drop so much that they could go a long ways in raising branded prices toward U.S. prices without actually paying anything more.

So, there is an element of trade restrictions there, that I think is probably worth pursuing at some level.

The CHAIRMAN. Anybody want to make a—is there any justification in your minds for we who represent the American people defending two and three times as much being charged for those brand-name drugs here as they are anywhere else.

Mr. Anderson.

Dr. ANDERSON. I can't think of one. I mean, I think, basically, the problem is that we have many people that are paying lots of money, \$5,000, to get through the doughnut hole. That is a huge amount of money. It really affects their access, and most of the reason why they are in that doughnut hole is the price and the utilization of brand-name drugs.

So it really affects the American senior substantially to pay these high prices, and I think—I wouldn't mind paying it if we didn't have a trade deficit and if all the seniors were getting drugs free of charge. But they are not.

The CHAIRMAN. OK. I wanted to get that clear. I assume you, Ms. McKenna, believe there is no real justification other than it is just happening, not that you believe it is right. Is that true?

Ms. MCKENNA. I have heard a lot of the comments about the research and development, and I understand that. But when I think about the last 5 to 10 years when we were bombarded with adver-

tisements on television, "Ask your doctor about this, that, and the other thing," that is so offensive when as just one person in Part D out of, what is it, 40 million people who are using Part D, one of us has a concern about that and is confronted with it every day, why isn't that spent on providing the drugs at less cost to the large group of people who are elderly?

The CHAIRMAN. Yes, Mr. Calfee?

Dr. CALFEE. If I could say something about marketing and R&D? A couple of things: First, is the 30 percent figure mentioned by Gerry Anderson. That number is inflated because it includes the samples that are provided, the free samples that are provided to doctors. Those are valued at wholesale prices, and that is a pretty big chunk. On the order of half of all marketing consists of giving away samples, which doesn't really cost the manufacturers very much at all.

If you correct for those numbers, they probably spend more in R&D than they do on marketing. But you have to remember that they do marketing in order to make money. They do it in order to increase their profits. Those profits are the source of their R&D.

Large manufacturers, don't go out and sell bonds in order to fund their R&D. They fund their R&D out of the cash that they bring in from selling their drugs. If you eliminate their marketing, you probably reduce sales. You reduce their profits, and you reduce the money that is available for R&D. It is not a tradeoff between the two.

Now 15 percent doesn't sound like very much for research out of total revenues, but in fact, it is extraordinarily high. I don't think there is any other industry that comes close to that level. Now we can sit here and we can try to figure out what that percentage ought to be, but I don't think anyone knows what that percentage ought to be. It is really a matter of how manufacturers want to spend their money in order to try to figure out what they can do to find a new cure.

It is a very, very difficult business, and there are a lot of drugs that we need that manufacturers are not working on, like new antibiotics, malaria drugs, and so on. No one else is coming up with these drugs. So, I think we have to remember it is a chase for profits that is the source of the drugs that we are getting, and it makes sense that we should at least pay attention to whether or not we are going to be getting a lot more new drugs in the future because there are a lot of unsolved problems, such as the illness that Ms. McKenna is dealing with.

The CHAIRMAN. Yes, sir, Mr. Hamilton?

Mr. HAMILTON. First of all, I am not going to try and justify those prices. But I can offer a couple of explanations.

One is that in the pharmaceutical industry, absent of generics—I am talking the brand-name world—cost to manufacturer to bring a product to market is only considered when you first look to launch a drug. Pharmaceutical companies will scope the market. How big is the market? How many patients could take this? How many pills or tablets or injections can I sell?

It may be some idea of what kind of price, and that will help them decide whether to pursue that drug or not. But once the drug is on the market, the cost of the drug has nothing to do with its

price. As Jack said, talked about the cost of samples, samples cost a lot more than yet the drug does going to the pharmacy, and that is because of basically the packaging and storage and shipment to reps.

So cost, unlike many other situations, you know, if you are going to make something, you think, "What is it going to cost me, and therefore, how much am I going to sell it for?" It doesn't exist in the pharmaceutical industry. You sell a product for whatever the market will bear.

Another factor that comes into play in domestic marketing is several other nations, I see many other nations benchmark their U.S. pricing. They will pay a percentage for a drug based off of the average selling price, calculated quarterly on domestic products. So the higher you can keep your price here in the United States, the more money you are going to make abroad.

The CHAIRMAN. Thank you.

Thank you, Mr. Chairman.

Senator NELSON. Thank you, Senator Kohl.

Senator LeMieux.

Senator LEMIEUX. Thank you, Mr. Chairman.

Thank you to my colleague Senator Nelson for having this hearing today.

Thank you all for being here to testify, especially you, Ms. McKenna. I appreciate your good words, and it is important for us to put a face on these problems.

Senator Nelson and I represent Florida, and this issue comes home loud and clear in our State, with the highest per capita population of seniors, more than 3 million folks on Medicare.

Now the issue that I want to focus on with you is just the cost and why it is so expensive and why it continues to be more expensive, and there has already been some good testimony on this today.

Mr. Hamilton, in a prior life, I was the deputy attorney general in Florida, and we dealt with AWP cases, and I guess they are AMP now, and I have been through those cases that we have tried to figure out in the Medicaid program in Florida why we weren't getting the best price. Really is average wholesale price truly the best price, or is there some discount, as you say in your testimony, 25 percent perhaps, below that?

So I am familiar with the work that you have done and know that the struggles that both the Federal Government and the State governments deal with in trying to make sure that we are getting the best price.

I think, Mr. Dicken, I want to ask you the first question, and that is, you know, the Federal Government representing, in a way, so many consumers of pharmaceuticals should be able to negotiate better prices on these drugs for Medicare and Medicaid and veterans recipients.

I understand the analysis you did, and I understand on a drug-by-drug basis those discounts don't seem so appealing. They might be 10 percent or so. But why can't the Government, when representing so many consumers, be able to go to a particular drug company and say we are not going to just negotiate on Lipitor, we are going to negotiate on all of the drugs?

Based upon the volume of the people that we represent in our consumer pool, we are going to get the best prices. Are we doing as much as we can to negotiate?

Mr. DICKEN. As you know, there are a variety of different approaches that different Federal programs use to attempt to negotiate or set prices for drugs. So, certainly, the Part D program in Medicare is relying on private plans to do those negotiations. Many of them will establish formularies within guidelines that are established by CMS that limit the ability to restrict drugs in certain classes, and so the Medicare program is relying on the private plans to do those negotiations.

Senator LEMIEUX. Is that through their PBMs?

Mr. DICKEN. Often contracting with a PBM that would do the negotiations with the manufacturers.

Senator LEMIEUX. How do we know that they are getting the best price? If we are segmenting the market, are we not getting the best price when they have a smaller volume of people that they are negotiating on behalf of than the entire Federal Government would be able to have that ability to negotiate?

Mr. DICKEN. Well, it is a very different approach for Part D that does rely on multiple different Part D plans to be negotiating. They may have differences in their formularies and the price that consumers may find on Plan Finder for different plans. So, it is relying on both those plans to negotiate and for consumers to choose the plan that would best meet their needs.

That may be different from, say, a VA program which does have a formulary and set prices that may look different from what may be existing in Medicare. So the Federal Government, through a number of different programs, has a number of different prices for the same drugs.

Senator LEMIEUX. Let me go to Mr. Hamilton and then to Dr. Anderson.

Mr. HAMILTON. A couple of things. First of all, the Federal Government, through two different programs—one is the Federal supply schedule, which is the VA, DoD, and Indian health, and the 340B program—through both of those programs, they negotiate on a national level, and they do a very good job of it. If that was applied to Part D, you would see discounts far better than anybody is getting right now.

But they also have an advantage in that they have a formula for the Federal supply schedule and the 340B runs off of the Medicaid rebate program. So they start off with a certain discount off of every drug, regardless of the number of competitors or what leverage a particular plan might have based on utilization or anything. They start off with a basic discount no matter what. Then they negotiate from there. That is called the ceiling price.

So we already have in place two systems that work very, very well to drive down the cost of drugs for patients. The DoD, for example, has a mail-order facility. As a matter of fact, they hired my former employer, Express Scripts runs it in Arizona, where they have literally massive machineries and canisters and gazillions of pills. They fill the scripts and send them out to DoD recipients at a fraction of what you would pay anywhere else. They do that be-

cause they buy off the Federal supply schedule, which starts with a discount and then negotiates after that.

So, certainly, regionalization of plans reduces their ability to negotiate. Remember, they don't start with a given discount. They start at retail.

Senator LEMIEUX. Dr. Anderson.

Dr. ANDERSON. Thank you.

If you look at the 2003 Medicare law that created Part D, there is something called "noninterference." Basically, that says that the Medicare program can't negotiate directly with the drug companies. So that is essentially the answer to your question why Medicare doesn't do it.

If you look across the Federal programs, what you will see is that they are paying a two-to-one difference. The DoD and the VA typically pay the least. The Medicare program typically pays the most for most things, and there is the two-to-one difference.

So if you are talking market power, the Federal Government is the largest purchaser of drugs in the world, and it should be getting a very good deal. But it is totally splintered in that it is buying all sorts of things in all sorts of different ways, which means that it is not using its market power or its regulatory power to its fullest. The seniors and everybody else is paying very different amounts.

Senator LEMIEUX. Mr. Calfee.

Dr. CALFEE. Yes, I think it is worth remembering that the ability to negotiate lower prices has almost nothing to do with the size of the entity that is doing the negotiating. Gerry Anderson mentioned that some of the lowest prices in the world are from New Zealand. New Zealand is a very small country. The entire population of New Zealand is probably less than the Medicare population of Florida alone.

What gives them the ability to negotiate these things is to look at several different competing drugs in a therapeutic category and to play off one manufacturer against another. The VA does very well in its negotiations, because it tends to have very narrow formularies.

In Medicare Part D, for many therapeutic categories, the formularies cannot be very narrow. It is against the law. You have to include every drug in a particular category. So that is what really drives the ability to negotiate lower prices.

I think it is also worth remembering that if you start out with a policy of having just a percentage discount, where does the price come from, the original price that you are discounting from? At some point, if all the drugs sold to the Federal Government are going to be 30 or 50 percent less than the prices in the private sector, those prices in the private sector are going to adjust, because manufacturers know that whenever they set those prices, they are setting a much lower price for the Federal Government.

So it is very hard to solve these things through just simple formulas, I think.

Senator LEMIEUX. Well, I appreciate the testimony, and I agree that these formulas, it is hard to set them, and they certainly can be gamed once you do set them. But the comments that were made, I think, from Dr. Anderson and Mr. Hamilton is that we are losing

our ability, based upon the size of the Government. I don't mean the size of our entity. I mean the size and the number of people that we represent, which is volume, and certainly that has something to do with the ability to negotiate.

Maybe not the only factor, Mr. Calfee, but certainly a factor, that this noninterference clause makes no sense to me. That we would give up our right to have that ability to negotiate doesn't make sense to me.

I mean, it occurs to me, Mr. Chairman, that we want to hit the sweet spot of allowing these companies to develop the best drugs in the world. We don't want to stifle that. We don't want to put this in a situation—we can't be Canada, where the research is not happening and just take, cap these prices and say, well, we will buy them at this price, and we won't buy them at any other. We can't do that because we are doing the innovation.

You have to applaud these companies for doing the innovation. It is saving lives around the world. But at the same time, we want to get the very best price. It is appalling to me that these other countries are freeloading off of our R&D. I wonder, Mr. Chairman, that our U.S. Trade Representative shouldn't be talking about these issues when he is dealing with folks from other countries.

I want to talk about what has been called the doughnut hole, and I know that my colleague from Florida will recognize doughnuts are—everybody likes doughnuts. I think we have named it the wrong thing. We should call it the black hole or the sink hole because a senior who falls into it has a tough time of getting out of it, and words matter.

What can we do under the existing law—I mean, maybe we can change the law. But what can we do under the existing law, if anything, to help seniors who are in this hole? They are struggling. They are certainly struggling in our State. Ms. McKenna has given us great testimony about that. Is there anything we can currently do, or do we just have to change the law?

Who wants to take a stab at that?

Dr. ANDERSON. Well, I think price transparency is an important thing and a Republican thing as well. I mean, we just don't know the prices for these drugs, and we should. I mean, it is important for the Medicaid program, as you know, in the past. It is important for the Medicare program.

We also don't know the level of cost-sharing. So I looked at Part D drugs, and sometimes the Medicare beneficiary is only paying 5 percent of the cost because the drug company is paying 95—I am sorry. The Part D plan is paying 95 percent of it. In other drugs, they are paying 60 percent of the cost.

So, it is sort of the Part D plan is making a judgment of what the beneficiary should pay for different drugs, and I can't understand a rhyme nor reason for it. But if I am a person that is going to sign up for one of these Part D plans, I want to know what the plan is going to pay, and we don't know that.

Senator LEMIEUX. Mr. Dicken.

Mr. DICKEN. I think certainly Dr. Anderson mentions a good point with price transparency. Just a couple of other things to think about. Some of the drugs that have high costs that lead individuals into the doughnut hole may be ones with a lack of thera-

peutic alternatives, and so, if there were options to have more competition there.

The other thing is one of the ways that plans that we have just talked about will attempt to reduce costs is through negotiating rebates. Those rebates may reduce the costs overall and are passed onto the programs through lower premiums but aren't affecting the costs that the individuals pay at the drugstore. Those will be reduced by discounts that are negotiated with the pharmacy.

But the rebates don't necessarily go to that individual who is showing up at the drugstore other than reducing the overall program cost.

Senator LEMIEUX. Can I just ask you one question about that? Does the pharmacy have any incentive under that rebate program to pass those savings along to the customer?

Mr. DICKEN. Well, there are different types of price concessions here. So I was speaking about rebates from the manufacturers that would go back directly to the plan or the PBMs. Certainly, the plans are also negotiating discounts with the pharmacies and competitive and trying to encourage, in some cases, networks of pharmacies where they will negotiate lower prices. That would be the incentive for the pharmacies to participate in those discounts.

Senator LEMIEUX. Mr. Hamilton.

Mr. HAMILTON. Those discounts you are talking about, the rebates. The rebates are typically negotiated by a PBM. Some insurance companies have their own PBM internally. So they would do it. But the PBM function negotiates the rebate, collects the rebate, sometimes passes those rebates on to the plan. Sometimes they keep them. It depends on what their contract with the plan is.

But those rebates don't go back to the pharmacy, to answer your question. No, the pharmacy doesn't get those rebates. Those rebates are kept by either the PBM or the plan. The PBMs negotiate network contracts with the pharmacies at some discount, again, off of AWP. There we go back to the problem of AWP.

Senator LEMIEUX. I remember a line of cases about pharmacies and AWP. That is why I remembered to ask that question.

Mr. HAMILTON. That is what happens. The PBM goes out, develops a network, and they pay, let us say, 14.5 percent is what they negotiate with the CVS or Walgreen's to pay them. Then they go back to their plans, and they say, all right, I will reimburse your claims, but I am going to charge you 14.6 percent. So, the plan pays one thing, the pharmacy gets another. But the rebates don't go back to the pharmacy. That amount is calculated based on AWP, and there again, we go back to the problem with the system.

Senator LEMIEUX. Anything on the first question that you think we can do without changing the law to help with this problem of people who are in this hole?

Mr. HAMILTON. I think—like John said, I think the best thing without changing the law is to negotiate more rebates and negotiate them in a way that guarantees they go back to patients.

Senator LEMIEUX. Thank you. Anyone else want to comment on that?

Ms. MCKENNA. I would just say a couple of things about that. I feel that the basic amount that is paid for the participation in Part D could be adjusted. Maybe increase that a tiny bit, but then have

just a standard drug plan. Get rid of the tiers and the formulas and everything else. These are impossible for most seniors to understand.

I have a lot of seniors who come to me in my practice, and continually, it is more and more questions each year that I get from them. Even from a neighbor who came, and I spent almost 2 hours with a person who is a college professor and couldn't understand the choices because it is foreign. It is not like any other insurance.

But that way, yes, there are going to be very expensive drugs. But probably on the low end of the scale, everybody is going to pay a little too much for the very inexpensive drugs. But those payments for those at a reasonable rate are going to accrue to the benefit of all the others who are participating and who are on higher drugs.

The formularies have a great deal of difference in how your copay is calculated. The higher your drug is on the formulary, the more you are going to pay. But I think that would be helpful.

Senator LEMIEUX. Thank you, ma'am.

Mr. Calfee.

Dr. CALFEE. Yes, just very briefly, I think it is worth remembering that when Part D was first created in the 2003 law and was implemented in 2006, there were a lot of estimates coming out of CBO and elsewhere about how much that program would cost. It ended up costing a lot less than was expected, and that under-shooting of cost continued for several years.

It was because of the extraordinary level of competition amongst the Medicare Part D plans, partly because of the activities of the PBMs. That competition has resulted in pretty good deals. Premiums have been down. Drug costs have been down. Medicare costs have been down below what they would have been.

So I would just exercise some caution when contemplating doing away with a lot of that competition. You might end up with something that would be very, very much simpler and easier to deal with, but it might be more expensive, too.

Senator LEMIEUX. Mr. Chairman, I want to give you an opportunity. I know you have questions to ask, and I thank you again for having this hearing.

I would like to just take a moment of State privilege, which I know you will appreciate, is that I was reading the Lakeland Ledger the other day, and our friends at the company of Publix are now offering some diabetic drugs for free. So there are good folks out there trying to do the right thing.

Thank you, Mr. Chairman.

Senator NELSON. You recall one of the major retailers in the country a few years ago turned the pharmaceutical world upside down, when Wal-Mart came out with a group of about five commonly used drugs, and they were offering them for something like 10 bucks. So, Mr. Calfee, what we are trying to do, regardless of what happened with the prescription drug bill back in 2003, we are trying to figure out how we can make it more affordable for folks that are on fixed incomes.

Dr. CALFEE. I certainly appreciate that, and as you know, the Part D program is, to some extent, means tested. I mean, if you are below a certain income, then drugs cost quite a bit less. In

some cases, a lot less. Of course, if you are eligible for Medicaid, that is a different story, and we get into all these squirrely problems of dual eligibles.

I think there is a strong case for means-tested subsidies generally. Maybe there is a case—it has been a while since I have looked at all the parameters of Medicare Part D, but maybe there is a case for extending those means-tested subsidies. So, there are fewer people who face the difficulties that have been described by Gerry Anderson and by Willafay McKenna. That, to me, strikes me as a reasonable way for addressing the Part D doughnut hole.

The reason it was there to begin with, I believe, was to have something that was structured in such a way that it would not exceed certain cost levels, but would also be attractive to almost every Medicare beneficiary because you wanted to have wide participation in this plan because that was going to keep down costs. That part of it actually worked pretty well, but it has generated all these other problems.

I don't think there is a simple solution without spending an awful lot more money, but there may be some middle ground in which there could be more in the way of means-tested subsidies without an extraordinary increase in costs.

Senator NELSON. Well, in your written testimony, you cited an article that argues that Medicaid rebate increases, that the Medicaid rebate that I offered in the committee, in the Finance Committee that was defeated for dual eligibles, that that increases the price of drugs in the private sector. I want you to please follow up on that.

Do you think that the private sector doesn't have the ability to keep prices low if the Government is obtaining a lower price?

Dr. CALFEE. The private sector negotiates prices with PBMs and other people, and they do that in competition with other manufacturers of similar drugs. When they are doing that, they take into account all of the pricing that is affected by their decisions.

For example if Pfizer is negotiating Lipitor price with Express Scripts on behalf of some large client, say, General Electric or something like that, they know that if they are going to give an extra discount for that particular buyer and that discount becomes their lowest price, they are going to have to go back and reduce all their prices in Medicaid.

While the dual eligible situation is a rather strange situation. Under your proposal, there would be more people who would be getting the Medicaid rebates. So, Pfizer and any other manufacturer when they are negotiating prices, would think about that, and they would know that when they are giving someone an exceptional discount, that exceptional discount is going to be very costly to them because of the Medicaid rebate. Consequently, they are not going to go as far in discounting prices, and that is more or less the logic that has been documented.

Now the paper that I cited did not look explicitly at your proposal. It simply looked at what has been happening in the past.

Senator NELSON. Well, let me give you the other side of that.

Dr. CALFEE. Sure.

Senator NELSON. Had my amendment, and this is an academic discussion because it didn't pass. Had it passed, dual eligibles

would get the same rebate when they got their drugs in Medicare that they were eligible to get those same prices under Medicaid. In fact, CBO scored it, and it would produce over \$100 billion over 10 years. What we could have done with that is we could have filled the doughnut hole for seniors and had money left over to apply to the Federal deficit.

Now here is what would have happened, Mr. Calfee. When you fill the doughnut hole, that means more people are going to get up into the catastrophic coverage up here. More people get up into catastrophic coverage, the pharmaceutical industry is going to sell more drugs, and as a result of that, the pharmaceutical companies are going to make more money as a result of saving the American taxpayer over \$100 billion of paying less by Medicaid folks that are getting their drugs through this Medicare program.

So, there are a lot of arguments that are common sense. We will have to see what comes out on the Internet tonight on the way that they are talking about filling this doughnut hole. But surely, one of the results is going to be more people will get that coverage like Ms. McKenna, or as Dr. Anderson had testified, they get into that doughnut hole. They can't afford it. They stop taking.

You fill that doughnut hole that the Government is going to pay for it. It gets them on up into the catastrophic coverage, and at the end of the day, more pharmaceutical products are going to be available to more people.

Now that is not a bad thing because these drug companies are doing wonderful things with some of the miracle drugs that they are coming out with. But at the end of the day, the drug companies are not going to be hurting. They are going to be making a lot more money.

Mr. Hamilton.

Mr. HAMILTON. I don't know if you know this or not, but there is a precedent. What you are suggesting in a way has already been done. The Veterans Healthcare Act of 1992 has a program called 340B, and the 340B program provides drugs at basically the Medicaid discount to certain clinics and disproportionate share hospitals, and it is all outpatient drug stuff.

But what that bill did, what that legislation did was basically take all the patients that were being treated at the outpatient facilities of disproportionate share hospitals—there are about 105 of those in the country, plus all the clinics. They did all the inner-city clinics and such and county health facilities—and turn them all into Medicaid patients.

So, consequently, when you are in a drug company—and Mr. Calfee is right—you do have to calculate if I give somebody a discount or a rebate, which amounts to a discount, then my Medicaid rebate is the amount of rebate per unit is going to go up. At the same time, your price to the 340B entities is going to go down.

But we have already seen all those 340B entities added to basically what is the Medicaid population, starting back in 1992, and that program actually is administered by the Office of Pharmacy Affairs that, in addition to taking the Medicaid rebate discount, they also negotiate prices so that it is another entity that has done basically what you are talking about with a different set of people.

Senator NELSON. I want to ask Ms. McKenna, you had testified that when the drug that you were taking for diabetes was not available in the United States, your doctor first put you on another one. It didn't work out for you, and you realized that you needed to go back on the original drug. You then got approval so that you could get that drug from Canada, and you said it cost you \$65, plus \$10 shipping?

Ms. MCKENNA. That is right.

Senator NELSON. Now what was that compared to the price that you were buying it when it was available in the U.S.?

Ms. MCKENNA. Two hundred thirty-nine dollars and ninety-nine cents.

Senator NELSON. Two thirty-nine, ninety-nine to 65. What was the name of that drug?

Ms. MCKENNA. Novolin N. N-O-V-O-L-I-N N.

Senator NELSON. Let me ask all of you, anyone, do you believe—hold up this chart. Since there is no limitation on what can be charged for the brand-name drugs for seniors, if tonight we find on the Internet that the President's proposal is that 75 percent of this is going to be covered for seniors, do you think the price of those drugs in the doughnut hole that are going to be more available to seniors because of the payment of 75 percent, with a senior paying 25 percent, do you think the price of those drugs are going to go up?

Dr. CALFEE. If you maintain the competitive Part D mechanism that you have right now, so that each individual PDP is competing with every other one in trying to gain sales from seniors, they will still have an incentive to negotiate lower prices. I think on the whole, all else being equal, if you increase Federal subsidies to that extent, which is a pretty big increase, it certainly isn't going to push prices down. It might push them up somewhat.

I think that the existence of competition would tend to moderate whatever price increase there might be. If you eliminate that competition, then, yes, you are asking for big price increases.

Dr. ANDERSON. Medicare beneficiaries are not buying some of these drugs because they can't afford them, and that may be that the pharmaceutical industry is saying we have got to keep our prices down in order to allow people in the doughnut hole to afford these drugs. If you make—if you reduce the price effectively to them, of course, the pharmaceutical industry is going to raise their prices, and they are going to raise it so that the beneficiary pays about the same amount as they are doing now. That would just be good economic sense on their part.

Senator NELSON. Any other comments on anything that we have covered here?

Mr. Dicken, are certain types of drugs more vulnerable to steep price increases for Part D beneficiaries?

Mr. DICKEN. Well, certainly, in the group of drugs that we looked at that were very high-cost drugs to begin with, we did see price increases that could be—I think the example that you cited was 46 percent over a 3- or 4-year period, and an average over 36 percent.

We had also done a separate report looking at drugs that faced truly extraordinary drug price increases. These are drugs that went

up 100 percent, literally doubling in price overnight, not a cumulative increase, but a one-time increase.

The types of issues that we saw that led to those dramatic price increases were things like lack of therapeutic alternatives, and so that there was not enough competition in that market. There could be consolidation and mergers, and so the pricing strategies that manufacturers were using changed.

In a few cases—this was not the typical—there were some unusual manufacturing issues such as disruptions in raw materials, or handling of hazardous materials that led to some of those very high increases. So those are the types of drugs that have had the most dramatic increases.

Senator NELSON. Mr. Hamilton?

Mr. HAMILTON. When you are looking at controlling price increases, you could look at the Medicaid rebate program. The Medicaid rebate program calculates every quarter what is called the AMP, which starts when the drug is first marketed, and they add the CPI-U to that every quarter. Any increase above the CPI-U is added to the Medicaid rebate.

So within the Medicaid rebate program, price increases are restricted to the CPI-U. Whether or not something like that could be done with Part D, I don't know. But it certainly works in the Medicaid rebate program.

Senator NELSON. In the Senate-passed healthcare bill, the amount of the rebate for brand-name drugs is being increased for Medicaid from 15 percent to 23 percent, in addition to what you just stated about the increase of the differential between the health inflation cost and the Consumer Price Index cost.

Now my question to you is what happened if we just changed the total Part D prescription drug, and we made it a rebate program like Medicaid drugs? What would happen to prices?

Dr. CALFEE. Well, my own view is that what would happen would be the same thing that happened with the Medicaid rebate. Manufacturers will take this discount into account when they are negotiating their own prices in the private sector, and those prices will tend to go up because every time they think about providing a discount, they will have to remember that there are several million Medicare patients whose prices will automatically go down along with whatever discount they are offering.

So I think that it would tend to disrupt prices in the private market significantly.

Senator NELSON. Even though the price of the drugs would be cheaper for Medicare beneficiaries, and therefore, there would be a lot more drugs sold?

Dr. CALFEE. Well, that is part of the mix, too. One of the more difficult things to predict is how much more you sell when that happens to prices. Gerry Anderson has a good point. There are some customers who right now don't buy drugs that would be bought if there were some subsidies.

Estimating the magnitude of that can be pretty tricky. In general, if everyone is in Medicare, their drugs are being paid for by the Government, yes, that is going to increase demand. If there is a mandatory discount from private sector prices, then I think it would tend to push those private sector prices up.

That is a little bit different from the last question you asked me which is what would happen to total sales and profits? That is a little bit trickier to answer.

Senator NELSON. Dr. Anderson.

Dr. ANDERSON. I think the problem here is that the private sector really can't negotiate drug prices very well. The CBO says this. The GAO essentially says this. MedPAC has said this. Basically, they are not able to get good discounts.

So, Jack Calfee is correct. I mean, they may have to pay a little higher prices, but it is because they are not very effective negotiators with the drug companies in getting prices. They can get some more rebates, but they don't get lower prices. I think it is uniform that they just can't get lower prices for brand-name drugs. They do very well for generics. They cannot do it for brands.

Senator NELSON. I thought in Economics 101, the free marketplace, competition, supply and demand, I thought we learned that the more that you bought in bulk, huge purchases, the more negotiating power that you had. Therefore, you could bring the price down by purchasing a lot of things instead of a few things.

With regard to the purchase of drugs for ultimately a population of some 44 million seniors through the Medicare drug program, although that is not how many are in it now, that is a lot of negotiating power, and the private sector marketplace could function. But that is not the way it is, and that is not the way it was designed in the prescription drug law of 2003. So, we are where we are.

You all have illuminated this complicated issue enormously. I am very grateful to you.

Thank you all for being public servants and especially sharing your expertise with us today.

The hearing is adjourned.

[Whereupon, at 4:46 p.m., the hearing was adjourned.]

A P P E N D I X

**STATEMENT OF SENATOR AL FRANKEN
FOR THE SENATE SPECIAL COMMITTEE ON AGING
HEARING ON
“SENIORS FEELING THE SQUEEZE: RISING DRUG
PRICES AND THE PART D PROGRAM”
MARCH 17, 2010**

Thank you, Mr. Chairman. And thank you for holding today's hearing on this topic of urgent concern for me and my fellow Minnesotans.

The numbers we're going to hear from today's witnesses are staggering. Brand name drugs in the U. S often cost double what they do in other developed countries. Brand name drugs are almost four times more expensive than generics. Prices on “specialty tier” drugs increased an average of twelve percent each year from 2006 to 2009.

The bottom line is that these skyrocketing drug prices are squeezing thousands of Minnesotans. And seniors bear the worst brunt of the problem. I hear from folks every day on this issue, including a letter from a constituent in Wadena, Minnesota.

This constituent and his wife live on Social Security and a small pension. He's in a wheelchair, his wife retired early to help him stay at home-- and he's in the donut hole. This is what he wrote to me: "We are barely making it from month to month. I can't work and my wife has to take care of me and I don't feel like I have any dignity left. I just don't know what to do."

Is this how we want to be treating our seniors in our country? Leaving them to choose between paying for food or filling prescriptions? The answer is NO—and so we just can't continue on this path. Health reform will help close the donut hole but we're still not getting to the source of rising drug costs.

What upsets me is that I hear these stories from Minnesotans at the same time that pharmaceutical companies are making record profits. In 2009, drug companies were number five in Fortune Magazine's list of fastest growing industries. Profits grew over 24 percent in a single year. 24 percent. I'm a big supporter of research and development, but something's wrong with an equation that puts billions into investors' pockets, but leaves seniors out in the cold.

I'm hopeful that today's witnesses can shed some light on these issues, so we can move toward real solutions. I want to thank all of the witnesses for being here today and look forward to hearing your testimony.

Thank you, Mr. Chairman.

MR. ANDERSON'S RESPONSES TO SENATOR McCASKILL'S QUESTIONS

Question. Importation: According to a Congressional Budget Office (CBO) cost estimate from 2007 importation of prescription drugs would have saved the government itself more than \$5 billion from 2009 to 2017 by allowing it to purchase cheaper drugs for Medicare and Medicaid recipients. In addition, the legislation would have increased federal revenues by about \$5 billion by reducing the cost of private health insurance, which would end up increasing the share of employees' salary that can be taxed. Should we not be pursuing this as an option? Can we afford not to do this? Are any of the pharmaceutical industry concerns related to safe reimportation legitimate? How do we do it safely and effectively?

Answer. Drugs are made all over the world not just in the United States. The FDA already has a process to make sure that drugs made overseas are safe and effective. We should make sure that the drugs that are imported from places like Canada are the same drugs that are dispensed in the US already.

We do not have any evidence that the drugs dispensed in Canada, the European Union or Australia and New Zealand have undergone any less rigorous testing or are any less safe than the drugs dispensed in the US. The only difference is that they are much less expensive. I discuss this in my written testimony.

There are legitimate concerns that internet dispensing of drugs could be dangerous. This would apply to both internet dispensing in the US and in other countries. It is critical for the internet companies to demonstrate that they have appropriate safeguards in place to make sure that the correct drug in the correct dose is dispensed and that it is the drug is legitimate. Some of the recent robberies in the US of warehouses full of pharmaceuticals suggest that tighter surveillance in the US is also needed.

Question. Role of Direct Marketing? (Only two countries—New Zealand and the U.S. allow direct to consumer drug marketing) Drug company spending on direct to consumer (DTC) advertising has increased twice as fast as spending on promotion to physicians or on the research and development of new drugs. Advertising is known to cause many consumers to go to their doctor and ask for the advertised brand name medication. One study of physicians found that in 5% of the cases when patients requested specific medications after seeing an advertisement, physicians prescribed the medication to accommodate the patients request despite thinking that another drug or treatment option would be more effective. Clearly, that is wasteful. I am trying to get a handle on how much this practice represents in unnecessary spending by the federal government. Is there a credible estimate that you know of regarding the cost to the taxpayer because of Direct To Consumer advertising? What measures would you suggest we take to try to crack down on this waste?

Answer. A study published in the New England Journal of Medicine in 2007 entitled "A Decade of Direct-to-Consumer Advertising of Prescription Drugs" by Julie M. Donohue, Ph.D., Marisa Cevalco, B.A., and Meredith B. Rosenthal, Ph.D. found that real spending on direct-to-consumer advertising increased by 330% from 1996 to 2005.

I do not have an estimate of the cost to the taxpayer of direct to consumer advertising. From a research perspective this would be a very difficult number to develop since it would require estimating what would happen if direct to consumer advertising was not permitted—something where there is no data.

Currently direct to consumer advertising for drugs is no different from direct to consumer advertising for hamburgers—both attempt to make you feel good about the product and do not attempt to convey any factual information about the product. A simple suggestion would be for them to be required to demonstrate the efficacy of their product instead of demonstrating that the person taking the drug is able to walk with their husband or to play with their grandchild. Insist that the information that is being conveyed be factual not inferential.

MR. ANDERSON'S RESPONSES TO SENATOR FRANKEN'S QUESTIONS

Question. Dr. Anderson, like most Minnesotans, I'm baffled by the wide variation in drug prices between countries. It's profoundly unfair that we continue to pay so much more for the same drugs. We invest billions of dollars in federal research and drug companies are making record profits. So it just doesn't make sense that all of the excess costs are going to research and development of new drugs. Can you please discuss the key factors that result in such wide price variation between countries?

Answer. Direct Negotiation. Most other countries have direct negotiation with the drug companies and they pay $\frac{1}{3}$ to $\frac{1}{2}$ what the US pays for the same drugs. It is

also well known that only 15–18 percent of the revenues that drug companies receive go for research and development.

I have testified in the Senate Finance Committee and in the House Government Oversight Committee that we should have direct negotiation with the drug companies. There is no reason why the seniors in the US should be paying higher prices than other people in the US or in other countries.

I would go a step further. I would have the federal government negotiate one price for all drug purchases. Currently the Medicare program has many different prices under Part D, the states have 50 different prices, the Public Health Service has a different price, the VA and DOD have different prices, and the prisons have their own prices. There is no reason why each government entity should be paying different prices when the funds all come from the taxpayers.

Wide Variations in prices. We pay 2–3 times more for brand name drugs than other countries. The reason is quite clear. Other countries have direct negotiation with the drug companies and the US does not. The drug companies are able to negotiate better deals with multiple payors than with a single payor.

We are the richest country in the world and as a result we may want to pay a higher amount than other countries. The amount should reflect our higher income and not our inability to negotiate a fair rate. If we as the richest country in the world can afford to pay more it would allow the drug companies to provide drugs to the poorest countries (e.g. Africa) at the marginal cost of producing the drugs.

Question. Dr. Anderson recommends that Medicare increase transparency and begin to report to beneficiaries the amount the Part D plans actually paid. Can you please discuss changes we can make at the federal level to ensure that rebates accrue to consumers and not to middlemen?

Answer. Middlemen. If the price transparency provisions that I recommended to the Senate Finance Committee were enacted it would be possible for the Secretary to protect the prices that individual drug companies negotiate with pharmacies and PBMs. What the Secretary would know is when a drug is much more expensive in Part D than it is in Canada or the VA. It would then ask the CEO of the company to explain the reasons for the price differential. If you had a top ten list (think David Letterman) of the most over priced drugs in Part D then it would be possible to put pressure on just these drugs. Since no drug company would want their drug on the top 10 list, the prices would drop in Part D.

In that way you would not need to have middlemen getting the rebates instead of the consumers'.

MR. DICKEN'S RESPONSES TO SENATOR McCASKILL'S QUESTIONS

Question. Importation: According to a Congressional Budget Office (CBO) cost estimate from 2007 importation of prescription drugs would have saved the government itself more than \$5 billion from 2009 to 2017 by allowing it to purchase cheaper drugs for Medicare and Medicaid recipients. In addition, the legislation would have increased federal revenues by about \$5 billion by reducing the cost of private health insurance, which would end up increasing the share of employees' salary that can be taxed. Should we not be pursuing this as an option? Can we afford not to do this? Are any of the pharmaceutical industry concerns related to safe reimportation legitimate? How do we do it safely and effectively?

Answer. We have not conducted work directly on the issue of cost savings and safety issues related to importation of prescription drugs. However, in a 2004 report we identified several safety concerns with prescription drugs obtained through Internet pharmacies located outside the United States.¹ Specifically, GAO identified problems associated with the handling, Food and Drug Administration approval status, and authenticity of samples received from such pharmacies.

Question. Help in choosing the right plan: There are over 1,000 different plans nationwide. In Missouri, there are just under 50 Part D plans to choose from. We know that there are widespread differences in benefits offered, copayments, formularies, donut hole coverage and so on. This makes it nearly impossible for seniors to choose the plan that is most cost-effective for them and in turn, most cost-effective for the government. In addition to frustration for seniors, these inefficiencies lead to significant wasteful spending. If seniors are not in the right plan, they enter into the donut hole faster, come out faster, and the taxpayers end up footing a higher bill. Ms. McKenna, I know that you suggest a grading system for plans, though I am not sure that such a system is detailed enough for individual seniors.

¹GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004).

Question a. Are there other suggestions for what can be done to get beneficiaries in the best plan?

Answer. We have not conducted work that focuses on what can be done to get beneficiaries in the best Medicare Part D plans. As you may know, Medicare offers a Prescription Drug Plan Finder (<http://www.medicare.gov/mpdpf>) as a tool to help beneficiaries determine which plan best suits their needs based on their unique circumstances. Among other features, the Plan Finder allows beneficiaries to input lists of specific drugs that they take, and provides information about plan options based on these specific lists of drugs.

While this tool provides specific information on beneficiaries' plan options, our work suggests that for certain beneficiaries—those taking high-cost drugs eligible for a specialty-tier—plan choice has only limited effects on out-of-pocket costs. Across plans with different cost-sharing structures, out-of-pocket costs for these beneficiaries vary initially but then become similar if beneficiaries' out-of-pocket costs reach the catastrophic coverage threshold, which was \$4,350 in 2009.²

Question b. Also, it is my understanding that low income beneficiaries are automatically enrolled in a plan by CMS. By law, the assignment of a plan is random. Do any of you have a handle on how much the government could be saving simply by placing those beneficiaries into a more cost-effective plan, particularly since these are the highest cost enrollees?

Answer. We have not conducted work on the potential savings from placing low-income subsidy beneficiaries into certain plans. However, in 2007, contractors produced a report for the Medicare Payment Advisory Commission that considers the potential impact on beneficiaries and the federal government of using random assignment for Part D plans compared to other options.³

Question. We have heard that the U.S. pays more than Canada, Europe and the rest of the world in general.

a. What policies enable this and what policies could we enact to discourage this disparity?

b. Have other countries seen the same increase in prices or is part of the rise in U.S. prices caused by cost shifting from other countries to the U.S.?

Answer. A wide range of approaches is used by other countries, such as those affiliated with the Organization for Economic Co-operation and Development (OECD),⁴ to negotiate drug prices that include the following:

Ceiling prices restrict market negotiations by setting maximum prices purchasers can pay for drugs. Ceiling prices allow purchasers to negotiate lower prices directly with drug manufacturers.

Reference prices use local or international price comparisons of drugs classified in a group as therapeutically similar to determine a single or maximum price for all drugs in that group.

Profit limits establish controls on drug manufacturers' profits that require manufacturers to pay rebates or lower prices if profits exceed certain levels.

Other factors—such as scope of coverage and national formularies, which are generally lists of preferred drugs—influence drug price negotiations.⁵ We have not examined the effects of applying policies used in other countries to negotiate drug prices to the United States.

We have not conducted any recent work on drug pricing in other countries and cannot comment on the extent or causes of price increases in other countries.

MR. DICKEN'S RESPONSES TO SENATOR FRANKEN'S QUESTIONS

Question. Mr. Dicken, GAO did a 2009 study for the late Senator Kennedy comparing copayments for specialty medicines in private Part D plans to the Federal Employee Health Benefit Plan. It's my understanding that federal employees get specialty drugs for a copayment of \$60 per month, while most Medicare Part D beneficiaries pay a percentage-based share of the cost. This can add up to hundreds, even a thousand dollars per month. As a member of Congress, I'm embarrassed that

² The catastrophic coverage threshold is \$4,550 in 2010.

³ J. Hoadley, L. Summer, J. Thompson, E. Hargrave, and K. Merrill, "The Role of Beneficiary-Centered Assignment for Medicare Part D," (special report prepared at the request of the Medicare Payment Advisory Commission), June 2007.

⁴ The OECD includes 30 member countries that "share a commitment to democratic government and the market economy," and OECD's work includes developing publications and statistics on economic and social issues.

⁵ GAO, *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs*, GAO-07-358T (Washington, D.C.: Jan. 11, 2007).

we're giving ourselves better coverage than our seniors get. Can you please comment on how this discrepancy occurs?

Answer. We found that some plans participating in each program—the Federal Employees' Health Benefits Program (FEHBP) and Medicare Part D—use varying cost-sharing requirements for specialty-tier eligible drugs, with some using a fixed copayment and others using a percentage-based coinsurance. Both programs provide consumers with information on the plans cost-sharing requirements to consider as they decide which plan to select during open enrollment. Also, while enrollees in Medicare Part D and FEHBP plans can be responsible for paying hundreds of dollars a month out-of-pocket, Part D plans have a catastrophic coverage threshold whereby Medicare covers most additional costs and nearly all FEHBP plans we studied have maximum out-of-pocket limits. However, for high-cost drugs such as those eligible for specialty tiers, the total annual out-of-pocket costs for enrollees in FEHBP depends on the plan chosen, whereas for Medicare Part D beneficiaries, the total annual out-of-pocket costs are generally similar regardless of the Part D plan chosen.

Specifically, GAO's 2009 correspondence to Senator Kennedy described the cost-sharing requirements and limits for specialty drugs covered by FEHBP plans.⁶ We found that enrollees in FEHBP plans were subject to varying cost-sharing requirements for the 18 specialty drugs we reviewed. Most FEHBP enrollees—more than 6.6 million of the nearly 7.8 million enrollees in the plans we reviewed (86 percent)—were generally subject to copayments that limit enrollee costs to about \$55 on average for a 30-day supply of the drugs. Nearly 900,000 enrollees (11 percent) were subject to coinsurance for more than 1 of the 18 specialty drugs, which required the enrollees to pay on average nearly 31 percent of the cost of the drugs. These FEHBP enrollees' coinsurance costs for specialty drugs were typically limited by per prescription dollar maximums or annual out-of-pocket limits, but depending on the plan, these varying requirements can result in a wide range of costs for enrollees for the same drug. For example, we estimate that under 3 different FEHBP plans with different cost-sharing requirements, an enrollee taking the multiple sclerosis drug Betaseron could pay \$420 per year if subject to a copayment, \$2,400 per year if subject to a coinsurance with a per-prescription dollar maximum, or \$6,000 per year if subject to a coinsurance with an annual out-of-pocket maximum.

Similarly, in our recent study on beneficiary out-of-pocket costs for certain high-cost drugs covered under Medicare Part D,⁷ we found that plans included in our sample of high-enrollment plans from various regions offered a variety of cost-sharing structures for the specialty tier-eligible drugs in our sample, including flat copayments as well as various percentage-based coinsurance rates. However, in contrast to the variation in annual out-of-pocket costs in FEHBP, our analysis showed that various cost-sharing structures—whether copayments or percentage-based coinsurance—utilized by Part D plans in 2006 through 2009 made very little difference in annual beneficiary out-of-pocket costs for beneficiaries using these drugs over an entire calendar year. Once Medicare beneficiaries reached the catastrophic coverage threshold of \$4,350 in out-of-pocket costs in 2009 (\$4,550 in 2010), they generally paid only 5 percent of the negotiated drug price for the remainder of the year regardless of the plan selected.

Question. Mr. Dicken, in my opinion, a primary purpose of Medicare—and all insurance—is to protect Americans against unforeseen costs from an unexpected illness like cancer or multiple sclerosis.

Do you think when seniors sign up for Medicare Part D that they truly understand the potential financial exposure they face if they get sick and end up needing a drug that's in a specialty tier?

Answer. We have not conducted work on beneficiaries' level of understanding of specialty tier drug coverage under Medicare Part D. However, our testimony included information on the out-of-pocket costs that one group of beneficiaries—those taking high-cost drugs eligible for a specialty-tier—may be subject to paying. Across plans with different cost-sharing structures, out-of-pocket costs for these beneficiaries may vary initially but then become similar if beneficiaries reach the catastrophic coverage threshold, which occurred in 2009 when total drug costs reached \$6,153.75, with beneficiary out-of-pocket drug costs accounting for \$4,350 of that

⁶ GAO, Federal Employees Health Benefits Program: Enrollee Cost Sharing for Selected Specialty Prescription Drugs, GAO-09-517R (Washington, D.C.: Apr. 30, 2009).

⁷ GAO, Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier, GAO-10-242 (Washington, D.C.: Jan. 29, 2010).

total.⁸ After the threshold is reached, most beneficiaries are responsible for 5 percent of any additional drug costs. For example, in 2009, beneficiaries responsible for full cost-sharing amounts who take drugs with a total negotiated price of \$1,100 per month, or \$13,200 per year, would face out-of-pocket costs of approximately \$4,700, regardless of their plans' cost-sharing structures.

MR. HAMILTON'S RESPONSES TO SENATOR MCCASKILL'S QUESTIONS

Question. Importation: According to a Congressional Budget Office (CBO) cost estimate from 2007 importation of prescription drugs would have saved the government itself more than \$5 billion from 2009 to 2017 by allowing it to purchase cheaper drugs for Medicare and Medicaid recipients. In addition, the legislation would have increased federal revenues by about \$5 billion by reducing the cost of private health insurance, which would end up increasing the share of employees' salary that can be taxed. Should we not be pursuing this as an option? Can we afford not to do this? Are any of the pharmaceutical industry concerns related to safe reimportation legitimate? How do we do it safely and effectively?

Answer. The safe importation of prescription drugs is an option to help lower US drug costs. However, how and/or if it can be safely accomplished is a science issue and beyond my scope.

Question. We have heard that the U.S. pays more than Canada, Europe and the rest of the world in general.

a. What policies enable this and what policies could we enact to discourage this disparity?

b. Have other countries seen the same increase in prices or is part of the rise in U.S. prices caused by cost shifting from other countries to the U.S.?

Answer. 2) I have had only limited experience with foreign market drug pricing and have no data on their price changes. Consequently, I do not believe I'm in a position to appropriately answer this question.

Question. Role of direct marketing? (Only two countries—New Zealand and the U.S. allow direct to consumer drug marketing) Drug company spending on direct to consumer (DTC) advertising has increased twice as fast as spending on promotion to physicians or on the research and development of new drugs. Advertising is known to cause many consumers to go to their doctor and ask for the advertised brand name medication. One study of physicians found that in 5% of the cases when patients requested specific medications after seeing an advertisement, physicians prescribed the medication to accommodate the patients request despite thinking that another drug or treatment option would be more effective. Clearly, that is wasteful. I am trying to get a handle on how much this practice represents in unnecessary spending by the federal government. Is there a credible estimate that you know of regarding the cost to the taxpayer because of Direct To Consumer advertising? What measures would you suggest we take to try to crack down on this waste?

Answer. a) I am unaware of any estimate of the cost to the taxpayer because of Direct To Consumer Advertising. b) In a free market the cost would not be considered a waste. So, it's a question of lease fair vs free market politics.

Question. Comparative effectiveness research. Drug companies have to prove that their drugs are safe and are better than a sugar pill to get approval, but the drug companies rarely compare their drugs to other drugs. What role does comparative effectiveness research have in making sure that doctors not only are prescribing a drug that works, but the best drug? Would this type of research just improve outcomes or would it also cut spending? Should we include price when comparing drugs against each other?

Answer. a) I'm not sure- it's a science question. b) It could affect spending if it went beyond the science into pricing. c) If by "we" you mean the government, then we already do include pricing when comparing drugs against each other. Examples include Medicaid and the VA. Also, in the commercial market Pharmacy Benefit Managers (PBM'S) include drug price in their formulary decisions.

MR. HAMILTON'S RESPONSES TO SENATOR FRANKEN'S QUESTIONS

Question. Mr. Hamilton AARP Minnesota held a series of teletown halls on health reform during the past year. More than 92,000 Minnesota seniors participated and

⁸ In 2010, the catastrophic coverage threshold is reached when beneficiary out-of-pocket costs total \$4,550.

the single most common question they brought up was—why doesn't the federal government negotiate directly with pharmaceutical companies for Part D drugs? Can you please discuss the potential effects of direct negotiation on U.S. drug prices and what you think holds us back from adopting this policy?

Answer. a) Direct negotiation by the government with drug manufacturers would result in a significant reduction in the cost of Part D drugs. b) I believe Mr. Calfee addressed the risk of such negotiations in saying he suspected the drug companies would respond by raising their commercial prices.

Question. Mr. Hamilton, you mentioned that some price increases in Part D can be offset by rebates, but we're hearing that these rebates aren't getting back to consumers. Do we know if any portion of the rebates is getting back to beneficiaries?

Answer. I do not know if any portion of rebates gets back to beneficiaries. It may (EG thru flat co pays), but it would be difficult to determine.

Question. Mr. Hamilton, I'd like to ask you the same question—do you believe the increases were a response to the potential of federal health reform? If so, what can we do so drug companies don't retaliate against federal reform with runaway drug pricing?

Answer. a) I can't read Pharma's collective mind, but given the facts and the timing it certainly appears the unusual price increases were in anticipation of federal health reform. b) Nothing short of government intervention (regulation).

MR. CALFEE'S RESPONSES TO SENATOR McCASKILL'S QUESTIONS

Question. You repeatedly warned of the danger posed by pushing prices down in government plans, arguing that prices elsewhere, primarily in the private sector, would correspondingly increase to compensate for lost profits from the government programs. This assumes an inflexibility for pharmaceutical industry business model and profits and secondarily implies that the U.S. government should contribute the bulk of the pharmaceutical industry's profit as opposed to other countries or the private sector. Do you have support that pharma's business model is as inflexible as you imply and if it is inflexible is there any reason why the U.S. government should fill the role as the primary profit center for this industry?

Answer. This question is about how drug prices in the private sector adjust to prices paid by the federal government. In my testimony, I had not intended to suggest that pharmaceutical firms increase private sector prices to compensate for lower Medicaid prices. Rather, the Medicare drug price rebate mechanism penalizes manufacturers if they aggressively discount their prices in the private sector. This tends to keep private sector prices higher than they would otherwise be.

Question. We have heard that the U.S. pays more than Canada, Europe and the rest of the world in general.

a. What policies enable this and what policies could we enact to discourage this disparity?

b. Have other countries seen the same increase in prices or is part of the rise in U.S. prices caused by cost shifting from other countries to the U.S.?

Answer. This question is about international price disparities between the U.S. and Canada, Europe, and other nations. I am unaware of policies that the U.S. could pursue to attack these disparities directly, because those disparities are largely the result of price controls that are constructed in each of those nations. U.S. authorities have in the past pointed out to those nations that their price controls tend to suppress innovation (such as in speeches by then FDA Commissioner Mark McClellan and in a 2004 report on international pharmaceutical prices). Such appeals seem not to have an effect. The reason seems to be that each nation is aware that because pharmaceutical revenues in their own nation comprise only a small percentage of international revenues, their own price controls have minimal impact on drug R&D (which is performed in search of worldwide profits rather than profits in a single nation). I myself would be glad to see new proposals to address the impact of international price controls on pharmaceutical R&D.

This question also asks whether foreign prices have increased apace with U.S. prices or firms have been raising U.S. prices in order to shift costs. Past research on international prices has usually found that foreign prices increase less rapidly than U.S. prices and sometimes decline as controls become tighter. But U.S. price levels are almost certainly not the result of cost shifting, but are simply reflect attempts to maximize prices (which as a general rule do not involve cost shifting).

Question. Comparative effectiveness research. Drug companies have to prove that their drugs are safe and are better than a sugar pill to get approval, but the drug companies rarely compare their drugs to other drugs. What role does comparative effectiveness research have in making sure that doctors not only are prescribing a

drug that works, but the best drug? Would this type of research just improve outcomes or would it also cut spending? Should we include price when comparing drugs against each other?

Answer. This question asks about comparative effectiveness research on pharmaceuticals. First, CER could help assure that physicians prescribe the best drug for each patient, but there are limits to the ability of CER to achieve this result. It is very difficult to perform CER that provides valid results for current practice, which is continually changing as new drugs and new information about drugs become available. Also, CER often focuses on the average effects of competing drugs, whereas a drug that is equal or worse on average (in terms of efficacy, side-effects, or both) may still be better for some patients. Solid, timely CER could in principle both improve medical treatments and cut spending, but again, it is all too easy for CER to discourage the best treatments for some patients or to encourage cost-cutting that could work to the disadvantage of some patients. Finally, CER does not involve drug prices as opposed to clinical outcomes. Incorporating prices into CER would shift the research toward cost-effectiveness analysis, which again can be very useful but is fraught with difficulties.

MR. CALFEE'S RESPONSES TO SENATOR FRANKEN'S QUESTIONS

Question. Mr. Calfee, in your testimony, you close by stating that the path forward to lower drug prices is unclear. I'd like to point out that from 1997 to 2007, retail prescription prices increased an average of 7 percent annually, much faster than the average inflation rate of 2.6%. During this same time, pharmaceutical companies increased their spending on direct-to-consumer advertising by an average of 65 percent annually, spending \$4.7 billion in 2007 alone. Of course, these companies have the right to advertise, but do you believe this is excessive?

Answer. This question is about the relationship between drug prices and direct-to-consumer advertising. So far, econometric studies have failed to reveal a connection between DTC advertising and drug prices. This is not surprising. As the question points out, DTC advertising totaled \$4.7 billion in 2007, which is only a few per cent of total drug spending of perhaps \$200 billion. With the possible exception of a few heavily advertised brands, it is most unlikely that consumer advertising could have a significant impact on prices. Also, I do think that DTC advertising is excessive. Not only is it quite small relative to the size of the market, it usually focuses on therapeutic classes that are often under-used, partly because consumers need to be made aware of, or be reminded of certain medical conditions for which drug therapy is effective.

Question. Mr. Calfee, last April, the Wall Street Journal ran a story entitled "Drug Makers, Hospitals Raise Prices." This article describes double digit increases compared to a year before on a dozen top-selling drugs. Then in November, a spokesperson from Merck was quoted in the New York Times stating that "Price adjustments for our products have no connection to health care reform." Do you believe these increases were a response to potential federal health reform?

Answer. This question asks whether drug prices were increased as "a response to potential federal health reform." I have heard nothing from anyone in the industry on this topic. I would point out, however, that if manufacturers are already charging prices that are designed to make as much profit from innovative drugs as possible, there is probably little incentive to increase prices simply because a sweeping version of health care reform might be passed. Nonetheless, I have no way to plumb all the ways in which pharmaceutical firms might anticipate the highly varied effects that would come from comprehensive health care reform.

Question. Mr. Calfee, I'm sure you're aware that the federal government invests significant funds in R&D. National Institutes of Health received more than \$30 billion in 2010 alone. Not every dollar goes for drug development but right now, Americans don't receive any direct return on these investments. Instead, the research is used to develop new products in the private market that make billions of dollars in profits. Your testimony doesn't mention the significant investment we make in R&D with taxpayer dollars. If you're making the argument that programs like Medicaid underpay for drugs, it's important to point out that most of these drugs wouldn't exist without the initial federal investment. Would you agree?

Answer. This question is about private vs public returns from taxpayer investment in medical research by the National Institutes of Health. Much of that research eventually undergirds research that leads directly to new drugs. I would emphasize, however, that almost never does NIH actually develop a new drug all the way to FDA approval. Hence private industry is responsible for transforming NIH research into useful therapies. It is true that the public receives no "direct return"

on NIH investments in the sense of manufacturer payments to the federal government. But research (including a book by Jena and Philipson published by the American Enterprise Institute) has demonstrated that the total benefits from pharmaceutical innovation are huge and that most of those benefits actually go to patients and payers rather than to the manufacturers. Nonetheless, I agree that NIH investment has been very important and valuable, not just to Americans but to residents of essentially every other nation.



Statement for the Record for the Senate Special Committee on Aging's Hearing

"Seniors Feeling the Squeeze: Rising Drug Prices and the Part D Program."

Medicare Rights Center President Joe Baker

The Medicare Rights Center extends its appreciation to Senator Bill Nelson and the Senate Special Committee on Aging for holding this hearing on the impact of rising drug prices on older adults who rely on Medicare Part D for their drug coverage. The Medicare Rights Center is a national nonprofit consumer service organization dedicated to helping older Americans and people with disabilities access quality, affordable health care through individual counseling and advocacy, educational programs and policy initiatives.

Medicare Rights has a frontline perspective on the effect of rising drug costs on people with Medicare. Through our free consumer help hotlines, we hear heartbreaking stories of older adults who go to extremes in order to afford medications or who must interrupt treatment as a result of the high costs of drugs during the coverage gap. In one case a woman was forced to share a prescription with a fellow patient, using the patient's unused drugs to avoid an interruption in her treatment regimen. The problem is especially troubling for those with chronic and serious conditions who require multiple expensive medications—in some cases they need to pick and choose the medications they use because they are unable to afford them all.

There is good news, however. President Obama's health reform proposal contains important provisions that will make medicines more affordable for people with Medicare. The president's proposal phases out the coverage gap, also known as the "doughnut hole," in the Medicare drug benefit, and includes immediate assistance by providing a 50 percent discount on prescription drugs purchased in the gap this year. In addition, the health reform legislation will allow consumers to purchase lower-priced generic versions of biologics—some of the most expensive medicines now on the market—that are essential for the treatment of diabetes, cancer and other serious illnesses.

The Doughnut Hole

Because of the design of the Part D drug benefit, most people with Medicare bear the full brunt of rising drug prices, unless they have very low income and qualify for Extra Help. Under the Medicare drug benefit in 2010, a person receives prescription drug coverage up until actual total costs reach \$2,830, when the coverage gap, or "doughnut hole," begins. In the coverage gap, people with Medicare must pay the full price of their medicines. The

2010 Part D coverage gap is \$3,610, the amount consumers must spend out-of-pocket while in the coverage gap before catastrophic coverage is triggered.² By 2018, the coverage gap is estimated to rise to \$5,755.³

In 2007, an estimated 3.4 million people with Part D coverage reached the coverage gap, and with the cost of prescriptions rising, more and more consumers will be unable to afford the high out-of-pocket costs during the gap.⁴ According to a recently released report by the Kaiser Family Foundation, between 2009 and 2010 the monthly prices for the top ten brand-name drugs increased by 5 percent or more in the coverage gap. Those affected are likely to have debilitating chronic diseases. For example, the price in the coverage gap of both Aricept, a medication used to treat Alzheimer's disease, and Plavix, used to treat blood clots, increased 7 percent in the last year.⁵ An examination of the long-term history of drug prices during the gap is even more alarming—between 2006 and 2010, monthly prices in the coverage gap for many commonly used drugs, including Lipitor and Nexium, increased by 20 percent.⁶

Expert studies confirm the devastating impact that entering the doughnut hole can have on older adults' ability to afford the medicines they need. In its March 2010 report to Congress, the Medicare Payment Advisory Commission (MedPAC) describes the results of a focus group study: Medicare consumers who did not have any type of assistance in the coverage gap split pills, took pills every other day, and in some cases stopped taking drugs altogether.⁷ These strategies, often executed without physicians' knowledge or supervision, raise serious concerns about potential health risks for these older adults.⁸

The stories we hear every day from consumers illustrate the desperation that people face while in the doughnut hole. One woman who recently contacted us suffers from a neurological disorder that requires extensive treatment. When she fell into the doughnut hole, she skipped doses and was unable to afford refills for many of her medications. The prescription drug coverage that should have been there to help her instead left her stranded and unable to treat her symptoms.

The evidence is in. The coverage gap in the Medicare drug benefit is bad for the health of older adults and people with disabilities. It is time for Congress to close the doughnut hole.

Generic Biologics

While switching to a lower-priced generic alternative is a smart strategy for consumers to reduce their out-of-pocket spending, this is not an option for people who take biologics, expensive medicines that are used in the treatment of cancer, diabetes and other serious illnesses. President Obama's health reform plan creates a pathway for regulatory approval of generic therapeutic equivalents of biologics. We hope this will allow generic biologics to enter the market without undue delay. Lower-priced generic biologics will not only provide savings for the consumers who take these medicines; it will also mean savings to both the taxpayers and people with Medicare who now pay for these drugs through higher premiums and reinsurance subsidies for Part D coverage.⁹

Steadily rising drug prices are detrimental to the health and financial security of people with Medicare. The health reform proposal put forward by President Obama would take important steps toward addressing this problem by closing the coverage gap in the Medicare drug benefit and allowing consumers to purchase lower-priced generic versions of high-cost biologics.

¹ Jack Hoadley, Laura Summer, Elizabeth Hargrave, Juliette Cubanski and Tricia Neuman, *Medicare Part D 2010 Data Spotlight: The Coverage Gap*, The Kaiser Family Foundation, December 2009.

² Hoadley et al., *Medicare Part D 2010 Data Spotlight: The Coverage Gap*.

³ Juliette Cubanski, Tricia Neuman, Elizabeth Hargrave, Jack Hoadley and Laura Summer, *Medicare Part D 2010 Data Spotlight: Prices for Brand-Name Drugs in the Coverage Gap*, The Kaiser Family Foundation, March 2010.

⁴ Cubanski et al., *Medicare Part D 2010 Data Spotlight: Prices for Brand-Name Drugs in the Coverage Gap*.

⁵ Cubanski et al., *Medicare Part D 2010 Data Spotlight: Prices for Brand-Name Drugs in the Coverage Gap*.

⁶ Cubanski et al., *Medicare Part D 2010 Data Spotlight: Prices for Brand-Name Drugs in the Coverage Gap*.

⁷ *Report to the Congress: Medicare Payment Policy*, Medicare Payment Advisory Commission (MedPAC), March 2010.

⁸ Cubanski et al., *Medicare Part D 2010 Data Spotlight: Prices for Brand-Name Drugs in the Coverage Gap*.

⁹ See *Report to the Congress: Medicare Payment Policy*, MedPAC ("In 2008 and 2009, Medicare's reinsurance payments for the highest spending enrollees were the fastest growing component of Part D, partly because of the difficulty of negotiating rebates for high-cost drugs and biologics that have few competing therapies.")



Navigating the
Prescription
Drug Program

STATEMENT FOR THE RECORD
Submitted to
Senate Special Committee on Aging
Following Committee Hearing on Medicare Part D Drug Benefit
March 24, 2010

MAPRx brings together beneficiary, family caregiver and health professional organizations committed to improving access to prescription medications and safeguarding the well-being of beneficiaries with chronic diseases and disabilities who are enrolled in the Medicare Prescription Drug Coverage (Part D). On behalf of millions of Medicare beneficiaries with chronic conditions who rely on Part D for essential medications, MAPRx thanks the Senate Special Committee on Aging for holding its recent hearing to address drug costs within Part D.

Although the hearing provided an excellent opportunity to learn more about rising costs and the process by which plans determine the final price of drugs, we had hoped that the hearing would also shed light upon the other policies and benefit designs which inhibit beneficiary adherence to their doctor's prescribed drug regimen.

We are grateful that the Patient Protection and Access to Affordable Care Act sets forth a plan and timeline to eliminate the Part D coverage gap and provides an immediate \$250 rebate to beneficiaries who will hit the "donut hole" this year. Nevertheless, MAPRx remains concerned about the increasing burden cost-sharing is having upon beneficiaries and their health. While the issue of cost-sharing for medications on the specialty tiers has received a great deal of attention, this is a problem facing all beneficiaries for treatments on all plan formulary tiers. The increasingly common mix of copayments and coinsurance is particularly noteworthy in this respect as coinsurance generally places more of the cost on consumers.

We urge Congress to ensure that the Centers for Medicare and Medicaid Services (CMS) truly analyzes beneficiary adherence behavior and conducts vigilant oversight of plan designs. Specifically, we request that Congress work with CMS to address:

- Raising the price threshold for specialty tier medications;
- Creating an appeals process for medications placed on specialty tiers; and
- Directing Medicare Payment Advisory Commission (MedPAC) to review prescription drug plan policies to make sure they do not violate nondiscrimination rules and study the impact cost-sharing is having upon beneficiaries' health.

Price Threshold for Specialty Tier Medications

For CY 2011, CMS will maintain the \$600 threshold for drugs placed on the specialty tier in Part D plans. This will be the fourth year that the amount remains at \$600. Because of plan provisions unique to the specialty tier, the threshold for drug inclusion is of vital concern to MAPRx and the communities it represents. Beneficiaries have no medication alternatives for therapies included on the specialty tier and there is no appeals process by which beneficiaries can request that a specialty tier drug be placed on a lower cost-sharing tier.

MAPRx has strong concerns about the continuation of this threshold. We have requested greater clarity from CMS on the rationale for utilizing \$600 as the baseline figure for inclusion on specialty tiers. Furthermore, MAPRx questions why the threshold has not increased over the past three years—even as drug prices rise. Many innovative therapies for the hardest to treat conditions are currently in development and likely to end up on the specialty tier if the threshold remains unchanged. Retaining the \$600 threshold fails to recognize this fact and has the effect of increasing the number of medications eligible for inclusion on specialty tiers. Ultimately, this will impact beneficiaries by placing a greater financial burden on those who find their medications are priced beyond the threshold. This would be particularly true for those taking a prescription that is reclassified from a lower tier to the specialty tier due to price increases.

The recent Government Accountability Office report *Medicare Part D: Spending, Beneficiary Cost Sharing and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier*, which was referenced in the Aging Committee's hearing, found that in 2007, \$1100 per month was the utilization-weighted average of the median negotiated price of all specialty tier drugs.

For these reasons, MAPRx believes an increase is merited in the cost threshold for inclusion on the specialty tier for CY 2011 and we urge the Committee to address this issue with CMS.

Create an Appeals Process for Specialty Tier Medications

Individuals living with cancer, multiple sclerosis, arthritis and other conditions often take several medications and must pay thousands of dollars out-of-pocket before reaching catastrophic coverage.

MAPRx is grateful to Senators John Rockefeller and Al Franken for, respectively, introducing and cosponsoring the Affordable Access to Prescription Medications Act of 2009, which seeks to protect all Americans from high out-of-pocket spending on prescription drugs and calls for the creation of an appeals process for specialty drugs in the Part D program. Currently, beneficiaries under a Part D plan or a Medicare Advantage plan cannot request an exemption to allow them access to these drugs by moving the drug to a lower tier on the plan formulary. We hope that Congress will work with CMS to resolve this disparity that is certain to impact more and more beneficiaries as additional specialty drugs are being developed to treat serious chronic conditions.

Study Impact of Excessive Cost-Sharing

We know from our collective work with people with chronic conditions and disabilities that many are struggling to afford increases in copays and coinsurance in order to effectively manage their health. Oftentimes, beneficiaries are making trade-offs between treating one condition over another, undermining their health. Ultimately such compromises in treatment can lead to more catastrophic events, resulting in hospitalizations that cost more to Medicare overall. We encourage the Committee to examine the health outcomes of Medicare beneficiaries and the cost implications across all Medicare programs.

Furthermore, we are concerned that plans are using excessive coinsurance rates to avoid attracting beneficiaries to their plans. The Medicare Modernization Act directs CMS to review tier placement to provide an assurance that the formulary does not discourage enrollment of certain beneficiaries. As called for in Senator Rockefeller's legislation, we urge the Committee to request that the MedPAC review prescription drug policies under Medicare Parts B, C and D to ensure compliance with nondiscrimination rules overall and to make recommendations for benefit design modifications that would alleviate the financial burden placed on beneficiaries, many of whom are on limited incomes and can least afford expensive drug treatments.

In closing, MAPRx thanks the Committee for its diligence and commitment to improving the Part D drug benefit for beneficiaries. We hope the Committee will consider our recommendations and call upon our member organizations as resources and willing partners to safeguard the well-being of beneficiaries with chronic diseases and disabilities. For questions related to MAPRx or the above statement, please contact Mary Beth Buchholz, Convener, MAPRx Coalition, at (202)-637-9732 ext 229 or Marybeth@maprxinfo.org.

Sincerely,

AIDS Action Council

National Council for Behavioral Healthcare

Alzheimer's Association

National Council on Aging

Arthritis Foundation

National Grange of the Order of Patrons of Husbandry

Breast Cancer Network of Strength

National Health Council

Easter Seals

National Kidney Foundation

Epilepsy Foundation

National Multiple Sclerosis Society

Men's Health Network

National Organization for Rare Disorders (NORD)

National Alliance on Mental Illness (NAMI)

(continued on page 4)

National Osteoporosis Foundation

The AIDS Institute

The ALS Association

The Lupus Foundation of America

RetireSafe

National Psoriasis Foundation

United Spinal Association

Drug Pricing Policies – Time for a More Rational Approach

The cost of prescription drugs is on track to exceed \$300 billion in the U.S. in 2009. For comparison, this cost was \$100 billion one decade ago. Many individual prescription drugs cost twice or more in the U.S. compared to identical drugs in other developed countries. Spending so much on prescription drugs would be justified if it led to higher quality medical care and better outcomes. However, there is no good evidence that the quality of care in the U.S. is higher than that in other developed countries. In fact, some studies suggest the opposite. These facts raise two questions: What brought us into this situation? How can we correct it?

There are three main reasons for higher drug costs in the U.S.:

First, the manufacturer typically sets the price of any commercial product sold in our society. This also applies to prescription drugs. The principles of such open or free market pricing of drugs are also accepted in developed countries. The difference lies in how reimbursement payments by the government and other providers are determined. In other countries decisions are made within a societal context through negotiations. If agreements on the level of reimbursement can't be reached, there are two options. The drug is marketed but without reimbursement payment or it is not marketed in that country. In the U.S., the pricing set by a manufacturer is typically accepted as the reimbursement payment without restriction.

In contrast, other developed countries have programs that are charged with making an assessment of the value of a new drug to society. Australia, Canada and the United Kingdom are among the countries with such programs. The evaluation includes reviewing the documented evidence of safety and effectiveness as well as the comparative effectiveness and cost-effectiveness of the yet-to-be valued product compared to currently available treatments. Recommendations for reimbursement are then made to the drug plans and may include a rejection of listing.

Second, drug manufacturers in the U.S. are free to raise their prices on prescription drugs at any time without justification. Last year the *average* increase was 9% and over time it has markedly exceeded the annual rate of inflation. Sustained increases of this magnitude over the next decade could double the nation's drug bill to approximately \$600 billion. This uncontrolled expense represents a serious challenge to the Health Care Reform being formulated by Congress. Moreover, the potential increase of \$300 billion in drug costs over the next decade dwarfs the drug industry's commitment of \$80 billion in savings towards the affordability of Health Care Reform over this same time period. It should be noted that, in contrast to the U.S., there are developed countries that reject unjustified, annual increases in reimbursements.

Third, some countries have used reimbursement to leverage reductions in drug expenditures. They have lowered payments by a certain percentage for all drugs. Such across-the-board decreases have occurred in both Germany and the U.K.

Congress recently tried to address the problem of excessive drug costs in the U.S. by proposing the lifting of restrictions on importation of cheaper drugs from Canada and other countries. While the proposal failed, it should be noted that it was a "band aid" approach that would not have addressed the heart of the problem. A more rational proposal would be to reform the systemically flawed process for determining drug prices and reimbursement in the U.S.

The good news is that there are solutions to each of these problems. The U.S. could follow the lead of other developed countries and introduce a process to determine reimbursement payments based on each drug's comparative effectiveness and cost-effectiveness. One caution is that it would take a couple of years before the benefits of such a program would be realized. Drugs already on the market would undergo a retrospective evaluation.

A decision to freeze or reduce reimbursement payments would likely be easier. No individual prescription drug should ever have its price increased by more than the annual rate of inflation. If Congress can freeze the traditional annual cost of living increases in Social Security payments, why not drug payments? Since current drug prices in the U.S. are so much higher than in other developed countries, an across-the-board reduction of reimbursements by 20% would be sensible and could lead to a savings of \$60 billion per year. This corresponds to \$600 billion over the next decade.

The opposition to any change in the current system will come from the pharmaceutical industry, which is one of the most profitable industries in the U.S. This industry and its supporters will claim that the excessive profits it makes are necessary for development of new treatments. Interestingly, drug companies in the U.K. invest proportionately more of their revenues from domestic sales in research and development than do U.S. companies. Moreover, the track record of major U.S. pharmaceutical companies for bringing new, important therapeutic advances to the market over the past several years has been less than stellar. Most new drugs offer no or little advantage over marketed drugs and are referred to as "me-too" drugs.

It should be pointed out that the cost of manufacturing as well as research and development is small compared to the cost of marketing, promotion, administrative overhead and profits to shareholders and senior executives. Other developed countries have decided that ethical and economic considerations justify limiting the profitability of products for treating the sick by subjecting them to an independent assessment of their value to society. The U.S. would do well to follow their example.

Curt D. Furberg, MD, PhD
Advance, North Carolina