S. HRG. 110–264

# PRESCRIPTION DRUG PRICING AND NEGOTIATION: OVERVIEW AND ECONOMIC PERSPECTIVES FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT

## HEARING

BEFORE THE

## COMMITTEE ON FINANCE
## UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

JANUARY 11, 2007

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE

39–938—PDF WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON FINANCE

MAX BAUCUS, Montana, *Chairman*

| | |
|---|---|
| JOHN D. ROCKEFELLER IV, West Virginia | CHUCK GRASSLEY, Iowa |
| KENT CONRAD, North Dakota | ORRIN G. HATCH, Utah |
| JEFF BINGAMAN, New Mexico | TRENT LOTT, Mississippi |
| JOHN F. KERRY, Massachusetts | OLYMPIA J. SNOWE, Maine |
| BLANCHE L. LINCOLN, Arkansas | JON KYL, Arizona |
| RON WYDEN, Oregon | CRAIG THOMAS, Wyoming |
| CHARLES E. SCHUMER, New York | GORDON SMITH, Oregon |
| DEBBIE STABENOW, Michigan | JIM BUNNING, Kentucky |
| MARIA CANTWELL, Washington | MIKE CRAPO, Idaho |
| KEN SALAZAR, Colorado | PAT ROBERTS, Kansas |

RUSSELL SULLIVAN, *Staff Director*
KOLAN DAVIS, *Republican Staff Director and Chief Counsel*

# CONTENTS

## OPENING STATEMENTS



## WITNESSES



## ALPHABETICAL LISTING AND APPENDIX MATERIAL

COMMUNICATION

# PRESCRIPTION DRUG PRICING AND NEGOTIATION: OVERVIEW AND ECONOMIC PERSPECTIVES FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT

---

**THURSDAY, JANUARY 11, 2007**

U.S. SENATE,
COMMITTEE ON FINANCE,
*Washington, DC.*

The hearing was convened, pursuant to notice, at 10 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Rockefeller, Lincoln, Wyden, Schumer, Stabenow, Cantwell, Salazar, Grassley, Hatch, Kyl, Smith, Bunning, and Roberts.

## OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

I look forward very much to this hearing because I think it is a great opportunity for this committee to, in a thoughtful, considered way, find the facts in as bipartisan a way as possible and try to find a solution to this basic question.

I supported the Part D drug benefit a couple of years ago because I felt it was the right thing to do. I felt that seniors needed some help. They needed a way to get a drug benefit.

Clearly, with all the new drugs that have been invented, and people living longer, it just made sense that, in addition to Part B, that there should be a direct benefit for drugs to be available to senior citizens.

The legislation that we passed a couple of years ago was not perfect, but it was a start. The old saying around here, which I subscribe to, is we cannot let perfection be the enemy of the good. It was not a perfect bill, but it was a good bill. It was a start. It moved, in my judgment, in the right direction.

I think, even though it was roundly criticized by many back then, I think most of those who criticized and tried to prevent the passage of that legislation now would agree that it is a good thing that Part D is in the law, because so many seniors are getting the benefit.

The program started out with lots of bumps, lots of delays. It is a big program. It is difficult for CMS to line up all that had to be put together for the benefit to begin to work in a fairly seamless

way. Many seniors had lots of questions, legitimate questions. There was much confusion.

But over time, it is my judgment that most seniors have begun to think, well, gee, after all those problems—and there still are a good number of problems—that they are basically satisfied. I know that is true in my State of Montana, where earlier there were a good number of dissatisfied people, but now seniors are generally much more satisfied.

I believe that the program is still too complex for seniors. I think there are way too many choices that seniors have to make which tend to prevent seniors from making a choice.

I think it is probably a good analogy to the insurance program, the Medigap insurance program, where there were way too many choices a long time ago, and I think a lot of seniors have been taken advantage of. But we stepped in and we tried to correct that problem. I think the same would apply here today.

The real question, though, now, for this committee at this point is what to do about the provisions in the current law prohibiting the Secretary from interfering, if you will, in the market. Of course, the bill that is probably going to pass the House places this issue before us.

It is my hope that, by asking a lot of good questions and getting a lot of good answers from our five panelists—and we thank you very much for coming to join us here today. We chose you because we think you know what you are talking about and you can help this committee make some very wise, considered choices. So I thank you for coming.

On the one hand, there are those who say the current program is working, that the Secretary should not interfere, the Secretary should not set price, the Secretary should not set formularies. It is: let the market work because the market is working pretty well, citing some reductions in the cost of the program—the Part D program is not costing as much as was earlier anticipated—and pointing out that the lower prices that some seniors are paying due to negotiation between the drug plans and the drug companies, some of those savings are being passed on. I do not know the degree to which or how much.

There are those, on the other hand, who say, wait a minute. With the massive power of Uncle Sam, with the massive purchasing power of CMS, we should get a much lower price from the pharmaceuticals. The VA system is often mentioned as an example. VA prices are often a lot lower than those under Part D.

So my goal here is to try—and I know it is almost impossible, but I am going to try—to get all of us to kind of minimize the rhetoric here, minimize the attacks against the other side, directly or indirectly, but stand back a little bit and find out what is really going on here.

To what degree is the market working and where in the current program is it working? To what degree is it not working, and where is it not working? For example, in the second category, some people say, well, cancer drugs. The monopolistic power of a single cancer drug is the reason why cancer drugs are way, way too expensive and we probably do need a little more intervention by the Secretary, jawboning or whatever, to get those prices down.

There are others who point to dual eligibles and Medicaid reduction, and is that not something that we should apply here, too? It is my belief that a lot of that analysis is somewhat on the surface.

When you go down to the third level of examination of what is going on, we can find better ways to get lower prices for seniors in a way that also means that seniors will tend to get good drugs off in the future, too. We cannot kill the goose that lays the golden egg here.

An area that I think is worth pursuing, an area that when it comes time for questions I am going to ask the panelists a lot about, is basically this: first, why can we not have a lot more comprehensive comparison—cost comparison, efficacy comparison—of drugs and make that a stronger analysis, have NIH do a lot more than it currently does, and make that information public so that doctors, hospitals, and patients have a better idea of the cost of this drug procedure versus another, and the efficacy of that drug procedure versus another?

I tend to think that the more that is widely known and the more NIH does the analysis—because currently it is my understanding that NIH does that analysis only on a very few drugs. But if NIH were to expand that analysis on many, many, many more drugs, particularly the ones that are most used and so forth, that that would be very, very helpful and then the price will tend to come down.

Second—and I am going to ask the panelists about this—it is my understanding that HHS does have one set of pricing information, that is, what the beneficiaries pay the pharmacies. That is available and the Secretary has that information.

The second set of information the Secretary has is the net discounts and the prices that the drug companies charge the plans. That also is available. The Secretary has that information as well.

So I am going to ask you panelists when it comes time for me to ask questions, why can both of those sets of pricing information not be transferred to public research entities like CBO, GAO, CRS and so forth to analyze what is happening here so they can then tell us what is working and what is not working?

I hope the panelists can shed some light on all that so, in the long run if all this works, we are going to get better prices, with more transparency, with more analysis, comparative analysis, and efficacy of plans without the heavy hand of price-setting and regulation. Now, maybe that does not work, I do not know. But it is an area that I think we should pursue.

Again, our goal here is for beneficiaries to get the lowest price not only today, but for tomorrow and future years. Our goal here is short-term, and it is also long-term.

Senator Grassley is not here. He plans to be here very soon. Ironically, I think Senator Grassley is on the floor giving a statement against the Pelosi bill. But, anyway, he is not here right now.

I just wonder, since he is not here, do any other Senators want to make very brief, short statements before we proceed with the witnesses? Very brief.

The Senator from Oregon.

## OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Mr. Chairman, thank you. Thank you for your very thoughtful assessment of where we are.

My own view is that it is possible to show that Medicare can be a smarter shopper without going to some form of price controls. That is, in fact, what Senator Snowe and I have been pushing for 3 years.

We have introduced another version of our legislation. In particular, when you have a drug that is a sole-source drug, I think there is an area where you do need some negotiating power.

That, for example, is what former Secretary of Health and Human Services Tommy Thompson did with Cipro: there were no price controls, there was no uniform formulary, but the government used its bargaining power to hold down costs.

I would also point out that many drugs are developed with taxpayer funds. For example, Taxol came from a trash tree in the Pacific northwest where essentially all the heavy lifting was done by the taxpayers of this country. There again, without price controls, without a uniform formulary, I think there ought to be the possibility of negotiating.

I will say, colleagues, I do not think Medicare is that different today than somebody going to Costco buying toilet paper one roll at a time. Nobody shops that way. They do not shop that way in Kansas, Oregon, or anywhere else.

So let us, colleagues, look for ways to avoid price controls, uniform formularies, and approaches that will discourage innovation, but rather promote, as Senator Snowe and I have sought for 3 years, smart shopping so as to take steps that are good for seniors and for taxpayers.

I want to wrap up by thanking you, Chairman Baucus, because you and your staff folks have been exploring this very constructively with us.

The CHAIRMAN. I appreciate that. Thank you, Senator.

I would like to go to the panel, but will let someone on this side of the aisle speak if he or she wants to. But I would like to get on to the panelists, too.

Senator Bunning?

## OPENING STATEMENT OF HON. JIM BUNNING, A U.S. SENATOR FROM KENTUCKY

Senator BUNNING. Thank you very, very much.

I just want to review from the beginning what we tried to set out to do in Medicare Part D. Just very short: we tried to give those who did not have a drug benefit a drug benefit.

According to an independent survey by J.D. Power & Associates, 75 percent of all Medicare beneficiaries enrolled in Part D are happy with their drug coverage. CMS recently announced that the average monthly premium for Part D in 2007 is $22 a month, which is substantially less than the $37 that was projected. Beneficiaries are averaging savings of almost $1,200 a year.

The drug benefit cost $13 billion less than expected in the first year, and more than 38 million Medicare beneficiaries have drug

coverage, and most of them, 70 percent, will not be affected by any donut hole.

So what we set out to do, we accomplished. Unbelievably, as you have said, Mr. Chairman, in spite of the fact that there were a lot of naysayers, we have a success, a very big success.

I was interested in a CBO letter that was sent yesterday at the request of Chairman John Dingle. He requested a letter from CBO. It said that, according to CBO estimates, H.R. 4 would have negligible effect on the Federal spending—H.R. 4 being the bill that is in the House presently—because we anticipate the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs under the current law.

So I say that before we get to our panel, because I want to hear what our panel has to say, and I want to be able to ask some specific questions of the panel.

Thank you.

The CHAIRMAN. Thank you.

Let us get to the panel now, if we could. I want to start out by introducing the panel. We have Mr. John Dicken, who is Director of Health Care for the U.S. GAO; Dr. Gerard Anderson, who is a Ph.D. and professor, Department of Health Policy and Management, and director at the Johns Hopkins Bloomberg School of Public Health; Edmund Haislmaier, who is a research fellow in health policy studies at The Heritage Foundation; Dr. Richard Frank, professor of health economics, Department of Health Care Policy at Harvard Medical School, with a collateral appointment to the John F. Kennedy School of Government, also at Harvard; and Dr. Fiona Scott Morton, who is a professor of economics at the Yale School of Management, Yale University.

So, Mr. Dicken, why don't you proceed? Your statements will automatically be included in the record, but I encourage you to stay within 5 minutes.

**STATEMENT OF JOHN DICKEN, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC**

Mr. DICKEN. Thank you, Mr. Chairman, members of the committee. I am pleased to be here today as you examine approaches to prescription drug pricing and negotiations.

In the United States and other countries, rising prescription drug costs have led to a wide range of market-based and governmental approaches to reduce drug spending. Some of these approaches include negotiations between drug purchasers and drug manufacturers.

Prescription drugs, as you know, are a particular focus for the Federal Government as Medicare begins the second year of the Part D drug benefit. Part D is characterized by multiple competing private plans. These plans may differ on the drugs they cover, the pharmacies they use, the prices they negotiate with drug manufacturers and pharmacies, and the costs to enrollees.

MMA prohibits the Federal Government from interfering with price negotiations between Part D plan sponsors and drug manufacturers. As you know, a bill recently introduced in the House pro-

poses amending MMA to require the Secretary of HHS to negotiate with drug manufacturers on behalf of Medicare beneficiaries.

My remarks today provide a broad overview of the approaches used to negotiate drug prices by governments in other countries, by private payors in the United States, and by Federal programs other than Medicare Part D. My remarks are based on previous GAO reports and other relevant literature.

Approaches for negotiating drug prices vary among Federal programs in the United States. While these approaches reflect U.S. laws, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payors in the United States. Other factors, such as scope of coverage and the use of formularies, influence drug negotiations.

In other countries, governments establish drug prices in three main ways. First, ceiling prices restrict market negotiations by establishing maximum prices drug manufacturers can charge, allowing purchasers to negotiate lower prices directly with manufacturers. For example, Canada has a review board that can fine drug manufacturers that sell drugs at prices higher than ceiling prices.

Second, 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. Germany sets prices this way, matching the price of all drugs in a group to the price of the lowest-priced drug in the group.

Third, profit limits establish controls on drug manufacturers' profits, requiring drug manufacturers to lower prices or pay rebates if their profits exceed certain levels. This approach is used in the United Kingdom.

Private payors in the United States, such as employer-sponsored health plans, often contract with pharmacy benefit managers, or PBMs. PBMs compete in the market, in part based on their ability to negotiate reduced prices with manufacturers and pharmacies.

PBMs generally receive compensation from health plans and from retaining some of the savings they negotiate with pharmacies or manufacturers. PBMs influence price negotiations with manufacturers through managing formularies and through the volume and market shares they represent.

Federal programs in the United States combine some of these approaches. Some programs set ceiling prices, others establish prices by referencing prices negotiated by commercial U.S. payors, and still others negotiate with manufacturers, either directly or through contracted private plans.

A few examples. First, the VA's prices for prescription drugs may be the lower of a ceiling price, the price listed on the Federal supply schedule, or the price that VA can negotiate with a manufacturer. VA's national formulary, which comprises at least one therapeutic alternative in categories of drugs, also influences VA's prices.

Second, State Medicaid programs reimburse retail pharmacies for dispensing drugs to beneficiaries at set prices, typically, the lowest of several prices established by the States within Federal limits. State Medicaid programs receive rebates from drug manu-

facturers that are meant to take advantage of the best prices private payors negotiate, including discounts and rebates.

Finally, for health plans offered to Federal employees, retirees, and their dependents, the Federal Government uses a different approach modeled after other large employers' health benefits.

Under this approach, rather than negotiating directly with manufacturers, the government contracts with participating health plans that typically use PBMs to negotiate drug prices and manage plans' specific formularies.

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

The CHAIRMAN. You are good, with 10 seconds left to spare.

[The prepared statement of Mr. Dicken appears in the appendix.]

The CHAIRMAN. Dr. Anderson?

**STATEMENT OF GERARD F. ANDERSON, Ph.D., PROFESSOR, DEPARTMENT OF HEALTH POLICY AND MANAGEMENT; AND DIRECTOR, CENTER FOR HOSPITAL FINANCE AND MANAGEMENT, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD**

Dr. ANDERSON. Thank you. It is a challenge.

Mr. Chairman, members of the committee, let me begin by stating that I believe in markets. Now let me qualify that statement: I believe in markets when certain circumstances are met, and unless those circumstances are met there will be distortions in the market, or even market failure.

Classic example of a market failure is a monopoly. When the Federal Government gives a pharmaceutical company a 17-year patent for a drug, the government is effectively creating a monopoly. I am not advocating removing patents for drugs, because they serve a very valuable purpose.

What I am saying, though, is it is important to monitor if the marketplace is working when the government has created a monopoly. My written statement contains numerous other examples of market failure for the prices that the Part D plans are paying.

So what do I believe? I believe, as the first step, the Congress should require the Secretary of HHS to simply collect data on the lowest price that any Part D plan obtains for each drug, and then compare it to the prices obtained by the VA, Medicaid, and Canada, and write a report.

Because the report will show relative prices, it will show where the Part D plans are paying a high price. As I said earlier, I believe in markets. But as Ronald Reagan said, "Trust, but verify."

In the report, the lowest price obtained in the marketplace by any Part D plan would be compared to the price that the VA's Secretary has negotiated with the pharmaceutical companies. Medicaid is an appropriate comparison because Medicaid has been paying for drugs for many years and has an extensive formulary.

Canadian prices are a relevant comparison, for two reasons. First, because they will show what other countries are paying for drugs, and second, and probably more important, a large price differential between the U.S. and Canada will cause a substantial number of American seniors to obtain drugs from Canada.

Without access to actual data on prices paid by Part D plans, I can only suggest where Part D plans are paying higher prices. Provisions in the MMA prevent the release of actual price data.

First, it is likely the prices for generic drugs will be comparable or even lower in Part D plans.

Second of all, I expect that Part D plans are paying substantially higher prices for drugs for dual eligibles than the prices the Medicaid program was paying before the passage of the MMA. Ultimately, the Medicare program is paying these higher drug prices because the Medicare program pays for the dual eligibles.

Third, it is likely that Part D plans are paying higher rates for many brand-name drugs. In my written testimony I discuss some of the market constraints that interfere with the market for brand-name drugs.

Finally, the fine print of the CMS actuary report shows that drug prices will continue to rise at above 7 percent per year, with Part D plans not becoming any more effective in controlling prices over time.

Negotiations are possible with an open formulary. The Secretary should start negotiating prices for drugs that Part D plans are paying when they are paying much higher prices.

Assume for a moment that the best price that any of the Part D plans could get for a drug is $10, and now assume also that the best price that the VA, Canada, and Medicaid are getting is $1.

In this case, the Secretary should begin by simply asking the pharmaceutical company to explain, why is it charging Part D plans 10 times more for that same drug? I cannot imagine any pharmaceutical company wanting to receive that call. The Secretary has other options to consider, but I would guess they would probably be unnecessary.

In preparing my written testimony, I read the editorials that have been written on this issue. As I read them, I was reminded of the Goldilocks and the three bears story and the "just right" solution.

Some editorials have proposed that the Secretary will be an ineffective negotiator because the Secretary cannot restrict the formulary. However, under this proposal, the Secretary will be negotiating prices only where the marketplace is already paying the very high prices.

Some editorials have argued that the Secretary will be such an effective negotiator that it is going to stifle research and development. However, because the pharmaceutical companies have already accepted the prices with the VA, Medicaid and Canada, that should be an acceptable starting place for negotiations.

I also find problems with the logic that, simply because the Medicare program is such a large payor for drugs, that it must pay higher prices than the VA, Medicaid, or Canada.

First of all, large purchasers never pay the highest prices. Second of all, the Federal Government is already supporting pharmaceutical research through NIH. Finally, the Medicare beneficiaries are facing a donut hole, and they should not be the ones to be asked to be the primary supporter of research and development.

Just like Goldilocks and the three bears, I am looking for the "just right" solution. In my opinion, a "just right" solution is for

Congress to repeal the non-interference clause and require the Secretary to identify places where the Part D plans are paying much higher prices. The Secretary then negotiates prices for those relatively high drugs only. A call by the Secretary may be all that is needed to conclude that negotiation.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

[The prepared statement of Dr. Anderson appears in the appendix.]

The CHAIRMAN. Mr. Haislmaier?

**STATEMENT OF EDMUND F. HAISLMAIER, RESEARCH FELLOW IN HEALTH POLICY STUDIES AND DOMESTIC POLICY, THE HERITAGE FOUNDATION, WASHINGTON, DC**

Mr. HAISLMAIER. Thank you, Mr. Chairman, for inviting me; Senator Grassley, members of the committee.

In my written testimony, which you have, I discuss the economics of negotiation in any area—I think that we may want to refer to that in the Q&A at some point—how price competition operates in the pharmaceutical marketplace, the strategies that private sector negotiators employ, and the additional options available to the government as well.

Three of my basic points are as follows.

First, it may be theoretically possible for direct government negotiation to lower drug prices further.

Second, in order for the government to obtain pricing concessions greater than those obtained by competing private purchasers, the government would have to employ tools not available to private players. Specifically, the government would have to be willing to broadly restrict market access for disfavored products and/or willing to limit or revoke the intellectual property right of producers. Of course, those actions would produce other significant economic and political costs.

Third, even disregarding those other potential costs, government attempts to achieve lower unit prices than those negotiated in the private market will not necessarily translate into lower program costs. That is because program costs are a product not only of the prices paid, but also of the volume and mix of pharmaceuticals used and prescribed.

Now, I would encourage you to think about that because, in all of the debates about pharmaceuticals, that is an extremely important point: pricing is only half the equation.

Indeed, the economic literature on the experience with government price setting, not only for drugs but other items, repeatedly finds that artificially lowering prices below competitive market levels does not necessarily reduce total costs. Rather, it induces consumers and providers to alter their behavior in ways that frequently increase aggregate costs.

Now, Mr. Chairman, I would like to now present to the committee some additional information that was not completely available as I was preparing my remarks. With your permission may I share some charts with the committee?

The CHAIRMAN. Certainly.

Mr. HAISLMAIER. In preparing for this hearing, I came across some interesting data that has been largely overlooked in this debate. The data I refer to indicate that, in fact, there appears to already be evidence that the competitive private market in Medicare Part D is significantly reducing total program costs below the levels achieved by a system of government-mandated price discounts.

If validated, it would mean that introducing into the program some new mechanism of government negotiation might actually result in an increase in total cost.

The CHAIRMAN. I am sorry, I cannot see it from here. What is the green line and what is the red?

Mr. HAISLMAIER. I am about to get to that, if you could give me a minute, Senator.

The CHAIRMAN. Sure.

Mr. HAISLMAIER. This is a little background information. The data are recent substantial downward revisions by both CMS and CBO to their estimates for State government payments to Medicare Part D. That is what we are showing.

The green is what CBO previously projected, and there is a dotted line as well. There are two projections there, very close. This year, they have significantly lowered their cost estimates. I have a similar chart that maybe we could put up for CMS which has similar reductions.

Now, a little background information to understand the significance. As you will recall, the legislation that established Part D provided that the dual eligibles—that is, those low-income Medicare beneficiaries who are also covered by Medicaid—would no longer receive their drug coverage through Medicaid, but would instead be covered by Part D, the same as other seniors.

Now, of course, under Medicare the cost of drug coverage was funded out of a combination of State and Federal payments, whereas, under Medicare Part D, it is all Federal, so in doing this the legislative drafters realized they would be giving the States a budget windfall and they sought to take that back.

So Congress included provisions that say the States have to pay the Federal Government money equal to what they would have otherwise spent on covering the dual eligibles.

That is what we have estimates of. How much do the States have to pay back to the Federal Government? These estimates have come down now that actual program costs are available. Both CBO and CMS have made substantial revisions.

Now, Medicaid, as noted, employs a mandated price discounting strategy, whereas Medicare Part D employs a competitive model of private players trying to negotiate better deals. So my hypothesis is that these changes in estimates may indicate that Medicare Part D is producing better results than the Medicaid program.

With your indulgence—I realize I am running out of time—we can go through the possible explanations. Otherwise, I could get into that later.

The CHAIRMAN. I think, in fairness to the other witnesses and Senators, we will wait.

Mr. HAISLMAIER. Fine. Thank you, Senator.

The CHAIRMAN. Thank you.

[The prepared statement of Mr. Haislmaier appears in the appendix.]

The CHAIRMAN. Dr. Frank?

**STATEMENT OF RICHARD G. FRANK, Ph.D., PROFESSOR OF HEALTH ECONOMICS, DEPARTMENT OF HEALTH CARE POLICY, HARVARD MEDICAL SCHOOL; AND COLLATERAL APPOINTMENT, JOHN F. KENNEDY SCHOOL OF GOVERNMENT, HARVARD UNIVERSITY, CAMBRIDGE, MA**

Dr. FRANK. Good morning, Mr. Chairman and members of the committee. I want to thank you for inviting me to discuss drug prices under Part D.

The drug benefit has clearly improved the lives of millions of low-income Americans by offering them a route to affordable prescription drugs that are critical to their health and their well-being.

Part D is also projected to add more than $1 trillion in cumulative spending to the Medicare program over the period 2006 to 2016, and so this raises the question of whether prescription drugs under Part D are being purchased in the most cost-effective manner.

Now, answering this question requires us to balance today's prices and spending against the future supply of innovative and potentially important drugs.

In my view, we can best think about Part D prices in terms of three market segments, and let me just tell you what they are. The first is drugs purchased on behalf of people who are dually eligible, which is about 29 percent of the people participating in Part D. The second is the drugs that face multiple branded or branded and generic competitors purchased on behalf of non-duals. The third are drugs that are unique and face little or no competition. I will discuss each in turn.

For the most part, the second group—that is, the drugs with the multiple therapeutic competitors—appear to be obtaining prices consistent with a market that is working. As a result, I think this segment of the market should largely be left alone. I will, therefore, direct most of my remarks at the other two segments.

Let me start with the dually eligible. Prior to 2006, the dually eligibles' drugs were purchased for them at the lower of the best price on the private side, or 15.1 percent below AMP, average manufacturer price. Comparing the old and the new prices is a little bit difficult, for some of the data reasons that you have raised. But we can get some important clues about this from examining the filings to the SEC of major drug manufacturers.

Major drug manufacturers that sell prescription drugs that are disproportionately used by the duals, like anti-psychotic medications, report significant reductions in the size of the rebates that they are granting during the first 6 months of the drug benefit. So, in effect, the switch has led to notable price increases for that segment of the market.

Some of the numbers reported during the first 6 months of 2006 are impressive; for example, the number that has now been cited of $325 million to Pfizer's bottom line for the same drugs and the same people.

Now, given that the drug companies appear to be making sufficient money to enter this market prior to 2006 suggests that the old prices were not hampering innovation, at least in this area. This evidence suggests that price increases stemming from the switch could be brought down without adversely affecting R&D.

Now, let me turn to the unique drugs. Competition only keeps prices down when there are competitors. In the case of prescription drugs without good substitutes, prescription drug plans, or PDPs, are in a potentially weak bargaining position.

For high-cost drugs, Part D participants are well-insured and PDPs are well-subsidized. In these circumstances, the combination of patents, the lack of therapeutic competitors, and generous insurance effectively put the patent system on steroids.

This allows manufacturers to effectively name their price, possibly at the expense of a worrisome Federal budget, yet taking action here is a tricky matter because unique and innovative drugs are exactly the drugs you want to be rewarding financially.

So how big a problem is this? Between 1970 and 2000, we were generating about three to four of these unique new drugs a year. However, we have been considerably below that in recent years—perhaps we should hope that this becomes a larger problem—but we do not yet know how big a problem this is, or will be. However, I believe the threat is real.

Therefore, I believe careful monitoring of these drugs and their prices—and I mean their transaction prices—should go ahead. Furthermore, the government should be prepared to take action if such a problem turns out to be a major one. I would suggest that this be done by considering a scheme for temporary administered prices until sufficient entry occurs to guarantee competition.

These prices should be designed to preserve R&D incentives, recognize health benefits produced by specific products, and limit economic rents paid by the Medicare program.

So, in conclusion, to address these two areas, the dually eligibles and the drugs they use and unique drugs, the government needs to have flexibility to act if it turns out they need to act.

Thank you, sir.

The CHAIRMAN. Thank you very much. Very succinct and very, very helpful.

[The prepared statement of Dr. Frank appears in the appendix.]

The CHAIRMAN. Dr. Morton?

**STATEMENT OF FIONA M. SCOTT MORTON, Ph.D., PROFESSOR OF ECONOMICS, YALE SCHOOL OF MANAGEMENT, YALE UNIVERSITY, NEW HAVEN, CT**

Dr. MORTON. Good morning. It is my pleasure to present at these hearings.

Let me plunge into the four points I would like to make. First of all, Medicare Part D is potentially so large that its prices will be average prices. One thing I just want to get across before discussing some of these harder issues is that, if you are half the market, you cannot get a below-average price.

So seeking low prices is a good goal, but thinking that seniors in America are going to get a discount is just not arithmetically

possible because seniors are now buying so many of the drugs out there. That is the first point.

The second point is, another drawback to the size of Part D is that reference pricing becomes essentially impossible. What do I mean by reference pricing? That is when you set the price of Medicare to be equal to the VA price, or the Canadian price, or 10 percent less than Kaiser Permanente's price, or something like that.

Manufacturers would prefer to raise prices to the VA than they would to sell to Medicare at a low price, and that is what they will do, they will just raise those prices. So what we do is, we harm the VA or we harm Canadians and we do not get ourselves lower prices. The reason that will not work is because Medicare is a very large market, so that is off the table.

Third, the way you get low prices in the pharmaceutical industry is by the ability to exclude drugs. What do I mean by that? You identify a few therapeutic substitutes and you essentially hold an auction. I am happy to buy any one of these cholesterol drugs. Whoever gives me the best price is the one I am going to buy from, and everybody else gets none of my business.

When you can do that, you force price competition. Even though those manufacturers may have intellectual property over that drug, you are going to force price competition among those drugs and that is how you get a low price. This is sometimes called moving market share.

So this is why some commentators have said allowing the Secretary to negotiate with drug companies, if the Secretary cannot exclude anybody, is not going to do anything.

So they phone up a representative drug firm and say, I would like you to offer a lower price. The answer is, why? You have to buy all the drugs for everybody on Medicare and so you have to buy my drug, so why would I offer you a lower price?

So unless we are going to give the Secretary the ability to announce that the price is 73 cents, I do not think you are going to get anywhere by just allowing the Secretary to negotiate, in and of itself. I do not think a national formulary is a good idea, and we can talk about that later if you would like.

So what should we do about the high prices Medicare is paying in some of these categories? I understand the feeling that we have no limit because we have insured buyers, and in protective classes we have plans that cannot exclude very well.

The thing I am afraid of is policies like: let us take 40 percent off the top; we are a big buyer, we are the government, we cannot afford this, let us just reduce prices. I think that is a terribly blunt instrument.

I think you lower prices for drugs that are delivering great value and you keep prices too high, arguably, for drugs that are useless. So, I really think that is a bad idea because we ultimately care greatly about the incentives for entrepreneurs to keep on inventing these drugs.

So how do we get the right price? Ideally, we like to use the market because we are all Americans, but the market depends on buyers having good information. I talked to you before about, the way you get a low price is deciding that three or four drugs are equivalent, and sort of holding an auction between them.

Well, how do you know they are equivalent? You have to have some studies that show that they are effective at curing the same disease in kind of the same way.

So this is where I would echo Senator Baucus's comments about the NIH being needed to do cost-effectiveness studies. What I would recommend is, if a drug is in a protected class where the plan is not allowed to do formulary management very effectively because that is what the legislation says, and we are spending a lot of money on that drug, that would be a trigger to send that drug for a cost effectiveness study to NIH. Then we could learn what was going on.

It might be that NIH concludes that that drug is no better than some others, and then plans could feel free to replace that drug with something cheaper. We might conclude that drug is fabulous and keeps people out of the hospital and saves the program lots of money, in which case we might say plans have to have that drug on the formulary.

Or we might discover that it is better for some people and not for others, and plans might be allowed to do a step therapy, start people on this drug and move them if it does not work.

So there are a variety of outcomes there. Instead of legislating a price or letting a Secretary pick a price which ultimately comes out of thin air, you would still be relying on plans to administer the market, but the plans would have better information and a better ability to do that.

Let me just say that it is not just releasing the information that is going to matter. So, for example, we could make the result of a cost-effectiveness study public, and that, of course, would do a lot.

But if that information said the drug is really expensive and it keeps people out of the hospital, do the PDPs want to cover it? Certainly not. They do not care about what happens to hospital costs. They are concerned, because they are private players and they want to make money, with keeping the drug benefit down.

So from your point of view, from the government's point of view, we really care about the interactions between drug costs, hospital costs, and physician costs. So if a drug is very expensive, and yet it saves 10 times its expense in hospital bills, we may need to give CMS the ability to mandate a drug is on a formulary so that it affects the bottom line to the taxpayer in the appropriate way.

So I think that, therefore, ideally we would like to set up an agency, have NIH have a cost-effectiveness center that is permanent, in a sense, because we care in an ongoing way about studying drugs so that we can set up the broader Medicare program cost effectively.

So, in short, I think there are a lot of options to consider. I think, like Dr. Frank, that the regular drugs with therapeutic substitutes probably do not need reform. I think we could consider loosening formulary restrictions in the protected classes because this would allow plans to create competition between drugs. Right now, those restrictions prevent that.

I would favor triggering cost-effectiveness studies to allow plans to increase competition between drugs, and at the same time rewarding really valuable drugs.

We could consider paying physicians to help enrollees choose plans. The way you compare a plan——

The CHAIRMAN. I am going to have to ask you to wrap up, Doctor.

Dr. MORTON. All right. I have one last remark, which is, we could also consider shifting the dual eligibles back into Medicaid. This would reduce the adverse selection problem and, as Dr. Frank pointed out, might save us some money.

Lastly, the *New York Times* had an article this morning about generic versions of biologics. I think that is a serious issue for the future.

Thank you.

[The prepared statement of Dr. Morton appears in the appendix.]

The CHAIRMAN. Thank you very, very much, all of you.

I would like to ask Dr. Frank to expand a little bit more on what we do about the third class, that is, those where there is more monopolistic power, and how we get at that. You suggested that maybe just a call from the Secretary inquiring what is happening might yield benefits. But how do we get at those unique drugs? It seems like the costs are way too high, in many cases.

Dr. FRANK. The evidence that is out there suggests that there are pretty big ones, and the ones that seem to have particularly high shares of users among the elderly have had quite a run-up recently. So, it is a point of concern.

As I said in my remarks, I am a little bit concerned about moving too aggressively on this because, as I noted, these are the drugs that really make a difference in people's lives. So, you have to be careful.

I think the first thing to do is to collect the data and to collect the detailed data, and to do as you suggested, have CBO, GAO, or somebody like that really look very carefully at them.

If in fact it turns out to be a problem, then there are a range of options, ranging from sort of administered prices, at least temporarily until competition takes over, to some kind of arbitration.

The CHAIRMAN. But is there a lesson here with some of the earlier HIV drugs, anthrax? Are there a couple of instances where the Secretary did jawbone? Cipro is a good example.

So is that something that might work here?

Dr. FRANK. Yes. I think that allowing yourself some flexibility, collecting data, and then allowing conversation, that certainly in the past has produced results.

The CHAIRMAN. I would like to follow up on Dr. Morton's suggestion that NIH do a much more expansive comparative analysis of the efficacy and the cost of drugs and make that information public. I would like others to comment on that suggestion. It seems to me that that has a lot of potential here. Anybody want to jump in? Dr. Anderson?

Dr. ANDERSON. Yes. I think it is also a very good idea. I think the Agency for Health Care Research and Quality already does some of that now, and their expertise could be expanded as well.

It is quite difficult to do some of that, though, because, when you are looking at a drug, you are generally looking at whether or not, for a diabetes drug, it works just in diabetics. But most of the pa-

tients, especially Medicare beneficiaries, have diabetes and congestive heart failure, and several other chronic diseases as well.

Two-thirds of Medicare spending is by beneficiaries with five or more chronic conditions. So the NIH would have to really change how it is looking at effectiveness to incorporate all the people with multiple chronic conditions in the study, and it is a very large expansion of their authority. I think it makes sense.

We have also dealt with this in the Medicare program a number of years in trying to do cost-effectiveness to evaluate new technologies, and that has been exceedingly controversial.

The CHAIRMAN. Other comments on this one point? Mr. Haislmaier?

Mr. HAISLMAIER. Let me just make one comment. I agree with the other panelists on this. It is difficult to do that. It is controversial. The reason that it is controversial is because, as Dr. Anderson noted, there are multiple variables involved.

The CHAIRMAN. Right. Right. Sure.

Mr. HAISLMAIER. So if you select out a few variables, you have a problem.

The CHAIRMAN. But you have that problem in all studies.

Mr. HAISLMAIER. Well, yes, that is true. And maybe the way to get around that, I would suggest—because private markets are doing this now—might be to have multiple competing studies of some kind so that you have a whole range of information out there. Some of that could be funded out of the government, some of that could be elsewhere, because private entities are already doing some.

The CHAIRMAN. I would like to ask about making pricing more transparent so that the organizations can do research and get on all that. I understand that, currently, the Secretary does have pricing information with respect to what beneficiaries pay to their pharmacies.

I also understand that the Secretary has available to him today the discounts, the net, the transaction prices that manufacturers pay to the plans. But I understand, further, that it tends to stop there. It stops at the Secretary's office.

My question is, would it be helpful if the Secretary analyzed the information and whatnot, if that information would be made available to various organizations, maybe even to the public, I do not know. But let us start with some organizations, CBO, whatever the organizations might be, in a way that also protects the proprietary interests that the companies have.

I further understand that currently that is not a problem with respect to Medicaid. That is, that information goes to the States under Medicaid and, I think, NLIS. I am not sure. But so far, as far as I am aware, there have not been proprietary problems in that area. I may be wrong as to exactly who has Medicaid pricing information.

But Dr. Morton, you raised your hand. If you could just comment on that, please.

Dr. MORTON. Certainly. Medicaid is not that great, actually. The best price under Medicaid is secret, to the best of my knowledge. So you can find out what the list price is, but——

The CHAIRMAN. A secret to?

Dr. MORTON. To researchers like me.

The CHAIRMAN. All right. You would like to have that.

Dr. MORTON. The prices paid by enrollees for their drugs are public because they are on the website, the Medicare website.

The CHAIRMAN. Right.

Dr. MORTON. However, in order to get a data set of these prices, it is really a hassle because you have to build a web crawler and go and collect these things, which takes a really long time. So I would advocate, given that they are public anyway, I do not see any reason why they could not be available in a database or a spreadsheet.

The CHAIRMAN. What about the other side of data?

Dr. MORTON. The other side, I would advocate not revealing. If I get a terrific price out of a company for a drug and I am a PDP, the last thing that company wants is any chance of that being made public and everybody else asking for that great price, too. Maybe for research, but it really would reduce the incentive of firms to give those discounts.

The CHAIRMAN. My time has expired, so I am going to follow up on this later.

Senator Grassley?

Senator GRASSLEY. Yes. Before my 5 minutes start, I am not going to give an opening statement. I apologize for not being here when you started. But I did want to compliment you, in your first hearing as Chairman, for taking on a very aggressive health care agenda. I look forward to working with you on that.

It is my understanding that SCHIP reauthorization is going to be a major part, so we will work together on that. Thank you.

Now, in my 5 minutes—and I would hope maybe you could do this in 2 minutes because I have a longer question for three of the panelists—I have only two questions.

So, Dr. Morton, some people think that negotiating power comes from having a large number of people that a purchaser would buy for. Number one, is that really the case? Number two, is there a point beyond which you really do not get greater purchasing power as far as what people would call a bulk rate?

Three, does it matter much whether you negotiate for 1 million people or 43 million people, as long as you use tools like formularies? What would be the case if there would be no formulary?

Dr. MORTON. So you have exactly identified the issue, that size, of course, is important. If I try to negotiate with Pfizer, I am not going to get very far as an individual. But we see quite small HMOs, like the Yale Health Plan or Kaiser, getting very good prices.

So, size quickly bottoms out, so to speak, as a way to negotiate. So the formulary is the way you negotiate, and you get a better price the better you can move market share.

So if you can promise the buyer that their cholesterol drug is going to be 100 percent of your usage and you are going to have zero market share of their competitors, that is what they want. That is what is going to get you a low price.

Senator GRASSLEY. So 1 million people or 43 million people, it does not make much difference.

I am going to start out with Mr. Dicken, but I wanted Mr. Haislmaier and Dr. Morton to comment.

Mr. Dicken, the Government Accountability Office has done some work on what would happen if Medicare got prices like those under the Federal supply schedule and had a 24-percent discount set in law.

In the GAO report of 2000, you concluded that mandating that Federal prices for drugs be extended to such large groups as Medicare could lower their prices, but increase prices for others.

This is an important point for people to understand. For the benefit of people not familiar with the GAO work, could you expand on the GAO's conclusions? I would like Mr. Haislmaier and Dr. Morton to comment.

Mr. DICKEN. Thank you, Senator Grassley. As you note, several years ago, before the implementation of Medicare Part D, GAO looked at some considerations if prices under various other approaches were expanded to larger populations such as Medicare. Certainly, one of the considerations is the potential for increases for some purchasers or decreases for other purchasers such as Medicare.

One of the things that we highlight in the 2000 report, as noted, is the experience when the Medicaid "Best Prices," which have been referred to, were implemented. Within 2 years, we noted in our earlier work that the best prices for commercial payors, which were the basis for that, had risen so that the rebates that were available to Medicaid under the best prices were at that minimum level. But there are a number of other factors.

There is some uncertainty as to what the effects would be for specific drugs, but there are some considerations as to whether the prices would change for some purchasers or others.

Senator GRASSLEY. Mr. Haislmaier?

Mr. HAISLMAIER. Thank you, sir. I think that Professor Morton actually really touched on that point when she noted that, because of Medicare's size in this market, it becomes, de facto, the average price. You really get into a mathematical question, and that is, everyone cannot get a below-average price. So what the effect will be is to drive it to a single price, really, for all markets.

In fact, to be critical of the industry, I think if I were in their shoes I would be looking at single pricing for all my markets right now, because in the Internet age when people can do price comparisons, the idea that you can charge one customer one thing and another another, I just do not see it working as well as it used to.

So, I think that will be the effect. It will, yes, raise prices on the outside, maybe, but in the end, as Dr. Morton points out, it drives to a single price for everybody.

Senator GRASSLEY. For small business and for individuals? It drives up the price for small business and individuals?

Dr. MORTON. It would drive up everybody else's prices, yes. So the 24-percent discount is off of something. What is it off of? Usually an average private price. As we move more and more people into purchases being paid for in some way by the Federal Government, the private sector is shrinking.

So, those poor guys. If we have 50 percent of the market that has to get a 24-percent discount, what happens to everybody else's

prices? They are up here, right, in order that the bulk of the market gets the price that the industry wants. So that is just going to raise prices for everybody else, so I think it is really a bad idea.

Senator GRASSLEY. Thank you, Mr. Chairman. Thank you.

The CHAIRMAN. Thank you, Senator Grassley.

Senator Bunning, you are next.

Senator BUNNING. Thank you, Mr. Chairman. I really appreciate this hearing, because it is very important with where we are at with Medicare Part D to have the distinguished panel that we have in front of us.

I assume the goal of requiring HHS to negotiate for drugs is that some think it will save money, obviously, therefore, for the government and the beneficiary.

However, CBO says that on several occasions, including yesterday, that removing the non-interference clause would have negligible effect on Federal spending because HHS would not be able to negotiate any better than the drug plans. I would like someone—whoever—to comment on this. Go right ahead.

Dr. ANDERSON. Thank you very much. I read the CBO report, and I recognize that CBO is very data-driven. I agree with Senator Baucus that CBO should get the information as to the prices that the private sector is paying for drugs and comparing it to the prices that the VA and other places are doing.

Senator BUNNING. Are you telling me that CBO is uninformed about any prices?

Dr. ANDERSON. CBO and CRS do not know the prices that the Part D plans are paying.

Senator BUNNING. They do not?

Dr. ANDERSON. They do not.

Senator BUNNING. Then how could they comment at all?

Dr. ANDERSON. Well, because we can estimate what the prices are. But my opinion is that they should be given the information as to what the Part D prices are.

Senator BUNNING. Is there anybody else on the panel that has a different opinion? Go right ahead.

Dr. FRANK. I do not know if it is different.

Senator BUNNING. Variety.

Dr. FRANK. I think the issue here is, there is a tendency to rely on theory here about how things ought to work, and I think there is a lot of opinion here that is being driven by that. I think we need to look at the data, so I agree with Dr. Anderson's comment.

But at least on the Medicaid dual side, the evidence reported by the pharmaceutical industry suggests that, in fact, the prices have gone up for the same people for the same drugs, so we need to get to the bottom of that because that may tell us——

Senator BUNNING. That is, on the average, for dual eligibles?

Dr. FRANK. That is for sets of drugs that are heavily used by those people.

Senator BUNNING. But not for the recipient.

Dr. FRANK. Not for the recipient, for the government.

Senator BUNNING. Oh. All right.

Dr. FRANK. Right. And so the question here is, if that is the case, what is it that is keeping us from using negotiating power to get close to that price? So, really, it is a data question.

Senator BUNNING. All right.

Number two, not many of us in this room have participated in drug pricing negotiations. How critical is it for the negotiators to be able to walk away from the table, first of all? Do you think it would be likely for Medicare to walk away from the table? If not, then what would the outcome be? Dr. Morton?

Dr. MORTON. I do not think it is likely that Medicare would walk away from the table unless we are ready to make a national formulary, which I think is probably inadvisable. If we are not going to walk away from the table, then all you can do is jawbone: you know, I would really like it if you could sell at lower prices. But I do not put a lot of faith in that.

Senator BUNNING. Or else?

Dr. MORTON. Or else nothing.

Senator BUNNING. Or else nothing.

Mr. HAISLMAIER. Senator, I covered that in the beginning part of my written testimony on the economics of negotiation. It is well understood in all areas of negotiation that what matters is not so much size or anything else, it is, what is your alternative if negotiations fail, and how good is that? What is that best alternative relative to negotiation?

Senator BUNNING. Well, if there is an alternative——

Mr. HAISLMAIER. That is the point. I think Dr. Morton and I would agree that the only way—and this is why CBO is not scoring it—is if the Secretary has another alternative and can walk away from the table and say, that is not good enough, I am going to do this instead.

Senator BUNNING. In other words, more information that CBO and/or HHS might have as an alternative to the current formulary or the drug that they are using?

Mr. HAISLMAIER. It is not so much more information, it is an alternative action. Each alternative action has a cost and benefit.

Senator BUNNING. All right.

Mr. HAISLMAIER. So the VA can say, look, you do not give me what I want, your drug is not on the formulary and you can forget it.

Senator BUNNING. We do not put it on.

Mr. HAISLMAIER. That is my alternative action.

Senator BUNNING. But then there has to be another drug that can be used for the same effect.

Mr. HAISLMAIER. There does not have to be.

Senator BUNNING. Well, if we want to help the patient, there does.

Mr. HAISLMAIER. Well, again, that then becomes a cost associated with your other alternative that you have to take into consideration. Will this mean that patients will come banging on my door? I mean, that is why Congress, for example—you cannot just hand this off to HHS. This will come back to you. That is part of the cost.

So if the alternative is to say, well, you are not going to get the drug, and then people come and say, well, wait a minute, I want the drug, I am going to have it excluded, well, there goes the Secretary's leverage.

Senator BUNNING. Thank you very much.

Mr. HAISLMAIER. In any negotiation, you have to have an alternative.

Senator BUNNING. Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Dr. Anderson, as you heard earlier, I am for markets, I am for Medicare being a smart shopper, and I am against price controls. Now, particularly under the approach Senator Snowe and I are talking about, simply saying in carefully described circumstances when you have a monopoly drug, when you have a drug developed with taxpayer money, would it not change the psychology of the marketplace for folks to know that, in those kinds of instances where there may not be some bargaining power, the Secretary might step in?

Now, in doing that, we have stipulated that there cannot be, Dr. Morton, any price setting. Nobody can say 73 cents a pill. Senator Snowe and I specifically bar price controls or setting up a national uniform formulary. But we do say that in certain limited instances, that kind of bargaining power in those instances I described could change the psychology of the marketplace.

What is your assessment of that?

Dr. ANDERSON. I do not think the Secretary can negotiate on 4,400 different drugs. I think the Secretary, however, can negotiate on a limited number of drugs each and every year.

If he or she has the information saying, how much does the VA pay for this, how much do other organizations pay for this, they can go right to the top of the list and say, well, this one is 10 times more than in the marketplace or that the VA is getting. Why is that?

The Secretary has a lot of things that he or she does with the industry besides just buying drugs in Medicare, and so does the committee here have a lot of things that it deals with with the pharmaceutical industry.

So when the Secretary or when the Chairman of the Senate Finance Committee calls and says, we have a problem with the price for this drug, I think they are going to listen.

Senator WYDEN. I cited Cipro in my opening statement, and Chairman Baucus did as well. So we can be clear on that, that was a pretty stark example where the Secretary did not come in and say, I am going to set up a national uniform formulary, I am going to ravage the private markets. He basically just said, let us talk. Is that not correct?

Dr. ANDERSON. That is what he did, and he paid half the price that he originally had to pay, which I think is a pretty good deal. That was something that was a monopoly.

Senator WYDEN. Mr. Chairman, because time is short, I would like to also put into the record, today we took off the website a list of drugs developed with a significant amount of taxpayer money. It came from the National Institutes of Health. I am going to try to get a quick question in for Dr. Anderson on that. Could we put that in the record?

The CHAIRMAN. Without objection.

[The information appears in the appendix on p. 192.]

Senator WYDEN. Staying with, again, the example, Dr. Anderson, of no price controls, but having the opportunity to talk and bargain, does it not make sense to do that in an instance like Taxol, this breakthrough drug that has brought billions of dollars in, and most of the work was done in government laboratories?

I thought Dr. Frank made a good point with respect to, we want to make sure we do not disincent the development of those drugs, but again, why should the government, in something like that that is so important to American women, not at least have the opportunity to talk?

Dr. ANDERSON. You just doubled the NIH budget over the last number of years. One of the reasons why you doubled the NIH budget was to get new research. One of the outcomes of new research is new drugs, so Taxol is a perfect example of the impact of doubling the NIH budget and getting new drugs there.

So you, the Congress, have invested a lot of money in NIH and drug development. I think one of the things that you should do is get a return on your investment. One of the things is, you create a monopoly, and now you have to make sure when Part D is negotiating in a monopoly, that it is able to pay a fair price.

Senator WYDEN. My time is up. I would just say to colleagues, particularly to those on the other side of the aisle, Senator Snowe and I voted for this program. I have the welts on my back to show for it, as my friend from Oregon knows. We want to make it work. We want to keep the basic infrastructure in place.

But we do think there is an opportunity to get a better value for seniors and a better value for taxpayers by making sure that there is some additional bargaining power, the kind of thing Dr. Anderson is talking about with respect to the marketplace that can make a real difference. We are hoping that we can work with colleagues on a bipartisan basis to do that, and look forward to our next round, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator.

Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman. Thank you. Thank you to everyone. I have many more questions than 5 minutes will allow, so I will be quick.

First, to follow up on Senator Wyden's comments in terms of the public. Dr. Anderson, when you spoke about the public investment, I think that is such an important point for us to look at. From the Pharma website, they have indicated $39 billion in R&D in the last year, $29 billion on the public side for NIH, plus the R&D tax credit, plus deductions, plus the patents, and so on.

So we, as taxpayers, have placed a major investment because it is so important. R&D is critical. It is critical to lifesaving drugs, so we have put a lot into that, and taxpayers have a real stake in that and have supported the industry to be able to do that. I think that is just important to say for the record.

In terms of pricing, we know that there was a report released this week that found that the lowest Part D plan prices are, in fact, significantly higher than the VA. And I am not suggesting we just take the VA approach, but there is a huge variation.

The median difference between the lowest Part D plan and the lowest VA price was 58 percent, and in some cases up to 1,000 per-

cent. So I would just contend that there is a lot of room there to negotiate in these prices.

But one area I wanted to specifically ask you about, it was interesting. Dr. Morton, you spoke about the fact that one area to save money would be dual eligibles. I know, Mr. Haislmaier, you spoke differently, but three panelists have spoken about dual eligibles. Dr. Frank, you said the same thing, and Dr. Anderson.

We know from not only testimony today, but we have had a *Wall Street Journal* story about the drug company profits under Part D. We have a *New York Times* story about drug companies raising prices on the top-selling drugs as Part D went into effect and there has been a shift in the market. Now we see the concern about moving from Medicaid, where there was negotiation.

Our State has done a very, very good job on that, as well as group purchasing with other States under Medicaid, to get very good prices now to Medicare.

I guess I would start with Dr. Anderson, then if the others would like to respond as well, about dual eligibles. It seems to me we have a clear situation here now where States are negotiating and Medicaid did one thing, and we now take up dual eligibles under Medicare and have seen, in general, higher prices. I think Mr. Haislmaier has a different testimony.

Dr. Anderson?

Dr. ANDERSON. Thank you very much. First of all, NIH is the crown jewel of the world, and we really sponsor much of the research in the world, so we should then pay reasonable prices in the world for drugs. Right now we are paying, generally, the highest prices for drugs in the world, yet we sponsor most of the drug development.

In terms of comparison of Medicare and Medicaid prices, Medicaid prices are generally much lower than the best price that the PDP plan has been able to obtain. As a result, the fact is that you, as the Congress who pays for the dual eligibles, are the organization that is paying those higher prices than before.

I agree with Dr. Frank that, if you look at the 10Qs and 10Ks, you see some evidence of that. But more importantly, if you look at the numbers that the GAO has put out and the CBO has put out comparing the best prices that the Medicaid program and the best prices that the private sector gets, the private sector is not getting as good a price for many drugs as Medicaid is getting.

Senator STABENOW. Dr. Frank, you spoke about that as well. I am running out of time, and I would welcome everyone here to respond, but I did particularly want to hear from you about that.

Dr. FRANK. The question is, there are sort of two parts, I think, to the question that underlies this. One is, are the Medicaid prices for the drugs that we know about set at a reasonable level in terms of, are they consistent with encouraging new investment and bringing on new drugs, particularly for things like anti-psychotic medications, which are very important to the dually eligible? And my impression is that the answer to that is yes.

So then the question is, if, then, we are taking that price and raising it above the level that is sufficient to bring in investment, that is an indication that we may be paying too much and so that is something to look at.

Senator STABENOW. Mr. Haislmaier, do you want to respond?

Mr. HAISLMAIER. Yes. Thank you for the opportunity to comment on that. I was one of the people who argued—and in fact, practically up until yesterday, literally—that I thought dual eligibles ought to be put back in Medicaid. I said that back in 2003, and I have held to that. I have had to rethink my position, simply because I have looked at the data.

The data, as I presented, shows that the cost—remember, cost is a function not only of price, but of a lot of other things, volume, mix, et cetera. The cost is down, according to CBO and CMS, by 22 to 25, 26 percent. In fact, I just literally got additional data after I had done this chart last night that shows it is even lower.

So the question in my mind is, well, why is Part D now spending, in effect, less on the dual eligibles than Medicaid was? So I thought, well, there are some explanations. One, it could be a difference in enrollment. But that does not seem to be the case, because we simply transferred everybody over. All right.

Maybe there is decreased access to drugs. But we know that is not the case, because actually some of the Medicaid formularies were pretty restrictive, and Part D is not. So maybe it is more cost sharing by the beneficiaries. But we put in all these low-income subsidies, we have a 100-percent premium subsidy, very little cost sharing, no donut hole. So I am running out of explanations.

So what did I come up with? Well, I think, as I said, this really has to be looked into more closely, but I think what is going on is, under a price-mandated discount system, there is all sorts of gaming that goes on. In fact, some of that, I think, was reflected in the *Wall Street Journal* article about a company that used to manage these drugs.

The CHAIRMAN. Senator, your time has expired. Thank you.

Senator STABENOW. Thank you.

The CHAIRMAN. Thank you very much.

Mr. HAISLMAIER. So there are some other explanations.

The CHAIRMAN. Thank you.

Senator STABENOW. Thank you, Mr. Chairman.

Mr. HAISLMAIER. Thank you, Senator.

The CHAIRMAN. Thank you very much.

Senator Salazar?

Senator SALAZAR. Thank you very much, Senator Baucus, for holding this very important hearing on a very important subject.

I approach this, first, as the most freshman member of this committee and not having been here when Medicare Part D was passed. I think Medicare Part D is an important program and something we need to support, and something where we need to figure out ways of making it better.

But for me, the striking reality is, when you look at the prices that VA and the Department of Defense are paying for drugs versus what it is that we are paying under Medicare Part D, it is incredible to me that we can say, well, I guess that is all right; maybe because of the size or the bulk that we are purchasing here for Medicare Part D, it is not going to make any difference.

So I guess my question to Dr. Anderson and to Dr. Frank—because it seemed to me that you were both advocating the repeal of the non-interference clause in negotiation, perhaps, for certain

unique drugs—is whether we would see the same kinds of results and savings that we have seen for the Department of Defense and VA.

Somebody gave me a copy of the report that Families USA did, where they actually came up with drugs that I think, for all of us who have elderly parents in our families, know too well: Lipitor, Plavix, and Zocor.

But you look at all those drugs and there is a 58-percent difference between what is being paid by DoD and the VA on the one hand, and what we are paying here for Medicare Part D.

So my question to you, as advocates of doing something with this non-interference position in Medicare Part D, is would we see these same kinds of cost savings if we were to repeal the law or to change it in some way?

Dr. ANDERSON. I am not sure that you would get exactly, nor would you necessarily want to, the same prices that are gotten by the VA or by DoD, but I think what you want to do is to look at the prices that DoD and VA are getting and compare it to the best price, the best price that the marketplace is able to get. Then that informs this committee, it informs the Secretary as to how good a deal is the private sector, in fact, receiving?

If we knew how good a deal the private sector was receiving compared to the best price that the VA is getting, then you would be able to see whether a negotiation on a particular drug is necessary or not. But without that information, we are all talking theory here.

What we need is to have CBO and everybody have the information. Then I think the Secretary does have a lot of bargaining power, because not only is the Secretary buying drugs, but he is regulating drugs, he is doing a whole variety of other things.

So the bargaining power that the Secretary has, if the Secretary chooses to use it—and I gather that Secretary Leavitt is not choosing to use it—they would have great bargaining power.

Senator SALAZAR. Let me ask you this question to push you a little bit more during my time. That is, so if you were to give that kind of authority to the Secretary and the Secretary then were to be able to make the comparison and find out that there is a 58-percent difference or some other difference, would it not then be appropriate for the Secretary to use the power vested in the Secretary that we would give the Secretary to go out and negotiate for prices, for example, some of the drugs that are listed in this list of 20 here?

Dr. ANDERSON. Yes. I think he or she would probably be negotiating on some of those. I would suggest you start at the top of the list where the prices that the Part D plans are getting are the worst and work your way down.

Senator SALAZAR. So you are saying, first we have the information, and if that information shows something, then the negotiation could take place.

Dr. ANDERSON. Then allow them to negotiate. Right.

Senator SALAZAR. How about you, Dr. Frank? What do you think about that conversation?

Dr. FRANK. As I said, I think on the unique drugs, I think there currently are very few breaks on the prices there. People are well-

insured. The plans are well-subsidized and there is very little bargaining power. So I think that allowing for some negotiation there is a reasonable thing, but certainly information first.

The second thing is, I just want to note that I do not think the VA would be the benchmark that I would ever choose, and there are a variety of reasons that we do not have time to get into.

The CHAIRMAN. Can you just tell us, in one sentence, why?

Dr. FRANK. Well, first of all, the way things are delivered, the way things are assembled, purchased, and administered are so completely different from the way they are in Medicare, that those basic prices are just very hard to compare.

Then I have no belief, necessarily, that those are the "right" prices that are consistent with that balance between encouraging new drugs and getting our budgets under control.

Dr. MORTON. Could I answer your question, just for 30 seconds?

Senator SALAZAR. You have 3 seconds.

Dr. MORTON. All right. If you cause the Secretary to look at VA prices and make that the basis for negotiating Medicare prices, VA prices will go up. I would imagine, tomorrow, VA prices will be higher because of the focus in this hearing on them.

If you think about a tiny little buyer who is the government, you give them a little break, fine. If it is everybody you are selling to because it is Medicare, you cannot recoup that. You cannot fund R&D out of those low prices, so you just will not give them.

Senator SALAZAR. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Roberts?

Senator ROBERTS. Thank you very much, Mr. Chairman. I want to thank the panelists.

Mr. Chairman, I have a very brilliant, comprehensive, and pertinent statement that I would like to insert in the record at this point.

The CHAIRMAN. We want to hear it. [Laughter.]

Senator ROBERTS. Well, my time is your time, sir. [Laughter.] I do not have enough time to do that.

The CHAIRMAN. It will be included.

Senator ROBERTS. All right.

[The prepared statement of Senator Roberts appears in the appendix.]

Senator ROBERTS. I just want to go on on this VA business. I think it has been pointed out that the VA drug program does restrict patient access to medicines and relies on a very limited number of VA pharmacies or mail order. That has been said before and I am simply repeating it.

But it is estimated that the VA formulary or the drug list contains only 38 percent of the drugs approved in the 1990s and 19 percent of the drugs approved since 2000, and, in addition, nearly 80 percent of the prescriptions in the VA program are distributed through the VA mail-order system.

That is not going to work in Dodge City, KS or Billings, MT. It just is not going to work that way. I do not think any community in America, or any senior citizen, would certainly welcome any limited access to their necessary medicines.

What I would like to basically ask, if I can get past this very brilliant statement, Dr. Morton, in your testimony you mention you are concerned with Medicare getting in the business of reference pricing because, as you have said before and now we have talked about it a lot, Medicare is such a large purchaser, you mentioned that such an approach to controlling prices harms other consumers of pharmaceuticals in the U.S. by potentially leading to higher drug prices in the private sector.

You suggest in your testimony that if the Secretary were to negotiate—and that is an interesting thing to me—I do not know how the Secretary is going to negotiate, other than smothering people with the milk of human kindness and then asking, "please."

I do not know what clubs the Secretary is going to use. I am used to clubs in regards to the Secretary of HHS, more especially with our hospitals and other health care concerns in the rural health care delivery system, and I do not particularly want to go down that road. But at any rate, he would have to rely on a national formulary to achieve the best bargaining leverage.

You then go on to state, this process of choosing which drugs would be excluded from the national Medicare formulary would become dominated by stakeholders such as manufacturers and patient advocacy groups.

Well, 60 percent of the small businesses in Kansas do not have any health care plan. In another committee, the Health Committee, Senator Enzi has a small business health care plan, and we came pretty close.

But one of the real concerns was that virtually every patient advocacy group—and I certainly do not blame them—said, hey, we want to be part of a comprehensive plan. Whoops! The small business cannot afford it, so they said, we want a lower-cost plan, or a bare-bones plan, or whatever you want to call it.

And so I just want to highlight this for my colleagues. I want to raise an issue here that may be sort of a curve ball here, but as a member of the Senate Ethics Committee, and as the Senate is currently debating an ethics reform package which I considered an oxymoron, but that is another whole subject, can we imagine opening up the Medicare prescription drug program to one dominated by one who can hire the best lobbyists to get their drugs on the formulary?

I think that that might happen, rather than the drug plan as it currently works, which allows seniors access to the drugs they need at whatever affordable cost they determine.

So would you elaborate on what you think such a process would look like? Because if you are going to give a break to one group, you are going to cost another group.

Dr. MORTON. So I think a national formulary is a poor idea. What we have instead, which is plans which offer different kinds of formularies, makes more sense. So if you are a senior who does not mind being restricted to one cholesterol drug and not having a choice between four of them, you sign up for a plan that is cheaper.

That plan can get you a cheaper drug and you can save money by being willing to be restricted. If you do not like being restricted, you have to pay more. That is, I think, a very nice way of allowing

formularies to exist and getting cost savings to people who want cost savings, and allowing some choice for people who care about that choice.

I think the negotiating, the "milk of human kindness" part, is exactly right. That is why I advocate having some kind of trigger that sends drugs out for a cost effectiveness study. That is the hammer. You say, look, we are really going to find out how good you are, and if you are good we will pay you, but if you are not good we are not going to.

Senator ROBERTS. Well, we will call that the Baucus plan. I have yielded back two seconds.

The CHAIRMAN. Thank you, Senator. I am still waiting for that statement, but we will get it. [Laughter.]

Senator Kyl?

Senator KYL. Thank you, Mr. Chairman.

First, I would like to ask some questions for the record, if that would be agreeable, since I will not have time to be here for a second round. I am going to have to go to the floor.

Second, I would like unanimous consent to put in the record a story appearing in the *Washington Post* this morning, and also an editorial by Secretary Leavitt.

The CHAIRMAN. Without objection.

[The article and editorial appear in the appendix on p. 164.]

Senator KYL. Third, it seems to me we have learned some lessons here. For example, when you supply over half of a product, it is hard to beat the average price. We appreciate that basic lesson.

Also, one of my colleagues made a comment, my friend from Oregon, that we need to be smart shoppers. He talked about buying toilet paper one roll at a time. Now, is this the way that PBMs—and anybody can answer this—negotiate for drugs?

Dr. MORTON. No.

Senator KYL. All right. Thank you.

Now, this is one of the lessons that I get out of this, that while there are a lot of different factors, a pretty basic bottom line here is that the best price is usually based on a monopoly use.

In other words, when you sit down and negotiate, you either have the carrot of saying to the person with the company you are negotiating, we will give you the monopoly use if you will give us a really good price, and the stick of saying, and if you do not, assuming there is a competitor, we are going to go to your competitor and he is going to get exclusive use. We agree on that. All right.

Would the record note nodding of heads in the affirmative.

Dr. ANDERSON. Let me interrupt for a moment.

Senator KYL. Sure. Dr. Anderson?

Dr. ANDERSON. As long as there is, in fact, a drug that is a competitor.

Senator KYL. Yes, indeed. Of course, that gets to the question of, if you only have one choice, you are going to be effective in negotiating, assuming people want that choice and you want to be able to provide it to them. So, thanks for that.

So it seems to me then, with this factor really being a key driver of negotiating power, that one of the things we could expect is, if this were the model, that patient choice would be dramatically re-

duced and in some cases would be eliminated altogether. Is that also a general proposition that you can derive from this?

All right. Again, nodding of heads.

Now, it seems to me, therefore, that there are two models. There is a government model——

Dr. FRANK. I do not think we were nodding as enthusiastically as you think. [Laughter.]

Dr. MORTON. Usually there is a medical exclusion.

Senator KYL. All right.

Dr. MORTON. So there is one cholesterol drug, but if I am allergic to it, I get to use another.

Senator KYL. Please understand, in, now, 3½ minutes, I am trying to speak in relatively broad terms here.

But we have two models here, and this is what I am getting at. We had a choice when we developed the Medicare Part D. We could go with the government-dominated model or we could try a model that uses a bunch of competitors, these pharmacy benefit managers, all of whom have incentives to beat each other to get to the lowest price.

Yet, the end result is this, it seems to me. Correct me if I am wrong. If you have the one government situation, you have made a decision for everybody: this is the drug you will use, and we have gotten you a good price because we excluded all of the others.

But if you have the pharmacy benefit manager concept with a variety of companies being supplied the drugs in a market which offers lots of different plans—companies for some drugs but not for others, and other companies having negotiated the lower price for other drugs, and they put all of these into insurance packages and offered them on the market with the result that the purchasers get the benefit of both lower price and choice as a general proposition.

Would anybody like to comment on that? Dr. Morton?

Dr. MORTON. Yes. So for these drugs with substitutes, that is exactly right. We have to be careful not to make the error of looking at the prices in a plan that has negotiated hard for Drug A, looking at their prices for Drugs B, C, and D that are substitutes, because those will be very high. So, that is exactly right.

The problem is, there are six protected classes in which plans are not allowed to do these kind of aggressive cost comparisons, and there they have much less negotiating leverage. I believe that to be a significant problem, because that is where all the duals are. Those classes are where all the medications are that the really sick people take.

Senator KYL. And I take your point that that is one of the areas we might want to look at. For political reasons—I should not say political—there was a real choice to make, whether we have a separate Medicare program with the dual eligibles or back to Medicaid. We made a choice, and we understood there were benefits and problems with that choice. But that is something that probably does bear looking at again.

I guess my time is up. But if Dr. Frank would like to comment, is that all right?

The CHAIRMAN. Yes, but very briefly, if he wishes to.

Dr. FRANK. I just want to offer a friendly amendment to Dr. Morton's comment, which is, I think there are good reasons why we have protected classes, because a market does not always work.

It is well known that if we were to unprotect, say, the anti-psychotic drugs, the last thing you want to be is a good anti-psychotic drug bargainer, because all the people with schizophrenia and multiple complicated illnesses will flock to your plan and you will lose money.

Senator KYL. And, Mr. Chairman, everybody will flock to us if we start to undo that kind of thing, which is the other problem of having to make these limiting choices. Thank you all very much. A very, very good panel.

The CHAIRMAN. Thank you. Thank you, Senator, very much.

Senator Snowe, you are next.

Senator SNOWE. Thank you, Mr. Chairman. I thank you for holding this hearing at the outset of your chairmanship, because it is a crucial issue.

Senator Wyden has indicated we have introduced legislation once again this week. I think this debate, not just here but throughout the country and in Congress, about the question, well, it has to be an all-or-nothing proposition, that in order to have price negotiations on the part of the Secretary, it either requires a restricted formulary or price setting.

That is why Senator Wyden and I were very careful to draw and craft a middle ground in which we do prohibit price setting and restricted formularies. What we are attempting to do is to get at some of the issues in the course of implementation. It does not have to be an all-or-nothing proposition.

First and foremost, if you look at the overall industry—and I know, Dr. Morton, you were referring to that about the R&D and having an impact on research and development—it is interesting to note that the industry, when you compare it to other industries such as computer software and cell phones, they have invested 14 percent of their revenues in R&D.

Their products have declined and there has been very competitive pricing. Now you look at the largest 12 pharmaceutical companies. They invest 14.7 percent, and their products are increasing at 2 and 3 times the rate of inflation.

So there is an issue at hand here. We are not seeking an approach that is going to impact research and development. I would suggest that it is not. In fact, they are benefitting from very high profitability—in fact, 3 times higher—than most industries in America when it comes to profits.

The GAO issued a disturbing report in November, stating that from 1993 to 2004, despite inflation-adjusted increase in investment of 147 percent, the number of new drug applications rose only 38 percent, and it was not because of a lack of capital. So I think that it is important to keep that in perspective as we examine the issue.

Then you get to the Part D implementation. What are we concerned about? It has not been fully implemented yet. We have not gone through a full year of implementation to see the true cost. That is a concern. Not all low-income seniors are on the program, for a variety of reasons.

We are seeing premiums going up at least 10 percent. Donut hole coverage is diminishing, and that is going up. In fact, Maine is one of three States that does not have donut-hole comprehensive coverage; now that is up to 11 States. Out-of-pocket costs have increased.

So then you think about the fact that drug prices are going up 2 and 3 times the rate of inflation. CBO projected that the cost of the Part D would be 8.7 percent back in 2003, and we are now up to 10 percent increases in the premiums, and so on. So, we are looking at all of that.

So what can government do to get a better price, to be a smart shopper, as Senator Wyden said? So that is why we delineated certain criteria and conditions under which the Secretary can use the power of the podium and that leverage.

I mean, there will be instances where, frankly, the plans might need the assistance of the Secretary in order for the pharmaceuticals to negotiate in good faith. So we are not just talking about restricted formularies. In fact, we are not talking about it at all.

What we are talking about here is being able to seek discounts. That is not unusual in business today. In fact, my staff did comparison shopping of retail drug pricing in Maine of the 24 drugs most used by seniors in this plan for 2 weeks, all throughout Maine. They compared CVS, Rite Aid, Hannaford, Miller Drugs, Wal-Mart, everybody. It was interesting. On average, they had an 11.9-percent advantage.

Now, seniors are facing a $38 monthly premium, so obviously their premiums are going up. But if you use Costco or drugstore.com, you can get almost the same discount, comparatively speaking. They do not use a restricted formulary.

So I would like to have Dr. Anderson speak to this question, Dr. Frank, and any of the panelists on this question. Is there not a way in which the Secretary can play a pivotal role, whether it is the power of the podium and leveraging in certain instances and that it does not require an all-or-nothing, you have to set prices or have restricted formularies, when, in fact, Costco and drugstore.com do not use a restricted formulary to achieve discounts? Why should it be any different for a public program such as Part D that is one of the single largest social programs we have in America?

Dr. ANDERSON. What I think you do is, you allow the marketplace to work when the marketplace is working. Probably most of the drugs, the marketplace is working just fine. I think you step in when the marketplace is not working when, because of patents, because of a variety of factors, the marketplace is not working and we need to jump in. I think your bill does exactly that.

Senator SNOWE. Dr. Frank?

Dr. FRANK. I agree. I think that targeting the trouble spots, using information, putting it on the table, shining a light on it, the government has lots of influence, lots of tools and has a lot of interaction with the industry, so I believe that there is some negotiating power there. It does not have to be all or nothing. In fact, I would agree with you that it should not be sort of relying on national formularies in order to accomplish these ends.

Senator SNOWE. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Hatch is not here. Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

If I could just ask each of the panelists a question, if you could just give me a simple "yes" or "no" answer, that would be very helpful. I know that not everybody here is an economist, but do you believe that functioning markets require transparency?

Dr. MORTON. If the market is already functioning?

Senator CANTWELL. No, just in general. In general, for a market to be functioning, does it need a certain amount of transparency, yes or no?

Dr. MORTON. Yes. But——

Senator CANTWELL. We will get back.

Dr. Frank, yes or no?

Dr. FRANK. Yes. But——

Mr. HAISLMAIER. Yes. But——

Dr. ANDERSON. Yes.

Senator CANTWELL. Thank you.

Mr. DICKEN. Price transparency is important for lots of different——

Senator CANTWELL. Can you just answer "yes" or "no?"

Mr. DICKEN. Yes.

Senator CANTWELL. Yes. All right. Great. So everybody is "yes", with a few "yes, buts."

Do we have enough transparency in this drug market for the government, yes or no? Then we can get into the whole discussion about the buts, ands, or ifs. Is there enough transparency now for this to function?

Dr. MORTON. Not on the effectiveness side.

Senator CANTWELL. Dr. Frank, yes or no?

Dr. FRANK. Probably not.

Mr. HAISLMAIER. Yes.

Dr. ANDERSON. No.

Mr. DICKEN. I cannot comment on that.

Senator CANTWELL. You cannot respond to that? You do not have an opinion or you do not have enough information to know?

Mr. DICKEN. We would have to give more thought to that and would be glad to follow up with you.

Senator CANTWELL. I think that is really what everybody is saying. At least that is my opinion, I think people said it best. We had the debate. There was one proposal that was under Medicare. It lost. Now we are saying we have a market. But do we really have a market if we do not have transparency?

Having chased the dysfunctional western energy crisis electricity market where there was not transparency, we saw how wrong markets could go. So the question seems to me, what level of data are we comfortable in having access to so that we know we have a functioning market?

So, Mr. Dicken—and I want people to have a chance—but I do not know that you looked at PBMs specifically on their data. Is that true? Did the GAO look at the effectiveness of PBMs?

Mr. DICKEN. Not in the Part D market. In the past we have looked at PBMs in the Federal Employees Health Benefit Program and looking at the role that they have played, both in negotiating

discounts, rebates, and other cost-containment tools, as well as the money that they have retained through some of their cost-containment negotiation efforts.

Senator CANTWELL. Because in 2003, the State of Maine passed a law that required companies doing business in the State to disclose their financial agreements with drug manufacturers.

So, under the law, PBMs do not have to make information on payments public, but they must disclose this information. They do not make it public; they disclose it to their clients. So this was upheld in the U.S. Appeals Court, and the Supreme Court has said it is not going to make a decision on it. So we at least have some States doing this reach to try to get the transparency that will make these markets function.

Dr. Morton?

Dr. MORTON. I do not think you need to know the cost of your automobile maker's—I do not need to know Ford's costs when I buy an automobile, and that is because I can compare a Ford car to a Chevrolet car, to a Toyota.

Senator CANTWELL. Right. Your web crawler analogy.

Dr. MORTON. If I am an employer in the State of Maine and there are a bunch of PBMs there, I do not care what they are paying for drugs. I care how much they are going to charge me for an equivalent benefit.

And how they choose to reduce their own costs is, I would argue, their problem. So I think we should strive for that goal here. That is to say, make sure consumers are presented with effective competition across plans. Plans are going to try hard. It is in their best interests to lower their acquisition costs, so we need to give them the tools to do that and make sure that consumers can choose between plans and understand the differences across them.

Senator CANTWELL. And the transparency.

Dr. Anderson, did you want to respond?

Dr. ANDERSON. I think it is important to know the prices that the drug companies are charging the different PDPs and other Part D plans so that we can compare the prices. So let the marketplace work, and when the marketplace fails, we should know it and we should intervene.

Mr. HAISLMAIER. Senator, I concur with Dr. Morton. To follow up on that analogy, it is not essential for the market to function for me to know what GM paid its supplier for a carburetor versus what Toyota paid its supplier for a carburetor. I am comparing the cars and I am comparing the prices.

So the answer is, from the perspective of the beneficiary and from the perspective of you as Federal lawmakers with oversight over this program, you have the single most important piece of data that matters. You know the ultimate outcome of all the numerous variables, and that is reflected in the premiums paid and the subsidies going out.

That, ultimately, is what matters. The test is, what does the program cost today? How could you make it cost something less? Would you, in fact, make it cost something less?

Senator CANTWELL. I would just point out that three of the panelists—one did not want to give an answer—said that we do need more information. What we are protecting ourselves from is manip-

ulation. What we are protecting ourselves from is for when markets do not function. That is why transparency is key.

So I think, actually, there is a lot of commonality for the need for more transparency. So I hope, Mr. Chairman, we can take this up and look more into what transparency of detail we really need to make sure we have a functioning market.

The CHAIRMAN. I appreciate that. Thank you, Senator.

Senator Rockefeller and I both have to leave very quickly. Go ahead, Senator Rockefeller.

Senator ROCKEFELLER. Mr. Chairman, you and I have to be at a Children's Health Care Radio forum, live, in 5 minutes. I will go ahead and do this very quickly, then I want to submit. I will just ask one question; I have lots, particularly on VA. There are a lot of misconceptions, I think, out there in VA.

This is to you, Dr. Morton and Mr. Dicken. Dr. Morton, you said in your statement something which was quite extraordinary, I thought: "One way to reduce a plan's desire to manipulate its formulary to avoid bad risk is to move many of the bad risks out of Medicare Part D. This could be accomplished by shifting dual eligible patients back into Medicaid. While pricing in Medicaid is not a simple problem either, at least these patients would not exert a negative externality on the rest of Part D recipients."

Dr. MORTON. What does that mean?

Senator ROCKEFELLER. No, I know what it means. It is just slightly condescending. It is condescending. I will make my point.

A couple of points to make. When we made Medicare a universal benefit, that is something that a lot of us gave blood for. We gave blood for it during the whole prescription drug benefit. I strongly believe that low-income seniors and disabled individuals are human beings, that they should not be excluded from Medicare benefits because of their income levels, which is what I think you are suggesting. Dual eligibles should not be treated as second-class citizens, which I think you are suggesting.

Dr. MORTON. No.

Senator ROCKEFELLER. Let me finish. I think you should know I feel very strongly on that, because when you make what I would call academic statements about dual eligibles being "bad risks" and "exerting negative externality," which is almost like an odor or something of that sort, and I am serious about that—I mean, this is the way policy gets made and the way it gets translated to the American people, and it creates perceptions which are not good.

One can easily get the impression that you are saying that low-income seniors should be excluded because they are poor. I come from a State called West Virginia where we have people with all kinds of incomes, but I just want you to know, I have a real problem with that.

Second, your argument about duals creating adverse risk in the Medicare drug benefit seems to me to be factually incorrect. I would also like to have Mr. Dicken comment on this when I have made my point.

It is my understanding that the prescription drug benefit plans get risk-adjusted payments. Plans get risk-adjusted payments for every Medicare recipient. Plans also get an add-on payment for dual eligibles, which is a very generous one. Plus, there are rein-

surance payments for anyone who goes through the donut hole, including dual eligibles.

In addition, plans do not have to spend marketing resources to find and enroll duals. Instead, plans have revenues from day one—it is a guarantee—because duals are automatically enrolled in the drug benefit, for better or for worse.

So the bottom line, to me, is that plans receive significant subsidies to cover dual eligibles. We did that. I think this is counter to what you have indicated.

So I think, in that sense, that you are targeting the wrong population. Are the high-risk beneficiaries not really those who do not have Medicaid, have high prescription drug costs, and who will fall into the donut hole? I would ask if you two would respond to that.

Dr. MORTON. So, certainly I had no intention of suggesting that anybody who is low income should not be entitled to a prescription drug plan. Quite the contrary. I think it is very important that they are included.

What I meant by a "negative externality" was that we have designed these protected classes without as much formulary management in them. The reason for that is, if I can manage my formulary so that I do not have any good anti-psychotic drugs, I can drive those people—exactly the ones you just identified who are sick and expensive because they do not perhaps have the extra subsidy—away from my plan. So that is what we have done to try to stop that.

My suggestion of moving these sick patients back into Medicaid just reduces the number of people in the category that the plan is trying to manipulate. If you reduce their financial incentive for manipulation, they have less reason to do it. That was the basis of my thinking.

Senator ROCKEFELLER. All right.

Dr. MORTON. But I understand they also get very good coverage in Medicaid. If that is not correct, then that would be an issue.

Senator ROCKEFELLER. Mr. Dicken?

Mr. DICKEN. Certainly, Senator Rockefeller.

The CHAIRMAN. You are going to have to be very brief here.

Mr. DICKEN. This is very, very important. So just three very brief things. Indeed, there are risk adjustments that are paid to make sure that CMS is paying the actual amount that the individuals would have paid for cost sharing if they were not dual eligibles.

Let me say just that there are a number of ways of looking at those that are going to be a high cost. Some of those high-cost individuals will also be those who are not dual eligibles, those that end up going through the donut hole and then being picked up again by CMS.

The CHAIRMAN. I appreciate that. I am going to have to leave here. Senator Grassley has very kindly agreed to chair the rest of this hearing.

I want to thank the panelists. You all have been just terrific, all five of you. I think it has been a very constructive hearing. I, for my part, first believe that we should strike the non-interference language.

Next, I plan to develop a proposal, in conjunction with all the members of this committee, to address the basic question we are

all trying to address to help make the market work better, perhaps intervene or just deal with those issues where there is a monopolistic position, or we are talking about the special drugs, or the dual eligibles, or whatnot.

I also believe that we have to give NIH a lot more authority to do a lot more comparative analysis of drugs. Further—and I am not able to follow up on this yet—I do believe that the pricing information that the drug companies currently give to NIH should, in a way that protects proprietary interests, be made available to research organizations so that we can get a better idea of what is and is not going on.

But I want to thank the panelists very, very much. I appreciate it.

Senator ROCKEFELLER. Mr. Chairman, can I just ask that my statement be included in the record? Also, that I be allowed to write individual members the questions that I had for them? We just both have to go. Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Senator Rockefeller appears in the appendix.]

[The questions appear in the appendix.]

Senator GRASSLEY. The next person is Senator Lincoln. I am going to stay for a second round because I have some more questions to ask, so be appreciative of everybody's time because it is getting close to the lunch hour.

Senator LINCOLN. Thank you, Mr. Chairman. Thank you so much for bringing us together on this very important issue.

I have several questions. Mr. Haislmaier, you, and I think it was someone else—maybe it was Dr. Morton—mentioned that the dual eligible costs had gone down under Part D from what they were in Medicaid. You mentioned that earlier, that you changed your mind about moving. Maybe Dr. Morton did not.

But, anyway, my question is, do you think that there is enough data to believe those numbers? We just started this program last year, and I have to tell you, I have a huge number of dual eligibles in Arkansas, and the pharmacist was paying for the first month or two of their prescription drugs because the transition was botched big-time.

Mr. HAISLMAIER. I agree, Senator. In fact, sort of apropos to Senator Rockefeller's comments, my previous advocacy of retaining the dual eligibles in Medicaid was largely for those administrative reasons, if nothing else. I mean, there are some considerations about risks and stuff like that. But, yes, it was because it would be an administrative problem, and frankly I was surprised to find it.

Senator LINCOLN. But obviously it was important enough that you changed your mind and your opinion on it.

Mr. HAISLMAIER. Well, I looked at this. It started with, there was data that came out of CMS, so I started calling around. Then I went back and looked at the CBO baselines and said, well, it is not just CMS, it is CBO that is revising their baselines downward. They are revising them downward. This is 20-plus percent that they are revising them downward.

So I went back and I looked at the law and I said, well, what did the law say for the estimating? The law said, well, if you go

back, you would start with the historic experience and these payments that the States would have to make, and it would be based on their 2003 experience. They did some updates for 2004 and 2005.

Then from 2006 on, the law specifies that it is based on the rate of per capita average annual Medicare. It is the same indexing as the deductible in the plan.

So I keep coming back to the fact that apparently the data is coming in that——

Senator LINCOLN. But do you think there is enough data to make that decision? Obviously you have to base your decision on it.

Mr. HAISLMAIER. We are now into the first quarter of the new fiscal year. I mean, I am kind of the wrong person to ask, and that is why I am being a little hesitant here, because I am not in the middle of CMS with all the data.

Senator LINCOLN. All right. Well, I will move on to my next question.

Mr. HAISLMAIER. But so far, it looks good to me.

Senator LINCOLN. I just noticed an enormous gap in our dual eligibles when we went into this program. It did not have to happen. It should not have happened because there should have been greater oversight from CMS in how they made that transition.

But I think Dr. Morton makes a good point, particularly about the anti-psychotic drugs and mental illness. We, for some reason, never really bring that issue up around here. It is a huge issue out there for Americans. Without that prescription drug coverage, it becomes a huge issue for taxpayers, so I think that is important.

Dr. Morton, you also mentioned "triggering" a couple of times. Your triggering, mostly, was referenced to studies or investigation, research, perhaps. Maybe you could elaborate on that, or maybe there are some views we might discuss in having the secretarial negotiations triggered by Medicare drug prices increasing above a specified level of some sort. We have talked about triggers in a lot of things up here in the last several years.

Dr. MORTON. I am just responding to the general sense I get from people in the field that there are many drug categories and individuals that we seem to be doing just fine on and getting good prices on, and I do not then see a need to have the Secretary intervene in such a market.

So I am trying to think, what would be the sort of a trigger that would be appropriate in addressing the needs that we have without being unnecessarily burdensome. So, in particular, the protected classes strike me as the place to focus attention because the plans are not as able to create competition in those fields. So if they cannot create competition, we cannot rely on the market to solve our problems in those particular classes.

Then I would just say, it is sensible not to spend a lot of effort trying to reduce prices on drugs that we do not spend very much money on.

Senator LINCOLN. Right.

Dr. MORTON. I mean, it is the big drugs in those classes that are the problem, I think.

Senator LINCOLN. Yes. Right. Go to the problem spots. Exactly.

One of the concerns of allowing, obviously, the government to negotiate drug prices, as we talked a lot about, is diminishing pharmaceuticals research and development activities. I do not know. We have talked about all kinds of studies.

GAO did have a study that found that, over the last decade, the increase in research and development expenditures, as reported by the pharmaceutical industry, has not been matched by the growth in the number of new drug applications.

So I think that as we talk about that, what evidence is there that R&D would diminish substantially if Federal negotiations were included, or if in fact we put a trigger in to negotiate drugs, because quite frankly, between research—and we have talked very little about patents and generics, the availability of generics, or how successful pharmaceutical manufacturers have been in developing breakthrough drugs.

I mean, we have a lot of "me, too" drugs out there. The vast majority of the new drugs are simply formulations of what is existing as opposed to what we really think research and development should be going to, and that is the newer breakthrough drugs.

So any comments you all might have about research versus patents and generics, and where is the carrot, where is the stick, and what do we do with that?

Dr. MORTON. I mean, I think that that is one reason not to interfere much with the breakthrough drug prices. If those are expensive, I do not know. My gut feeling is that that is the place, if any place, that we want to reward research and development, a breakthrough drug that does something new that we never could do before that is really helping us out.

Senator LINCOLN. But if it is a monopoly drug that has had a patent for 17 years——

Senator GRASSLEY. Let them answer your question because your time is up.

Dr. MORTON. But then a "me, too" usually comes along pretty soon.

Senator GRASSLEY. Go ahead and answer the question, and then we will go on.

Mr. HAISLMAIER. Can I make a comment, Senator Grassley, in response to that? This is a little different topic, but it is an important one. There seems to be in pharmaceutical R&D—and I have talked to various experts in the field and nobody really has a handle on why—a sort of general, 15- to 20-year cycle where some leap forward in technology—whether it was computers back in the 1970s that allowed for them to screen more, and now I think the new cusp is genetic information—produces a curve of increasing breakthroughs and developments, and then that curve tapers off.

We are sort of, right now, in a trough, I think, in this cycle. The last time was in the late 1980s. Then we had, in the early 1990s, a whole slew of new drugs. All the statin drugs for treating cholesterol, for example, came onto the market then. There were the antidepressants and things like that. So you have this sort of curve, and nobody is sure exactly why.

The point that I would make about the leverage on single-source drugs, is this. If the manufacturer of the single-source drug—there is no competitor to it—is a large manufacturer with other drugs,

then both the private players and the government have some other leverage because they have other products.

If you are looking at a sole-source drug where there is one small manufacturer and that is the only thing they have, small biotechs, then it is a very different equation. As to the evidence, it is that last group that is virtually non-existent in Europe because of these policies.

I mean, the only biotech industry, really, in Europe, is in the U.K. In fact, this is an issue the Europeans are looking at, as they have, in effect, discouraged that kind of small biotech development.

Senator LINCOLN. Dr. Anderson?

Dr. ANDERSON. Yes. I still want to make sure that the American senior is not the only one in the world that is supporting R&D.

Senator LINCOLN. Exactly. Thank you.

Mr. HAISLMAIER. I would agree on that.

Senator LINCOLN. Dr. Frank?

Dr. FRANK. Just two points. I think the question we are trying to get at is, you want enough money on the table to have an incentive for these people to keep going there. But when people are fully insured and heavily subsidized, you do not want the sky to be the limit, and you have to try to find that place. That is why negotiation may make sense on the unique drugs.

Let me just try to clarify, I think, what may be a misconception. I do not think that it is an easy sell to say that European biotech is not there because of rules in Europe, because if they are selling half their products to the United States with U.S. prices then they have all the incentive in the world to invest, even if they are in Bordeaux.

Senator LINCOLN. Thank you.

Senator GRASSLEY. I would like, before I ask a couple of questions, to call your attention to the fact of something that we were able to just now hand out. It follows on, yesterday, OMB saying that in the House bill, H.R. 4, that there would be no effect on lowering drug prices if that bill were to pass.

We have CMS, today, and the Office of Actuary putting out the same information: "Although the bill would require the Secretary to negotiate with drug manufacturers regarding drug prices, the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of the negotiation."

I am going to start my first questioning with Dr. Morton. It is a follow-up of the questioning of Senator Cantwell.

Are there any potential pitfalls we should know about, for example, if all best prices had to be made public? I want to give a little background before you do that so I can quantify, because there is a quantifiable part of this road that Senator Cantwell was going down. She had an amendment last year to make best prices required, and CBO scored it at $40 billion. So, now, the question.

Dr. MORTON. So if you make manufacturers sell to Medicare at their best price, which is their lowest price, they will not give a low price to anybody else in the economy because half of their business is being sold at that price.

So the VA's prices would go up, Department of Defense's prices would go up, Kaiser's prices would go up. Anybody who is getting

anything that is below average would come straight up to the average.

Senator GRASSLEY. All right.

Dr. Anderson, the Congressional Budget Office, yesterday, released that letter I referred to. I am not going to quote again from it, but they also emphasized the lack of leverage to obtain significant discounts because of not having a formulary.

So my question is this. How do you believe the government would have the leverage to lower prices if, as in the House bill, there is no ability for the government to set up a formulary that enables it to shift beneficiaries to lower-cost drugs?

Are all the professional economists at CBO and the professional actuaries, and most of the other economic and health policy experts just wrong in saying that their universal experience has been that you need a formulary to move market share?

Dr. ANDERSON. Well, let me answer two questions. First of all, I think that is is important to have the data to know whether or not the marketplace is, in fact, working.

So right now, CBO does not have the requisite information to know whether or not the prices that the best Part D plan is paying are any better or worse than what the Medicaid program, the VA, or Canada is getting. I think they should know that before they answer the question.

The second thing, I think, is if Secretary Leavitt is not willing to negotiate prices, then I would totally agree with the CBO that the Secretary is not going to have any negotiating power. But I think a Secretary who has a lot of dealings with the pharmaceutical industry, besides the Medicare program, would be listened to.

I think if this committee were to have the people that were in charge of the pharmaceutical industry come here and try to explain their drug prices and why they are charging the Medicare beneficiary more than the VA—more than the other places—and put them on the spot, I think you would get lower prices right away. They would not even want to come here.

Senator GRASSLEY. Another question to you. As you are aware, the non-interference clause also prohibits the government from establishing a price list that prohibits the Secretary from imposing price controls on drugs purchased by Medicare. So are you saying that the Secretary should have the authority to impose price controls instead of negotiating?

Dr. ANDERSON. No. I think it is totally in negotiation. I think you get the information as to what the price is that the Medicare program is paying and compare it to VA, compare it to Canada, compare it to Medicaid, see where the prices are substantially higher, and that is where the negotiation begins. I would not do it on all of them. I would not have a price list. I would have a negotiation.

Senator GRASSLEY. Dr. Morton, would you comment in reaction to what he said?

Dr. MORTON. I think if you do not have anything to threaten the manufacturer with, you are not going to get anywhere with a negotiation. It seems that what Dr. Anderson has in mind for the threat is generally worse regulation going forward: next time you come to me to ask for something, I am going to be upset with you because

your price is not low enough on Drug X, and that is going to be the reason that you get a low price on Drug X.

Certainly that might well be true, but I do not know that it is a sustainable way to do policy. It would depend on how good a negotiator the Secretary was, and it would depend on how and whether the Secretary could affect other parts of the government to make the climate adverse for manufacturers.

Senator GRASSLEY. I want to get my last question in before the 5 minutes are up.

Dr. Anderson, foreign governments have attempted for some time to control access to different types of drugs. I have examples from three countries, but I am only going to use Australia at this point to speed things up. In Australia, as a matter of government policy, a woman has to break a bone before she can get medicines to treat osteoporosis.

If the Secretary is required to negotiate but cannot use a formulary as leverage, would you say that these policies of government-run health care systems are the kind of policies that the Secretary could use to negotiate lower drug prices in Medicare?

Dr. ANDERSON. I think the Secretary should have that available to him, but I would not do that as my first or second choice. But I think the Secretary should be aware of what other countries are doing because we are in an international market.

Senator GRASSLEY. Senator Wyden?

Senator WYDEN. Mr. Chairman, thank you. You and I started punching and counter-punching this morning at 7:30, and you are such a good friend, I just want to make sure a couple of points are clear on the record.

Senator GRASSLEY. Just understand, we were smiling all the time. [Laughter.]

Senator WYDEN. Every time. Every time. Your friendship, as you know, with our victory this week to end secret holds, is something that is very important to me.

Just so the record is clear, what Senator Snowe and I are proposing is quite different than what the House of Representatives is looking at in H.R. 4. So that it is clear for the record, we are talking about making Medicare a smarter shopper, number one. We have a strict statutory prohibition on setting up a national uniform formulary.

We have statutory language barring price controls, and we try to address—as virtually all of you have been interested in today—this issue of getting more information, more transparency so that people are in a position to make markets work. So, I want to be clear about the differences between what Senator Snowe and I are proposing and H.R. 4.

I also want to come back, so that the record is clear, to this example of Cipro, because I have heard throughout this morning all kinds of threats and the like.

Respectfully, Dr. Morton, to review the situation, there was a simple negotiation. It was not some trumped-up kind of exercise where people were hauled into the back and beaten with a club. The Secretary said, we are going to have to talk. We have a problem here. It does not seem to me the marketplace is working particularly well, and we have to have a negotiation.

So I hope, particularly as we wrap this up—and I anticipate that this will go on for some time longer—that we can understand that a number of us, on a bipartisan basis, believe that there is a clear and sharp line between Medicare shopping smart and Medicare crossing the line into price controls and having a national uniform formulary.

We are very grateful to you, Dr. Anderson, for making it clear today on the record that you support the approach that we are talking about, because I think it goes right to the point you started out with 3 hours ago: this is about the psychology of markets.

Those of us who voted for this legislation, Senator Snowe and I specifically, want to make markets work. We know that this program is helping a lot of people who have very big bills, thousands and thousands of dollars' worth of bills, and very low incomes. Nobody wants to tear that up.

The question is, can you shop smarter? That is why we have described three or four instances in our legislation where we want to make the program a smarter shopper. You can be sure that Senator Snowe and I and the others who have supported this are going to be anxious to have the input and counsel from all of you so that we can make sure that that line remains very bright between shopping smart, which we favor, and price controls and uniform formularies, which we oppose.

So, Mr. Chairman, you have been very gracious. You and I are going to be on the same side more often than not, and I look forward to continuing this discussion with you and our colleagues.

Senator GRASSLEY. Thank you very much.

Senator Lincoln?

Senator LINCOLN. Thank you, Mr. Chairman. I appreciate the opportunity to just follow up with one question, I believe.

I echo the words of my colleague from Oregon. There are those of us who voted for this believing that not only was it an important advancement and modernization to Medicare, but also recognizing some points that you all have brought out.

That is, with the correct application of prescription drugs for, particularly, the Medicare population in this country, there are other health savings down the road, whether it is hospitalization, whether it is nursing homes, whether it is long-term care and a host of other things. But the appropriate application of getting medications to the Medicare population makes a huge difference in the overall cost of our health care system.

I think we have to look at that bigger question as we look through solving the problems of making the Medicare Part D the best possible program it can possibly be, and certainly that is my objective.

The one thing I would like to finish with is that I hope and encourage us all to not underestimate the role of the pharmacist in this. To echo the words of Senator Roberts, I grew up in a very small town in the Mississippi delta of Arkansas.

My grandmother lived with us. At 82, she did not want to talk to the doctor, she wanted to talk to the pharmacist. She knew what her chronic diseases and her ailments were. She wanted to know how to manage them better. She did not want to disturb the doctor,

she wanted to talk to the pharmacist who could deal with her on that level. I think it is important.

When we talk about negotiations here, we are talking in this huge, bulk, broad arena of CMS and pharmaceutical companies and millions of people. We have to remember that it has to be administered.

I know that some of the complications we went through, some of which still exist, in the implementation of the first year were that pharmacists were getting one price or they were purchasing prescription drugs at one price, and within a week the pharmaceuticals were changing that price, so that when they got reimbursed they got reimbursed at a much lower rate. We cannot allow that to happen, because if we do we will eliminate the kind of quality care that people in rural areas need and deserve.

So I just hope that we will certainly look at that issue in terms of reimbursement. Also, when we talk about negotiating, that negotiations mean that you have to have a fair playing field.

If, in fact, formularies or providers can change the access, which they have done—I cannot tell you the number of calls that have come into my office where someone signs up for a plan and, 3 months later, access to the prescription drugs that were on that plan is now gone and they have changed what they have access to. So it has to be a fair playing field when we talk about those that are going to be negotiating and those that need the resources for research and development and whatever to provide these drugs, that they are going to be fair to those whom we are providing it to in terms of their access, and at least continued access.

They are only allowed to change during the open period. If the formularies and the drug providers are allowed to change at any time, then you have a disadvantaged circumstance for those beneficiaries.

Anybody who has comments there, I would appreciate those.

Dr. MORTON. We are trying to get data now to look at that, because I think there is a significant incentive now for a bit of a bait-and-switch. So I am going to post some prices and some formularies in November, enroll people, and then as of March I can change those in any way I please. I do not know if that is a problem, but potentially it could be.

Senator LINCOLN. But we do not hear from you until November? Today is January.

Dr. MORTON. My colleague, Mark Duggan, and I are working on this, so hopefully sooner.

Mr. HAISLMAIER. Senator, this is analogous to other work that I am doing in insurance markets. Yes, you need to have a set of predictable and fair rules that applies to everybody. If the beneficiary only gets to change once a year, then the update should only be once a year. That is right.

That is how you would do it with the other provisions in a health benefit plan like FEHBP. They get a shot at redoing their benefit package before the open season, but once it is in they do not change it midstream. That is a fair point, and there ought to be a consistent set of rules for everybody.

Senator LINCOLN. Yes. Anybody else? [No response.] Thank you, Mr. Chairman.

Senator GRASSLEY. Could I have a dialogue with you before you go on a couple of points, Senator Lincoln? First, the point that you just made about a plan dropping a drug sometime after you have joined the plan and started taking it. If you are taking that drug, they are required to let you keep taking it until the end of the year when you have a chance to change to plans that would have it. So if they cut you off in June, take it through until the end of the year, whenever the year ends for that plan.

Senator LINCOLN. The patient has to petition for that, do they not, for the additional coverage? I do not know. I just know that I have a lot of patients who have run into that problem.

Again, Mr. Chairman, for seniors, requiring additional paperwork and additional petition just becomes one more issue that our elderly are dealing with. You may be correct that there is nothing that is required, but my indication was that they were.

Senator GRASSLEY. I want to give you what I tried to do for my constituents in Iowa.

Senator LINCOLN. Good.

Senator GRASSLEY. If what you say is happening and it is not supposed to happen, let us know so we can get on the plans about that, please. We need to know these ad hoc, where things are being done differently in different States than what the law intended.

The second point for you, before I get to Senator Wyden, is that your concern about community pharmacists is entirely legitimate. We took great care in the compromise to work to preserve community pharmacists, and it is not quite working out the way we intended. We have taken several steps in the last 12 months to take care of some of these problems. They are not all taken care of yet. So, I do not find any fault with that.

But the point I wanted to have dialogue with you on was this. I do not know whether you are one of these that says we need to do it because the Veterans Administration does it.

Senator LINCOLN. No.

Senator GRASSLEY. But just for those who do—it does not apply to you then—do not forget that the Veterans Administration does not have community pharmacists.

Senator LINCOLN. Yes.

Senator GRASSLEY. And remember that 80 percent of it is mail-order. So if you do something like the Veterans Administration does, you are not going to have any community pharmacists in rural, or even urban, Arkansas, rural or urban Iowa, if that is the case.

Senator LINCOLN. Yes, sir. I understand that.

Senator GRASSLEY. And there is something about the Community Pharmacists Association, whoever represents them here in town, whoever their elected leaderships are, they are not speaking out against people who say we ought to use the Veterans Administration as an example.

If we did it that way, they would not have any membership. I think somebody in the Community Pharmacists Association ought to be studying what these opponents of this are all about, and come forth.

If there is any pressure on the other side, through the Democratic party, to have them keep their mouth shut and you are doing

it through the leadership, let me assure you that that leadership is dancing to the wrong tune for the good of their members.

Senator LINCOLN. Well, Mr. Chairman, that goes a lot further than anything I had intended, I will be honest with you. [Laughter.] All I know is, my local pharmacist—can I comment?

Senator GRASSLEY. Yes, you can comment.

Senator WYDEN. I would like to on that point as well, if I could, Mr. Chairman.

Senator GRASSLEY. Yes. Then I have something I wanted to tell you about your bill. [Laughter.]

Senator WYDEN. Just, again, so we are clear. Last year when Senator Snowe and I got 54 votes in the U.S. Senate, we did not go with the kind of approach that you have described that involves a pharmacy approach that could be inconvenient to seniors.

We said, once again, we want to make sure that they are smart shopping and there are not price controls, uniform formularies, nor the kind of cumbersome operations which you have correctly described. So we steered clear of that approach last time, we are steering clear with the legislation that we proposed yesterday. I am happy to take a question. I know Senator Schumer has been patient for a long time, too.

Senator LINCOLN. Can I just make a compliment to you?

Senator GRASSLEY. Yes. Go ahead. [Laughter.] I will even listen to your insults.

Senator LINCOLN. I just brought that up because my local pharmacists are very important to me. It is critical in implementation. But the meetings that you had last year, Mr. Chairman, were very useful when we sat down with CMS and the Social Security folks and talked about what the problems were that we were seeing.

So, we know that there will be difficulties and challenges in implementing all these things. The kind of dialogue that you facilitated last year was tremendously helpful in us going back to CMS.

The problem is, if we cannot avoid any of those problems to begin with, the lag time that it takes for CMS to address them just seems to be pretty lengthy, and I hate to see our constituency go through those problems unnecessarily. So there was tremendous help that we had when you approached those issues and concerns we had in our States last year.

Senator GRASSLEY. For Senator Wyden, I am just going to make a statement. I was going to ask a question of Dr. Morton on this. Just so you know, I have a concern about something that is in your bill.

This may not be a consequence, but I would see a possibility of this being a consequence, where you are going to let a plan ask the Secretary to negotiate, if that plans wants the Secretary to negotiate instead of their negotiating. Now, we have maybe 44 plans in Iowa, 42 or 44.

Would it not be the weak plans, the ones that are not very strong, if they cannot negotiate anyway, do we want them in this business? Do we not want them to get out of there? I mean, for instance, your party has said more than my party, that we have too many plans already.

So are you going to let the Secretary prop up a weak plan by letting the Secretary negotiate them when they cannot negotiate—let us say, what is it, Humana or one of the other big ones?

Senator WYDEN. Mr. Chairman, first of all, Senator Snowe and I do not anticipate a plan asking very often for the Secretary to step in and provide this additional opportunity. That is why, in effect, it comes after the single source drugs and it comes after the taxpayer funded drugs and the like.

We just wanted to make sure it was something of a fall-back position. Perhaps you could have a plan that really did not have much bargaining power, and it was in a rural area, say Oregon, Iowa, or somewhere else, and you said, gosh, I want to make sure that those people might—again, as we relate to the psychology of markets Dr. Anderson is talking about—have some influence.

So, Mr. Chairman, so we are clear on this point——

Senator GRASSLEY. Well, then would you not want to make it——

Senator WYDEN. Can I just finish my sentence?

Senator GRASSLEY. Yes.

Senator WYDEN. Thank you. We do not anticipate it happening very often, but in some instances, particularly in rural areas where you might not have any coverage for folks, we think it might be appropriate, again, to bring in the Secretary. But we certainly do not want to have it go on in hundreds of instances across the country, and I think it is very unlikely that it would.

Senator GRASSLEY. Would you not want to change it to "may" instead of "shall" then?

Senator WYDEN. Well, if the Chairman tends to change his position and not filibuster Snowe-Wyden, we are open to that, yes.

Senator GRASSLEY. I am not bargaining here.

Senator WYDEN. All right. Thank you, Mr. Chairman.

Senator GRASSLEY. Senator Schumer?

Senator SCHUMER. Well, thank you, Mr. Chairman. I apologize to all the witnesses for being late.

I have two points I want to make, because many of them have been made. I know we have talked a lot about the potential of a formulary or not a formulary. Look, it is pretty obvious, even though you could probably bring prices down without it, you get a lot lower prices if you have a formulary.

When you go to the maker of Lipitor and say, I am going to buy 10 billion Zocor unless I get a good price, that is a lot better than saying, let us just negotiate Lipitor versus no Lipitor.

So I think a formulary, the way the VA has it, should be worked into a bill. You have to have an easy appeals process. I mean, I went through this. I take Lipitor. My medical plan switched us over to Zocor. It is actually my wife's plan. New York City's plan is better than the Federal Government, so I am on New York City's plan. She works for the city.

We did a test to see if Zocor worked, and it did. So now I am on Zocor and I am saving somebody a whole lot of money, and that is fine with me. But if Zocor did not work, I would have gone back to Lipitor.

But I think we should seriously explore putting a formulary in there, provided there is a very easy appeals process. That will save

us the most money, and I hope we can consider that when the time comes.

The point I want to make, though, is about biologic drugs, which I think you mentioned, Dr. Morton. Biologic drugs are a large part of the Nation's drug spending. They are costing tens of billions of dollars, and they are growing. They are the latest and the greatest in terms of, if you need one you can have one.

But there is no mechanism for generic versions of these drugs that could bring down the prices and provide the same kind of savings we have seen in traditional generic areas.

The PCMA, the association of the pharmacy benefit managers, came out with a study this month demonstrating that Medicare Part D could save billions of dollars if there were generic alternatives to biologic drugs on the market.

Now, I am a sponsor here in the Senate—generic drugs have been an issue that I have cared about for a long time—with Henry Waxman in the House, of the Access to Lifesaving Medicine Act.

Today, by the way, there was an article in the *New York Times* just about insulin which talked about this, but you could do it in a lot more places than insulin, although insulin is very important, maybe the leading one.

Our bill would create a pathway to generic versions of biologic drugs. We are going to reintroduce it shortly. It has the potential, as I said, for savings in this country.

So I would like to ask the panel just one quick question, leading with Dr. Morton. Do you agree with the PCMA that if we had generic biologics we would save a whole lot of money in the Medicare program? Do you see any good reason why we should not move to generic biologics?

Dr. MORTON. Generics have been absolutely huge in the American health care story. We do generics better than most other countries, and they are very inexpensive here. I think we absolutely have to have them for biologics, because otherwise intellectual property is a joke. I mean, you get your patent and it lasts forever, and that is not really the contract we have with innovators in this country. So, I think it is extremely important.

Senator SCHUMER. Anyone else want to comment on that? Dr. Frank?

Dr. FRANK. Yes. I want to agree. I think that the biologics need to be looked at. I think there are some technical problems, but I think most of them are probably reasonable candidates. I think that there is more work to be done on regular generics as well.

Senator SCHUMER. Oh, indeed.

Mr. HAISLMAIER. Senator, yes, I would like to comment. Two points. One is, one of the effects we have seen in other countries, not in the biologics but in the chemical entities, is because of price caps on on-patent drugs, what happens is, when patented drugs go off-patent, the generic manufacturer has an incentive to shadow price. So as a result, that huge gap that we have in this country between on-patent and off-patent prices does not occur, and therefore no other country in the world has the level of generic drug use that we have.

Actually, if I could make three points. Before Zocor went off patent, Lipitor was still more expensive than Zocor. But one of the in-

teresting things about the pricing is Lipitor, from the very beginning, as a unit price, lowered cholesterol for a smaller dose of the drug better than Zocor and Mevacor. So, even though the price per tablet was higher, the bang for the buck was greater. From the very day that they launched Lipitor, that is what drove its market ascendancy, is that there was a bang-for-buck calculus.

The third point on the generics——

Senator SCHUMER. And by the way, just to interrupt, briefly, if we were to have a system with a formulary, you would have to take all those things into account. You could not do one size fits all; because one pill is 20 percent cheaper than another pill, you just go ahead and use it.

Mr. HAISLMAIER. And this is why the idea of multiple competing formularies—which is what the PDP plans are doing today—has some merit, in my view, over a national formulary.

But to answer your question about the generic biologics, I have not seen the PCMA study, but let me say this. I would caution anyone about thinking that, even with a generic biologic law, that the savings will be anywhere near as great as with chemical entities. The reason for that is this. As we saw with the flu vaccine, these are living organisms.

Even with the same manufacturer from batch to batch, you have a whole set of issues. Consequently, the disparity between the price of sale and the unit price of production is not as great.

The unit price of production for biologics of any kind is much higher than for chemical entities. So even with a generic biologic law—and this is a very rough, off-the-back-of-the-envelope calculation—20 percent savings, 30 percent savings, not the 80, 90 percent savings.

Senator SCHUMER. No. But you would not disagree that it is in the billions, and probably the tens of billions of dollars.

Mr. HAISLMAIER. Yes. I mean, I have not analyzed the numbers. Certainly, I think this is a huge issue that faces all payors in the market going forward. The other issue that will face us is—the flip side of genomics—we will get better at personalized medicine.

Senator SCHUMER. Right.

Mr. HAISLMAIER. Now, that means that the old economic model for the pharmaceutical industry, if you get a big blockbuster like Lipitor out there and sell it to everybody and make billions and that covers all the other stuff, that economic model is going away because you can better target, with genetic testing, which drug works for which person.

But on the flip side, now, with a biologic like Herceptin, if the woman with breast cancer has this profile, Herceptin works, if she does not, you do something else. It becomes very difficult to deal with the fact that if you want that drug, especially if it is a biologic, there is no way to really bring the price down. It is going to cost you.

Senator SCHUMER. Yes. Fair enough.

Mr. HAISLMAIER. It is a tough world we are in.

Senator SCHUMER. It is a different system.

Dr. ANDERSON. May I just respond?

Senator GRASSLEY. Yes.

Dr. ANDERSON. I agree with you on the generic biologics. I am a little concerned about your formulary proposal. That is, essentially what you would have, if you had 50 percent or 40 percent of the drugs, you would essentially eliminate them from all the Part D plans having that option. I think the Part D plans ought to have the option of choosing whatever drug——

Senator SCHUMER. But is there not a way to have them have the option, and at the same time create the greater competition by allowing people who can use either drug to go to one or the other?

Dr. ANDERSON. That would be, for me, quite a difficult set of activities, but I would have to take a look.

Senator SCHUMER. Do you think the VA has done a good job that way?

Dr. ANDERSON. I think the VA has done an excellent job in terms of that. But they are not, then, running a whole set of PDPs underneath them.

Senator SCHUMER. I see. All right. Well, I would be interested in following up with you. Because certainly you want to preserve choice for people who need it.

Dr. ANDERSON. Right.

Senator GRASSLEY. Senator Schumer, I would hope that, in your question about the VA doing a good job, and if these answers are dependent upon how you might see the VA as something, I hope you would take into consideration that the VA only has 30 percent of the drugs available to veterans that we make available to others.

You surely do not want to do something to cut our senior citizens out of that 70 percent of the drugs that they now get, that, if we had a VA program, they would not get.

Thank you all very much. For the chairman and myself, we appreciate it. This is very helpful to us in not only our review of the whole program, as many things have been discussed here, but an immediate piece of legislation that is going to be up in this area.

Thank you all very much. The hearing is adjourned.

[Whereupon, at 12:33 p.m., the hearing was concluded.]

# APPENDIX

## ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

---

JOHNS HOPKINS
UNIVERSITY

**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 Senate Finance Committee thank you for inviting me to testify this morning. I am Gerard Anderson a professor of Health Policy and Management, Professor of International Health and Professor of Medicine at Johns Hopkins University.

*Overview*

Let me begin by stating that I believe in markets. Now let me qualify that statement. I believe in markets if certain circumstances are met. Some of the circumstances that can cause market failure are discussed in my testimony. Unless those circumstances are met there can be distortions in the market or even market failure. Much of the debate and legislation involving the Senate Finance Committee involves issues of market distortions and market failure in various industries and very commonly in health care.

My suggested approach has several parts. As a first step the Congress should repeal the non interference clause and require the Secretary of HHS to compare the lowest prices that any Part D plan obtains to the prices obtained by the VA, Medicaid, and Canada.

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

The report by the Secretary will compare the relative prices for the VA, Medicaid, Canada and the lowest price the Part D plans were able to obtain in the market place. As I said earlier, I believe in markets but as Ronald Reagan said – Trust but Verify. This report will verify when the market is working and where there is market failure.

Without access to the data on the price obtained by the Part D plans, it is impossible to compare the prices received by Part D plans to prices obtained by the VA, Medicaid or Canada. However, based upon available data it is possible

to anticipate some of the findings. I will explain why and estimate the impact in the report that follows.

First, it is likely that the prices for generic drugs will be comparable or even lower in Part D plans.

Second, prices for drugs used by dual eligibles are likely to have increased from what Medicaid paid for the same drugs. With the passage of the Medicare Modernization Act, responsibility for drug coverage for dual eligibles was transferred from the Medicaid program to the Medicare program. Drug prices for dual eligibles are now determined by a negotiation between the pharmaceutical companies and the Part D plans. It is likely that Part D plans are paying substantially higher prices than the Medicaid program used to pay for drugs used by the dual eligibles. Because the Medicare program provides drug coverage by the dual eligibles, it is the Medicare program that is paying these higher drug prices.

Third, it is likely that the Secretary's report will show that the Part D plans are paying higher rates for many brand name drugs. This is because there are several market constraints that interfere with a functioning market for brand name drugs.

With this data the Secretary of HHS can begin to negotiate with the pharmaceutical industry. My recommendation is that the Secretary start with the drugs where the market prices are highest compared to what the VA, Medicaid and Canada pay for the same drugs and work down the list. Assume for a moment that the lowest prices that any of the Part D plans could obtain for drug A is $10.00 and the VA, Medicaid and Canada were all paying approximately $1.00 for that same drug. In this case the Secretary could begin by simply asking the pharmaceutical company why it is charging the Part D plans 10 times more and then take additional steps if necessary. The VA, Medicaid directors and other countries have been engaging in this dialogue with pharmaceutical companies for years. Two Congressional Research Services Reports detail the approaches that have been taken. It is important to recognize that these approaches have been taken without large bureaucracies and there is no reason to believe that CMS could not be equally efficient.

It is sometimes suggested that because the Medicare program is such a large payor for drugs that it must pay higher prices than the VA, Medicaid, or Canada. I find problems with that logic as well. First, large purchasers seldom pay the highest prices. Second, the federal government is already supporting pharmaceutical research through the NIH. Third, Medicare beneficiaries should not be asked to pay the highest prices and Medicare beneficiaries should not be

the primary supporter of pharmaceutical research and development in the world when other payors and other industrialized countries benefit.

Like the story of *Goldilocks* and the *Three Bears* I am looking for the "just right" solution. Some editorials have suggested that the Secretary will be too aggressive while other editorials have suggested that the Secretary will be ineffective. Surprisingly, some editorials have made both arguments in the same editorial.

Some editorials have proposed that the Secretary will be an ineffective negotiator because the Secretary cannot restrict the formulary. Under my proposal the Secretary would negotiate prices only for drugs where the market place is already paying relatively high prices.

Some editorials have argued that the Secretary will be such an effective negotiator that the low prices will stifle pharmaceutical research and development. However, because the pharmaceutical companies have already accepted the prices at the VA, Medicaid and Canada this should be an acceptable starting point for negotiations.

In my opinion the "just right" solution is to have the Secretary identify the drugs where the Part D plans are paying much higher prices and have the Secretary negotiate prices for those drugs to make sure the Medicare program and Medicare beneficiaries are getting a good deal. This will require that Congress repeal the non interference clause, mandate that the Secretary of HHS examine the prices that the market place is getting relative to other entities, and negotiate when the market has failed.

*Begin By Collecting The Facts*

It is fine to believe in markets. However there are times when markets do not work. Congress should tell the Secretary of HHS to find out when the market is working by mandating that the Secretary collect comparative price data.

As a first step, the Secretary of Health and Human Services should identify the lowest price that any of the Part D plans were able to obtain from the pharmaceutical companies. It is likely that one Part D Plan will have obtained the lowest price for one drug while another Part D Plan will have obtained the lowest price for another drug. All that should be included in the Secretary's report is the lowest price that any Part D Plan was able to obtain for each drug. The Secretary's report would not disclose the price that each Part D plan paid or the name of the Part D plan that paid the lowest price. It represents the lowest price the market place could obtain. The price should include all discounts, price concessions and rebates.

This information is currently not available on www.Medicare.gov. The prices on www.Medicare.gov reflect the prices that Medicare beneficiaries pay for the drugs and not the purchase prices of the Part D plan. They do not include the price concessions, rebates, or discounts the Part D plans receive.

Congress should then require the Secretary to prepare a semi-annual report that compares the lowest price that any of the Part D plans obtain to the prices obtained by the VA, Medicaid program, and Canada for each drug. It will show where the market is working and where there is market failure. A recent Congressional Research Service Report and a 2005 Congressional Budget Office Report details how these various organizations establish the drug prices.

It is important to compare the drug prices received by other government programs. The VA is an appropriate comparison because the VA Secretary negotiates prices with the pharmaceutical industry and receives the best prices. Medicaid prices are an appropriate comparison because the Medicaid directors are a government program that has been paying for drugs for many years. Canada is an appropriate comparison because it is a government entity that pays for drugs. More important, if the price differential between US and Canadian prices is large, then millions of seniors will go to Canada to obtain drugs.

It is important to compare the prices at the individual drug level since the market place will be more competitive for certain drugs than for other drugs. With this information the Secretary of Health and Human Services will be able to compare the lowest prices that are obtained in the market place to other prices. This will give the Secretary the necessary information to determine where the market place is effective and where negotiation is needed.

*The Facts That Are Available About Comparative Prices*

Unfortunately we do not know the prices that the Part D plans are paying for individual drugs. CMS collects the data on prices, price concessions, rebates, and discounts but is prohibited by the MMA from sharing this data or even analyzing it internally. As a result, no one knows the rebates, price concessions or discounts that the Part D plans receive. The MMA prevents CBO, GAO, CRS and university researchers from obtaining this data. Fortunately there is some data that compares the prices Part D plans are getting to the prices obtained by the VA, Medicaid and Canada.

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

However, we also found that the markups were not uniform across the 30 drugs. This illustrates why it is important to analyze the relative prices for each individual drug. Table 1 compares the prices in the US to the prices in the other countries for each of the 30 drugs. For example, in 2003, 10 doses of Lipitor cost 36% more in the US than Canada, 86% more than in France and 65% more than in the UK. 20 doses of Zocor cost 42% more in the US than Canada, 190% more than in France, and 69% more than in the UK. Sometimes the US gets the lowest price (Viagra) and in most cases the US pays the highest price. Also note that some drugs are not sold at certain doses in certain countries. Price variations exist between the US and the other countries for all 30 drugs and there is even considerable variation in the relative prices for the same drug by dose.

In developing S2354, Senator Nelson from Florida asked me to perform the same analysis using the VA as the comparison group. The empirical results were remarkably similar to the earlier findings in the Health Affairs article. It appears that the VA is paying approximately the same prices as Canada, France and the United Kingdom. In 2006, I presented these findings in two hearings conducted by the Democratic Policy Committee chaired by Senator Dorgan.

In June 2005, the Congressional Budget Office prepared a report that compared the prices for "brand name" drugs that were obtained by different federal

agencies in 2003. The report compared the discount that various federal agencies received to the average wholesale price (AWP). Average wholesale price is the "publicly available, suggested list price for sales of drugs by a wholesaler to a pharmacy of other providers." CBO selected the average wholesale price "as the reference price for the analysis because it is commonly used in pharmaceutical transactions". It should be noted that the pharmaceutical companies will often provide discounts, rebates, and other price concessions and so the average wholesale price is not the actual price the wholesalers pay. It is also not the price that most patients pay.

*Price Comparisons*

CBO estimated that average price paid by the Medicaid program was 51% of average wholesale price and the VA paid 42% of the average wholesale price. Both the VA and Medicaid have price lists that could be easily be compared to the lowest prices that any Part D plan is able to obtain. Canada also has a price list although each province has a different price list.

Because of provisions in the Medicare Modernization Act data on the actual prices that Part D plans pay is not publicly available. In order to estimate the actual prices paid by the Part D plans, it is necessary to rely on the numbers produced by the CMS actuaries. In their report (Table 2) on the projected costs in the Part D program, the CMS actuaries assume a 21 percent reduction in average wholesale price and a 6 percent rebate for a total of 27 percent reduction from the average wholesale price (Table 2). In other words, the CMS actuaries assume that the Part D plans pay 73% of the average wholesale price.

First, it should be noted that the reduction the CMS actuaries estimate is considerably less than what the VA or Medicaid have obtained. The 73% number is comparable to the 51% number of the Medicaid program and 42% number by the VA.

Second, it is important to notice in Table 2 that the CMS actuaries do not anticipate that the Part D plans will become any more effective over the years in negotiating price reductions from the pharmaceutical companies. They do not anticipate that market forces will continue to lower prices over time. In the CMS projections, the discounts are constant over the years from 2006 to 2015.

Who Benefits From Price Transparency in Drug Pricing

Two groups will benefit from having greater drug price transparency – Medicare beneficiaries and the Medicare program.

Because drugs are sold under the same name to all purchasers, a Medicare beneficiary can compare the VA, Canada, and Medicaid prices to the price that the drug store is charging. Because they will know the drugs they are purchasing at that moment they will be able to do the price comparison. Medicare beneficiaries in the "doughnut hole" pay retail prices and they should know the relative prices since they purchase the drugs out-of-pocket while they are in the "doughnut hole."

The Medicare program also benefits from price transparency. The Medicare program pays the full bill for millions of low income beneficiaries. The Medicare program should be monitoring drug prices to make sure that it is getting the best prices for drugs for these beneficiaries. Otherwise, the government is spending money unnecessarily. As will be shown in the next section, the Medicare program pays higher drug prices for dual eligibles than the Medicaid was paying for the same drugs for the same dual eligibles.

*Likely Areas of Negotiation*

Without data on the actual prices that the Part D plans are paying for drugs, I cannot say exactly which drugs will have the highest price differentials compared to the VA, Medicaid, or Canada.

However, the limited available data does suggest that the Medicare program is paying more for dual eligibles than the Medicaid program paid. The data also suggests that the Part D plans are likely to be paying higher prices for certain "brand name" drugs. Part D plans are probably getting reasonable prices for most generics.

The available data suggests that the private sector is likely to obtain reasonably good rates for generic drugs. Wal-Mart has just announced a list of drugs that it will sell for $4.00 and other retailers are matching prices. A study conducted by Professor Patricia Danzon from the Wharton School of Business published in Health Affairs suggests that prices for generic drugs may be lower in the United States than they are in many other counties because the price competition for generics is greater in the United States.

My expectation is that Secretary of HHS would find that the prices obtained by the Part D plans for generics would be comparable to those at the VA, Medicaid and lower than in Canada. If this is the case, the Secretary probably would not choose to negotiate on generic drugs and allow the marketplace to operate.

*Dual Eligibles*

According to data from the CBO and CMS actuaries, the rates that the private sector is paying for "brand name" drugs is higher than the rates paid by Medicaid. The Medicare Modernization Act moved millions of dual eligibles from Medicaid to Medicare for prescription drug coverage. Because the Part D plans are paying substantially higher rates than Medicaid used to pay for the same drugs for the dual eligibles, the amount that the Medicare program ends up paying for drugs for the dual eligibles has increased substantially.

One simple way to estimate the increased payments that the Medicare program is making is to compare the rates that CBO estimates that Medicaid and the private sector pay for "brand name" drugs. According to the CBO report, the average manufacturer price is 79% of the average wholesale price. The average manufacturer price is the "average price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies". The CMS actuaries' then subtract an additional 6% discount for rebates. This suggests that the private sector is paying 73% of average wholesale price. However, Medicaid was paying only 51% of average wholesale price. This suggests that Medicare is paying substantially more than Medicaid for the same drugs for the same dual eligibles. There is collaborating evidence from the pharmaceutical companies own reports to the financial industry.

Pharmaceutical companies are required to file 10Ks and 10Qs with the Securities and Exchange Commission whenever a major event occurs that could influence the stock price. There are indications in some of the 10Ks and 10Qs filed by the pharmaceutical companies that they are getting higher prices from Medicare than they did from Medicaid. For example, in its 10Q report dated October 1st 2006, Pfizer acknowledged that additional they paid fewer rebates, price concessions and gave fewer discounts due "to the impact of the Medicare Act". On page 34 of their report, Pfizer states that "Our accruals for Medicaid rebates, Medicare rebates, contract rebates and charge backs totaled $1.5 billion as of October 1,2006, a decrease from $1.8 billion as of December 31, 2005, due primarily to the impact of the Medicare Act".

*Brand Name Drugs*

Negotiation may be necessary for certain "brand name" drugs. The specific drugs that will be subject to negotiation will depend on the data collected by the Secretary of HHS. Where there is a large difference between the lowest price determined by the market and the prices obtained by Medicaid, the VA or Canada, the Secretary should consider a series of actions.

*Will Negotiations Be Necessary?*

As noted earlier, it is unlikely that negotiations will be necessary for many drugs. The market place will be able to obtain a reasonable price for many drugs. For some drugs, however, negotiation may be necessary.

My recommendation is that the Secretary start with the drugs where the market prices are highest compared to the VA, Medicaid and Canadian price and work down. Assume for a moment that the lowest prices that any of the PDPs could obtain for drug A is $10.00 and the VA, Medicaid and Canada were all paying approximately $1.00 for that same drug. In this case the Secretary could begin by simply asking the pharmaceutical company why it is charging the Part D plans 10 times more and then take additional steps if necessary.

Medicaid directors and the VA have been engaging in this dialogue with pharmaceutical companies for years. Secretary Thompson recently negotiated a price discount for CIPRO following the anthrax scare. The Congressional Research Service recently prepared a report detailing how the VA and Medicaid program determine the rates they pay. Another Congressional Research Service Report details the approaches taken by other countries. The Secretary should review these options and proceed accordingly.

It is important to recognize that these programs have developed prices without large bureaucracies.

*Bully Pulpit*

It is possible that having the Secretary of HHS simply conduct the price comparison and report the drugs where the Part D plans are paying much higher prices will alter the market sufficiently. Drugs companies will not want to have to explain large price disparities to the Secretary or to the public.

Without some type of intervention it is important to note that CMS actuaries do not expect drug prices to continue to fall under current law according to the data presented in Table 2. The Secretary's bully pulpit could cause additional price reductions in the market place.

*Formularies*

One concern that has been expressed repeatedly in editorials and newspapers is that the Secretary will not be able to negotiate as effectively because nearly all drugs will have to be on the Medicare formulary. This is because each of the

Part D plans has their own formulary and the Medicare program would have to accommodate the formularies of all the Part D plans.

This would be true if the Secretary tried to negotiate prices for each and every drug. However, the Secretary of Health and Human Services is negotiating prices only for those drugs where the Part D plans have been unable to obtain prices comparable to Medicaid, VA, and Canada. The Secretary of HHS should intervene only when the relative prices are high and there is market failure. In these cases I expect the Secretary will be an equally effective negotiator as the Medicaid directors.

*Administrative Costs*

It has been suggested that CMS will need to greatly expand the bureaucracy in order to negotiate prices. Medicaid programs, the VA, Canada, and the Part D plans have been able to negotiate rates with minimal bureaucracies.

Because the Secretary of Health and Human Services would need to negotiate rates only for those drugs where the prices paid by the Part D plans are much higher than the rates in the VA, Medicaid, and Canada, the number of negotiations would be relatively few. Fewer staff would be needed than if the Secretary were trying to negotiate prices for each drug.

Goldilocks Arguments

I now return to the *Goldilocks* arguments that have been proposed. Sometimes the editorials argue that the Secretary will be too aggressive and sometimes the Secretary will be ineffective. Surprisingly both arguments have been made in the same editorial.

One argument is that the Medicare program will set the price too low and this will stifle pharmaceutical research and development. However, the pharmaceutical companies already have voluntarily signed contracts with the VA, Medicaid and Canada. While the pharmaceutical companies need to have prices that should allow them sufficient resources to fund research and development, it is not appropriate for the Medicare program and Medicare beneficiaries to be paying a large portion of the world's pharmaceutical research and development costs. Second, only a small portion of the drug company spending is actually for research and development. Pharmaceutical companies spend more on marketing than they do on research and development. Finally, the federal government recently doubled its investment in NIH to foster biomedical research and development and this investment should defray some of the cost of pharmaceutical development.

An opposing argument is that the rates will be too high because the Part D plans can negotiate more effectively than the Secretary. If this is the case then the Secretary of Health and Human Services will not have to negotiate for many drugs because the data will show that the Part D plans have obtained the lowest prices from the pharmaceutical companies.

The argument is made that Medicare can not negotiate effectively unless the Secretary is willing to walk away and not include a drug in the formulary. However, for many years state Medicaid programs have paid lower prices for drugs than the Part D plans have been able to obtain for the "dual eligibles." So have VA Secretaries and there is no also evidence that VA patients are suffering clinically because of the formulary in the VA.

The pharmaceutical industry is paying for advertisements citing a Kaiser Family Foundation study showing the most Americans are satisfied with the Medicare Part D plan. What these advertisements do not mention is that 67% of the public strongly favors and another 14 % somewhat favors "allowing the government to negotiate with drug companies for lower prices for Medicare RX drugs" Negotiating with drug companies has strong public support.

The bottom line is that Medicare beneficiaries often pay the highest drug prices in the world and it is the Medicare beneficiaries and the Medicare program that suffers.

*Summary*

In summary, I think that the Secretary should collect price data on every drug and then compare the lowest private sector price to the prices paid by the VA, Medicaid, and Canada. With this information the Secretary can determine where the differentials are the greatest and where negotiation is needed. The Congress should repeal the non interference clause and give the Secretary of HHS the authority to negotiate prices in circumstances where the Part D plans cannot get reasonable prices.

Table 1 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003

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

Table 1 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003 (Continued)

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

Table 1 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003 (Continued)

| | | | | |
|---|---|---|---|---|
| Synthroid | 0.2 | 8.55 | . | . |
| Synthroid | 0.18 | 6.84 | . | . |
| Synthroid | 0.3 | 6.34 | . | . |
| Ortho-tri-cyclin | 0 | 2.98 | 3.19 | . |
| Allegra-D | 60 | 3.02 | . | . |
| Glucotrol | 10 | . | 1.61 | . |
| Glucotrol | 5 | . | 1.68 | . |
| Glucotrol | 2.5 | . | . | . |
| Zestril | 20 | 2.74 | 0.99 | 1.12 |
| Zestril | 10 | 1.11 | . | 1.22 |
| Zestril | 40 | . | . | . |
| Zestril | 5 | 1.41 | 2.81 | 1.55 |
| Zestril | 30 | . | . | . |
| Zestril | 2.5 | . | . | 1.34 |
| Amoxicillin | 500 | . | 0.72 | 0.74 |
| Amoxicillin | 250 | . | . | 0.70 |
| Amoxicillin | 875 | . | . | . |
| Atenolol | 50 | . | 0.32 | 0.66 |
| Atenolol | 25 | . | . | 0.74 |
| Atenolol | 100 | . | 0.29 | 0.99 |
| Flonase | --- | 2.41 | 3.90 | 2.36 |

## Table 2

### Key Factors for Part D Expenditure Estimates

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

Source: CMS Actuaries

**Responses to Questions for the Record From Dr. Gerard F. Anderson**
**Senate Finance Committee Hearing of January 11, 2007**
**Prescription Drug Pricing and Negotiation:**
**An Overview and Economic Perspectives for the Medicare Drug Benefit**

***Senator Grassley***

1. What Other Negotiating Tools Could Medicare Have?

   Dr. Anderson, foreign governments have attempted for some time to control access to different types of drugs. For example, in Australia, as a matter of government policy, a woman has to break a bone before she can get medicines to treat osteoporosis.

   The U.K recently decided not to cover Alzheimer's medicines for patients with mild to moderate Alzheimer's disease. They also proposed denying coverage for important new medicines for multiple sclerosis, until a public outcry forced them to make it available to some patients in clinical trial protocols. In Germany, individual doctors are penalized if they spend more than an allotted amount on medicines.

   If the Secretary is required to negotiate but cannot use a formulary as leverage, would you say that these policies of government-run health care systems are the kind of policies that the Secretary could use to negotiate lower drug prices in Medicare?

1) I agree that governments in other countries have often made poor choices in their determinations of medical necessity. It is also true that the U.S. government has made similar errors, and so have private insurers. When any organization or government makes medical necessity decisions, errors will sometimes be made. Fortunately, the political process and the marketplace are generally responsive to these errors, and generally they are corrected.

   I do not think that the Secretary needs to use the lever of a formulary to obtain reasonable prices for drugs. I explained this in my testimony. The first thing the Secretary needs to know is when the market is not working for specific drugs. This information can be obtained by comparing the prices the Part D plans are getting to the prices that the VA, Medicaid and Canada are paying for the identical drugs. Where there are large disparities in what Part D pays, the Secretary should investigate the reasons. This should begin with a dialogue with the relevant pharmaceutical company. The simple question the Secretary should

ask is, why Part D plans are paying much higher rates than the VA, Medicaid and Canada. If that question is not sufficient to get the companies to lower their prices then the Secretary has additional alternatives. Also the Senate Finance Committee could hold hearings.

2. Comparing Part A and B Prices.

   Medicare's coverage of hospital and physician coverage also has significant coverage gaps. Medicare Parts A and B offer less than complete coverage. For example, the deductible under Part A for a hospital visit is $992—that is a pretty sizable deductible. There are also significant levels of patient cost-sharing, and, unlike Part D, there is no catastrophic protection for hospital or physician costs, or for anything else in Medicare for that matter.

   You have said that Medicare should compare what it pays for drugs with Europe and Canada and negotiate to get those rates. Would you also advocate setting hospital and doctor prices in the U.S. at the same level that they're set in Europe and Canada, to help fill these coverage gaps in Parts A and B?

2) First, the coverage gaps in Medicare Part D are significantly larger than the deductible in Medicare Part A. The "doughnut hole" is significantly larger than the $992 deductible in Part A. It is over a $3000 gap in coverage.

   Second, while Medicare beneficiaries can fill in the gaps in coverage for Part A and Part B coverage (and most do), they are precluded in the Medicare Modernization Act of 2003 of filling in the Part D gaps.

   Third, I write an article every year in the journal *Health Affairs* that makes the point that the U.S. pays higher rates for hospital and physician services than other countries. The title of one of these articles was "It's The Prices, Stupid: Why The United States Is So Different From Other Countries." I am not advocating lowering prices for Doctors and Hospitals—my point is simply that we pay higher prices and this is a major reason for higher health care spending in the U.S. I do think Congress should examine why health care prices are so much higher in the U.S. It seems to me that the competitive market is not bringing down health care prices.

***Senator Rockefeller***

1. Dr. Anderson, in your testimony you state that, "unfortunately, we do not know the prices that the Part D plans are paying for individual drugs. CMS collects the data on prices, price concessions, rebates, and discounts, but is prohibited by the MMA from sharing this data or even analyzing it internally."

What impact does this lack of transparency have on the Medicare program? Would great transparency lead to more prescription drug savings?

1) The Medicare program does not know if the Part D plans are getting good prices for drugs unless the Medicare program looks at the data. CBO, CRS and other Congressional agencies should also get access to the prices that the Part D plans are paying. The relevant comparison is the lowest price any Part D plan can obtain to the prices that the VA, Medicaid and Canada pay for the same drugs. Price transparency will allow the Secretary and the Congress to know if the Part D plans are getting a good deal. It will also suggest where the Secretary needs to negotiate because the market has failed to get comparable prices.

2. One of the areas I have been particularly interested in is the sharing of Medicare prescription drug data with state Medicaid programs. As you know, states are still responsible for coordinating care for dual eligibles beyond their prescription drug needs.

    a. What impact would data sharing between Medicare Part D and Medicaid have on health care costs?

    b. Wouldn't state Medicaid costs, and therefore federal Medicaid matching payments, decrease as a result of better coordination between the two programs?

2) Medicare beneficiaries with 5+ chronic conditions represent 67% of Medicare spending. Many of these beneficiaries are dual eligibles. On average they fill 48 prescriptions during the calendar year. Often these patients are on multiple medications and no single physician is responsible for their care.

   You have identified a critical issue that warrants much more attention. I tried to identify the problems Medicare beneficiaries are having with care coordination in an article I wrote in *The New England Journal of Medicine.* I have attached a copy. The article makes several specific suggestions that the Medicare program could undertake that would facilitate care coordination.

   I agree that Medicaid (and Medicare) spending would be reduced.

3. Last year I cosponsored legislation entitled the Medicare Prescription Drug Gap Reduction Act. This bill would have allowed the Secretary of Health and Human Services (HHS) to negotiate on behalf of Medicare beneficiaries for lower drug prices and applied these savings to diminish the doughnut hole. In a July 2004 *Health Affairs* article entitled "Doughnut Holes and Price Controls," you indicated that allowing Medicare to negotiate would reduce total beneficiary drug spending in 2006 by 45 percent and completely close the doughnut hole.

    a. Can you elaborate on your research in this area?

b. How much do you estimate total drug spending would be reduced if this approach were applied in 2007? What about over the 5-year budget window, 2008-2012?

c. Would we be able to use these savings to completely close the doughnut hole in 2007? What about each of the years from 2008-2012?

3a) I am attaching a copy of the article "Doughnut Holes and Price Controls." It explains that if the U.S. paid the same price for drugs as Canada, France or the United Kingdom that the "doughnut hole" could be completely eliminated with the Medicare program paying exactly the same amount of money and beneficiaries paying less for premiums and out-of-pocket expenditures.

3b&c) We assumed that prices would increase at the same rate under our proposal as the increase would be under current law. In this case it would be possible to eliminate the "doughnut hole" for the 2008-2012 period if the U.S. paid the same prices as Canada, the United Kingdom, France or the VA.

*Question for Dr. Anderson and Dr. Frank:*

1. My expectation when the dual eligibles were included in the Medicare drug benefit was that they would be able to save at least as much as they were saving on their prescriptions under Medicaid because of the expanded purchasing power of Medicare over Medicaid. However, that is not what has happened with the private plans.

   In fact, drug companies are reaping historic profits under Medicare. A November 6 *New York Times* article by Alex Berenson reported that drug companies raised prices on several top-selling drugs at double the rate of inflation after the drug benefit went into effect.

   I don't believe the answer for dual eligibles is to shift them back into Medicaid. Instead, I believe we have to find a solution for all Medicare participants that allows them to save at least as much as Medicaid on the cost of their prescriptions.

   a. Dr. Anderson and Dr. Frank, isn't one of the answers to guarantee better prices for all Medicare participants through Medicare price negotiation?

   b. What other tools used by Medicaid prescription drug programs could be used by Medicare to lower the price of prescriptions?

1a) I totally agree with you that the solution is to keep the dual eligibles in the Medicare program. I do not want the dual eligibles to get second class treatment.

My suggestion is to compare the prices for drugs in the Medicaid and Part D plans and see where the Part D plans are paying much higher prices. This represents a price increase to the Medicare program. The Secretary should then intervene and ask why the Part D plans are paying higher prices for those drugs. There is no reason why Medicare should pay substantially higher drug prices than Medicaid pays.

1b) There are numerous tools available to the Secretary of HHS. These are outlined in a series of CRS reports by Gretchen Jacobson and Jim Hahn. Before selecting a specific tool I believe it is best to see for which drugs the Part D plans are paying higher prices and then decide on the course of action. It makes a difference if it is orphan drugs, generics, single source drugs or competing brand name drugs.

*Question for All Witnesses:*

1. The essential difference between the Medicare pricing framework that Democrats envisioned and what was actually signed into law is that our proposals would have put Pharmacy Benefit Managers (PBMs) at risk for performance.

   In other words, payment to PBMs would have been on a per-script basis and according to factors such as keeping costs low for beneficiaries, filling prescriptions on time, using comparative effectiveness studies to determine covered drugs, offering generics, and effectively communicating plan changes to beneficiaries.

   Under the prescription drug law, plans hold all the power, but bear little profit risk for failing to meet certain performance standards. This is despite the massive subsidies provided to plans by the federal government.

   If Congress were to put prescription drug plans at greater risk for achieving standards like the ones I just mentioned, wouldn't that also be an effective way to achieve savings for seniors?

1) I totally agree that there should be pay-for-performance for filling prescriptions on time and conducting comparative effectiveness studies.

   I would oppose putting them at risk for some of the other items on your list because there are several things that they could do that would jeopardize the health of Medicare beneficiaries.

   For example, they could discourage beneficiaries from filling prescriptions or pushing generics when a brand name is clinically more appropriate. This is something better left to a doctor and a pharmacist and not a large health plan or bulk purchaser.

I would prefer having the government communicate plan changes to beneficiaries and not some entity trying to keep costs down.

***Senator Hatch***

*Question for Dr. Anderson:*

1. How would the Secretary of HHS determine the price that Medicare is willing to pay for a drug? How do you know that the prices paid in foreign countries would not stymie research or deny patients a needed drug? (From 1992-2002 the U.S. share of pharmaceutical industry profit grew from 47 percent to 62 percent while the EU share fell from 35 percent to 18 percent.)

1) Under my proposal the Secretary would not determine the price that Medicare is willing to pay for a drug.

I would have the Secretary compare the lowest price any Part D plan was able to obtain in the marketplace to the prices obtained by the VA, Medicaid and Canada. It would indicate to me where the Part D market was failing to obtain competitive prices. My expectation is that for the vast majority of drugs the market place is working very well and getting comparable prices. The VA, Medicaid and Canadian prices would be the starting point for the negotiations. The Secretary could focus his/her attention on the drugs where the market is not working.

I would compare the prices to Canada for two reasons. First, Canada is representative of what other countries pay for drugs. Second, and more important, a large price differential between U.S. and Canadian prices encourages American seniors to purchase drugs in Canada.

The pharmaceutical industry is multinational and they sell drugs all over the world. They cannot afford to ignore the rest of the world.

Finally, the U.S. patients should not be the primary supporter of pharmaceutical R&D in the world. The American senior should not be the primary support of pharmaceutical R&D in the world. This is what is currently happening.

***Senator Crapo***

*Questions for Dr. Anderson, Mr. Haislmaier, and Dr. Scott Morton:*

1. We know that large PBMs, such as Advance PCS (75 million covered individuals), Medco Health Solutions (65 million) and Express Scripts (57 million) have significant market power and are larger than Medicare. How can a government agency, working on behalf of 22.5 million seniors, match the purchasing power of a very large, very experienced industry working on behalf of hundreds of millions of Americans? How can we expect savings?

1) The Secretary should compare prices that large PBMs obtain to the prices that the VA, Medicaid and Canada obtain. My expectation is that they can obtain reasonably good prices for most drugs. However, without the data we do not know.

   My proposal would focus the attention of the Secretary on those drugs where the large PBMs cannot obtain low prices compared to Medicaid and/or Canada. The Secretary should intervene and negotiate only for those drugs where the market is not working.

2. Some have talked about non-interference as if it is a Republican creation. Isn't it true that in 1999 President Clinton offered this language in his Medicare proposal and Senator Daschle included this provision in his Medicare bill? And isn't it true that this provision was embraced by Democrats, some of my colleagues here included, as the best way to contain cost and protect patient access to prescription drugs? What has changed? Given the data that has been published since the implementation of the program, I would suggest the case for the noninterference clause has strengthened.

2) My proposal would allow the market to work where the market works best. However, when the market fails to obtain reasonable prices (perhaps because the government has given a pharmaceutical company a virtual monopoly when it grants a patent) then government intervention is needed.

3. If government negotiations happened to be successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost-shifting to small businesses and working families in the private insurance market?

3) It could cause some increases to the private sector. This, however, is not an adequate justification for the Medicare beneficiary continuing to pay the highest prices.

   It also assumes that pharmaceutical companies can dictate prices for small business and working families. If this is the case then this is not an efficient market and Congress should take action in this market as well.

**Read a related paper by Patricia M. Danzon**



# MARKETWATCH

## 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—indeed, 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 (ganderso@jhsph.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.*



DOI 10.1377/hlthaff.W4.396 

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 preclude 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.[8]

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]

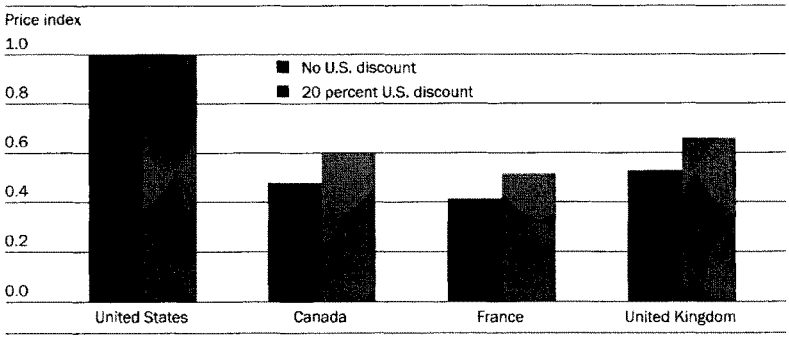
■ **Caveats.** The price differences noted above should be interpreted with several caveats in mind. First, since the market basket used for comparison was chosen to maximize standardization, it may not accurately reflect the average prices across the entire range of prescribed products in each country.[13] 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.[15] 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.[16]

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.[17] Deductibles, coinsurance, and premium subsidies were adjusted for low-income beneficiaries to match as closely as possible the features of the bill passed.[18] 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).[19] 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 assumptions | | Drug spending by Medicare beneficiaries in 2006 (billions of dollars) | | | |
|---|---|---|---|---|---|---|
| Model version | 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.

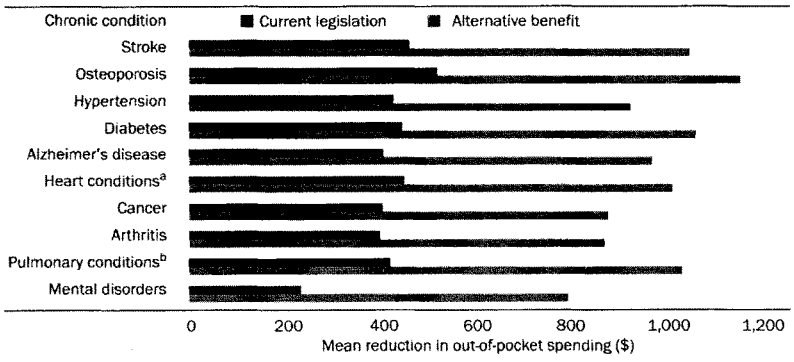
■ **Impact on beneficiaries with chronic conditions.** Elimination of the doughnut hole would affect Medicare beneficiaries in different ways. Here we highlight one group that would most likely benefit from the elimination of the doughnut hole: beneficiaries with multiple chronic conditions. These beneficiaries 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 alternative 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.

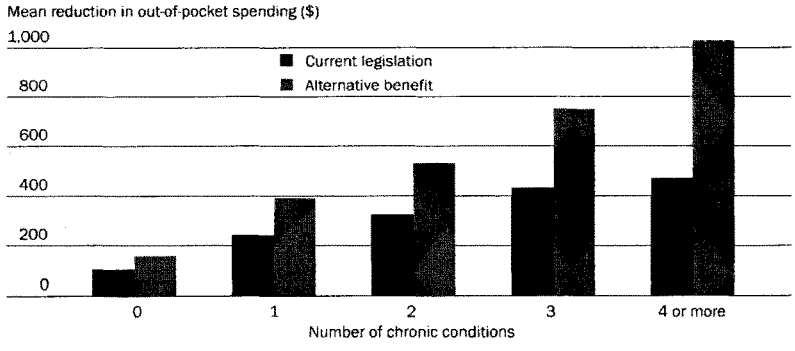
Higher prices, especially for brand-name drugs, allow the industry to sponsor high levels of R&D investment in the United States. In 1999, 60 percent of domestic investment in R&D was made by the pharmaceutical industry ($33.9 billion), 34 percent was made by the National Institutes of Health ($18.9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




**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. NIHCM 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 pharmacoeconomic 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?index=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?index=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, 1.0501 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/hlthaff.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* 25, 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_1.pdf (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* 325, 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. Hilty Moore and Associates, "Pharmaceutical In-

dustry—Segment Profile," 3 October 2002, www.hiltymoore.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 R&D Myths: The Case Against the Drug Industry's R&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 Oehson 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.

SOUNDING BOARD

# Medicare and Chronic Conditions

Gerard F. Anderson, Ph.D.

When the Medicare program became operational in 1966, its primary orientation was the treatment of acute, episodic illness.[1,2] The design of the program's benefits, coverage policies, payments to providers, and criteria for determining medical necessity were all oriented toward the treatment of acute diseases. Medicare retained this orientation for the next 40 years in spite of the growing number of Americans with chronic conditions.[3,4] The Medicare Prescription Drug Improvement and Modernization Act of 2003 was an important first step in the reorientation of the Medicare program toward the care of patients with chronic disorders. Additional changes, however, will be necessary if the Medicare program is to be truly responsible to its millions of beneficiaries who have chronic conditions, especially those with multiple coexisting illnesses.

## BENEFICIARIES WITH FIVE OR MORE CHRONIC CONDITIONS

A total of 83 percent of Medicare beneficiaries have at least one chronic condition. As additional diseases are diagnosed, expenditures and the probability of an adverse outcome increase rapidly. Any policymaker who is considering the modernization of Medicare must recognize that the 23 percent of beneficiaries with five or more chronic conditions account for 68 percent of the program's spending. In addition, the treatment of these beneficiaries is likely to remain a high-cost item until they die, since every year they see an average of 13 physicians and fill an average of 50 prescriptions.[5] They are also the beneficiaries who are most likely to have a preventable hospitalization and have the highest out-of-pocket spending because of gaps in coverage and cost-sharing arrangements.

## BEGINNING MODERNIZATION OF MEDICARE

The part of the legislation to modernize Medicare that has received the most attention is the prescription-drug benefit.[6] Coverage of prescription drugs can be viewed as part of a larger initiative to make the Medicare program more responsive to the needs of beneficiaries with chronic conditions (Table 1).

Section 721 created the Chronic Care Improvement Program, which represents an important new initiative to improve the quality of care for beneficiaries with chronic conditions in the Medicare fee-for-service program.[7] It is not a demonstration program but a newly covered service. Initially, a pilot program will offer self-care guidance and support to Medicare beneficiaries who have one or more of three chronic conditions: complex diabetes, congestive heart failure, and chronic obstructive pulmonary disease (COPD). These three diseases were chosen by Congress for multiple reasons, including their high prevalence in the Medicare population and the likelihood that beneficiaries with any one of these chronic conditions has one or more coexisting illnesses. An analysis of Medicare claims data for 2001, for example, shows that 96 percent of beneficiaries with COPD have at least one other coexisting illness, and 68 percent have four or more coexisting illnesses. The objective of Section 721 is to increase adherence to evidence-based care, reduce unnecessary hospital stays and emergency room visits, and help beneficiaries avoid costly and debilitating complications.

The program will be implemented in two phases. A pilot phase will help determine the final design. On December 8, 2004, pilot programs in Maryland, Pennsylvania, Oklahoma, Mississippi, Tennessee, Georgia, the District of Columbia, Florida, Chicago, and Brooklyn and Queens, New York, were selected.[7] These regional programs will be responsible for providing appropriate services to all Medicare beneficiaries who have complex diabetes, congestive heart failure, or COPD. Most of the organizations selected to oversee these programs are disease-management organizations. Payments to the pilot programs will be dependent on improvement in the quality of clinical care, the satisfaction of beneficiaries and providers, and a demonstration

**Table 1. Selected Provisions of the Medicare Modernization Act That Address the Needs of Patients with Chronic Conditions.**

| Section of Act | Title | Focus | Purpose | Current Status |
|---|---|---|---|---|
| 101 | National Standards for Electronic Prescriptions | Physicians | To work with clinicians and industry experts to develop national standards | Proposed rule issued February 4, 2005 |
| 108 | Electronic Prescription Grants | Physicians | To provide grants to implement electronic prescription-drug programs | Under way |
| 231 | Specialized Plans for Patients with Special Needs | Managed care | To provide incentives for managed-care plans to enroll patients with complex chronic conditions | Planning stage |
| 721 | Chronic Care Improvement | Fee for service | To improve adherence to evidence-based medicine and reduce unnecessary use of care | Funding for pilot programs awarded, mostly to disease-management companies |
| 721* | Care Management for High-Cost Beneficiaries | Fee for service | To involve clinicians in care management | Awards in 2005 |
| 723 | Strategy | Medicare program | To develop a long-term plan to improve the quality and reduce the cost of care for beneficiaries with chronic conditions | Under way |

* Medicare created this program as a companion to Chronic Care Improvement.

of success in lowering costs — all with the use of comparisons with control groups. Phase 2, which is scheduled to begin after 2006, may expand to other geographic regions (or perhaps nationally) programs or program components that have proved to be successful.

## GETTING PHYSICIANS INVOLVED

The Medicare program has developed its own companion initiative to Section 721. The focus of the companion initiative is high-cost beneficiaries with chronic conditions who do not have complex diabetes, congestive heart failure, or COPD. Unlike the Chronic Care Improvement Program, which awarded the funding primarily to disease-management organizations, the Care Management for High-Cost Beneficiaries demonstration is targeted primarily at physician groups, hospitals, and integrated delivery systems. One possible reason for this targeting is that Medicare wants to get the clinicians and delivery systems more directly involved in care management, especially for beneficiaries with multiple coexisting illnesses. One congressional study has reported that disease-management programs might not be cost-effective for beneficiaries with multiple coexisting illnesses.[8] The demonstration will require that applicants specify performance standards to improve clinical quality, measure the satisfaction of beneficiaries and providers, and achieve financial savings. Program funding should be awarded later this year.

## MANAGED CARE

Section 231 will encourage managed-care organizations to offer specialized plans that serve beneficiaries who have special health care needs. It has been a long-standing concern that managed-care organizations do not have a financial incentive to enroll beneficiaries with multiple serious chronic conditions.[9] Section 231 attempts to address this concern. Beneficiaries who are eligible for these specialized plans will be persons who live in institutions or who qualify for both Medicare and Medicaid; other persons who have chronic conditions or disabilities may be included. On November 8, 2004, the Centers for Medicare and Medicaid Services held a meeting to discuss issues involved with policy and operations. The specifics of this program are also scheduled to be announced later this year.

## ELECTRONIC PRESCRIPTIONS

Sections 101 and 108 begin the process that could lead to the integrated electronic medical record. Section 101 requires that the Medicare program work with industry experts to establish national standards for electronic prescriptions, and Section 108 will award grants to physicians to implement

electronic-prescription programs. The legislation envisions a Medicare program in which a doctor can write a prescription on a computer and electronically transmit that prescription to a pharmacy. This is the first step toward a broader objective of creating integrated electronic medical records with shared data repositories.

The Medicare Modernization Act contains numerous other provisions that set the stage for additional transformations in the program. For example, Section 723 mandates that the secretary of the Department of Health and Human Services "develop a plan to improve quality of care and reduce the cost of care for chronically ill Medicare beneficiaries." One of the targets of this report will be beneficiaries with multiple chronic conditions.

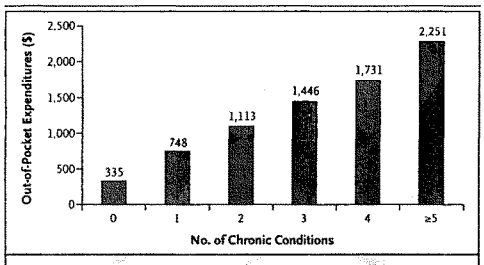



**Figure 1. Annual Out-of-Pocket Spending by Medicare Beneficiaries.**
Data are from the Medical Expenditure Panel Survey of 2001.[11]

## NEXT STEPS

Although the Medicare Modernization Act is an important first step toward reform, additional steps will be needed before the Medicare program is truly oriented toward the treatment of beneficiaries with multiple chronic conditions. The Medicare program cannot do this alone, however. It will also be necessary to change the delivery system, the research infrastructure, clinical education, and methods of financing medical care in order for the health care system to become more responsive to the needs of people with chronic conditions.[10]

One step is to restructure the cost-sharing arrangements in fee-for-service Medicare. Out-of-pocket spending by Medicare beneficiaries increases by an average of nearly $400 with each additional chronic condition (Fig. 1).[12] The current cost-sharing arrangements, such as the 20 percent coinsurance for physician visits or gaps in the prescription-drug benefit, are especially onerous to beneficiaries with multiple chronic conditions because these people are the highest users of medical services.[13] One possible solution is an out-of-pocket maximum. Most private insurers place a limit on the patient's out-of-pocket expenses, and Medicare could adopt a similar approach. Accomplishing this objective while still maintaining budget neutrality could require greater cost sharing by Medicare beneficiaries who have few or no chronic conditions. Alternatively, additional funding could be sought.

A second step is for Medicare to make an additional payment when a standardized electronic medical record is sent to a secure data repository. This would be an expansion of Sections 101 and 108 in the Medicare law and would allow for the creation of integrated electronic medical records, which would be especially helpful for beneficiaries with multiple chronic conditions. The Department of Veterans Affairs already has operational electronic medical records, and countries such as Canada and the United Kingdom are investing billions of dollars to create such systems.

One potential problem is the cost to the Medicare program. Given the tremendous volume of health care visits by Medicare beneficiaries, if Medicare were to pay $5 to a physician, hospital, or other provider to send an electronic medical record to the secure data repository, the cost to the Medicare program would exceed $4 billion annually. However, the Medicare program might be able to reduce costs and improve quality if widespread use of electronic medical records reduced the number of duplicate tests, adverse drug reactions, and unnecessary hospitalizations. To be successful, this program would require the active participation of clinicians — an area in which acceptance so far has been relatively slow.

For Medicare beneficiaries with five or more chronic conditions, who see an average of nine physicians on an outpatient basis and four hospital-based physicians annually, coordination of care is especially important. Both physicians and patients are aware of the problems that can occur when care is not coordinated.[14] A third step in reforming the Medicare program might be to require that the program explicitly pay for care coordination. Under one proposal, each beneficiary with five or more chronic conditions would designate a care coordi-

nator who would be required to communicate with all other clinicians on a periodic basis and help coordinate services.[15] More research will be necessary in order to identify the precise characteristics of beneficiaries who will benefit from care coordination and the specific interventions that will be successful. A major stumbling block could be the minimal training in care coordination that most physicians currently receive.[16] It may also be necessary to restructure the way in which Medicare pays for graduate medical education in order to emphasize training in care coordination in ambulatory settings.

## MEDICARE PAYMENT RULES

Important changes in Medicare's payment systems will be needed to pay for some of the proposed improvements in care for chronic conditions.[15,17] Fee-for-service payments will need to be restructured to encourage clinicians to work cooperatively; to encourage additional means of communication, such as e-mail; and to permit doctors to see a group of patients at once and allow other providers to participate in, and be reimbursed for, the care of patients.[15] Current Medicare rules make each of these improvements problematic. One problem is that the cost of processing claims for things such as e-mail communication could be greater than the amount Medicare would pay for the encounter. For some services, it could be difficult to limit the number of encounters between physicians and patients to a medically appropriate number. Patients could send five or more e-mail messages a day to a physician and expect a response if the physician were being reimbursed by Medicare. It is also difficult for the Medicare program to verify that an e-mail communication has occurred.

Current Medicare regulations are very specific about which providers are eligible to be paid and under which circumstances.[18] Nonphysicians are generally not eligible to be paid by the Medicare program unless the service is "incident to" a physician's service, and even then, payment is possible only under certain circumstances. Existing rules preclude payment for services that are commonly furnished in a physician's office or rendered without charge. As a result, explicit payment for patient education, some group visits, and multidisciplinary group conferences will be difficult under existing Medicare rules unless Congress explicitly authorizes payment (e.g., for education about diabetes, as it currently does).

Payments to managed-care plans will need to cover the full expected cost of care for beneficiaries with multiple chronic conditions — something that the current system does not do. Beginning in 2007, Medicare will pay managed-care plans on the basis of a system that is 100 percent risk-adjusted for the types of patients the managed-care plan enrolls. In theory, this risk-adjusted payment would reflect the additional costs of treating a beneficiary with multiple chronic conditions. In reality, the payment will still underestimate the cost of treating a beneficiary who requires expensive care or multiple hospitalizations.[18]

There are several problems to overcome before Medicare can implement any of these recommendations in the next round of program reforms. Some of these proposals are likely to increase the costs of Medicare, at least in the short run. However, spending could be cut by reducing the number of hospitalizations, drug interactions, and duplicate tests. Any savings would need to be demonstrated. The second problem is the potential for fraud and abuse. The concern, as discussed earlier, is how to determine whether services are actually being provided, especially for activities such as e-mail communication. The third problem is how to demonstrate improvement in health outcomes. Both physicians and beneficiaries will need to be convinced that the reforms result in better clinical outcomes. The fourth problem is the unwillingness of some clinicians to participate in the reforms. In some ways, the fourth consideration may be the most important obstacle. Costs can be lowered, fraud and abuse minimized, and outcomes improved only if a high percentage of clinicians perceive that Medicare's new orientation is improving outcomes.

Because of the recent legislation, it can now be said that Medicare is becoming a program for people with chronic conditions. However, we have just begun the journey.

Supported by the Robert Wood Johnson Foundation.

From the Center for Hospital Finance and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore.

1. Corrigan JM, Eden J, Smith BM, eds. Leadership by example: coordinating government roles in improving healthcare quality. Washington, D.C.: National Academies Press, 2003.
2. Williams RD II. The unique needs of Medicare beneficiaries. Brief no. 10. Washington, D.C.: National Academy of Social Insurance, October 2004.
3. Thorpe KE, Florence CS, Joski P. Which medical conditions ac-

count for the rise in health care spending? Bethesda, Md.: Health Affairs, August 25, 2004 (Web exclusive). (Accessed June 30, 2005, at http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.437/DC1.)

4. Wu S, Green A. Projection of chronic illness prevalence and cost inflation. Santa Monica, Calif.: RAND Health, October 2000.

5. Johns Hopkins University. Partnership for solutions: better lives for people with chronic conditions. (Accessed, June 30, 2005, at http://www.partnershipforsolutions.com.)

6. Frank RG. Election 2004: prescription-drug prices. N Engl J Med 2004;351:1375-7.

7. Medicare health support. Baltimore: Centers for Medicare & Medicaid Services, 2005. (Accessed on June 30, 2005, at http://cms.hhs.gov/medicarereform/ccip.)

8. An analysis of the literature on disease management programs: letter to the honorable Don Nickles. Washington, D.C.: Congressional Budget Office, October 13, 2004.

9. Kuttner R. The risk-adjustment debate. N Engl J Med 1998;339:1952-6.

10. Anderson GF, Knickman JR. Changing the chronic care system to meet people's needs. Health Aff (Millwood) 2001;20(6):146-60.

11. 2001 Medical Expenditure Panel Survey. Rockville, Md.: Agency for Healthcare Research and Quality, 2001.

12. Hwang W, Weller W, Ireys H, Anderson GF. Out-of-pocket medical spending for care of chronic conditions. Health Aff (Millwood) 2001;20(6):267-78.

13. Anderson GF, Shea DG, Hussey PS, Keyhani S, Zephyrin L. Doughnut holes and price controls. Bethesda, Md.: Health Affairs, July 21, 2004 (Web exclusive). (Accessed June 30, 2005, at http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.396/DC1.)

14. Anderson GF. Physician, public, and policymaker perspectives on chronic conditions. Arch Intern Med 2003;163:437-42.

15. Berenson RA, Horvath J. Confronting the barriers to chronic care management in Medicare. Bethesda, Md.: Health Affairs, January 22, 2003 (Web exclusive). (Accessed June 30, 2005, at http://content/healthaffairs.org/cgi/content/full/hlthaff.w3.37v1/DC1.)

16. Darer JD, Hwang W, Pham HH, Bass EB, Anderson GF. More training needed in chronic care: a survey of US physicians. Acad Med 2004;79:541-8.

17. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. Milbank Q 1996;74:511-44.

18. Pope GC, Kautter J, Ellis RP, et al. Risk adjustment of Medicare capitation payments using the CMS-HCC model. Health Care Financ Rev 2004;25(4):119-41.

Committee
On Finance
Max Baucus (D-Mont.)

NEWS RELEASE http://finance.senate.gov

**Opening Statement of U.S. Senator Max Baucus (D-Mont.)**
**Drug Pricing and Negotiation under the Medicare Prescription Drug Benefit**
**Hearing before the Senate Finance Committee**

The Medicare prescription drug program just turned a year old. Like all one-year-olds, it grew at a rapid pace. And like all one-year-olds, it needs careful monitoring — and guidance — to ensure that it matures properly.

In its first year, Medicare's drug program provided coverage to more than 22 million people. Many of these people could not have afforded their medicines without Medicare's help. Prescription drug costs have been growing faster than other health care costs. And drug costs have been growing much faster than Social Security checks. That is why Medicare's drug benefit is so important.

I have heard from many seniors in Montana and across the country about how pleased they are with the new drug benefit. They are getting real help purchasing the medicines that they need. Four out of five seniors are satisfied with the new benefit. That is good, but not nearly good enough.

One in five seniors is not satisfied. I have heard from these folks too. Many were confused by the myriad plans. Many were perplexed by the formularies. Or worse yet, many are still not able to access affordable medicines.

We must ensure that the Medicare drug program works well for all seniors and people with disabilities.

This hearing is the Committee's first step on what will be a long road. We will be overseeing the Medicare drug benefit throughout the 110th Congress. Working together, Senator Grassley and I are planning an aggressive Committee agenda. We will address CMS oversight. We will address pharmacy access. We will address the low income subsidy asset test. And those are just a few of the topics we will examine.

More than five million seniors without drug coverage did not enroll in the program. We need to reach out to these folks. Many of them are eligible for extra financial help in the program. They may not know it.

*--more--*

For those who did enroll, Congress needs to keep an eye on how well they are able to get the medicines that they need. We also need to monitor how CMS regulates the activities of the private plans that deliver the benefit.

We are like any parent of an active one-year old. We are going to spend a lot of time watching over the new benefit as it develops.

Today's hearing will focus on prescription drug pricing and negotiation under Medicare. The law prohibits the Secretary of Health and Human Services from negotiating or setting prices under the Medicare Part D program. Legislative proposals in both the House and the Senate have sought to eliminate that prohibition — what people refer to as the "noninterference clause." These proposals have generated a great deal of debate.

We all have questions about government price negotiations. Should we eliminate the prohibition? Should we give Medicare authority to negotiate? Should we require it?

I know that my Colleagues on the Finance Committee want to consider carefully any proposal that affects drug prices. Today is our opportunity to put aside the politics. Today we can take a step back and get the facts.

We can explore the wide range of approaches used by other purchasers and countries to affect prescription drug prices. We can ask academics and other experts who have no stake in the matter to share their research and their views on the market for prescription drugs. We can ask what they think of the way that private plans set drug prices. And we can ask what should be done to improve the system.

Before we move forward, I will closely consult with Committee Members. We will consult with the administration. And we will consult with other stakeholders who care deeply about this issue and about making this benefit work best for seniors.

Today, I am pleased we have a distinguished panel of witnesses to help us understand prescription drug pricing and to answer our questions.

We will hear from John Dicken from the Government Accountability Office -- GAO. He will provide an overview of Federal drug pricing programs and approaches used by other countries to affect drug prices.

We will also hear economic perspectives on the Medicare prescription drug market from a distinguished group of academic economists.

I thank all our witnesses for joining us today in this first check-up of the year for our one-year-old program. We have raised the program through its toddler stage. Let's learn what we can do even better as the program heads into its terrible twos.

###

**Statement for Senator Bunning**
**January 10, 2007**
**Medicare Hearing on Non-Interference Provision**

By most accounts, the Medicare drug bill has been a success.

- According to JD Power and Associates, 75% of Medicare beneficiaries enrolled in Part D are happy with their drug coverage;
- CMS recently announced that the average monthly premium for Part D in 2007 is $22 a month, which is substantially less than the $37 originally projected;
- beneficiaries are averaging a yearly savings of almost $1,200 on drug costs;
- the drug benefit costs $13 billion less than expected in its first year; and
- more than 38 million Medicare beneficiaries have drug coverage, and most of them – 70% -- won't be affected by the donut hole.

In my book, that is a success. Beneficiaries have access to drugs. They have choices among plans, and they are saving money.

One of the reasons this program has worked so well is because we didn't want to just create another big bureaucratic system within Medicare to run the program. Instead, we wanted to create a competitive system that provided beneficiaries with choices of coverage and allowed private insurers who have the expertise and skill at negotiating for drugs to be involved in the process. That is why the drug benefit relies on health insurance companies and others to provide the benefits to seniors.

To make sure that the market was allowed to work, the non-interference provision was included in the Medicare bill. This provision basically says the Secretary of HHS cannot interfere in the negotiations between the private Medicare plans and the drug manufacturers. This was not a new idea in 2003.

In fact, President Clinton had a similar provision in a 1999 bill to modernize Medicare, and multiple Democratic bills have used similar language.

Now, several of my colleagues are complaining that this provision is unfair to seniors and the government could get a lower discount on drugs. This is the focus of the hearing today, and I look forward to hearing from our witnesses.

However, I am disappointed that the Secretary of the Department of Health and Human Services has been left off the witness list today. As the person who would be required to actually negotiate for drug prices, the Secretary should be here today. We should hear what he has to say in a public setting, and have the opportunity to ask him questions.

Not inviting the Secretary to be here today is a disservice to the Medicare beneficiaries enrolled in the drug benefit.

The last thing we want to do is turn the Medicare drug program into a government-run system. While I agree that there are some changes that need to be made to the Medicare drug benefit, gutting the private competition in the bill isn't one of them.

The benefit, by and large, is working, and the private competition between plans is helping to hold down costs and provide a good benefit to seniors. I hope we can put the campaign rhetoric behind us, and actually take an honest look at the Medicare program to do what is best for America's seniors.

Thank you.

United States Government Accountability Office

GAO

Testimony
Before the Committee on Finance, U.S. Senate

For Release on Delivery
Expected at 10:00 a.m. EST
Thursday, January 11, 2007

# PRESCRIPTION DRUGS

## An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs

Statement of John E. Dicken
Director, Health Care


GAO-07-358T

January 11, 2007

GAO
Accountability · Integrity · Reliability
**Highlights**

Highlights of GAO-07-358T, a testimony before the Committee on Finance, U.S. Senate

PRESCRIPTION DRUGS

# An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs

## Why GAO Did This Study

Rising prescription drug spending has led the United States and other countries to seek ways to negotiate lower prices with drug manufacturers. Currently, the Medicare Part D benefit, which offers outpatient prescription drug benefits to beneficiaries including elderly and certain disabled people, comprises competing prescription drug plans overseen by the Centers for Medicare & Medicaid Services. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 prohibits the Secretary of Health and Human Services from interfering with price negotiations between Part D plan sponsors and drug manufacturers and pharmacies. Some Members of Congress have proposed amending the statute to allow the Secretary of Health and Human Services to negotiate directly with drug manufacturers on behalf of Part D beneficiaries.

GAO was asked to describe how prescription drug prices are negotiated. This testimony provides an overview of such efforts (1) by governments in other countries; (2) by U.S. private payers, such as employer-based health plans; and (3) by federal programs other than Medicare Part D. This testimony is based on previous GAO reports from 2002 through 2006 on federal programs that purchase or cover prescription drugs and other relevant literature from congressional agencies and federal or international organizations.

www.gao.gov/cgi-bin/getrpt?GAO-07-358T.

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

## What GAO Found

Governments in other countries use a range of approaches to limit the amount they pay to acquire drugs:

- Ceiling prices establish a maximum price manufacturers may charge for their products. Purchasers may sometimes negotiate more favorable 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 control how much profit a drug manufacturer may earn per product or within a specified period of time.

Other factors—such as scope of coverage and national formularies, which are generally lists of preferred drugs—influence drug price negotiations.

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

Approaches for negotiating drug prices vary among federal programs in the United States. In part, these approaches depend on whether the programs purchase and distribute drugs directly or reimburse retail pharmacies or other providers for dispensing or delivering drugs. While the approaches used by federal programs in the United States reflect U.S. laws, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payers. Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and still others rely on negotiations with manufacturers, directly or through private health plans. For example, the Departments of Veterans Affairs's and Defense's prices for a prescription drug may be the lowest of a ceiling price, other established price, or a price negotiated with the manufacturer. State Medicaid programs, joint federal-state programs that finance medical services for certain low-income adults and children, reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. The programs receive rebates from manufacturers that are meant to take advantage of the prices for drugs in the commercial market and are required to reflect discounts and rebates negotiated by private payers with manufacturers. For health benefits offered to federal employees, retirees, and dependents, rather than negotiating with manufacturers, the government contracts with participating health plans that typically use PBMs to negotiate drug prices and offer other pharmacy benefit, administrative, and clinical services.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you examine approaches for prescription drug pricing and negotiations. In the United States and in other countries, the rising cost of prescription drugs continues to pose significant financial burdens on governments, private payers, and individuals responsible for paying for drugs. This has led to a wide range of market-based and governmental approaches to reduce drug spending. Some of these approaches rely on negotiations between payers for prescription drugs and drug manufacturers.

In the United States, prescription drugs are a particular focus for the federal government as Medicare—the federal health insurance program that serves nearly 43 million elderly and disabled individuals—begins the second year of its voluntary outpatient prescription drug benefit. This benefit, known as Medicare Part D, was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) beginning January 1, 2006.[1] Medicare beneficiaries may choose a Part D plan from multiple plans offered by private sponsors, largely commercial insurers, under contract with the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that administers Medicare. These plans differ in the drugs they cover, the pharmacies they use, and the prices they negotiate with drug manufacturers and pharmacies. In addition, costs to the enrollee for the monthly premium, the annual deductible, and copayments for covered drugs vary by plan.

While the Medicare Part D benefit is characterized by multiple competing prescription drug plans that are overseen by CMS, MMA prohibits the Secretary of Health and Human Services from interfering with price negotiations between Part D plan sponsors and drug manufacturers and pharmacies.[2] Some Members of Congress, contending that the combined purchasing power on behalf of all Medicare Part D beneficiaries could be used as leverage, have proposed amending the law to provide for the

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

[2]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-111(i)).

Secretary of Health and Human Services to negotiate directly with drug manufacturers.[3]

As Congress considers these issues for Medicare Part D, you asked that we broadly describe the variety of approaches used to negotiate drug prices. Specifically, my remarks today will provide an overview of the approaches used to negotiate drug prices by governments in other countries, by private payers in the United States, and by federal programs other than Medicare Part D.[4] My remarks are primarily based on our previous reports from 2002 through 2006 on federal programs that purchase or cover prescription drugs, which were done in accordance with generally accepted government auditing standards, as well as other relevant literature on approaches in the United States and other countries prepared by congressional agencies and international and federal organizations.[5]

In summary, a wide range of approaches is used by other countries and by private payers and federal programs in the United States to negotiate drug prices. The approaches governments in other countries use 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.

[3]For example, H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, was introduced on January 5, 2007. It would require the Secretary of Health and Human Services to negotiate Part D drug prices on behalf of Medicare beneficiaries.

[4]For this testimony, we reviewed information summarizing approaches used by members of the Organisation for Economic Co-operation and Development (OECD). 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. http://www.oecd.org (accessed January 9, 2007). As appropriate, we present examples of drug pricing approaches used in five OECD member countries other than the United States.

[5]A list of related GAO products is included at the end of this statement. For additional information on approaches used by other countries, U.S. private payers, and federal programs, see, for example, Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (Washington, D.C., 2005); Congressional Research Service, *Federal Drug Price Negotiation: Implications for Medicare Part D* (Washington, D.C., 2007); Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Washington, D.C., 2005); and Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* (Washington, D.C., 2004).

- 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 key factors—such as scope of coverage and national formularies, which are generally lists of preferred drugs—influence drug price negotiations.

Private payers in the United States, including employer-based health plans and private insurers, typically contract with pharmacy benefit managers (PBM). PBMs negotiate rebates or payments with manufacturers and prices with retail pharmacies, and they provide other related administrative and clinical services. PBMs compete in the private market based on their ability to negotiate reduced prices and contain costs, and PBMs may receive compensation from health plans and from retaining some of the savings they negotiate with pharmacies or manufacturers. PBMs influence price negotiations with manufacturers through formulary development and management and through the large number of health plan enrollees they typically represent.

Approaches for negotiating drug prices vary among federal programs in the United States. Factors contributing to this variation include the use of formularies and whether the programs purchase and distribute drugs, reimburse retail pharmacies or other providers for drugs dispensed and delivered, or contract with private health plans that provide and manage pharmacy benefits. For example, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) often purchase drugs from suppliers, then distribute drugs to beneficiaries through internal facilities or mail-order pharmacies. State Medicaid programs, on the other hand, reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. While the approaches used by federal programs in the United States reflect the laws governing them, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payers. Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and still others rely on negotiations with manufacturers, either directly or through private health plans. For example, VA's and DOD's prices for particular prescription drugs included on their formularies may be the lowest of a ceiling price, a

price listed on a federal supply schedule (FSS), or the price negotiated with a manufacturer. For health benefits offered to federal employees, retirees, and their dependents, the federal government uses a different approach, modeled after other large U.S. employers' health benefits. Under this approach, rather than the government negotiating with manufacturers, the government contracts with participating health plans that typically use PBMs to negotiate drug prices, manage formularies, and offer other pharmacy benefit, administrative, and clinical services.

## Background

Prescription drug spending, paid for by a mix of public and private payers, has outpaced total health care spending in the United States and other countries in recent years. In the United States, federal programs either directly purchase and distribute prescription drugs or reimburse pharmacies or other providers for drugs dispensed or delivered.

### Prescription Drug Spending and Cost Containment Strategies in Other Countries and the United States

According to the Organisation for Economic Co-operation and Development (OECD), drug spending in member countries (including the United States) increased on average by about 6 percent a year from 1998 through 2003.[6] On average, growth in drug spending outpaced the growth in spending for total health expenditures. Among OECD member countries, the share of public and private spending for prescription drugs varies, but in 2004 public sources accounted for the bulk of spending in most countries.

In the United States, rising prescription drug prices and increased spending have been a concern to federal and state governments and to private payers, including private insurers and employer-based health plans. CMS reports that total national spending by all public and private payers for prescription drugs from retail outlets increased on average by about 11 percent a year from 1998 through 2005—faster than the average 7 percent a year increase in total U.S. health expenditures for the same period.[7] CMS also reports that national spending by all public and private

[6]Growth in drug spending for these nations includes both prescription and over-the-counter drugs.

[7]Centers for Medicare & Medicaid Services, Trustees, National Health Expenditure, Historical Data (Baltimore, MD: Centers for Medicare & Medicaid Services, 2007), http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp (accessed January 9, 2007). These figures reflect spending on prescription drugs through retail outlet sales, but do not account for nonretail outlet sales, such as those for drugs dispensed in inpatient hospital or nursing home facility settings.

payers for prescription drugs from retail outlets totaled about $201 billion in 2005. Nearly three-quarters (73 percent) of this spending came from private funds—including private insurance and out-of-pocket payments—while the remaining share came from public sources. The public share includes the federal government's share of total spending for prescription drugs from retail outlets. Federal spending for prescription drugs was about 16 percent of the total, or $33 billion, in 2005. However, these data precede the 2006 establishment of Medicare Part D, which increased public and federal shares of prescription drug expenditures.

In the face of rising prescription drug spending, the governments of other countries, U.S. private payers, and federal programs have applied both demand- and supply-side measures to contain prescription drug spending. Demand-side measures are aimed at wholesalers, retailers, doctors, and patients and include such strategies as prescribing guidelines, generic substitution policies, and fixed and tiered copayments. Supply-side measures are aimed at limiting the cost of prescription drugs by negotiating prices and by requiring or encouraging the use of certain drugs through formularies established by a government, health plan, or federal program. Formularies have long been used to control the cost and utilization of prescription drugs. Some formularies are more restrictive than others; open formularies provide coverage for both listed and nonlisted drugs, and closed formularies generally provide coverage only for drugs that are included on the list. Many other formulary approaches fall somewhere in between, encouraging the use of listed drugs by charging higher copayments for those not listed. Under a tiered cost-sharing approach, for example, generic and preferred drugs require lower copayments than brand and nonpreferred drugs. Health plans that use formularies typically have provisions that enable enrollee access to nonformulary drugs when they are medically necessary and allow patients to appeal coverage decisions.

In the U.S. private market, PBMs offer health plans a variety of prescription drug management services, including negotiating rebates with manufacturers, negotiating price discounts with retail pharmacies, operating mail-order prescription services, managing drug formularies, and processing claims. PBMs also provide health plans with clinical services, such as formulary development and management, prior authorization and drug utilization reviews to screen prescriptions for such issues as adverse interactions or therapy duplication, and substitution of

generic drugs for therapeutically equivalent brand drugs.[8] Health plans pay PBMs fees for these administrative and clinical services as well as for retail and mail-order drug costs. PBMs may also retain savings from or have other financial incentives to negotiate lower drug prices and rebates. In 2004, an estimated 200 million people, or about 68 percent of the U.S. population, were enrolled in private health plans that used PBMs.[9]

## Federal Programs

Beyond Medicare Part D, a range of federal programs, established by statute, in the United States offer drug benefits to individuals meeting various eligibility criteria. These programs cover a broad and varying array of prescription brand and generic drugs.[10] These drugs are made available to beneficiaries through multiple approaches, ranging from direct purchase and provision by federal programs to contracts with private insurers and PBMs to provide drug coverage.

The VA pharmacy benefit is provided to eligible veterans and certain others. In general, medications must be prescribed by a VA provider, filled at a VA pharmacy or through a VA Consolidated Mail Outpatient Pharmacy, and listed on the VA national drug formulary, which comprises 570 categories of drugs. In addition to the VA national drug formulary, VA facilities can establish local formularies to cover drugs not on the national formulary. VA may provide nonformulary drugs in cases of medical necessity.[11] In 2005, VA spent $4.2 billion on drugs and medicines.

[8]Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drugs.

[9]PricewaterhouseCoopers. *The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation.* A report prepared at the request of Pharmaceutical Care Management Association. July 2004.

[10]Brand drugs are single-source and multisource drugs that are marketed under a proprietary, trademark-protected name. Single-source drugs include those brand drugs that have no generic equivalent on the market and are generally available from only one manufacturer. Brand multisource drugs include those brand drugs that have generic equivalents available from multiple manufacturers and are marketed under a proprietary name. Generic drugs include multisource drugs that are chemically identical to their branded counterparts and are generally marketed by multiple manufacturers under a nonproprietary name.

[11]In a 2000 report, the Institute of Medicine characterized the VA formulary as "not overly restrictive."

The DOD pharmacy benefit is provided to TRICARE beneficiaries,[12] including active duty and retired uniformed service members. In addition to maintaining a formulary, DOD provides options for obtaining nonformulary drugs. Beneficiaries can get prescription drugs through network retail pharmacies, nonnetwork retail pharmacies, DOD military treatment facilities, and DOD's TRICARE Mail Order Pharmacy. In 2005, DOD spent $5.4 billion on prescription drugs.

Medicaid is the joint federal-state program that finances medical services for certain low-income adults and children. While some benefits are federally required, prescription drug coverage is an optional benefit that all states have elected to offer. State Medicaid programs, though varying in design, cover both brand and generic drugs. Drug coverage depends on the manufacturer's participation in the Medicaid drug rebate program, through which manufacturers pay rebates to state Medicaid programs for covered drugs used by Medicaid beneficiaries. Retail pharmacies distribute drugs to Medicaid beneficiaries, then receive reimbursements from states for the acquisition cost of the drug and a dispensing fee. In 2004, Medicaid outpatient drug spending peaked at $31 billion—including $19 billion as the federal share—which was calculated after adjusting for manufacturer rebates to states under the Medicaid drug rebate program. Medicaid spending on outpatient prescription drugs is expected to decrease with the transition of prescription drug coverage for dual eligibles—those eligible for both Medicaid and Medicare—to the Medicare Part D program.

The 340B drug pricing program gives more than 12,000 entities of various types—community health centers, AIDS clinics, and disproportionate share hospitals[13] among them—access to discounted drug prices, called 340B ceiling prices.[14] These entities must enroll in the program, which is administered by the Health Resources and Services Administration. The program requires drug manufacturers to offer covered drugs to enrolled

[12]DOD provides health care through TRICARE—a regionally structured program that uses contractors to maintain provider networks to complement health care provided at military treatment facilities.

[13]Disproportionate share hospitals are hospitals that serve a relatively large volume of low-income patients and are eligible for payment adjustments under Medicare's prospective payment system or under Medicaid.

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

entities at or below 340B ceiling prices.[15] Enrolled entities establish their own formularies and may dispense drugs through in-house pharmacies, dispensing physicians, or contracted retail pharmacies. Enrolled entities spent an estimated $3.4 billion on drugs in 2003.

Medicare, the federal health insurance program that serves the nation's elderly and certain disabled people, in addition to the outpatient prescription drug benefit offered in Part D, covers certain other drugs through Part B.[16] Drugs covered by Part B are typically administered by physicians or other medical professionals rather than by patients themselves. These drugs include, for example, those furnished in conjunction with dialysis services or durable medical equipment. In 2005, Medicare paid more than $9 billion for drugs covered under Part B.

The Federal Employees Health Benefits Program (FEHBP) is the largest employer-sponsored health insurance program in the country. Through it, about 8 million federal employees, retirees, and their dependents receive prescription drug coverage through participating private health insurance plans. Most of these plans contract with PBMs to manage their drug benefits. The drugs covered vary by plan, but are typically part of relatively broad formularies of drugs. In general, beneficiaries have several options for obtaining drugs, including through retail or mail-order pharmacies. In 2005, FEHBP prescription drug spending was an estimated $8.3 billion.

[15]Drug manufacturers must participate in the 340B drug program in order to get their drugs covered by Medicaid.

[16]The Medicare Part B program covers a broad range of medical services, including physician, laboratory, and hospital outpatient department services and durable medical equipment.

## Approaches Used by Other Countries for Negotiating Drug Prices

According to the OECD, member countries that offer subsidized drug programs are grappling with how to manage increased drug spending given limited budgets. These countries have three main approaches to limiting the amount they pay to acquire drugs:

- ceiling prices,
- reference prices, and
- profit limits.

*Ceiling prices.* 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. One approach is for a government to set prices for drugs and prohibit sales at greater prices. In France and Australia, for example, a government committee sets the prices at which drugs must be purchased and reimbursed. Alternatively, a government may set a price ceiling and allow purchasers to negotiate more favorable prices with manufacturers directly. In Canada, the Patented Medicines Prices Review Board sets the maximum price a manufacturer can charge direct purchasers. It can impose fines on any manufacturer that attempts to sell a drug at a price greater than the established ceiling. An additional method used to control prices is for a government to set reimbursement rates for new drugs at low levels; because any price above the set reimbursement rate would be an out-of-pocket expense to the consumer, the reimbursement rate effectively becomes the market price.

*Reference prices.* Reference prices use local or international price comparisons of drugs classified in the same therapeutic group to determine a single or maximum price for all drugs in that group. The therapeutic group of drugs can encompass old and new drugs, including brand or generic drugs. The lowest priced drug may then establish the maximum price for the entire therapeutic group. Germany, for example, sets such prices based on local price comparisons of drugs classified in the same therapeutic group.

*Profit limits.* Profit limits control the amount of profit a drug manufacturer may earn on a product or within a specified period of time. If the established threshold is exceeded, the manufacturer is required to accept a price cut or pay rebates to the government. In the United Kingdom, for example, there are limits on the profits that a drug manufacturer can earn on sales to the National Health Service.

Several other key factors can influence drug price negotiations in OECD countries. Unlike the United States, many OECD countries, such as Australia and France, have universal health care systems that allow a mandated, relatively more unified approach to drug pricing. While these countries vary in their government's respective share of drug spending, some set national, uniform maximum prices to be paid by all purchasers, including private payers. Many countries also establish national formularies that define which drugs are to be covered by all purchasers.

## Approaches Used by U.S. Private Payers for Negotiating Drug Prices

In the United States, private payers represent the largest source of prescription drug spending. These payers, including employer-based health plans and private health insurers, typically contract with PBMs to help manage their prescription drug benefits. PBMs employ several cost containment strategies for lowering drug prices for the health plans and enrollees they represent. PBMs negotiate rebates or payments with manufacturers and prices with networks of retail and mail-order pharmacies, passing along at least some of the savings to health plans and enrollees. Manufacturers and pharmacies agree to these price concessions in exchange for both the large number of enrollees PBMs represent and the ability of PBMs to influence enrollee choice of drugs and pharmacies.

One of the key ways PBMs influence price negotiations with manufacturers is through formulary development and management. PBMs may assist health plans in developing or managing a formulary that the health plan will cover. Health plans often provide financial incentives, such as lower enrollee cost-sharing, to encourage use of preferred drugs listed on the formulary.[17] Since PBMs represent a large number of enrollees, manufacturers have a strong interest in having their drugs listed on plan formularies. Manufacturers pay PBMs through rebates or other payments to be included on plan formularies and to capture greater market shares for their drugs. For example, many mail-order pharmacies are owned by PBMs, and PBMs can obtain greater manufacturer rebates or payments by dispensing a high volume of the manufacturer's drug.

The extent to which pharmacy discounts and manufacturer rebates or payments are shared with health plans and enrollees depends on contractual arrangements with the health plan and the plan's benefit design. For example, PBMs negotiate contracts with health plans and their

[17]In some cases, a plan may charge more or may not provide coverage for drugs not listed on the plan's formulary.

networks of pharmacies separately, which means that health plans may pay PBMs higher prices for drugs than the PBM negotiated between itself and the pharmacy. Similarly, PBMs often set up contractual arrangements with manufacturers based on manufacturers' entire line of products rather than per drug. Further, PBMs may retain a portion of the rebates or payments they receive associated with individual health plans or all the health plans they represent. PBMs may also obtain additional rebates or payments from manufacturers for administering formularies or providing certain services, such as encouraging the use of one therapeutically similar drug over another.

## Approaches Used by U.S. Federal Programs for Negotiating Drug Prices

Approaches for negotiating drug prices vary among federal programs in the United States. While these approaches reflect the laws that govern them, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payers. Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and still others rely on negotiations with manufacturers, either directly or through private health plans. For example, VA's and DOD's prices for particular prescription drugs may be the lowest of an FSS price, a ceiling price, or the price that each agency can negotiate directly with the manufacturer. The FEHBP uses a different approach, modeled after other large U.S. employers' health benefits; health plans participating in the FEHBP typically contract with PBMs to negotiate drug prices and offer other pharmacy benefit, administrative, and clinical services. Further, like many of the other OECD countries, U.S. federal programs use a mix of strategies to contain prescription drug spending. Many federal programs have formularies that define which drugs are to be covered. While some federal programs' formularies are comprehensive and some are more restrictive than others, the programs use lists of covered drugs as the basis for negotiations with drug manufacturers.

### VA and DOD

VA and DOD have several options available to obtain favorable prices for drugs covered on their formularies. Both agencies pay the lowest of several prices available for a given drug, and both can negotiate with suppliers to receive additional discounts. In addition, both have adopted certain practices that affect negotiations, such as the use of formularies, or that otherwise contribute to lower costs, such as the use of mail-order pharmacies.

VA and DOD have access to a number of prices to consider when purchasing drugs.

- *FSS prices.* VA's National Acquisition Center negotiates FSS prices with drug manufacturers. These prices are available to all federal purchasers. FSS prices are intended to be no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. Under federal law, drug manufacturers must list their brand drugs on the FSS to receive reimbursement for drugs covered by Medicaid.[18] All FSS prices include a fee of 0.5 percent of the price to fund VA's National Acquisition Center.

- *Federal ceiling prices.* Federal ceiling prices, also called Big Four prices, are available to VA, DOD, the Public Health Service, and the U.S. Coast Guard. These prices are mandated by law to be 24 percent lower than nonfederal average manufacturer prices.[19]

- *Blanket purchase agreements.* Blanket purchase agreements are national contracts with drug manufacturers that allow VA and DOD—either separately or jointly—to negotiate prices below FSS prices. The lower prices may depend on the volume of specific drugs being purchased by particular facilities, such as VA or military hospitals, or on being assigned preferred status on VA's and DOD's respective national formularies.

  In a few cases, individual VA and DOD medical centers have obtained lower prices through local agreements with suppliers than they could have through the national contracts, FSS prices, or federal ceiling prices.

  In addition, VA's and DOD's use of formularies, pharmacies, and prime vendors can further affect drug prices. VA and DOD formularies encourage the substitution of lower-cost drugs determined to be as effective or more effective than higher-cost drugs. Both VA and DOD use prime vendors, which are preferred drug distributors, to purchase drugs from manufacturers and deliver the drugs to VA or DOD facilities.[20] VA and DOD

[18]See 38 U.S.C. § 8126(a)(4).

[19]See 38 U.S.C. § 8126(a)(2). The nonfederal average manufacturer price is the weighted average price of a single form and dosage unit paid by wholesalers to a manufacturer, taking into account cash discounts or similar price reductions. Big Four prices, in general, do not apply to generic drugs.

[20]As of June 2004, VA used one prime vendor, while DOD used five prime vendors that serviced different geographic areas.

receive discounts from their prime vendors that also reduce the prices that they pay for drugs. For DOD, the discounts vary among prime vendors and the areas they serve. As of June 2004, VA's prime vendor discount was 5 percent, while DOD's discounts averaged about 2.9 percent within the United States.

## Medicaid

Unlike VA and DOD, state Medicaid programs do not negotiate drug prices with manufacturers, but reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. Under the Medicaid drug rebate program,[21] drug manufacturers provide quarterly rebates for covered outpatient prescription drugs purchased by state Medicaid programs. The rebates are meant to take advantage of the prices manufacturers receive for drugs in the commercial market and are required to reflect the results of negotiations by private payers such as discounts and rebates.

The rebates are based on two prices per drug that manufacturers report to CMS: best price[22] and average manufacturer price (AMP).[23] The relationship between best price and AMP determines the unit rebate amount and thus the overall size of the rebate that states receive for a brand drug. The basic unit rebate amount is the greater of two values: the difference between best price and AMP or 15.1 percent of AMP. If the drug's AMP rises faster than inflation, the manufacturer is required to provide an additional rebate to the state Medicaid program.[24] A state's rebate for a brand drug is the product of the unit rebate amount plus any

[21]See 42 U.S.C. § 1396r-8.

[22]Best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or government entity, with some exceptions. Among other things, sales made through the FSS, single-award contract prices of any federal agency, federal depot prices, and prices charged to DOD, VA, Indian Health Service, and Public Health Service are not considered in determining best price.

[23]AMP is defined by statute as the average price paid to a manufacturer for a drug by wholesalers for drugs distributed to the retail pharmacy class of trade. Under the rebate agreement manufacturers negotiate with HHS, AMP does not include prices to government purchasers based on the FSS, prices from direct sales to hospitals or health maintenance organizations, or prices to wholesalers when they relabel drugs they purchase under their own label.

[24]State Medicaid programs receive an additional rebate for brand drugs when a drug's AMP rises faster than inflation, as measured by changes in the consumer price index.

applicable additional rebate amount and the number of units of the drug paid for by the state's Medicaid program.

## The 340B Drug Pricing Program

Entities eligible for the 340B drug pricing program can purchase covered outpatient prescription drugs from manufacturers at or below statutorily defined prices, known as 340B ceiling prices, that take advantage of discounts resulting from the Medicaid drug rebate program. These prices are the maximum amount eligible entities can pay for covered drugs, and the program allows for eligible entities to negotiate more favorable prices directly with drug manufacturers. As such, the 340B drug pricing program offers covered entities access to a prime vendor with which they can contract to negotiate discounts at or below the mandatory 340B ceiling price.

State AIDS drug assistance programs (ADAP) are examples of entities eligible for the 340B drug pricing program. ADAPs participating in the 340B program use either the 340B direct purchase option or the 340B rebate option. Under the direct purchase option, ADAPs purchase drugs from drug manufacturers or through a third party, such as a drug purchasing agent, and ADAPs receive the 340B price discount up front. In addition, ADAPs using this option can access the prime vendor program to assist in negotiating discounts at or below the mandatory 340B ceiling price. Under the rebate option, ADAPs typically contract with entities such as a pharmacy network or PBM for the purchase of covered drugs and later request a 340B rebate directly from the drug manufacturers. ADAPs using the rebate option do not have access to the prime vendor program.

## Medicare Part B

Like Medicaid, Medicare does not purchase drugs but rather reimburses physicians for drugs covered under Part B. The maximum Medicare reimbursement for covered Part B drugs is statutorily defined using the average sales price (ASP) plus 6 percent.[25] ASP is the average price for a drug based on a manufacturer's sales to all purchasers in the United States, with certain exceptions. Under this reimbursement methodology,

[25]See 42 U.S.C. § 1395w-3a.

Medicare takes advantage of the prices negotiated by private payers, as ASP is required to reflect the discounts and rebates they negotiate.[26]

## FEHBP

The FEHBP is generally modeled after other large U.S. employers' health benefits, including that participating health plans typically rely on PBMs to negotiate drug prices and offer other pharmacy benefit, administrative, and clinical services. In a 2003 report[27] that reviewed the use of PBMs by three FEHBP plans representing about 55 percent of FEHBP enrollment, we found that the PBMs used three key approaches to achieve savings for FEHBP participating health plans:

- passing on certain rebates negotiated with manufacturers to the plans;
- obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies; and
- using intervention techniques that reduce utilization of certain drugs or substitute other, less costly drugs.

The FEHBP plans we reviewed also had formularies that include most therapeutic categories, and these formularies had few restrictions on which drugs enrollees could obtain. Each plan also provided enrollees access to nonformulary drugs, although sometimes with higher cost-sharing requirements than for the preferred formulary drugs.

The PBMs were compensated through various methods, including retaining some portion of the negotiated savings rather than passing the full portion to the FEHBP plans. These compensation methods also included collecting fees from FEHBP plans for administrative and clinical services; retaining a portion of the payments from the FEHBP plans for mail-order drugs in excess of the prices negotiated with manufacturers to acquire the drugs; and in some cases retaining a share of the rebates the PBMs negotiated with drug manufacturers.

[26]The MMA also required HHS to implement a competitive acquisition program (CAP) for certain Medicare Part B drugs. The CAP is a voluntary program, which began in July 2006, that offers physicians the option to acquire many drugs they use in their practice from an approved CAP contractor.

[27]*Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*. GAO-03-196. Washington, D.C.: January 10, 2003.

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

## Contacts and Acknowledgments

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

# Related GAO Products

*Medicare Part B Drugs: CMS Data Source for Setting Payments Is Practical but Concerns Remain.* GAO-06-971T. Washington, D.C.: July 13, 2006.

*Ryan White CARE Act: AIDS Drug Assistance Programs, Perinatal HIV Transmission, and Partner Notification.* GAO-06-681T. Washington, D.C.: April 26, 2006.

*Ryan White CARE Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs.* GAO-06-646. Washington, D.C.: April 26, 2006.

*Medicaid: States' Payments for Outpatient Prescription Drugs.* GAO-06-69R. Washington, D.C.: October 31, 2005.

*Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States.* GAO-05-850T. Washington, D.C.: June 22, 2005.

*Mail Order Pharmacies: DOD's Use of VA's Mail Pharmacy Could Produce Savings and Other Benefits.* GAO-05-555. Washington, D.C.: June 22, 2005.

*Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States.* GAO-05-102. Washington, D.C.: February 4, 2005.

*Contract Management: Further Efforts Needed to Sustain VA's Progress in Purchasing Medical Products and Services.* GAO-04-718. Washington, D.C.: June 22, 2004.

*Medicare: Observations on Program Sustainability and Strategies to Control Spending on Any Proposed Drug Benefit.* GAO-03-650T. Washington, D.C.: April 9, 2003.

*Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies.* GAO-03-196. Washington, D.C.: January 10, 2003.

*VA Health Care: Expanded Eligibility Has Increased Outpatient Pharmacy Use and Expenditures.* GAO-03-161. Washington, D.C.: November 8, 2002.

**Response to Questions**
**For GAO Witness John E. Dicken**
**Regarding the January 11, 2007 Hearing on**
**Prescription Drug Pricing and Negotiation:**
**An Overview and Economic Perspectives for the Medicare Drug Benefit**

**Responses for Chairman Baucus**

1. *Of the countries you looked at, do any of them negotiate prices with drug manufacturers without in effect setting them? If so, who negotiates on behalf of the government? How do they avoid price setting in those instances?*

   *I'm particularly interested in the United Kingdom. To what extent are the profit controls voluntary? Why do manufacturers agree to them?*

   *In Australia, as well, I understand that the manufacturers work with government to arrive at prices. How are they able to set prices without dictating them there?*

   Based on our review of documents published by the governments of the United Kingdom and Australia, please find below information on whether the systems are voluntary, why pharmaceutical manufacturers agree to participate in the systems, who negotiates on behalf of the government, and how price setting is avoided.

   The United Kingdom's Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary system of price regulation between the government and the pharmaceutical industry—if pharmaceutical manufacturers do not participate in the scheme the Secretary of State can statutorily control their drug prices. The Department of Health, acting on behalf of Ministers of Health and the National Health Service in all the UK nations, negotiates the PPRS agreements with the Association of the British Pharmaceutical Industry, which represents the pharmaceutical manufacturers. The PPRS applies to pharmaceutical manufacturer sales on branded drugs to the UK National Health Service. This system is unique in that it leaves manufacturers free to price new products at market-determined levels but within the overall constraints of a company's PPRS profit cap. The profit cap is intended to restrict each company's aggregate profits on sales for branded to the National Health Service to a target return on capital employed—that is, a given profit net of allowances for expenses including research and marketing. But no profits are guaranteed, and there are tight restrictions on the circumstances in which drug prices can be increased.

In Australia, the government provides a subsidy for drugs listed on the Pharmaceutical Benefits Scheme (PBS). Before a drug can be subsidized via the PBS, the Pharmaceutical Benefits Advisory Committee (PBAC) must assess it. The PBAC, an independent expert body, whose membership includes doctors and other health professionals, recommends new drugs to be listed. The Pharmaceutical Benefits Pricing Authority (PBPA) then makes recommendations to the Minister for Health and Ageing for items recommended by the PBAC for listing on the PBS. Based on recommendations from the PBPA, the Secretariat at the Department of Health and Ageing negotiates with manufacturers, on behalf of the Minister of Health and Ageing, prices for drugs supplied under the PBS. The Australian government does not provide subsidies for drugs not listed on the PBS and is not involved in establishing prices for those drugs.

2. *The VA prescription drug program has been criticized for being too restrictive and not giving access to a large number of medications. Both physicians and veterans have expressed satisfaction with the VA prescription drug benefit.*

   *Are there processes for the veterans to receive drugs off the formulary or other means to make it less restrictive? Please describe briefly.*

   As we reported in 2001, The Department of Veterans Affairs (VA) includes an approval process for coverage of nonformulary drugs when they meet certain criteria for being medically necessary. Specifically, VA's national formulary directive requires that a request to use a nonformulary drug be based on at least one of six criteria: (1) the formulary agent is contraindicated, (2) the patient has had an adverse reaction to the formulary agent, (3) all formulary alternatives have failed therapeutically, (4) no formulary alternative exits, (5) the patient has previously responded to the nonformulary agent and risk is associated with changing to the formulary agent, and (6) other circumstances involving compelling evidence-based reasons exist.

   However, the directive does not dictate a specific nonformulary approval process. We reported that the processes health care providers followed to obtain nonformulary drugs differed among VA facilities, including how requests were made, who received them, who approved them, and how long the process took. In addition, VA did not have systematic data to determine the extent to which nonformulary drugs were being requested, approved, or denied. Therefore, VA did not know whether approved or denied requests were appropriate.

   In 2001, nonformulary drugs accounted for about 3 percent of all prescriptions filled, based on estimates from the VA and the Institute of Medicine. Earlier this year, a VA official indicated nonformulary drug use accounted for about 5 percent.

**Responses for Senator Hatch**

3. *Thank you Mr. Dicken. I read your testimony with great interest. Please correct me if I am wrong but after reviewing your testimony, it appears to me that the Secretary of HHS has limited experience negotiating drug prices for a federal program that has over 38 million beneficiaries, am I correct? I know that the Medicare Part B programs pays for prescription drugs and for a long time, Medicare was paying way too much for those drugs, correct? I believe that GAO investigated the Medicare Part B program and what it was paying for prescriptions.*

   *So if that is the case, how difficult is it going to be possible for the Secretary to negotiate drug prices for the Medicare Part D program for 38 million beneficiaries? How many prescriptions are we talking about? Thousands? Millions?*

   *I guess my question to you is how is the Secretary going to be able to do this not only efficiently but within the timeframe that is included in H.R. 4? The bill states that the Secretary must begin negotiating drug prices on Jan. 1, 2008. How realistic is that provision? Personally, I think that would be next to impossible.*

   Yes, Senator Hatch, you are correct that prior GAO reports raised concerns about whether, under a prior reimbursement methodology, the Medicare Part B program was over-paying for drugs. In 2001, GAO reported that physicians were able to obtain Medicare-covered drugs at prices significantly below Medicare payment rates, which were set at 95 percent of average wholesale price (AWP). While the difference between these prices and AWP for physician-administered drugs in our sample varied by drug, the average discount from AWP ranged from 13 percent to 34 percent. In 2005, the Centers for Medicare & Medicaid Services (CMS), as required by law, began paying for physician-administered Part B drugs using information on the drugs' average sales price (ASP). In 2006, GAO reported that using an ASP-based method to set payment rates for certain Part B drugs was a practical approach compared with methods based on alternative data sources. We also reported that CMS lacked certain information about the composition of ASP that prompted GAO, in commenting on CMS's 2006 proposed payment rates for a subset of Part B drugs, to call ASP "a black box." Significantly, CMS lacked sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs or other products; this is important, as CMS does not have the detail it needs to validate the reasonableness of the data underlying the reported prices.

   As our statement notes, there are a variety of approaches international, private and federal entities use to negotiate drug prices. While the issue of whether the Secretary of HHS can effectively and efficiently negotiate drug prices within the time frames proposed in H.R.4 is an important issue worthy of careful consideration, GAO is not a position to speculate how effectively or efficiently the Secretary of HHS would perform if given the authority to negotiate drug prices on behalf of Medicare beneficiaries enrolled in Part D plans.

4. *In your opinion, do you believe that the Secretary of HHS will be better able to negotiate prescription drug prices than the private market? And, how could this impact those who are not Medicare beneficiaries? Would the price of their prescription drugs go up?*

   While we have not considered whether the Secretary of HHS will be able to negotiate better prescription drug prices than the private market, in 2000 we reported that extending federal prices for outpatient prescription drugs to a large group of purchasers, such as Medicare beneficiaries, could lower the prices for that group but raise prices for others. Such price changes could occur because drug manufacturers would be required to charge Medicare beneficiaries and federal purchasers the same prices. To protect revenues, manufacturers could raise prices for federal purchasers. Furthermore, because federal prices are generally based on prices paid by nonfederal purchasers, manufacturers would have to raise prices to these purchasers in order to raise the federal prices. In particular, large private purchasers that tend to pay lower prices, such as health maintenance organizations (HMO) and other insurers, could see their prices rise.

   While it is not possible to predict the extent or timing of any changes in manufacturer pricing strategies if Medicare beneficiaries gained access to the same prices available to federal purchasers, the experience following implementation of a Medicaid drug rebate program suggests that manufacturers would adjust prices quickly. After the rebate program's enactment, the discounts that large private purchasers, such as HMOs and hospitals, received for many outpatient drugs dropped substantially. Within 2 years, we found that the average best-price discount for the drugs they purchased was no greater than 15.3 percent of AMP—about the mandated minimum rebate for Medicaid programs. The magnitude of these potential effects would vary by drug and would depend on a number of factors, including the relationship between the specific federal price extended to Medicare beneficiaries and the price paid by nonfederal purchasers, as well as the number of Medicare beneficiaries with access to the federal price.

5. *Finally, and probably most important, how is the Secretary going to be able to collect data to determine the appropriate price for a prescription drug? Isn't there a lot of information sources on drug prices? According to your testimony, there are numerous ways to determine drug prices – how will the Secretary know which is the best approach for Medicare beneficiaries and the rest of the country for that matter.*

   While the best approach for negotiating drug prices for Medicare beneficiaries may be different from those used in other federal programs—and vary by drug and other factors—the Secretary of HHS has access to a broad array of drug pricing data. The Secretary of HHS has access to the federal supply schedule prices and VA national contract prices, as these prices are publicly available. The Secretary of HHS is in the unique position, due to HHS oversight authority of the Medicaid drug rebate program, to have access to AMP and best price, which are not publicly available at this time.

However, due to differences in drug benefits across federal programs, all of these prices are not available for every drug.

**Responses for Senator Rockefeller**

6. *Price negotiation has been enormously successful for the Department of Veterans Affairs and state Medicaid programs. Yet, some have tried to discredit the success of the VA's prescription drug program.*

   *First, the claim has been made that the VA's national formulary is extremely limited and Veterans aren't getting the prescriptions they need because of so-called "price controls."*

   *If veterans aren't happy with their drug access and pricing, it is news to me, and to the VA. Yesterday, the VA announced results of a survey done by an independent reviewer of customer satisfaction.*

   *For the seventh straight year, the Department of Veterans Affairs has received significantly higher marks than the private health care industry. VA's marks keep going up with ratings for outpatient care at eight points higher than in the private sector.*

   *Mr. Dicken, can you talk a little bit about the VA's formulary?*

   a) *Isn't it true that the VA offers nearly 5,000 different drugs through a core national formulary which requires that these drugs be available at all VA hospitals and clinics?*

      According to a VA official, the VA dispensed 4,778 specific drug products in 2006, which represent the 1,294 chemical compounds listed on the VA national formulary. All items listed on the national formulary are available throughout the VA health care system.

   b) *Isn't it also true that drugs which are not on formulary and are requested by a physician can be ordered through VA's solid non-formulary process?*

      Yes, the VA includes an approval process for coverage of nonformulary drugs when they meet certain criteria for being medically necessary.

   c) *In fact, didn't the VA dispense prescriptions for an additional 1,400 drugs not listed on the core formulary last year?*

According to a VA official, in 2006 VA dispensed prescriptions for 1,416 drugs not listed on its national formulary. Overall, utilization of nonformulary drugs was about 5 percent of all drugs dispensed.

d) *Hasn't your agency reviewed the VA's non-formulary approval process and found that approvals are made within hours or minutes?*

In a 2001 GAO report, we found that the nonformulary approval processes varied across facilities. Sixty percent of prescribers that responded to our survey reported that the average length of time to approve nonformulary drugs was 9 days, but could be as short as a few minutes in some medical centers. Some prescribers reported that it took only a few hours (18 percent) or minutes (22 percent) to obtain such approvals.

7. *Mr. Dicken, over the years, there have been rumblings about a potential for increased pharmaceutical costs for the VA if price negotiation is required for other payers like Medicare.*

*The Government Accountability Office, and others, have found that the financial effects of Medicare price negotiation on the VA are uncertain. GAO found, specifically, that VA's prices will continue to depend on the outcome of negotiations between the VA and drug manufacturers.*

*Can you talk a little bit more about this research?*

In 1997 and 2000, we reported the potential for extending federal prices for outpatient prescription drugs to a large group of purchasers, such as Medicare beneficiaries, to lower the prices they pay but raise prices for others. We reported that it was not possible to predict the extent or timing of any changes in manufacturer pricing strategies if Medicare beneficiaries gained access to the same prices available to federal purchasers, but that the magnitude of these potential effects would vary by drug and would depend on a number of factors, including the relationship between the specific federal price extended to Medicare beneficiaries and the price paid by nonfederal purchasers, as well as the number of Medicare beneficiaries with access to the federal price.

**Questions Beyond the Scope of GAO's Work**

We do not have completed work that enables us to answer certain questions that were posed to all witnesses. We hope the other witnesses will be able to provide responses based on their expertise and work. Those questions follow, organized by the Senators who asked them in the letter requesting our responses.

**From Senator Hatch**

- *Timing of Negotiation: I am concerned that the timing of government negotiation may not be consistent with the Part D bidding process. Under current regulation, 2008 bids for Prescription Drug Plans (PDPs) and Medicare Advantage plans (MA-PDs), which include premiums and benefits, are due on June 4, 2007. Even if legislation requiring government negotiation was enacted tomorrow, it seems unlikely that the Secretary of HHS could negotiate drug prices for the roughly 4,300 Medicare covered drugs in time for plans to renegotiate with manufacturers before submission of 2008 bids. Do you think a requirement to adjust bids mid-year will create substantial administrative problems for the Part D program and for seniors covered under Part D?*

- *Reduction in Private Negotiation Ability: It is unclear how HHS negotiation will affect private plan negotiations over discounts, dispensing fees, and formularies. The HHS negotiated price may or may not be the lowest price given that HHS will not use a formulary and will negotiate on behalf of fewer members than some Pharmacy Benefit Managers (PBMs). I am concerned that drug manufacturers may use the HHS negotiated price to refuse to give private plans better discounts. Do you share my concern that government negotiation could actually reduce private plans' ability to get bigger discounts from drug manufacturers, or in other words, that the result of government "negotiation" could actually be to establish a floor rather than the intended ceiling on prices?*

- *Cost-Shifting: If government negotiation were successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost-shifting to small businesses and working families in the private insurance market?*

**From Senator Rockefeller**

- *The essential difference between the Medicare pricing framework that Democrats envisioned and what was actually signed into law is that our proposals would have put Pharmacy Benefit Managers (PBMs) at risk for performance.*

  *In other words, payment to PBMs would have been on a per-script basis and according to factors such as keeping costs low for beneficiaries, filling prescriptions on time, using comparative effectiveness studies to determine covered drugs, offering generics, and effectively communicating plan changes to beneficiaries.*

  *Under the prescription drug law, plans hold all the power, but bear little profit risk for failing to meet certain performance standards. This is despite the massive subsidies provided to plans by the federal government.*

  *If Congress were to put prescription drug plans at greater risk for achieving standards like the ones I just mentioned, wouldn't that also be an effective way to achieve savings for seniors?*

**Testimony of:**

**Richard G Frank, Ph.D.**
**Margaret T Morris Professor of Health Economics**
**Harvard University**

**Before the US Senate Committee on Finance**

**January 11, 2007**

**Introduction and Overview**

Good morning Mr. Chairman and members of the Committee. My name is Richard G. Frank, and I am a Professor of Health Economics at Harvard University and a Research Associate at the National Bureau of Economic Research. Thank you for inviting me to share some observations of drug prices under the new Medicare Part D drug benefit.[1]

The new drug benefit has offered millions of low-income elderly Americans the ability to access drugs that are vital to their health and continued longevity. The Part D drug benefit is also projected to add more than $1 trillion in cumulative spending to the Medicare program between 2006 and 2016 (CBO 2006a). These new expenditures come at a time when the federal budget is running substantial deficits and the long-term financial projections for the Medicare program are troubling. These fiscal constraints raise the question of whether prescription drugs under Part D of Medicare are being purchased in the most cost-effective manner.

Answering the question of pricing cost-effectiveness in the area of prescription drugs is more complicated than in many other areas of the economy: prescriptions drugs can be produced for "pennies a pill," but developing new and important pharmaceutical agents is a costly, time consuming and risk enterprise (CBO 2006b). If prices are driven too low to satisfy today's budget concerns, there is a real risk that the supply of future innovative drugs will be reduced. My observations will therefore account for this tension in drug pricing.

---

[1] The comments included in this testimony are based on results from joint research with Joseph P. Newhouse of Harvard University. Our research is reported in a paper prepared for the Hamilton Project (Frank and Newhouse, 2007). The testimony presented here represents only my views.

In the following testimony, I will consider three categories of pricing circumstances that arise under Medicare Part D.[2] They are:

1. Pricing for drugs purchased for people who are dually eligible for Medicare and Medicaid (about 29% of Part D participants). For these people, responsibility for purchasing prescription drugs was largely shifted from the Medicaid program to Part D prescription drug plans (PDPs).
2. Pricing for drugs that are unique and face little or no competition and are purchased on behalf of Part D recipients other than those dually eligible for Medicare and Medicaid.
3. Pricing for drugs that face either multiple branded competitors or a mix of branded and generic competitors and are purchased on behalf of Part D recipients other than those dually eligible for Medicare and Medicaid.

Each of these circumstances has created different price behaviors, and each creates a different sort of policy challenge. For the most part, price patterns for the third category of drugs suggest that the market is working reasonably well and indicate that no policy action is needed. I will therefore focus my analysis primarily on the other two categories—pricing for drugs used by dual eligibles and pricing for unique drugs. I will discuss the economic logic of what pricing patterns the program designers might have expected and why there might be some departure from those expectations. I will conclude by discussing possible policy actions.

## I. The Logic of Existing Pricing under Medicare Part D

One of the promises of Part D was that, by linking elderly Americans with PDPs, Medicare could benefit from bargaining power of larger and more sophisticated purchasers. The PDPs were to build on the purchasing successes that had been observed in the private sector, in particular the emergence of the PBM industry and its use of formularies. Private sector purchasing strategies to bargain for lower prices are most

[2] In this testimony I will not focus on prescription drug prices under the MedicareAdvantage program.

successful when there is robust competition between drugs. If multiple drugs are therapeutic substitutes, the insurance plan can obtain a favorable price by steering purchasing volume to particular products over others in response to price offers from manufacturers (CBO 2002, Frank 2001, Newhouse 2004). Part D's design to allow PDPs to use such purchasing strategies represents a substantial departure from the take-it-or-leave-it pricing used by Medicare for all other medical care goods and services, as well as a departure from the principle that services from all providers should be available for almost the same price.[3]

A. *Expectations for Drug Prices under Part D*

In general, the expectation was that the use of PDPs would lead most prices to fall or not increase notably. These expectations relied on how prices are set for various segments of the market and how PDPs would change those market dynamics (CBO 2002).

A.1 *Medicare-Medicaid Dual Eligibles*

Price increases for those dually eligible for Medicare and Medicaid were expected to be modest (CBO 2002 Chapter 3). Prior to 2006, people who were dually eligible for Medicare and Medicaid had drugs purchased for them under Medicaid's "best price" rebate system (Scott-Morton, 1997). This system requires that Medicaid receive either the "best private price" at which a manufacturer sells a drug or 15.1 percent less than the average manufacturer price (AMP) for that drug, whichever is lower.[4] Thus, a manufacturer that negotiates a lower price for any payer has to offer that price to

[3] The 20 percent coinsurance in Part B creates modest differences among prices charged by physicians for the minority of beneficiaries who pay the coinsurance, and there is also some difference created by the minority of physicians who do not accept assignment.

[4] AMP is the price at which manufacturers sell to wholesalers net of prompt pay discounts.

Medicaid. Under Part D, drug purchasing drugs for dual eligibles was automatically shifted to from the Medicaid system to PDPs. PDPs operate under special rules with respect to Medicaid's rebate system. If they negotiate prices below Medicaid's "best price," these prices are not counted under the best price system, thereby creating a bargaining advantage for PDPs over other private plans.

At the same time, the enactment of Part D meant demand for prescription drugs was sure to increase among Medicare beneficiaries who did not previously have comparable coverage. The increase in demand, combined with the market power of most brand name drug products that are protected by patents, would create upward pressure on prices for brand name drugs covered by the PDP. Yet, because PDPs are not affected by "best price" rules and have some ability to steer demand between competing products, the expectation was that any price rise relative to Medicaid prices would be modest.

A.2 *Medicare recipients that previously had no drug coverage*

Medicare recipients that had no drug coverage prior to 2006 generally paid the highest prices in the market because they purchased drugs through retail pharmacies. Retail pharmacies have little bargaining power with respect to the prices of brand name prescription drugs, reflecting their inability to implement a formulary that would enable them to move market share between competing products (Frank 2001).

As a result, Medicare recipients with no prior drug coverage were expected to have lower prices paid on their behalf under Part D. By enrolling in Part D, their drug purchasing would be done through PDPs that have formularies and other means of steering demand towards products that offer price concessions. For this group, the shift in purchasing arrangements has the effect of making the demand curve for individual

products in most drug classes more price responsive. The expected result was therefore lower prices for this group.

A.3 *Unique Drugs*

Unique drugs used by the elderly offer important clinical advantages but also pose a challenge to the Part D approach to prices based on competition (Newhouse, 2004). Nevertheless it was expected that this issue would have little overall effect on the prices paid by Medicare. There were three reasons for this expectation. First, unique drugs were thought to be few in number, and new unique drugs would remain unique for only a short time (CBO 2002; Newhouse, Seiguer, and Frank 2006). Second, there is substantial cost sharing below the $5,450 level under Part D, which serves as a constraint on pricing. Third, the private sector would purchase a substantial volume of such medications and could use more powerful tools to contain costs (CBO, 2002).

**III. What Happened?**

In this section I identify some areas where prices may not behave in the expected fashion. I focus on two market segments identified earlier: (1) drugs purchased on behalf of people dually eligible for Medicare and Medicaid and (2) unique drug products. I begin by describing prescription drug spending under Part D in the context of the federal budget.

*A. Part D Spending*

In 2007, Medicare and Medicaid will account for 23 percent of federal outlays and 5.8 percent of GDP (counting the state Medicaid share) (CBO August 2006 Baseline). If historical spending growth rates persist in both health care and the federal

budget, by 2016 these programs would account for 32 percent of the federal budget and 7.8 percent of GDP.[5] Under the more optimistic assumption that health care will grow at a rate only one percentage point above growth in GDP, by 2016 Medicare and Medicaid would still account for about 30 percent of the federal budget and 6.5 percent of GDP (calculations based on CBO, 2006). Thus, the growth of Medicare and Medicaid will continue to place enormous strains on the budget.

The Part D benefit is projected to add net claims of about $53 billion to Medicare outlays in 2007, about 17 percent of the projected Part A and B net outlays for 2007.[6] By 2015, Part D is projected to account for 21 percent of net Medicare outlays. Thus, cost effective purchasing is important to the financial health of the program.

*B. Prices and Dually Eligible Part D Participants*

For Part D participants that are dually eligible for Medicare and Medicaid, drug purchasing was shifted from Medicaid's "best prices" system to PDPs. Comparing Medicaid and PDP prices for drugs that are heavily used by dually eligible beneficiaries can offer some insight into the ability of PDPs to get the "best" private prices or reduction below the AMP. Unfortunately, these prices cannot be directly compared because both Medicaid and PDP prices are confidential. However, we were able to glean some information about pricing changes by examining financial statements of prescription drug manufacturers during the first six months of 2006. These statements allow us to infer pricing differences by assessing the impact of shifting dually eligible people from Medicaid to PDP pricing arrangements on manufacturer revenues.

---

[5] This prediction is based on health care spending continuing to grow at 2.5 percentage points over the rate of growth in national income, the average trend over the past 50 years.

[6] We use the net outlays for Parts A and B from the CBO March 2005 baseline projections for 2007, about $310 billion. We then apply the projected net Part D outlays of $53 billion to that total (see CBO, An Analysis of the President's Budgetary Proposals for Fiscal Year 2006, March 2005).

A review of Form10Q filings with the SEC offered some commentary and data on drugs that are heavily used by dually eligible Part D participants. One class of such drugs is antipsychotic medications, 70 percent of which were purchased by Medicaid prior to January 2006. Astra Zeneca (maker of Seroquel), Bristol-Meyers-Squibb (maker of Abilify), Lilly (maker of Zyprexa) and Pfizer (maker of Geodon) all noted the favorable changes in prices that resulted from the shift of large numbers of users of anytipsychotic medications from Medicaid to Part D. For example, Bristol-Meyers-Squibb stated that the shift in patient enrollment from Medicaid to Medicare Part D resulted in a decrease in Medicaid rebate accruals, partially offset by managed care rebate accruals. Similarly, Lilly noted an increase in effective net selling prices for Zyprexa that was partially due to the transition of certain low-income patients from Medicaid to Medicare. Finally, Pfizer pointed to a more general impact of the price gains from the payment shift that resulted in a $325 million increase in revenues for the first six months of 2006 compared to the same period in 2005, approximately an 8 percent increase in net revenue. The implication is that prices have increased.[7]

Why this may be so is speculative. Because the market for PDPs is currently

---

[7] Neither the population covered nor cost sharing changed materially for the dually eligible people. See
AstraZeneca: FORM 6-K, Current Report of Foreign Issuer for July 2006, available
at http://www.sec.gov/Archives/edgar/data/901832/000095010306001898/dp03246_6k.htm
Bristol-Myers Squibb: FORM 10-Q for the Quarterly Period Ended June 30, 2006, available
at http://www.sec.gov/Archives/edgar/data/14272/000119312506164507/d10q.htm
Eli Lilly: FORM 10-Q for the Quarterly Period Ended June 30, 2006, available
at http://www.sec.gov/Archives/edgar/data/59478/000095013706008651/c07379e10vq.htm
GSK: FORM 6-K, Current Report of Foreign Issuer for July 2006, available
at http://www.sec.gov/Archives/edgar/data/1131399/000102123106000439/b834273-6k.htm
Merck: FORM 10-Q for the Quarterly Period Ended June 30, 2006 available
at http://www.sec.gov/Archives/edgar/data/64978/000095012306010023/y23763qe10vq.htm
Novartis: FORM 6-K, Current Report of Foreign Issuer, filed July 18, 2006, available
at http://www.sec.gov/Archives/edgar/data/1114448/000110465906047401/a06-16261_16k.htm
Pfizer: FORM 10-Q for the Quarterly Period Ended June 30, 2006, available at
http://www.sec.gov/Archives/edgar/data/78003/000007800306000203/q2-06pfe1.htm
Wyeth: FORM 10-Q for the Quarterly Period Ended June 30, 2006, available at
http://www.sec.gov/Archives/edgar/data/5187/000119312506163572/d10q.htm

quite fragmented, because PDPs receive substantial subsidies from Medicare, and because they face only small levels of financial risk, the motivation to move market share and bargain hard with manufacturers may be more limited than previously expected. In addition, a number of drugs used by people dually eligible for Medicare and Medicaid fall into the so-called "protected drug classes." In these classes, the use of formulary design to steer demand is limited by regulation, which serves to reduce PDPs' bargaining power with manufacturers.[8] As a result, the upward pressure on Part D prices and spending may be greater than was anticipated.

*C. Prices for Unique Products Used by the Elderly*

In the case of prescription drugs without good substitutes, PDPs are potentially in a weak bargaining position because they have limited ability to redirect demand away from the unique product. There are indications that prices have responded in fashion. Some of the most significant price changes during the first half of 2006 reported by manufacturers of brand name prescription drugs occurred in drugs that were relatively unique and had high shares of elderly buyers. Examples include Plavix, Forteo, and Evista, all of which were reported to have experienced important gains in prices. Frank and Newhouse (2007) compared brand name drugs with high shares (55% or more) of elderly purchasers and brand name drugs with relatively low shares (35% or less) of elderly purchasers from among the brand name drugs among the top 50 in sales. They showed that the drugs sold to the elderly grew at a faster rate after August of 2004 and

[8] It should be noted that there are good reasons for this regulation given the strong incentives for PDPs to enroll the healthiest people (who use the fewest drugs). The protected classes were created to blunt incentives to compete for enrollees who spend little on drugs by offering very narrow formularies for drugs used to treat complex and costly conditions. For a more complete discussion of this issue see Frank and Newhouse (2007).

that this trend has continued into 2006.[9] Other sources offer consistent reports.[10] The extent to which the two trends will continue to diverge in the future, of course, remains unknown.

As outlined above, there were three reasons the special challenges of unique drugs to Part D pricing was not expected to have a big impact. With respect to the first reason, limited numbers of unique drugs, it should be noted that unique drugs arise in two ways: new products with important therapeutic advantages are regularly introduced into existing therapeutic classes of drugs, and some new products result in the creation of new therapeutic classes. Significant market power can arise in either case. In other work, we have identified drugs that were first in their class. Between 1970 and 2000, the number of such drugs averaged about 3.5 per year (Newhouse, Seiguer, and Frank, 2006). That number has markedly dropped recently, with only five such drugs in the entire four-year period between 2000 and 2004, or just one per year. However, in recent years, drugs that were first in their class have remained in that position for about 3 years. Identifying drugs that offer unique therapeutic advantages within an existing class is more difficult than identifying first-in-class drugs. But we can point to some recent examples, including Forteo, which treats osteoporosis, and Plavix, which treats heart disease. In addition, some drugs maintain a dominant position in sales to elderly Americans despite having therapeutic competitors. Such drugs include Norvasc, an antihypertensive, Xalatan for glaucoma, and Toprol for heart disease.[11]

---

[9] Berndt et al (1998) found that during the early 1990s there were no significant differences in price indexes for drugs used by the elderly versus others.

[10] For example, the AARP shows larger increases for the average cost of treating chronic conditions of the elderly between 2005-2006 than in any of the prior 5 years (AARP Rx Watchdog Report, September 2006).

[11] For example AstraZeneca reports 20% growth in sales of Toprol in the first six months of 2006. Toprol contributed 26 cents to earning per share in the first half of 2006.

As for the potentially stymieing effect of cost-sharing, the incentive for a PDP to bargain hard with the manufacturer over price is blunted by the government's responsibility for 80 percent of the costs of spending above $5,450 and the consumer's responsibility for 5 percent. PDPs face only a 15 percent liability at the high end of spending.

Because of the insurer's sharing the cost, the manufacturer of unique products — especially those that are heavily used by the elderly — can set a price that is potentially much higher than that of a monopolist selling to an uninsured market and still sell the same quantity. In other words, the manufacturer's market power comes not only from the patent(s) protecting against entry but also from the patient's insurance coverage, which in the frequent case of a fixed copayment below the donut hole means the patient faces no incremental cost from a higher price and above the donut hole only 5 percent of the impact. As a result, consumer demand for drugs is markedly less responsive to a monopolist's price than it would be in a market of uninsured consumers, the usual case outside of health care. The combination of patent protection, lack of competitor drugs, and insurance covering a high percentage of the patient's cost effectively puts the patent system on steroids.

Last, the ability to use negotiation to lower prices for unique drugs is limited. In the Medicare context there will surely be strong political pressure not to allow PDPs to leave such unique (and presumably superior) products off the formulary. Thus, the threat of exclusion from coverage because of a high price is unlikely to be credible and, because of the formulary regulations, may even be precluded.[12]

[12] That is, the regulations on allowable formularies, which are set on clinical grounds, may well require coverage of the drug.

Thus, it appears that the enhanced market power of the manufacturer created by Part D has the potential to create a distributional imbalance in the direction of offering substantially greater economic rents to prescription drug manufacturers of some drugs than would be observed in an uninsured market. Any such rents, of course, further aggravate the worrisome future financial health of Medicare.

## II. What to do?

Any proposal to alter approaches to setting prices for prescription drugs must recognize the threat posed to research and development (R&D) incentives and the industry's ability to attract capital if prices are set "too low" (or even if there is merely a threat that they may be set too low). Pharmaceutical R&D has produced enormous economic value in recent decades (Murphy and Topel, 2003), and clinically important unique drugs are the drugs for which it is most beneficial for society to offer the largest rewards to prescription drug manufacturers. However, many important diseases, including Alzheimers and many cancers, have little effective therapy, and recent assessments of existing evidence suggest that the pharmaceutical industry exhibits profitability rates that are modestly above those of other Fortune 500 firms, even after adjusting for intangible capital and risk differences (CBO 2006b Chapter 6). Thus, the key trade-off involves risking reduced R&D incentives on the one hand and bestowing additional rents on an industry and creating greater stress on an already troubled federal budget on the other.

I believe a first step toward establishing a better balance between control of Medicare spending and protection of R&D incentives is to require manufacturers to sell

drugs that will be used by people dually eligible for Medicare and Medicaid to PDPs at a price approximating Medicaid prices. This price might be average manufacturer price minus 17%.[13] This step would return the balance between government budgets and firm R&D incentives to its pre-January 2006 level, a situation that appeared acceptable to all parties. The impact on Medicare spending is likely to be significant, given that dually eligible people represent 29 percent of Part D participants and an even higher share of drugs purchases under Part D. Further, this action involves little additional administrative cost. PDPs would report purchases on behalf of dually eligible enrollees, and a corresponding rebate would be provided by the manufacturer to the federal government in much the same fashion that rebates are now provided to Medicaid.

Pricing of unique prescription drug products represents a particularly difficult policy challenge. By focusing cost control efforts on treatments that could represent major gains over today's therapy, there may be particular risks to precisely the R&D that should be most encouraged. I believe that it is premature to conclude that there are enough unique drugs to create a meaningful budget problem. Therefore, I propose that the Centers for Medicare and Medicaid Services (CMS) and the Congress carefully monitor the prices of such products. This monitoring means that CMS should obtain price data from the industry that includes information on rebates granted to PDPs for specific drugs. Furthermore, the government should be prepared to intervene if a problem arises. Should such a situation present itself, I propose that the government then put into place temporary administered prices for unique drugs. The goal of the temporary administered price proposal would be to establish a price for Part D that would preserve

[13] It should be noted that I am explicitly not recommending return to the Medicaid "best price" approach because of the private sector pricing distortion it causes.

R&D incentives, recognize the health benefits produced by specific products, and limit the economic rents paid by the Medicare program.

## III. Concluding Remarks

The evidence suggests that there is reasonable cause for concern. Yet these concerns are specific and invite a nuanced policy with a "light touch." Specifically, with respect to the pricing of drugs purchased on behalf of people dually eligible for Medicare and Medicaid, there appear to be some price increases that are generating economic rents. As a result, there is little risk to R&D incentives of returning those prices to something that approximates pre-2006 levels.

For unique drugs, there is certainly the potential for prices involving significant economic rents and important pressures on the federal budget. Yet it is premature to conclude that action needs to be taken right away. In my view, however, it is important for CMS and the Congress to be vigilant of these prices and to have a plan ready that could implement a set of temporary administered prices like those I have discussed.

Thank you for your attention.

**References:**

Berndt ER et al (1998), "Is Drug Price Inflation Different for the Elderly? An Empirical Analysis of Prescription Drugs" in AM Garber (ed) *Frontiers in Health Policy Research* Volume 1, Cambridge: MIT Press

Congressional Budget Office (2002) *Issues in Designing a Prescription Drug Benefit*, Washington D.C., October

Congressional Budget Office (2006), *Fact Sheet for CBO's 2006 Baseline: Medicare*, Washington D.C., March 15.

Congressional Budget Office (2006), *Research and Development in the Pharmaceutical Industry,* Washington D.C., October.

Frank RG (2001), "Prescription Drug Prices: Why Do Some Pay More Than Others Do?" *Health Affairs* 20(2): 115-128

Medicare Payment Advisory Commission (2006), *Report to Congress: Increasing the Value of Medicare* Washington D.C. June

Murphy KM, and Topel R. (2003), "The Value of Medical Research" in K. Murphy and R Topel (eds) Measuring the Gains from Medical Research: An Economic Approach, Chicago; University of Chicago Press.

Newhouse, JP. (2004), "How Much Should Medicare Pay for Drugs?," Health Affairs, 23(1): 89-102.

Newhouse JP, Seiguer E and Frank RG (2006), "Was the Medicare Drug Bill a Giveaway to the Pharmaceutical Industry" Harvard University, Department of Health Care Policy Working Paper

Scott-Morton F (1997), "The Strategic Response by Pharmaceutical Firms to the Medicaid Most Favored Customer Rules", *Rand Journal of Economics* 28(2): 269-290

U.S. Congress, Office of Technology Assessment (1993) Pharmaceutical R&D: Costs, Risks and Rewards. Washington, DC:. USGPO

**Responses by Richard G. Frank to Questions from U.S. Senate Committee on Finance**

*Questions from Senator Rockefeller:*

*a) Dr. Anderson and Dr. Frank, isn't one of the answers to guarantee better prices for all Medicare participants through Medicare price negotiation?*

a) In my initial written testimony of January 11, 2007, I pointed out two areas where I believe the prescription drug purchasing arrangements specified under Part D of Medicare led to prices that may be "too high". These two areas are: 1) prescription drugs purchased on behalf of people who are dually eligible for Medicare and Medicaid; and 2) prescription drugs that are unique and face no close therapeutic competition. In the case of people that are dually eligible for Medicare and Medicaid the existing evidence suggests that manufacturers have increased prices for prescription drugs heavily used by this population. Given that the previous Medicaid prices were sufficient to encourage active research and development (R&D) in the therapeutic areas used to treat these people; this means that the Part D prices for drugs used by this population could be returned to their original levels while maintaining the incentives to invest in R&D that existed prior to Part D. For unique drugs, the government faces a situation where the prescription drug manufacturer can essentially name its price. This situation may have important budgetary circumstances if the number of unique drugs grows in the coming years. As I noted in my testimony it is as yet too early to tell the magnitude of the problem. Nevertheless the potential problem is real. For these reasons I believe that the so-called non-interference provision in Part D is counterproductive.

The degree to which price "negotiations" will result in lower prices depends on the specifics of how negotiations would be conducted. Currently there is skepticism among some that the government would obtain better prices than existing prescription drug plans or PDPs.[1] In the absence of specificity on a mechanism that would drive manufacturers to offer lower prices some skepticism is warranted. Nevertheless, I believe that there are negotiation processes that could be put into place that would potentially result in better prices for the two sets of procurement circumstances I noted earlier. For example, a binding arbitration process might well be specified in cases where the Secretary of Health and Human Services and a

[1] See the letter to the Honorable John Dingell from Donald B. Marron Acting Director, Congressional Budget Office, January 10, 2007.

manufacturer could not agree on a price for a unique prescription drug product. A well designed arbitration process would create incentives for the government and the industry to reach negotiated agreements and in cases where agreements could not be reached would set out a fair process where arbitrated prices would be based on price proposals by the interested parties and on economic and clinical data. It is important to underscore that I believe that the price gains would only occur in the two general instances set out earlier and that it would require a great deal of specificity in defining the negotiation process.

*b) What other tools used by Medicaid prescription drug programs could be used by Medicare to lower the price of prescriptions?*

b) Medicaid relies primarily on a "most favored buyer" pricing scheme for the purchase of prescription drugs. That is manufacturers must sell drugs to Medicaid at the lower of the best private purchaser price or 15.1% less than average manufacturer price. This mechanism essentially creates price ceilings for prescription drugs purchased by Medicaid. Individual state Medicaid programs may then negotiate still more favorable prices, known as supplemental rebates. The threat of prior authorization requirements are one tool used by state Medicaid programs to negotiate supplemental rebates. Preferred drug lists are another key tool used by states to steer demand in order to obtain additional price concessions.[2] The result is that Medicaid programs obtain significant price concessions from manufacturers. These price concessions come at a cost to the private sector. Because Medicaid rebates are tied to the "best private price" it makes manufacturers more reluctant to grant private payers large price reductions since those will have to be extended to the Medicaid program.[3] From my review of the practices of PDPs that serve Part D, it appears that most if not all are using prior authorization arrangements along with tiered formularies and related tools to negotiate prices. The lessons from Medicaid have therefore largely been learned. The main problem areas are unique drugs and those heavily used by people that are dually eligible for Medicare and Medicaid. These require a new approach to defining negotiation.

---

[2] For a more complete discussion of these issues see Congressional Budget Office (2005), *Prices for Brand Name Drugs Under Selected Federal Programs*, Washington DC: CBO, June; and Holz-Eakin D. (2005), *Payments for Prescription Drugs Under Medicaid*, Testimony before U.S. Senate Special Committee on Aging, July.

[3] Scott-Morton, F. (1997), "The Strategic Response by Pharmaceutical Firms to the Medicaid Most Favored Customer Rules", *Rand Journal of Economics* 28(2): 269-290.

*Additional question from Senator Rockefeller:*

*a) If Congress were to put prescription drug plans at greater risk for achieving standards like the ones I just mentioned, wouldn't that also be an effective way to achieve savings for seniors?*

a) The use of competitive markets for PDPs involves a balancing of the gains from price and quality competition against the incentives created to engage in practices aimed at enrolling the healthiest Medicare beneficiaries and avoiding the sickest high cost people. Increasing the financial risk held by PDPs clearly strengthens the incentives to control costs, it also strengthens the incentives to avoid the sickest enrollees through a variety of practices that are difficult to regulate. I recognize that premiums are risk adjusted but my reading of the existing evidence suggests that the risk adjusters used by CMS leave considerable room to profit from attracting healthier Medicare beneficiaries. Therefore there may be some room for increased risk sharing but that the potential severity of problems created by incentives to engage in selection related practices suggests great caution be exercised in considering substantial increases in the amount of financial risk health by competitive PDPs.

*Questions from Senator Hatch:*

*a) Do you think a requirement to adjust bids mid year will create substantial administrative problems for the Part D program and for seniors covered under Part D?*

a) The question presumes that "negotiations" would be mandated for all drugs covered under Part D. As I noted in my original testimony I have not found any evidence suggesting that this is either necessary or advisable. As I noted in my testimony and earlier in these supplemental materials I believe the pricing problem related to Part D is quite focused. That is, the potential problems in prices are limited to unique drugs and those heavily used by people that are dually eligible for Medicare and Medicaid. As a result the scope of the problems is quite narrow, involving far fewer drugs than the 4,300 referred to in the question. As a consequence of this narrower definition of the problem, I believe the administrative issues and their costs are greatly reduced.

*b) Do you share my concern that government negotiation could actually reduce private plans' ability to get bigger discounts from drug manufacturers, or in other words, that the result of government "negotiation" would be to establish a floor rather than the intended ceiling on prices?*

b) Your concern goes to the details of what is meant by the word negotiation. If negotiation means a "take it or leave it price" based on a formula along the lines of the Medicaid best price rule, then government negotiation would affect the incentives of manufacturers in bargaining with Pharmacy Benefit Managers (PBMs) purchasing on behalf of commercially insured clients. The evidence on Medicaid best price rules suggest an effect on private payers along the lines suggested in the question. Using such a formulaic approach is certainly not necessary and does not accord with most common views of the term negotiation. The question raises the challenge to be clear what is meant by negotiation. As discussed in the response to Senator Rockefeller's question (a) it seems possible to design a binding arbitration system that would allow for a period of true negotiation that does not involve a take it or leave it proposition that would at once encourage a negotiated settlement and specifies a fair process for settling unresolved disputes. Such a system would diminish the types of spill over effects in the private sector that are raised by the question.

> *c) If government negotiation were successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost shifting to small businesses and working families in the private insurance markets?*

c) The existing evidence on the behavior of pharmaceutical markets and prescription drug manufacturers support the idea that prescription drug manufacturers are profit maximizing organizations. A profit maximizing firm will choose the prices that maximize profits across the various markets to which it sells. Therefore if circumstances change for one market, but not the others, one would not expect prices to be altered in the markets where no changes occurred. So raising prices in market Y because changes occurred in market X would serve to reduce the firm's profit if it was pricing to maximize profits in the first place. So as long as price formulae are not used to link previously unlinked markets I would not expect to see the types of cost shifting behavior you ask about.

Thank you for the opportunity to respond to these questions.

# *United States Senate Committee on Finance*

Opening Statement of Sen. Chuck Grassley
Hearing, "Prescription Drug Pricing and Negotiation: An Overview and Economic Perspectives for the Medicare Prescription Drug Benefit"
Thursday, January 11, 2007

I want to thank Senator Baucus for holding today's hearing. Today's hearing is the Committee's first on health care of the new Congress. The Committee has an important health care agenda this year. We have the reauthorization of S-CHIP, and we're going to need to spend some time on physician payment issues. I look forward to working on that agenda with the Chairman and members of the Committee.

The topic of today's hearing has received a lot of attention over the past few years. I think we'd all agree that's actually an understatement. A lot of political hay has been made about the so-called prohibition on Medicare negotiating with drug makers for lower prices under the Medicare drug benefit. We all know, though, that the law doesn't prohibit Medicare from negotiating, it prohibits the government from interfering in those negotiations.

Those negotiations take place between Medicare prescription drug plans, which have years of experience in that area, and the drug makers. And it's working. Competition among plans has lowered costs for the taxpayers and beneficiaries. It has led to lower drug prices. Nevertheless, here we are, with Congress set to consider legislation to fundamentally change the prescription drug benefit. This change is being proposed after just one full-year operation and two rounds of bids by plans. I might add that this year's bids came in 10 percent less than last year's bids. I've said it before and I'll say it again: the Medicare drug benefit is not perfect. There are improvements that can be made.

The Chairman and I spent many hours working together on the Senate version of the Medicare drug benefit. And in my opinion, the Senate bill had some important features, which are better than what's in the law. For example, the Senate bill did not have an asset test for the low-income subsidy. But one area that is working well is the negotiating power of Medicare drug plans. After we get past this issue, I hope that we can work in a bipartisan way to look at constructive improvements in the benefit, such as eliminating the asset test. I also think we need to look at pharmacy issues and aspects of the enrollment process.

But let me go back to the matter at hand. Chairman Baucus, I just want to say that you deserve credit for holding today's hearing. You've assembled a panel of experts who will help the Committee have a meaningful discussion so it can consider this issue in a thoughtful and deliberative way, rather than one caught up in politics. The campaign slogans and sound bites are easy -- have it work like the VA, just have the government negotiate. But I really don't think that many people have a clear understanding of how drug pricing and purchasing works today and what any changes to how Medicare purchases drugs could mean in the way of higher costs mean for small businesses, for example. And past experience shows that changes along the lines proposed by some people would have some pretty painful consequences, namely higher drug prices. Again, this hearing will help shed more light on these issues.

214 Massachusetts Ave. N.E Washington D.C. 20002 (202) 546-4400 www.heritage.org

*CONGRESSIONAL TESTIMONY*

# Hearing on Prescription Drug Pricing and Negotiation for the Medicare Prescription Drug Benefit

**Testimony before the**
**Committee on Finance**
**United States Senate**

**January 11, 2007**

**Edmund F. Haislmaier**
**Research Fellow**
**Domestic Policy Studies**
**The Heritage Foundation**

My name is Edmund F. Haislmaier. I am Research Fellow at The Heritage Foundation. The views I express in this testimony are my own, and should not be construed as representing any official position of The Heritage Foundation.

Chairman Baucus, Senator Grassley, and members of the committee:

Thank you for inviting me to testify today on government negotiation in the Medicare prescription drug program.

In order to determine whether the government has a role in, or would be successful at, negotiating prices in Medicare one must first consider how price negotiations work, then examine how drug negotiations could be conducted for Medicare, and lastly assess the likely outcomes and implications.

**The Elements of Negotiation**

Negotiation is a bargaining process and an aspect of everyday life. Family members negotiate over dinner options. Employees and employers negotiate levels of compensation. Buyers and sellers often negotiate the prices of goods and services such as cars or houses. Even members of Congress negotiate over legislation.

But negotiation is not a haphazard or arbitrary exercise. While it is true that people sometimes negotiate foolishly or with unrealistic expectations, the negotiation process itself is always and everywhere governed by a set of simple, understandable, but inflexible, rules.

**Rule 1.** Each party to a negotiation has a final price, called a reservation price or "walk away" price, beyond which that party will not negotiate.

**Rule 2.** A party's reservation price is, by definition, the point at which the party thinks it would be better off with no deal.

**Rule 3.** If a deal cannot be reached, then each party will, by definition, pursue some other alternative. Therefore, a party's reservation price is equal to the cost (self-perceived) of pursuing its "best alternative to a negotiated agreement" (BATNA).

**Rule 4.** Negotiation consists of coming to agreement on a price somewhere between the respective reservation prices of the two parties. Thus, successful negotiations cannot occur if the two parties range of acceptable prices don't overlap.

These basic rules governing any negotiation have a number of clear implications. First and foremost, is that the most important consideration in any negotiation is each parties' "best alternative" to consummating a deal. For each party the "best alternative to a negotiated agreement" can be determined as follows:

1. List the actions it might conceivably take if no agreement is reached.

2. Estimate the costs of each conceivable alternative option.

3. Select the one option that seems best.

While this is a rational set of steps, people do not always behave with perfect rationality. But this framework can be used, by the parties themselves, or by an outsider, to calculate what is the likely best alternative for each party. Furthermore, to the extent that actual negotiating behavior differs from anticipated behavior based on such an assessment, it can reveal flaws or vulnerabilities in one or the other, or both, parties negotiating strategy.

In some cases, a party might miscalculate the costs of one or more possible alternatives – either underestimating or overestimating them – which skews its decision as to which alternative is best. For example, someone might rush to buy a condominium in an escalating real estate market, only to discover six months later that the market has flattened and prices are falling. If the cost of the condo dropped by more than the additional rent the buyer would have paid if he waited six months, then we can say that the buyer overestimated the costs associated with waiting to buy. Waiting to buy might have been his best alternative, or his best alternative might have been buying a similar property in another neighborhood where demand wasn't as likely to shift.

In other cases a party may miscalculate for emotional reasons. Consider the homeowner who has to sell his house to take a job in another city, but is emotionally stuck on getting a high price to cover the cost of what he wants to buy when he relocates. His emotions may lead him to disregard the additional expense of renting in the new location while his previous home sits unsold. Thus, he fails to see that selling his home quickly at a lower price and buying a smaller house in his new locale is really his best alternative.

Working through these steps also enables us to assess how the equation might change if there is a change to an external variable that affects the calculation of which alternative is best. For example, last year's run up in gas prices led many car buyers to rethink the trade-offs between vehicle size and operating costs. Suddenly, a smaller more fuel-efficient car became a best alternative to the roomier, but low-mileage vehicles many buyers originally wanted. Indeed, market observers were even able to quantify the phenomenon. They noted that the average price paid for a new SUV dropped by almost exactly the same amount as the increase in the one-year average cost of operating an SUV due to higher gas prices.

Thus, the change in the external variable of gas prices led to a recalculation among buyers of their best alternative and a shift in demand. That shift weakened the negotiating position of SUV makers and strengthened the negotiating position of fuel-efficient carmakers by changing their best alternative scenarios. Selling SUVs for less became a better alternative than waiting for buyers willing to pay the old asking price.

Conversely, sellers of smaller cars stuck to their asking prices since if a buyer walked away from the table, they could expect another one to soon walk in the door.

In the case of prescription drugs, the most important external variable is the reaction by those consuming the drugs (patients) to the strategy and choices of those negotiating on their behalf. This holds true whether those negotiations are conducted, as presently, by private plans or are conducted by the government. As will be seen in my later remarks, patient reactions inevitably shape and limit the negotiating freedom of those who negotiate on their behalf. This means that, the "buy side" negotiators must always be mindful of how patients will react to their decisions, lest their actions produce a consumer response that undermines their negotiating strategy. Indeed, they must also be sensitive to the possibility that the "sell side" negotiators could spark or encourage such a consumer reaction as a way of altering the negotiation parameters in the sellers' favor.

**Is Bigger Always Better?**

One of the variables most commonly thought of as affecting negotiating position, or "leverage," is the relative size, or "scale," of the parties to a negotiation. People presume that if a manufacturer has little or no competition it can simply dictate prices, since buyers have no reasonable alternatives. Conversely, people also presume that large volume buyers have an inherent negotiating advantage over sellers. This thinking further leads many to conclude that the only effective counterweight to a producer monopoly or oligopoly is to somehow organize a very large buying group.

This thinking is certainly present in the debate over pharmaceutical purchasing. But before moving to that topic, let us pause to consider what is missing from such an analysis. The missing piece is the failure to account for other variables in the negotiating equation.

Let us take Wal-Mart as an example. Clearly, Wal-Mart regularly uses it size – an enormous customer base – as leverage to extract price concessions from its suppliers. But what if Wal-Mart encounters the phenomenon of price-inelastic demand for a product in limited supply? Say, for example, something like the Cabbage Patch Doll craze in the Eighties. Why should the manufacturer give Wal-Mart a discount? Supply can't meet demand and buyers will seek out the product regardless of where it is sold. Indeed, other stores will be happy to carry the product at the manufacturer's price, if for no other reason then to attract customers away from Wal-Mart. In such a situation, one can imagine the negotiations going the other way. Wal-Mart might end up not only abandoning any effort to get a price discount, but offer inducements of its own, such as stocking more of the manufacturer's other products, in exchange for being the only distributor of the desired product, in an attempt to protect its customer base.

At this point it would appear that the monopoly producer clearly has the upper hand – even over the largest potential purchaser. But we need to also consider some of the other variables involved, such as time. The inelastic demand for that "must have" product is only a temporary phenomenon. Eventually, the manufacturer will produce enough

supply to meet the initial, overwhelming demand. What happens then? If the manufacturer still wants to sell more of the product it will have to start making price concessions. Also, fads and fashions change quickly, and the manufacturer shouldn't expect that the phenomenon of sudden, inelastic demand would be repeated with each new product. Maybe it's in the manufacturer's interest to give a bit in its negotiations with Wal-Mart in exchange for a better, long-term relationship once it's current negotiating advantage has dissipated.

This example does not invalidate the common perceptions about the role of scale in negotiation, or the efficacy of pitting bulk purchasers against monopoly suppliers. But it does show that there is a great deal more complexity and nuance involved than most would imagine at first glance. It also shows how much scope exists for even the biggest of purchasers and the most monopolistic of sellers to miscalculate their own "best alternative" and significantly disadvantage themselves in a negotiation. Size may be important, but it's far from everything.

**Negotiating Pharmaceutical Prices.**

From the buyer's perspective another term for "best alternative" is substitutability. In other words, how practical is it to substitute one product for another if agreement can't be reached on the price of the preferred product.

While in some case non-pharmaceutical therapies, such as diet or surgery, can be substituted for drugs for certain patients with certain conditions, in most cases with respect to prescription drugs substitutability refers to replacing one pharmaceutical product with another. In that regard, the pharmaceutical market can be divide into four broad categories, based on the relative substitutability of drugs.

1) **Generic products.**

   Strictly speaking, generic products are identical to each other in all important respects. That is, the active ingredient is the same, the dosing is the same, and the bioavailability, (the length of time that the drug is absorbed, present in the body, and then excreted), is the same.

   True generics are the commodities of the pharmaceutical market. They are easily substitutable and price is their only real difference. Thus, pricing pressure on manufacturers is greatest for generic drugs and they are the cheapest of all drugs.

2) **Products with the same compound but different bioavailability.**

   These products are safely substitutable for many patients, but for some patients with some drugs, such substitution is not medically appropriate. A common example would be two drugs with the same compound (or active ingredient) but one has a dosing regime of three times a day, and the other is a once a day dose.

While to the patient the main difference may be one of convenience, to the physician the difference in bioavailability between two dosing regimes can sometimes be important to the success of the treatment, given the condition being treated and the particulars of the individual patient.

As with true generics, there is considerable leeway for substituting drugs when the active ingredient is the same but the bioavailability is different. The exception is when an innovator company uses a patented drug delivery technology to create a new version of an existing drug.

In these cases, while the drug may be available as an off patent, low-price generic, the manufacturer of the new version can charge more because the delivery technology used by the drug is still on patent. The greater the benefit from the new formulation of the drug, the more scope the manufacturer has to charge higher prices for the new version. But if the outcome for the patient is likely to be much better, then the total cost of treatment is also likely to be less, even though the new drug costs more than its generic competitors. In such cases it would make sense for the buyer to agree to pay a higher unit price, since the benefit will be greater and the total cost will be lower.

3) **Therapeutically similar products.**

These drugs have different active ingredients, but treat the same condition in a similar manner. For example, the various drugs that regulate cholesterol levels. With therapeutically similar products, all the drugs in a class may be on-patent, or some may be on-patent while others are off-patent generics. When doctors can safely substitute one of drugs for another for a particular patient (a practice known as 'therapeutic substitution'), then relative price differences can become a consideration in the decision. (Technically, substituting drugs with the same compound but different bioavailability is also therapeutic substitution.)

However, for some patients, such substitution is not medically appropriate. For example, if a doctor has different patients with the same condition but with different severities of the illness, and/or with other medical conditions present (called 'co-morbidities'), the medically appropriate thing is for the doctor to prescribe the best drug for each patient from among the different ones available in that therapeutic class. Also, different drugs in a therapeutic class may have different side effects and individual patients will differ in their abilities to tolerate those side effects. Again, the appropriate course is for the doctor to prescribe the drug that does the best job of treating the condition with the least potential to otherwise harm the patient.

If therapeutic substitution is medically appropriate, then the relative prices among drugs within a therapeutic class can be a legitimate consideration. But the size of the price differences among those drugs, and the extent to which competition will force down prices for most, or all, drugs in a class is a function of the degree of appropriate substitutability among the various drugs. When two or more drugs in a therapeutic

class are very similar, and thus appropriately substitutable for most patients, significant price competition occurs, and prices for all the drugs in the class drop as similar drugs enter the market. Indeed, this price discounting occurs even if all the drugs in a given class are on-patent, and thus their manufacturers could theoretically charge monopoly prices.

Conversely, the less the similarities and the greater the differences in relative therapeutic benefit and side-effect profiles among drugs in the same class, the fewer the number of patients for whom therapeutic substitution is medically appropriate and thus, the less competitive pressure on manufacturers to offer discounts will arise.

4) **Unique innovator products.**

These are products which are not only on-patent, but for which there is no reasonably substitutable drug, either on- or off-patent. In some cases, there may actually be no previous treatment for the condition at all. That was the situation when the first drugs to treat HIV entered the market back in the 1980s. In other cases, the new drug may offer such a significant advance in either treatment effectiveness or reduced side effects that substituting an older drug for the new one would be inappropriate.

It is only in these, fairly limited, circumstances that the maker of a new drug has real freedom to charge monopoly prices. But, again, such monopoly pricing power lasts only until such time as either the patent on the new drug expires or, as is more often the case, another company introduces another new drug that is similar to the first one, and therapeutic substitution for some patients becomes a possibility.

Thus, price competition in pharmaceuticals occurs at several levels and is principally a function of the degree of substitutability. As with other goods, volume purchasers can leverage drug substitution to extract price concessions from manufacturers. It was this insight that lead to the rapid growth during the past two decades of new companies specializing in reducing pharmaceutical costs, called pharmacy benefit managers or PBMs.

**PBMs and Discounting in Pharmaceuticals.**

The basic business strategy behind a PBM is to aggregate a large number of drug consumers and use the resulting purchasing power to extract discounts from drug makers. But while volume purchasing encourages manufacturer discounting, it is not, in and of itself, sufficient to extract large discounts. Manufactures will only offer substantial discounts if the buyer combines the 'carrot' of volume purchasing with the 'stick' of being able to substitute one supplier's goods with those of another.

However, compared to other businesses that purchase goods in large volume, such as a bakery that buys flour in bulk, a PBM faces five obstacles to effectively wielding the 'stick' of substitutability to extract large discounts from drug makers:

1) The patient, not the PBM, is the end user of the product.

2) The ultimate purchaser is the patient or the patient's insurer, not the PBM.

3) The PBM doesn't fully control product demand. Ultimately, demand is a function of the specific drugs prescribed by doctors for patients enrolled in the PBM.

4) The PBM cannot legally make substitution decisions on its own authority. Only a physician may legally prescribe one drug instead of another.

5) Drugs aren't commodities. They have different degrees of substitutability.

Confronted with these limits to traditional volume purchasing power, PBMs developed various tools and strategies to reduce the cost of drug benefits. Those strategies can be grouped into four basic categories:

**1) System efficiencies.**

The first set of strategies center on reducing costs through system efficiencies. An early step was to cut transaction costs by introducing computerized systems for filling prescriptions and processing claims. PBMs also leveraged their economies of scale by creating large volume mail order pharmacies to handle refills for 'maintenance therapies,' or drugs that patients take regularly over a period of months or years.

In addition, PBMs developed networks of retail pharmacies to service their enrollees. In exchange for the PBM steering more patients to a particular pharmacy, the pharmacy agrees to reduce its per prescription dispensing fee. The theory is that by providing a pharmacy with a larger share of customers, the pharmacy will be able to achieve its own economies of scale, with some of the savings passed back to the PBM and its customers.

**2) Substitution incentives.**

While costs can be reduced somewhat through system efficiencies, much greater savings can be achieved by substituting lower priced drugs for more expensive ones. The greatest savings can be achieved by substituting a generic drug for a branded drug. Substituting one on-patent drug for another, similar on-patent drug can also yield savings, though they are generally not as great as those from generic substitution.

However, a PBM can't legally make such substitutions on its own authority. It needs agreement from the patient or the doctor, who are mainly concerned about the relative benefits of the drugs in question. Thus, PBMs devised a strategy to create incentives for doctors and patients to weigh cost as well as benefit in prescribing and purchasing drugs.

At the heart of this strategy is the concept of a drug 'formulary.' Essentially, a drug formulary is a list of drugs grouped according to therapeutic class. Within each class the specific drugs are then ranked by preference. The considerations in determining a drug's

rank within its class are its effectiveness and cost. Thus, a drug that should be effective for a substantial subset of the population being treated (a criteria called 'clinical appropriateness'), and also has a lower price would rank as the preferred drug in its class.

However, designing a drug formulary is more of an art than a science. For each class of drugs there are a number of variables to consider that require judgment calls, including the relative effectiveness and side effect profiles of different drugs. Indeed, even cost comparisons may not be straightforward. For example, if drug B is twice as effective in managing cholesterol as drug A, but costs 50 percent more, a 'bang for the buck' calculation would conclude that the more expensive drug is the better buy. In addition, once it has constructed a formulary, a PBM must constantly update it to reflect the introduction of new drugs, both on-patent and generic.

To make the decisions involved in constructing and updating its drug formulary, the PBM assembles a Pharmacy and Therapeutics (P&T) Committee consisting of independent outside experts including physicians, pharmacists and others with particular clinical expertise. This helps the PBM ensure that clinical appropriateness, as well as price, is factored into decisions about drug preferences within its formulary.

With a formulary in place, the PBM next creates incentives for doctors and patients to follow the formulary preferences in prescribing and purchasing drugs. Those incentives typically include charging the patient lower copays for a generic drug than for an on-patent drug, and lower copays for a preferred, on-patent drug versus another, non-preferred, on-patent drug. The PBM will also have pharmacists call doctors to get physician approval for substituting one drug for another.

**3) Manufacturer discounts and rebates.**

While the use of formularies and related incentives can, as a standalone strategy, generate substantial savings, they also give PBMs another lever to further reduce drug costs. If the PBM has a large market share, its programs to encourage drug substitution will have a follow-on effect on the relative market shares of the different drugs in each class. That phenomenon, of course, is a powerful tool to induce drug makers to offer the PBM further discounts or rebates as a way to get their drugs better placement on the formulary.

However, because many drugs are not perfectly substitutable, a PMB must be careful in pursuing this strategy. While doctors and patients want the PBM to obtain drugs at lower prices, they naturally resist having the PBM interfere too much in decisions about the clinical appropriateness of specific drugs for specific patients. If patients perceive the PBM's formulary to be mainly driven by cost considerations, then they will seek another avenue for purchasing drugs. This natural market check on PBMs again reinforces the incentives on them to seek savings only within the context of clinical appropriateness.

**4) Health care quality assurance systems.**

To provide further value for their customers, PBMs have also developed strategies to

reduce health care cost through better prescribing and dispensing practices. In this regard, it is important to remember that price is only one half of the cost equation. The other half is volume. Thus, fewer, but more expensive, drugs used more effectively can result in a lower total cost than more, but less expensive, drugs used less effectively.

One such tool is called 'drug utilization review,' or DUR. The basic insight behind DUR is that the PBM is often in the unique position of having all the relevant data about a given patient's drug consumption. When a patient sees different doctors for different ailments, each doctor only knows what the patient tells him about any other drugs he is taking. Similarly, without a PBM involved, a retail pharmacist only knows about the particular prescriptions a particular patient has had filled at his pharmacy.

But the PBM can see the total picture. PBMs quickly realized that they could use that information to improve the quality of care while also reducing costs. For example, a basic DUR strategy is to identify any potential harmful interactions between a drug the patient is already taking and a new drug that has been prescribed, before the new drug is dispensed. Armed with this information, the PBM can then call the doctor, warn him about the potential drug-drug interaction and suggest alternatives for the doctor to prescribe instead. Another common flag is to check whether the prescription is appropriate for the patient's age, or whether the dosing should to be adjusted.

While these interventions benefit the patient's health, they may at times increase total drug costs. However, they can also result in much greater savings by avoiding adverse events that result in additional doctor visits or hospitalization. Thus, the greatest benefit of PBMs practicing DUR is within the context of the PBM managing the drug component of a comprehensive health insurance plan that pays for the patient's total care.

Other, related, quality strategies include patient and physician education programs, disease management programs, and patient compliance programs. For patients with chronic conditions, such as diabetes, disease management and education programs can increase the effectiveness of their drug regimens and avoid costly of doctor visits and hospitalizations. The same results can also be achieved through patient compliance programs that help ensure patients take their medications as directed.

Finally, PBMs can use the data in their systems to generate prescribing profiles for individual physicians. If a PBM identifies a doctor whose prescribing patterns vary substantially from the norm, it may target the physician for one of its education programs, since the doctor's atypical prescribing pattern may be the result of unfamiliarity with the latest drug effectiveness research. Recognizing that it is difficult for physicians to keep abreast of new information, and that drug company representatives, while providing doctors with valuable information, have an incentive to emphasis that which favors their company's products, PBMs use physician education programs to give doctors a more comprehensive picture of information on clinical best practices in prescribing.

Using these various strategies, PBMs have demonstrated through their success in the competitive private market that they provide value for patients in the health care system.

That value takes the form not only of reduced spending on pharmaceuticals, but also better use of prescription drugs to achieve improved patient outcomes and constrain overall health system costs.

The creation and growth of PBMs is an example of the genius of the decentralized, private market in health care. In essence, the private market 'invented' PBMs not only as a way to increase health system efficiency but also as a mechanism for balancing conflicting incentives within the pharmaceutical marketplace. By acting as advocates for patients and payers, PBMs exert countervailing pressure on drug makers and doctors. One set of what economist call 'learned intermediaries' (PBMs) interact with other sets of learned intermediaries (drug makers and doctors) and the result is a balanced approach that seeks optimum quality at optimum cost for a complicated set of services and products about which the average consumer has little expertise.

To be sure, PBMs can be subject to their own biases. The perennial temptation for a PBM is to overemphasis cost considerations to the detriment of benefit considerations. However, to the extent that a PBM functions as part of a comprehensive health plan responsible for the total cost of patient care, and particularly to the extent that consumers are free to choose the health plan and/or PBM in which they have the greatest confidence, the competitive marketplace will also check this temptation on the part of PBMs. Thus, through its complex system of natural checks and balances, the private market seeks the most clinically appropriate care for the individual patient at the best price.

**Could the Government do Better?**

One year into the Medicare Part D program, private drug plans appear to have extended their successful record to the senior market. Individual prices for many drugs have declined, the program's costs (which are the product of price times volume) are coming in well below initial projections, premiums are significantly lower than expected, and high rates of patient satisfaction with the program are being reported.

The question on the table, then, is whether the government could reasonably expect to get a still better deal by negotiating directly with pharmaceutical companies?

To answer that question it is necessary to consider the other tools the government, but not PBMs, could use to obtain drugs at even lower prices. Governments essentially have four other sets of tools, not available to private entities, for extracting discounts from drug makers. Those tools are the government's unique powers to: 1) Impose increased substitution of drugs; 2) Restrict market access; 3) Limit manufacturers pricing freedom, and; 4) Extract price concessions by non-market means.

**1) Impose increased substitution**

Encouraging the substitution of cheaper drugs is an important lever PBMs use to extract price discounts, but there are limits on how far a PBM can go in encouraging drug substitution. The most important limitation is that PBMs must compete for the business

of consumers who, while they like paying less for drugs still want access to the drugs they need. If a PBM attempts to get deeper discounts by making its formulary too restrictive or by making it too costly or difficult for physicians to prescribe "off-formulary," then customers will be inclined to switch their business to another, less restrictive, PBM. Thus, the market power PBMs can exert over drug makers is effectively limited by the market power being exerted over PBMs by their customers.

In contrast, when the government is the sole, or "monopsony," purchaser for a group of individuals, such as the Medicare population, it is free to pursue a strategy that puts price considerations ahead of patient benefit or clinical appropriateness. That is because patients have no alternative purchasing avenues, or at least none for which the government program will help pay the costs. PBMs are also tempted to act that way, but unlike the government they must compete for business by satisfying consumers, who want access to the drugs that benefit them.

Thus, as a monopsony purchaser, the government can impose a single, restrictive drug formulary in a program like Medicare. Because manufactures no longer have other avenues to reach that market, they must offer significant discounts to ensure placement of their drugs on the formulary, and even deeper discounts to get preferred placement.

Such a policy can further drive down drug prices, but at the expense of quality patient care. Under a single formulary, doctors are more likely to be forced to prescribe drugs that are cheaper, but may not be as effective for the patient, as other drugs. This is the situation with single, government set, formularies in other programs such as the Veterans Administration (VA) health system and foreign national health systems.

Indeed, it may also come at the price of higher program costs. Forcing patients to accept lower priced, but less effective drugs can actually result in increased total drug spending as the volume of drugs prescribed increases.

Furthermore, even if a government imposed, restrictive formulary does lower total drug expenditures it may still backfire on the government as the savings it achieves in drug spending are more than offset by added costs for hospitalization and physician visits due to the prescribed course of drug treatment being sub-optimal.

The same effects occur when the government uses a related tool; the imposition of a single fee schedule for covered drugs. In this case the government simply tells manufactures what it will to pay for drugs and refuses to cover those for which the manufacturer won't accept the government set price. However, such as system must be enforced, or otherwise the costs will simply be shifted back to patients. For example, if Medicare refused to cover a specific drug, the patient could instead use his own money to buy it. Similarly, if the government decided to only pay half the market price of a particular drug, the patient could still obtain the drug by paying the balance out-of-pocket. Any purchaser, even the government, that doesn't control a captive market, will lack the necessary stick with which to enforce lower *real* prices.

In sum, Medicare *could* extract deeper discounts from drug makers than PBMs, but only if it is willing to limit, or deny, patients coverage for a manufacture's drugs if the manufacturer won't 'play ball.' Thus, the government's power to extract additional discounts is entirely a function of its willingness to limit market access to drugs, for both patients and drug makers.

But a government that pursues such a strategy also risks creating a patient backlash against access restrictions. If enough patients exert enough political pressure on their elected representatives, then the government will be forced to abandon some or all of its access restrictions. In such a situation, the government could actually end up worse of and spending more on the program than it would have had it left the negotiations over price and access to a competitive private market better able to calibrate patient willingness to accept access restrictions in exchange for lower prices.

**2) Restrict broad market access**

Unlike private PBMs and health plans, governments have the power to impose broader market access restrictions on drugs if manufacturers refuse to limit the prices they charge to levels acceptable to the government.

While a private plan can refuse to cover a drug as a way to extract price concessions from the manufacturer, that option is limited by the plan's need to satisfy customers who want the drug covered. However, a government program faces no such pressure from consumers. Patients denied access to drugs under a government program can't simply choose a different plan. Instead, they must lobby the government to change its reimbursement policy – a much more difficult, lengthy and costly undertaking.

Thus, a government that is willing to deny patients access to drugs can extract price concessions by threatening to deny manufacturers access to a major market segment. In such a situation the distinction between threatening to not cover a drug and actually refusing to cover the drug is largely irrelevant, since without a genuine willingness to deny coverage any such threat would be meaningless.

Furthermore, while governments can use their control over market access to extort below average prices in limited circumstances, not even a government can contravene the laws of economics and mathematics to ensure that *everyone* pays 'below average' prices. All it will really do is ensure that manufactures are eventually forced to eliminate pricing differences (mainly by eliminating price discounts) until all purchasers are charged the same price. Thus, not even control over market access is sufficient for a government to force down *real* prices across the board. To achieve that, a national government must be willing to wield its biggest stick– direct control over manufacturers pricing freedom.

**3) Limit manufacturers pricing freedom**

The most severe tool a national government can deploy is control over the drug maker's intellectual property. The manufacturer can set its own price for a drug only because the

government has granted it a patent giving it, legally enforceable, exclusive marketing rights. Once a drug's patent expires, anyone can copy and sell it after proving to the FDA that their copy is identical to the original. Then, as generics enter the market, the innovator company's pricing power with respect to a drug vanishes, literally, overnight.

But if the government can grant such limited monopolies, it can also extend, reduce, restrict or eliminate them entirely. Thus, if a government wants to coerce a manufacturer to lower prices across the board it can do so by threatening to limit or revoke its patent rights. In the most extreme form, called 'compulsory licensing,' the government takes away the innovator company's patent protection and allows one or more other companies to make and sell the drug at a price that is acceptable to the government.

The imposition, or even threat, of compulsory licensing is the ultimate weapon that a national government can wield against drug makers. But it carries a high price for any government that wields it, and the price would be particularly steep for the U.S. Such a move would seriously undermine confidence in the basic fairness and consistency of intellectual property protections granted by the government. Without those assurances, not only drug makers, but other companies as well, will avoid investing in developing new products since they risk having their investments effectively expropriated by the government. Innovation throughout the industry, and even throughout the economy, would diminish or cease, and the flow of new products to consumers would dry up.

If the U.S. Government adopted such a strategy, America would be particularly hard hit. The U.S. is already, by a large measure, the global leader in pharmaceutical and biotech research, thanks to a combination of reliable patent laws and the freedom of companies to engage in market pricing. As such, America benefits from hundreds of billions of dollars of investment in the pharmaceutical and biotech industries and hundreds of thousands of well paying, highly skilled jobs in those industries. All of that would be jeopardized if the U.S. Government began to make its intellectual property policies inconsistent and arbitrary, by adjusting them to accommodate short-term political pressures.

Nor would the effects be confined to a single industry or to a single country. Other industries that rely heavily on intellectual property protections such as electronics, software, aerospace, medical devices, film, music, etc. would be forced to discount the value of their intellectual property, since what the government was willing to do to one industry it might be willing to do to others. Furthermore, the U.S. would be unable to argue that other countries should respect the intellectual property of U.S. citizens or corporations. Given that the U.S. probably has a greater share of its economy and export sales dependent on intellectual property than any other nation, the U.S. economy would disproportionately suffer the economic effects of such a move.

**4) Extract price concessions by non-market means.**

The final set of tools that governments, but not private companies, can use to extract price concessions from manufacturers lie with the non-market powers governments exercise. Those are powers over aspects of the manufacturer's business that are not

directly related to the manufacturer's products, and include tax policy, financial market access and a host of other regulatory regimes. Governments can impose adverse policies in any of these areas on companies that refuse to accept it's pricing dictates.

But as with intellectual property, any such actions would likely have other adverse effects on the economy. In some cases the effects might be localized, while in other cases the effects might be economy-wide. For example, imposing for political reasons tax penalties or financial market access restrictions on companies in one industry, will naturally lead companies in other industries to question the fairness and consistence of the government's policies in those areas with respect to their own businesses.

The introduction of any policy that makes the rewards of economic activity uncertain will serve to diminish economic activity in general. It is precisely the uncertainty and perceived arbitrariness of government policies in many other countries that keep their economies stagnant and millions of their citizens poor. Indeed, economic historians can point to various examples of once reasonably prosperous nations that impoverished themselves by their government's arbitrary economic policies.

**Conclusion**

In the final analysis, the government's power to negotiate lower drug prices is entirely a function of two things. The first is its ability to deny access to a larger number of beneficiaries. The second is its ability to limit property rights.

Absent provisions requiring the exercise one or the other, or both, of those unique governmental powers, it is completely unrealistic to expect any meaningful result from legislation authorizing direct government negotiation with pharmaceutical companies.

But if Congress chooses to pursue those options, I must warn you that they carry very high price tags. I can also assure you that the price will be political as well as monetary. The economic distortions resulting from restricting market access for drugs in Medicare could not only lead to increased overall Medicare spending but would likely spark a political backlash on a scale not seen since senior citizens forced Congress to repeal the 1987 Medicare Catastrophic Coverage Act.

In the case of compulsory licensing, or other similar threats to intellectual property rights, the economic consequences would be much more severe, though the political backlash would likely be slower in coming. Nevertheless, the backlash will occur when those seeking treatments for their, or a loved one's, illness figure out that Congress has destroyed the incentives for researchers to develop the cures they seek. The precedent will be the pressure from AIDS activists that lead Congress to reform the FDA drug approval process and speed to market life-saving drugs for HIV.

In the end, both the government and the drug makers "best alternative" to direct negotiation may prove to be the same thing -- the current system enacted in the Medicare Modernization Act of 2003.

Thank you, Mr. Chairman. That concludes my prepared remarks. I will be glad to answer any questions you or the other Senators may have.

**********

The Heritage Foundation is a public policy, research, and educational organization operating under Section 501(C)(3). It is privately supported, and receives no funds from any government at any level, nor does it perform any government or other contract work.

The Heritage Foundation is the most broadly supported think tank in the United States. During 2004, it had more than 200,000 individual, foundation, and corporate supporters representing every state in the U.S. Its 2004 income came from the following sources:

| | |
|---|---|
| Individuals | 56% |
| Foundations | 24% |
| Corporations | 4% |
| Investment Income | 11% |
| Publication Sales and Other | 5% |

The top five corporate givers provided The Heritage Foundation with 2% of its 2004 income. The Heritage Foundation's books are audited annually by the national accounting firm of Deloitte & Touche. A list of major donors is available from The Heritage Foundation upon request.

Members of The Heritage Foundation staff testify as individuals discussing their own independent research. The views expressed are their own, and do not reflect an institutional position for The Heritage Foundation or its board of trustees.

The Heritage Foundation

January 11, 2007

# Medicaid Restrictions vs. Private Negotiations

(Addendum to testimony of Edmund F. Haislmaier, Research Fellow in Health Policy Studies, Domestic Policy, The Heritage Foundation.)

**Media Contact: Matthew Streit 202.608.6156 cell: 202.439.0271**

New data indicate that there is already evidence that the competitive private market in Medicare Part D is significantly reducing total program costs below the levels achieved by a system of government mandated price discounts. Therefore, introducing into the program some new mechanism of government negotiation might actually result in an increase in total program costs, and not the widely assumed further reduction.

The data are recent, substantial, downward revisions by both CMS and CBO to their estimates for state government payments to Medicare Part D.

The legislation establishing the Medicare Part D Program provided that "dual-eligibles"–those low-income Medicare beneficiaries who are also covered by Medicaid–would no longer receive their drug coverage through Medicaid but would instead be covered by Medicare Part D like other seniors.

Under Medicaid, the cost of drug coverage for dual-eligibles was funded out of a combination of state and federal money, while in Medicare Part D the Federal government is the only payer. Thus, the legislative drafters realized that, absent an offsetting provision, such a transfer of responsibility would result in states receiving a budget windfall.

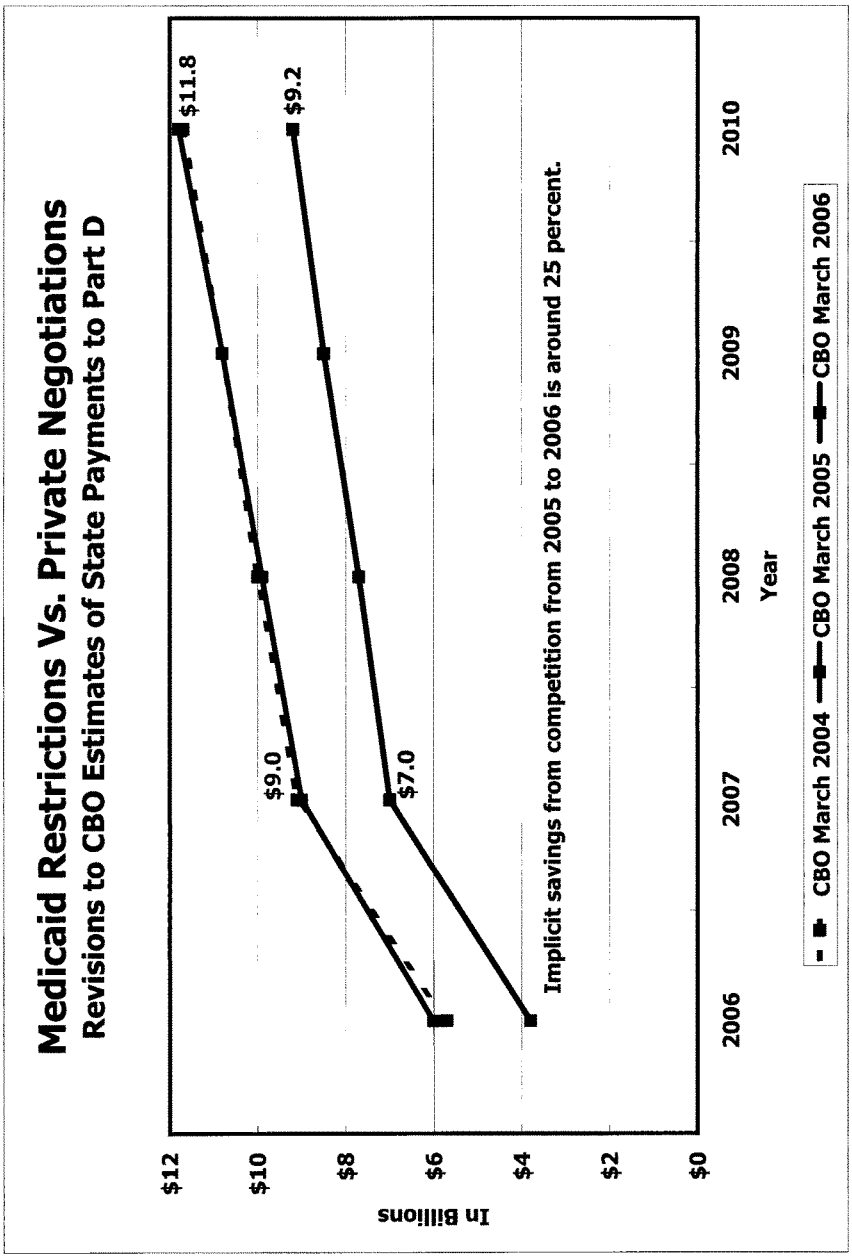
To offset that effect, Congress included in the legislation a provision requiring states to make payments to the federal government equal to the estimated cost states would have incurred had they continued to provide their dual-eligibles with drug coverage under Medicaid. The law provided for the state payments, or "claw-back," to initially be based on historical Medicaid data, and then, from 2006 onward, indexed to the growth in average per-capita Part D costs.

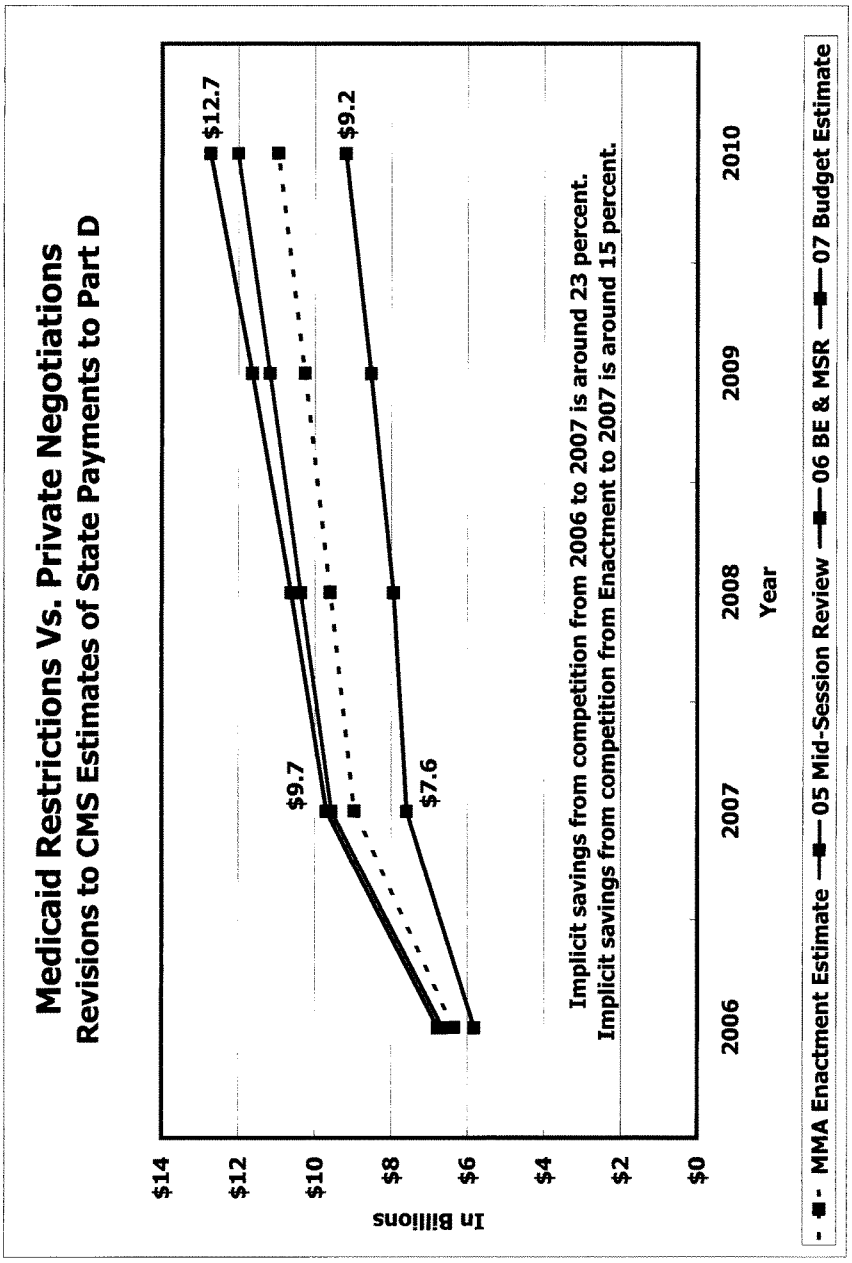
Now that actual program costs are available, and those actual costs have come in much lower than the original estimates, CMS and CBO have made substantial downward revisions to their projections for state payments to Part D.

Medicaid employs a government mandated price discount system of best price or a 15 percent rebate off of the average manufacturer price. In contrast, Part D relies on a system of competing private plans each trying to negotiate better deals with manufacturers.

These changes in estimates indicate that the system of competing private plans is producing better results than an already existing system of government mandated price discounts.

Attached: Chart 1-- Revisions to CBO Estimates of State Payments to Part D
Chart 2-- Revisions to CMS Estimates of State Payments to Part D


Medicaid Restrictions Vs. Private Negotiations
Revisions to CBO Estimates of State Payments to Part D
In Billions
$12
$10
$8
$6
$4
$2
$0
2006
2007
2008
2009
2010
Year
$11.8
$9.2
$9.0
$7.0
Implicit savings from competition from 2005 to 2006 is around 25 percent.
CBO March 2004
CBO March 2005
CBO March 2006


Medicaid Restrictions Vs. Private Negotiations
Revisions to CMS Estimates of State Payments to Part D
$14
$12
$10
$8
$6
$4
$2
$0
In Billions
$12.7
$9.7
$9.2
$7.6
2006
2007
2008
2009
2010
Year
Implicit savings from competition from 2006 to 2007 is around 23 percent.
Implicit savings from competition from Enactment to 2007 is around 15 percent.
MMA Enactment Estimate
05 Mid-Session Review
06 BE & MSR
07 Budget Estimate

**United States Senate Committee on Finance Hearing**
**Prescription Drug Pricing and Negotiation:**
**An Overview and Economic Perspectives for the Medicare Drug Benefit**
**January 11, 2007**

**Questions Submitted for the Record**
**Mr. Edmund F. Haislmaier**

**Chairman Baucus**

*Questions for Mr. Haislmaier and Dr. Scott Morton:*

1. One of the main reasons for designing the drug benefit as a private market with competing plans, each with their own formulary, rather than a government benefit with one formulary, was to offer seniors greater choice. However, it seems to me that the plans have a major advantage over seniors. Seniors are required to choose a plan once a year during an open enrollment period while the drug plans can change their formularies at any time. Under pressure, CMS issued guidance that plans should "grandfather" for the remainder of the year any drug a beneficiary took before the plan's formulary change. However, it still allows plans to change formularies for enrollees that weren't on the affected drugs. Can this type of asymmetry distort the market? If so, how? Or is it just unfair?

*Haislmaier Response:*

I agree that such an asymmetry might distort the market and that such changes might disfavor beneficiaries. Theoretically, it would be preferable and fairer to apply the 'lock-in' for a plan year to both beneficiaries and plans equally. That is certainly the standard practice for other features of health insurance coverage such as deductibles, co-pays, covered services, or provider networks. The one caveat is that new therapies (e.g., new drugs, new devices, new procedures, etc.) reach the market throughout a given year and not on a predictable schedule geared to when coverage decisions for the next plan year are being made. Consequently, too strict a rule could delay patient access to the benefits (improved treatment and/or reduced costs) associated with new therapies.

As a practical matter, such delays of several months generally don't make much of a difference with regard to new surgical procedures, treatment protocols, or medical devices, as it usually takes a while for them to be adopted in clinical practice. However, prescription drugs present a somewhat different situation. Changes in the pharmaceutical market can very quickly result in widespread behavioral responses by doctors, plans and patients. Furthermore the volume of changes in any given year can be significant.

For example, according to the FDA's most recent report, in 2005 the Agency approved 80 new drugs and biologics, of which 20 were new medicines never before marketed in the US. The Agency also approved new or expanded uses (indications) for 141 drugs and biologics already on the market, and granted final approvals to 344 generic versions of

existing drugs. The FDA also took major actions on significant new safety concerns identified for 16 drugs already on the market, including safety advisories, labeling changes, and suspending the sale of two drugs. Thus, in 2005 FDA took over 500 hundred separate regulatory actions affecting drugs available to patients and payers. While the volume of FDA actions naturally varies somewhat from year to year, this data for 2005 is not atypical when compared to previous years.

Now, it is true that most generic drugs approved in a given year are for the third or subsequent manufacturer of a generic product, and only the first and second generic entrants have any significant impact on pricing. It is also true that by the time FDA approves an efficacy supplement (e.g., ads a new approved use to a drug's label), the supporting research is generally available to clinical practitioners and many doctors have already been prescribing the product 'off-label' for the indication.

But even after discounting for those considerations, that still leaves about 50 to 100 FDA actions each year for which any responsible pharmacy benefit manager would need to legitimately consider whether altering it's formulary in response might significantly improve patient care or safety or lower plan costs.

Consequently, any statutory or regulatory revisions designed to prevent plans from making mid-year formulary changes that might disadvantage beneficiaries would need to be crafted in such a way as to not preclude plans from making formulary changes that favor beneficiaries by giving them quicker access to better treatments or lower cost products.

2. Prices for single-source drugs can be astronomical. Yet, you have cautioned against interfering in prices for these drugs because they may be truly innovative. However, I know that the federal government funds a significant amount of the basic science research that leads to privately manufactured and sold drugs. The drug companies may further develop and test the drugs, but government is paying for a significant amount of the legwork. Senators Snowe and Wyden proposed that the Secretary of HHS should take steps to negotiate prices for drugs developed with a significant amount of publicly funded research. What do you think of this idea?

*Haislmaier Response:*

My concern is that single source drugs and biologics are almost always result from research at the leading edge of scientific knowledge. As such, they are the riskiest of all investments in the bio-medical sector. The higher the risk, then the higher the potential rewards need to be in order to attract investment. Government policies that set limits on the level of potential rewards induce investors to look for less risky activities that better match the lower level of potential reward – and thus, funding for research shifts away from the frontiers of science and back toward safer projects involving better understood issues and already proven concepts.

However, as you point out, taxpayer funded bio-medical research is the foundation for some drugs that are later developed and brought to market by private industry. Under such scenarios is appropriate that taxpayers receive a measure of the 'returns' for their 'investment' when the product eventually reaches market – the same as the investors in a small, innovative bio-tech company get a return on their investment when that company licenses it's discovery to a larger firm that develops it, tests it and brings it to market.

I think the preferred solution would not be for the government to try to 'capture' the return on the taxpayer's investment by limiting the eventual product price as that might discourage investment in the follow-on R&D needed to bring the product to market. Rather, my preferred solution would be for the government to receive royalty payments for drugs developed with government research. Congress could also dedicate such revenues to offsetting the costs of Part D. The place to start would be to look at the statutes and rules already on the books governing "Cooperative Research and Development Agreements" (CRADAs), and determine whether any modifications and amendments might be in order. Another advantage of this approach is that part of the revenue stream captured on behalf of the taxpayers would be coming from foreign customers for the products.

**Senator Hatch**

*Questions for All Witnesses:*

1. Timing of Negotiation: I am concerned that the timing of government negotiation may not be consistent with the Part D bidding process. Under current regulation, 2008 bids for Prescription Drug Plans (PDPs) and Medicare Advantage plans (MA-PDs), which include premiums and benefits, are due on June 4, 2007. Even if legislation requiring government negotiation was enacted tomorrow, it seems unlikely that the Secretary of HHS could negotiate drug prices for the roughly 4,300 Medicare covered drugs in time for plans to renegotiate with manufacturers before submission of 2008 bids. Do you think a requirement to adjust bids mid-year will create substantial administrative problems for the Part D program and for seniors covered under Part D?

*Haislmaier Response:*

It would, indeed, be disruptive to alter the negotiation process and bid process in the middle of a plan year. Consequently, I would expect that should Congress enact changes, of any kind, to the Part D Program, the effective dates set for those changes would have to take into account the need for sufficient lead time to implement them and the advisability of not disrupting already settled arrangements in the middle of a plan year.

2. Reduction in Private Negotiation Ability: It is unclear how HHS negotiation will affect private plan negotiations over discounts, dispensing fees, and formularies. The HHS negotiated price may or may not be the lowest price given that HHS

will not use a formulary and will negotiate on behalf of fewer members than some Pharmacy Benefit Managers (PBMs). I am concerned that drug manufacturers may use the HHS negotiated price to refuse to give private plans better discounts. Do you share my concern that government negotiation could actually reduce private plans' ability to get bigger discounts from drug manufacturers, or in other words, that the result of government "negotiation" could actually be to establish a floor rather than the intended ceiling on prices?

*Haislmaier Response:*

The results would largely depend on the timing of the separate government and private plan negotiations. If the government and private sector negotiations were conducted concurrently it is unlikely that there would be any effect whatsoever on the outcome of the private sector negotiations. That is because the private plans would presumably not know the results of any negotiations between the manufacturers and the government until such time as they were concluded and the agreed prices made public. With no knowledge of the outcome, the fact that the government was conducting concurrent negotiations would have no greater or lesser influence on a private plan's negotiating strategy than the fact that other, competing private plans were also engaged in separate, concurrent negotiations.

However, if the negotiations were conducted sequentially, with the government going first, then the likely opening position of the manufacturers in subsequent negotiations with private plans would be one of offering only modest incremental reductions from the price agreed to in negotiations with the government.

How aggressively private plans might then negotiate down from that point is uncertain and would depend on how motivated the private plans were to obtain further concessions. In particular, it would depend on a private plan's assessment of what the manufacturer's 'reservation price' was – defined as the price point below which the plan thinks the manufacturer would be willing to accept its product being excluded from the plan's formulary rather than making further price concessions – and how wide a zone remained between that reserve price and the government negotiated price. The wider the spread between the two, the more aggressive the private plans would likely be in the second round of negotiations. Conversely, the narrower the spread, the less likely private plans would be to invest effort in negotiating over what, in the best case, might only be a further one or two percent price discount.

Thus, it is possible under certain scenarios that the eventual lowest price negotiated by the private plans might, in some instances, be marginally higher than what would have been otherwise negotiated without the government involved in the equation. What is more certain is that none of these scenarios would result in the government negotiators obtain greater price concessions from manufacturers than those obtained by private sector negotiators.

3. Cost-Shifting: If government negotiation were successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost-shifting to small businesses and working families in the private insurance market?

*Haislmaier Response:*

That is indeed possible, but the extent of the effect would depend on the specific structure of the government involvement in the process. In any market characterized by differential pricing the larger the number of customers insisting on the lowest price, the narrower the price concessions manufacturers will be willing to grant. Since it is mathematically impossible for a majority of customers to pay a 'below average' price, the more widespread the demand is for discounts the more likely it will be that manufacturers will eventually move to a position of charging all customers the same price. However, in such a transition it will always be in the interest of manufactures to 'level-up' rather than 'level-down' their prices. As GAO reported in their testimony and in previously published studies, this effect occurred in response to Congress legislating a 'best price' requirement in Medicaid. Manufactures responded to that law by reducing the level of discounts previously granted to private payers in order to avoid more of their sales being priced at those levels. Thus, their new 'best price' for all customers was higher than their old 'best price' for a few customers.

**Senator Rockefeller**

*Question for All Witnesses:*

1. The essential difference between the Medicare pricing framework that Democrats envisioned and what was actually signed into law is that our proposals would have put Pharmacy Benefit Managers (PBMs) at risk for performance.

   In other words, payment to PBMs would have been on a per-script basis and according to factors such as keeping costs low for beneficiaries, filling prescriptions on time, using comparative effectiveness studies to determine covered drugs, offering generics, and effectively communicating plan changes to beneficiaries.

   Under the prescription drug law, plans hold all the power, but bear little profit risk for failing to meet certain performance standards. This is despite the massive subsidies provided to plans by the federal government.

   If Congress were to put prescription drug plans at greater risk for achieving standards like the ones I just mentioned, wouldn't that also be an effective way to achieve savings for seniors?

*Haislmaier Response:*

The alternative the Senator describes sound to me more like a system of incentives for rewarding presumed administrative efficiency -- analogous to what might be the case with the private fiscal intermediaries that administer claims for Medicare Part A and Part B, but which are not at risk for the price or utilization of the services for which they process claims.

In contrast, the Part D plans – like Medicare Advantage Plans and Medicaid Managed Care plans – operate within a pre-established premium that puts them 'at risk' for not only administrative efficiencies but also for the price, volume and mix of reimbursed services provided to beneficiaries. To the extent that beneficiaries are paying part of the premium and plans are free to set their premiums lower than those of their competitors, the plans that offer lower premiums are voluntarily taking on a larger performance risk than their competitors in an attempt to attract more business. Thus, with plans that are 'at risk' for the total package, it is hard to envision how micromanaging certain pieces of the package will result in lower total costs. Indeed, in the context of a plan at risk for the aggregate cost and performance, spending on a particular function might justifiably be higher than otherwise expected if the managers have determined that increased spending in that area produces even greater off-setting savings in one or more other areas.

**Senator Crapo**

*Questions for Mr. Haislmaier, Dr. Anderson, and Dr. Scott Morton:*

1. We know that large PBMs, such as Advance PCS (75 million covered individuals), Medco Health Solutions (65 million) and Express Scripts (57 million) have significant market power and are larger than Medicare. How can a government agency, working on behalf of 22.5 million seniors, match the purchasing power of a very large, very experienced industry working on behalf of hundreds of millions of Americans? How can we expect savings?

*Haislmaier Response:*

As I noted in my written testimony, while market size is certainly a factor in negotiations, the key factor is always the willingness of a party to the negotiation to walk away from the table and pursue an alternative option. In the case of drug price negotiation that alternative is the willingness of the payer (whether government or a private plan) to refuse to cover a drug for which it is unable to obtain a satisfactory price. The degree to which government negotiators are authorized and willing to enforce such access restrictions will be the prime determinant of the success of such negotiations. It is true, however, that given the Medicare program's lack of previous experience in negotiating drug prices and constructing formularies, it would need to obtain the necessary expertise either through hiring qualified staff or outsourcing to private firms with existing expertise. Thus one could expect that, at best, it would take some time before Medicare was able to match the results achieved by existing private plans.

2. Some have talked about non-interference as if it is a Republican creation. Isn't it true that in 1999 President Clinton offered this language in his Medicare proposal and Senator Daschle included this provision in his Medicare bill? And isn't it true that this provision was embraced by Democrats, some of my colleagues here included, as the best way to contain cost and protect patient access to prescription drugs? What has changed? Given the data that has been published since the implementation of the program I would suggest the case for the noninterference clause has strengthened.

*Haislmaier Response:*

I have not compared these provisions with those included in previous legislative proposals, but given that they are publicly available it should be relatively easy for someone to verify the legislative history you describe. As for the data so far on the operation of the Part D program, it does show that premiums and program costs are coming in significantly lower than the levels previously projected by either CMS or CBO. Furthermore, while in some instances the results are partially attributable to lower than projected enrollment, much of the savings are indeed coming from a combination of lower prices and more appropriate utilization. At the same time, beneficiaries are expressing high levels of satisfaction with the program now that it is operational, and that is confirmed by the low level of beneficiary appeals of plan coverage decisions recorded by CMS. This rules out the alternative possibility that the savings are somehow attributable to widespread denials of coverage or significant access restrictions on beneficiaries.

3. If government negotiations happened to be successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost-shifting to small businesses and working families in the private insurance market?

*Haislmaier Response:*

As I noted in my previous response to the same question posed by Senator Hatch, that is indeed possible, but the extent of the effect would depend on the specific structure of the government involvement in the process. Such a phenomenon did occur following the enactment of the 'best price' requirement for Medicaid.

# Medicare and the Market

Government Shouldn't Be Negotiating Prescription Prices

By Mike Leavitt
Thursday, January 11, 2007; A25

We all want people with Medicare to get the prescription drugs they need at the lowest possible prices. The issue before Congress this week is how best to do that. Should consumer choice and private-sector competition determine prices—or should government?

The success of the Medicare prescription drug benefit provides strong evidence that competition among private drug plans has contributed significantly to lowering costs. The average monthly premium has dropped by 42 percent, from an estimated $38 to $22—and there is a plan available for less than $20 a month in every state. The net Medicare cost of the drug program has fallen by close to $200 billion since its passage in 2003.

Seniors and people with disabilities like the benefit. Studies consistently show that three-quarters of Medicare beneficiaries are satisfied with their coverage. Individuals like being able to choose the plan that best fits their needs. A single, one-size-fits-all drug plan would have made the choice easier, and Congress did create a standard plan. But fewer than 15 percent of enrollees have selected that standard plan—opting instead for plans with lower premiums, no deductibles and enhanced coverage.

Despite the success of the benefit, some people believe government can do a better job of lowering prices than a competitive marketplace. Legislation under consideration would require the secretary of health and human services to negotiate and set the prices of drugs. In effect, one government official would set more than 4,400 prices for different drugs, making decisions that would be better made by millions of individual consumers.

There is also the danger that government price setting would limit drug choices. Medicare provides access to the broadest array of prescription drugs, including the newest drugs. But price negotiation inevitably results in the withholding of access to some drugs to get manufacturers to lower prices.

The Department of Veterans Affairs, often cited as an example of how government can negotiate prices, operates an excellent program for veterans, but the VA formulary excludes a number of new drugs covered by the Medicare prescription benefit. Even Lipitor, the world's best-selling drug, isn't on the VA formulary. That may be one reason more than a million veterans are also getting drug coverage through Medicare.

Some observers point to the massive buying power of the federal government as the means to exert clout over drug companies, but the federal government has nowhere near the market power of the private sector. Private-sector insurance plans and pharmacy benefit managers, who negotiate prices between drug companies and pharmacies, cover

about 241 million people, or 80 percent of the population. Medicare could cover at most 43 million.

The independent Congressional Budget Office has said that government price negotiation would have a "negligible effect on federal spending." And previous experience with Congress and Medicare regulating drug prices has not been reassuring. Medicare Part B, which covers physician services, outpatient hospital care and other services, sets the prices for some medicines—notably a number of cancer drugs. It has a history of reimbursing at rates substantially greater than prevailing prices. In 2005, Part B drug spending increased by almost 20 percent.

If the federal government begins picking drugs and setting prices for all Medicare beneficiaries, administrative costs would add a new burden to taxpayers. The Department of Health and Human Services would have to hire hundreds of new employees. Legions of lobbyists would follow, each seeking higher Medicare payments for the drug companies they represent. As a Post editorial noted in November, "having the government set drug prices is a sure way of flooding the political system with yet more pharmaceutical lobbyists and campaign spending."

There is a proper role for government in setting standards and monitoring those who provide the benefit. We should ensure that beneficiaries have access to medically necessary treatments. But government should not be in the business of setting drug prices or controlling access to drugs. That is a first step toward the type of government-run health care that the American people have always rejected.

There are many ways the administration and Congress can work together to make health care more affordable and accessible. But undermining the Medicare prescription drug benefit, which has improved the lives and health of millions of seniors and people with disabilities, is not one of them.

*The writer is Secretary of Health and Human Services.*

# Experts Fault House Bill on Medicare Drug Prices

Comparison With VA Called Invalid

By Christopher Lee
Washington Post Staff Writer
Thursday, January 11, 2007; A14

Democrats are fond of citing the Department of Veterans Affairs as evidence that Medicare officials could squeeze lower prices out of drugmakers if the government merely used its negotiating clout. But that comparison ignores important differences between the two systems, experts say.

Unlike Medicare, VA by law receives an automatic 24 percent discount from the average price that wholesalers pay. Its prices are also low because VA, which prescribes medications for 4.4 million veterans annually, has a relatively narrow formulary, or list of approved drugs. The agency secures big discounts from the manufacturers of a few drugs in each class by promising not to offer competing drugs. The Centers for Medicare and Medicaid Services (CMS) is prohibited by law from adopting such a list for the year-old Medicare drug benefit, in part because seniors enrolled in what is known as Part D want to have a wide range of drug choices.

The legislation that House Democrats hope to pass tomorrow to require the Bush administration to negotiate drug prices for Medicare would neither permit a formulary nor require an automatic discount. It would simply require the secretary of health and human services to pursue negotiations and report back to Congress in six months.

That is part of the reason that many experts do not expect the measure to deliver significant savings even if it overcomes opposition in Congress and escapes a possible presidential veto.

In fact, the nonpartisan Congressional Budget Office said yesterday that the House bill would have a "negligible effect" on federal Medicare spending because without a formulary the HHS secretary probably could not obtain better drug prices than those negotiated by the many private insurers who offer Medicare drug plans.

"The federal government can get lower prices, but only if it's willing to exclude a certain number of drugs from the formulary," said Robert Laszewski, a nonpartisan health policy consultant in Washington. "And that's a huge political leap that I would be very surprised if this Congress took. I don't think they are going to give CMS any teeth."

"The VA is really a different animal than Medicare Part D," said Robert B. Helms of the American Enterprise Institute, who was an assistant secretary of health and human services in the Reagan administration.

But Democrats and their allies say that the gulf between drug prices under the VA system and those under Medicare is too large to ignore, and that requiring the government to negotiate prices for Medicare would help narrow the gap significantly.

On average, prices are 58 percent higher in Medicare than in the VA system for the 20 drugs most commonly prescribed for seniors, according to a study released Tuesday by the nonprofit advocacy group Families USA. The lowest price for a year's supply of 20-milligram pills of the cholesterol-lowering drug Lipitor, for instance, was $1,120 in Medicare and $782 in the VA system, the report said.

"These high prices are devastating seniors," said Ron Pollack, the group's executive director.

Rep. Frank Pallone Jr. (D-N.J.), chairman of the House Energy and Commerce subcommittee on health, called eliminating the current prohibition on government negotiations a "no-brainer."

"It makes absolutely no sense to say that the administration should not be able to negotiate prices for all these seniors," Pallone said. "There's no way it's not going to save a significant amount of money."

Pallone said Medicare could obtain prices similar to the VA system's even without a formulary. "I have every reason to believe that there is enough persuasion power, with different things that could be implemented by the secretary, that could get down to those levels," he said. He added that Democrats will consider further changes down the road.

Energy and Commerce Committee Chairman John D. Dingell (D-Mich.), lead sponsor of the House bill, discounted the importance of the CBO analysis. "Common sense tells you that negotiating with the purchasing power of 43 million Medicare beneficiaries behind you would result in lower drug prices," he said.

Critics of the VA comparison note that some of VA's costs are buried in overhead. The department employs the doctors and nurses who write the prescriptions, and it operates the mostly mail-order pharmacies through which 76 percent of veterans' prescriptions are distributed. Medicare does not have that kind of infrastructure, and seniors have demonstrated a preference for retail pharmacies, CMS officials say.

CMS officials also note that about a quarter of the 3.8 million Medicare beneficiaries who get VA health-care benefits are also enrolled in Part D, in which the choice of drugs is broader.

"It's apples to oranges," former CMS administrator Mark B. McClellan said of the comparison. "The VA is a closed health-care system relying on mail order and a tighter formulary than Medicare beneficiaries have shown they prefer."

**Testimony for the Senate Finance Committee**

**"Prescription Drug Pricing and Negotiation: An Overview and Economic Perspectives for the Medicare Prescription Drug Benefit"**

**11 January 2007**

Fiona M. Scott Morton
Professor of Economics and
Senior Associate Dean for Faculty Development
Yale School of Management
New Haven, Connecticut

**Industry Background**

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

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

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

---

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

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

The second feature of the pharmaceutical industry that makes it difficult to regulate is consumer behavior. First, many consumers have insurance for their healthcare expenditures. (To appreciate how unusual this is, imagine if the market for home computers had buyers that were insured for their expenses in the event they needed to buy a new computer.) An insured consumer is not price-sensitive (or quantity-sensitive) in the way that she would be if she were bearing the full cost of her medication. The fact that demand does not respond to prices leads manufacturers of drugs to set relatively high prices. The manufacturers know that raising price will not lose them very many sales because consumers are only paying a fraction of the price the manufacturer gets. Of course, it is desirable for consumers to be insured for those times when they experience an adverse health event and do not have the financial resources at hand to pay for their drugs. However, insuring consumers for their pharmaceutical purchases removes the major source of price competition and pressure for low prices that keeps standard markets functioning well. One function of a deductible and co-insurance is to create some price sensitivity on the part of the patient.

The second type of consumer behavior that causes difficulties is the fact that sicker consumers have the incentive and ability to seek out more generous plans and enroll in them. This is known as 'adverse selection.' A sicker consumer is obviously more expensive to insure, and so plans would like to have fewer of them. This creates an incentive for a plan to design its benefits so they are attractive to healthy consumers and not so attractive to unhealthy consumers. Average consumers may want a plan with generous benefits, but might not find one in the market because no plan wants to supply a product that will attract all the expensive risks as well.

**1. Medicare is too large to pay a below-average price; it is the average.**

The individuals who are eligible to participate in Medicare Part D (whether they currently do or not) generate approximately 40% of prescription drug spending in the United States.[3] Up until this point, the federal government has not sought to purchase drugs for such a large group, but has focused on much smaller populations. (Medicaid was close to 12% of the market for many years and grew dramatically to 20% fairly recently.) Of course, legislators would like to obtain discounts for American seniors. However, with close to half of all spending being generated by those seniors, whatever price they pay will tend to be the average price in the market. It is arithmetically very difficult for such a large group to receive below-average prices.

Lowering the absolute level of prices is a reasonable goal, but obtaining prices that are substantially lower than the average is not.

**2. Reference pricing will raise prices because Medicare is a large purchaser**

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

For smaller populations, such as Medicaid, procurement prices have been set by linking to a private sector reference price. For example, the price the Medicaid program pays for a drug is a 15% discount off the average price in the private sector (or the minimum price, whichever is less).[4] Note that both the average and the minimum prices here are generated by non-public buyers of pharmaceuticals. This works well when the proportion of the market covered by the scheme is small; for example, if Medicaid represents 6% of the sales of a cholesterol drug. It does not work well when the Medicaid share gets large (e.g. 50% or more) because then the manufacturer of the drug has a strong incentive to raise private sector prices. While the manufacturer may lose some private sector sales due to the higher price, it loses no Medicaid sales (because Medicaid enrollees are completely unresponsive to price) and collects more revenue on all those prescriptions. Thus, tying the price of a large sale to a reference price under the control of manufacturers simply results in high prices for everyone.

Because Medicare is now so large, it would be in the interest of pharmaceutical companies to raise almost any reference price rather than accept a low price from Medicare. For example, if Medicare announced it would only pay the level of price charged in Mexico, drug manufacturers would raise prices in Mexico. If Medicare chose to pay the average price based on a sample of HMOs, manufacturers would raise prices to HMOs in order to earn more on their Medicare sales. Nor will benchmarking using a discount provide a long term solution. If Medicare decides to pay 50% less than the private price, instead of 15% less, manufacturers will still have an incentive to raise the private price. This approach to controlling prices harms all other consumers of pharmaceuticals in the US and is bad policy.

Importing drugs from Canada or paying Canadian prices for drugs is a type of reference pricing. Pharmaceutical firms have already announced they would limit supply to Canada in such circumstances. Since presumably the government of Canada would like to ensure its people have access to drugs, one would imagine they would take steps to prevent exports of drugs and close their border. If the US insisted on paying Canadian prices, manufacturers would increase Canadian prices - or stop selling to Canada if its government did not agree to higher prices. Because Canada is such a small market compared to the US, any policy that links our drug prices to theirs only hurts Canadian citizens and fails to help US consumers.

### 3. In the pharmaceutical industry, the ability to exclude a drug or "move market share," is the most effective way to get a low price

Volume and the ability to walk away from a transaction are two determinants of acquisition price. In a simpler market, such as that of a consumer purchasing toilet paper at CostCo, one can see these two factors at work. CostCo is a large buyer and can extract a discount for that reason. However, CostCo also typically only offers a couple of brands of toilet paper. One is the store brand (or generic), and there might be one or two others. Let's imagine the other brand is Scott's. You would not see on the CostCo shelves all the many brands of toilet paper that you might see

[4] Medicaid pays 90-95% of list price of a drug less approximately 15% of the average manufacturer's price, or the lowest price offered, whichever is less.

on the supermarket shelves. CostCo can extract a low price from Scott's because it can promise Scott's that it will "move market share." A significant fraction of CostCo customers who like Charmin but who cannot find it at CostCo will buy Scott's instead. In this way Scott's gains market share vis a vis Charmin and 'pays' for that gain by charging CostCo a relatively low price. When CostCo was negotiating with Scott's over the purchase price of the toilet paper, CostCo could walk away at any time and open a negotiation with Charmin instead. CostCo considers the different brands of toilet paper to be substitutes and can exclude one or more very easily.

In the pharmaceutical industry the situation is analogous. HMOs and PBMs have committees of physicians and pharmacists that meet to consider which drugs are therapeutic substitutes (cure the same diseases). When two or more drugs are found to be close substitutes, the plan considers which one is less costly. The manufacturers of those drugs essentially bid for the business of the buyer, with the lowest priced drug winning. The winner gains market share at the expense of its substitutes because the HMO makes the winner the default choice its physicians and consumers. (Typically, the competing drugs are only available to patients when there is medical need as argued by a physician.) The more market share the buyer can "move", the more valuable a manufacturer finds a contract with that buyer. Staff-model HMOs and other organizations that can easily communicate with all their physicians and regulate prescribing can move market share effectively, and thus typically obtain lower prices than plans that cannot change the behavior of their physicians.

A Secretary negotiating for lower prices for all Medicare beneficiaries would find it difficult to go through this process. First, it seems clear that a Medicare formulary that excluded many therapeutic substitutes in each therapeutic class would be inappropriate. As a nation we would like essentially all drugs to be available in some Medicare plan due to Seniors' diverse health needs and preferences. Secondly, the process of choosing which drugs would be excluded from the national Medicare formulary would become dominated by stakeholders such as manufacturers and patient advocacy groups; the decisions of a Medicare formulary might determine whether particular manufacturers could stay in business or whether particular patient subgroups would be cured. However, in the absence of a formulary, a negotiator for Medicare is unable to exclude any drug. Each manufacturer would know that, fundamentally, Medicare must purchase all products. The Medicare 'negotiator' would have no bargaining leverage, and therefore, simply allowing bargaining on its own would not lead to substantially lower prices.[5]

A single PDP on the other hand, can have a preferred brand which it offers to enrollees at a preferred price. Thus plans are well situated to bargain for low prices with manufacturers in cases where a drug has one or more good therapeutic substitutes. Patients that prefer the omitted brand can choose to join a plan that includes their preferred brand and omits a different one. Therefore, in classes in which drugs have therapeutic substitutes, patents do not provide an

[5] "If the non-interference provision is repealed, CMS must still decide whether or not to adopt a formulary and decide how restrictive it might be. At the national level, these decisions would be much more difficult and problematic. If the formulary prohibition is not repealed then the bargaining power of the Secretary and CMS would be diminished in the absence of the threat of formulary exclusion." Page 8, James Hahn, "Federal Drug Price Negotiation: Implications for Medicare Part D," CRS Report for Congress,.January 5, 2007

economic monopoly; rather, plans identify substitutes and use those substitutes to create price competition which lowers prices.

**4. Relax restrictions on formulary management in protected classes**

In contrast, the Part D regulations provide for six protected classes that have less management (weaker formularies) and thus do not follow the logic of point 3 above.[6] In these classes, PDPs have limited ability to create price competition among drugs. Furthermore, these drugs are often consumed by people who are very sick and who spend more than $5100 per year on drugs. For these enrollees, the consumer pays 5% of the cost, the plan pays 15% of the cost, and the government pays 80% of drug costs. The high rates of subsidy *for the plan* significantly dampen its incentives to put maximal pricing pressure on manufacturers. An additional dollar of spending is paid almost entirely by Medicare, not the plan or the patient. Thus, neither consumer nor plan has a strong incentive to reduce cost. Further, the plan is not permitted to use the full set of tools it has available to reduce costs.

My view is that these classes are the main problem with Medicare part D because the current regulations have created weak incentives for cost minimization *and* do not permit plans to affect demand in response to the cost of a drug, as they do in other classes. One solution is to loosen the restrictions on plans' ability to manage drug utilization in these categories.

Of course there is a cost, or trade-off, to making the protected classes less protected. Giving plans the ability to manage drug costs for sick consumers may allow them to structure formularies so that sick consumers are not attracted to those plans. However, the two rules that are designed to stop adverse selection, namely insuring the plan against high-cost patients and preventing therapeutic competition, both prevent price competition that would lower acquisition costs. We do not yet know empirically how strong a motive adverse selection is for PDPs and this is a critical area for future study.

One way to reduce a plan's desire to manipulate its formulary to avoid bad risks is to move many of the bad risks out of Medicare Part D. This could be accomplished by shifting dual-eligible patients back into Medicaid. While pricing in Medicaid is not a simple problem either, at least these patients would not exert a negative externality on the rest of Part D recipients. In Medicaid, focus could be brought to bear on this special population that consumes large proportions of particular drugs.

**5. Allow cost effectiveness studies for top ten drugs in protected classes**

Plans can create price competition for drugs outside the protected classes, and as discussed above, in my opinion these are not a problem. I therefore do not recommend interfering with market forces in those categories.

---

[6] Antidepressants, antipsychotics, anticonvulsants, antineoplastics, antiretrovirals, and immunosuppressants.

However, if management restrictions within protected classes continue, plans will be unable to create price competition between drugs in those classes. If a particular drug is very costly to Medicare, Medicare could consider subjecting that drug to a careful cost effectiveness study by the Agency for Healthcare Research and Quality or another government agency. For example, this would have been useful in the last few years given recent findings of the lack of efficacy of drugs with high sales to Medicaid.[7] Such an agency would issue a formulary or drug management protocol consistent with the findings from the study. For example, a finding might be that a drug is essentially equivalent to a competitor and so an appropriate formulary could prefer either one or the other. Medicare could then allow PDPs to adopt such a protocol. In this example, where the protocol allows PDPs to create competition between drugs, they would all have an incentive to adopt it (and there would be no adverse selection consequences).

This policy has several appealing characteristics. First, it is an intervention by government only in instances where market forces have been removed by regulation. Second, rather than choosing an arbitrary price for a drug, such a process will providing the informational basis for competition between drugs. Third, it would be applied only to high expenditure drugs that are generating a burden for the taxpayer. Fourth, a true breakthrough drug would not be harmed, and might gain, from a cost-effectiveness study. Fifth, the risk of a cost-effectiveness study and subsequent pricing pressure would reduce the desire of industry to create protected categories for their drugs because drugs in non-protected categories would not be subject to reviews. Lastly, encouraging high prices for innovative drugs and lower ones for drugs with good substitutes creates incentives to do the kind of R&D that is most useful to society.

**6. Cost-effectiveness studies are necessary for the long-run as well as short-run**

A fundamental problem with outsourcing the pharmacy benefit for Medicare enrollees is that the choices made by PDPs, and therefore the drugs that enrollees consume, affect the physician and hospital needs of those enrollees and therefore the total cost of Medicare. For example, a very expensive drug may be introduced that plans do not want to cover. However, a cost-effectiveness study may reveal that, while expensive, the drug avoids ten times its cost in hospital expenses. In such an instance, the federal government has a strong financial interest in having plans cover that drug, while plans have a strong financial interest to make it expensive or difficult for patients to obtain.

Current regulations provide CMS with broad authority to oversee PDP formularies to ensure they follow best practice and are not designed to drive away people with particular health problems. In addition to these roles, it is important for CMS to study the relationship between pharmaceutical spending and hospital spending, and then regulate formularies, cost-sharing, or protocols accordingly.

---

[7] See Mark Duggan (2003) "Does Medicaid pay too much for prescription drugs? A case study of atypical antipsychotics" *Journal of Health of Economics*, January 2005.

For example, it has been shown that compliance in taking medicine falls with out of pocket costs.[8] Therefore, Medicare enrollees with diseases like diabetes that require regular medication may not adhere to their drug regimen when faced with high co-payments. A diabetic who does not take his or her medication often ends up in the hospital – and this generates very high costs for the Medicare program. A recent article in the New York Times profiled the small town of Ashville NC that saved four times the cost of free diabetes medications (and the required free counseling) in reduced hospital bills.[9] Analogously, Medicare might benefit financially from providing free diabetes medications to patients due to the large savings in hospital costs.

However, notice that the for-profit PDP plan does not consider the savings to the government from reduced hospitalizations. This is a general problem with a market-based healthcare system that lets separate providers manage different parts of healthcare delivery. (MA-PDPs, however, pay for all care and do internalize the relationship between out of pocket costs, compliance, and hospitalization.) Additionally, a PDP that did reduce the out of pocket costs of diabetes medications would attract many diabetics to its plan and therefore bear increased costs from those expensive patients (adverse selection). Instead, in this circumstance, the correct policy is to create a rule that applies to all plans. In this example, CMS would mandate free diabetes medications for those enrolled in PDPs and total Medicare costs for diabetics would fall.

**7. Unique drugs**

If drug is a breakthrough drug that solves a major health problem, it will necessarily (at least at first) have no therapeutic substitutes. Plans can create little price competition in this case. While the manufacturer may charge a high price for this drug, it could be even more costly to regulate this price. If there is any kind of innovation our society wants the most, it is breakthrough innovation, rather than another drug that is similar to something we already have. Therefore, paying innovative manufacturers high prices provides an incentive for venture capitalists and entrepreneurs to work hard to find the next breakthrough drug. I am very hesitant to recommend regulating the prices of these drugs. In addition, at the moment these drugs do not seem to be a large component of expenditure.

**8. Complexity of plans could be reduced and price competition enhanced**

One sensible reform to Part D would be to structure coverage in a more natural way so that the coinsurance rate falls smoothly instead of jumping up to 100% for an interval (the donut hole). The easiest change might be to pick a pattern that is actuarially equivalent. For example: a deductible, coinsurance of 50% up to $X, then 25% coinsurance rate for spending between $X to $Y, then 5% coinsurance above $Y.

Because of the large number of plans in each market, enrolled seniors have many options to evaluate. Some observers have found evidence that the complexity of the decision is standing in

---

[8] See page 12, footnote 37 in James Hahn, "Federal Drug Price Negotiation: Implications for Medicare Part D," CRS Report for Congress,.January 5, 2007 for a list of references.

[9] "New job title for druggists: diabetes coach" *New York Times*, December 30, 2006 page A1.

the way of seniors making good decisions about which plan in which to enroll.[10] A consumer's physician is the person who is best qualified to help him or her choose a plan because the physician knows if and when it is appropriate to switch a prescription from one therapeutic substitute to another in response to price.

Medicare could create a new reimbursement code for helping Medicare Part D beneficiaries choose a plan. If physicians could assist beneficiaries in making tradeoffs based on price during the open enrollment period, it would put substantial competitive pressures on plans. A plan with a high price or a poor choice of drugs would not attract consumers. If plans compete on price to attract consumers, we do not need to worry about what is happening to any savings they negotiate with drug manufacturers: the savings will be returned to consumers in the form of lower price or higher quality.

**9. Transparency should be increased**

The Medicare Part D program needs to be studied further by academics and others because of the difficult issues it raises and because of its continued evolution and the evolution of products and prices.

To this end, more information about the program is needed. For example, currently researchers who want to collect information on the prices the plans are charging must collect them with a 'crawler' from the Planfinder website. This is time consuming because the website is protected against data collection by requiring a pause between each data request, so it takes many weeks to gather even a subset of prices from different zip codes. Instead, CMS should provide this data directly to researchers.

[10] [10] See top of page 12 in James Hahn, "Federal Drug Price Negotiation: Implications for Medicare Part D," CRS Report for Congress, January 5, 2007.

**Appendix: Attempt to obtain Part D price data**

What follows is recent correspondence between me and an official at CMS concerning price data for the Medicare Part D plans.

---

**From:** Scott Morton, Fiona
**Sent:** Tuesday, September 05, 2006 3:15 PM
**To:** REESE, Donald W. (CMS/OESS)
**Subject:** question

Dear Mr. Reese,

I am contacting you with a request. I am an Economics Professor at Yale University with a research interest in the area of prescription drugs. I have done a fair bit of academic research on drug pricing over the years and now I have a new grant from the National Science Foundation to study the Medicare Part D Program. I have a research assistant collecting various kinds of data, most of which are efficiently and quickly supplied by CMS, which is great.

The issue we are facing now is how to collect the prices consumers pay -- in a reasonably efficient manner. As you know, all those prices are available on the CMS web site using the Medicare Prescription Drug Plan Finder. So it is not at all difficult to insert the name of a particular drug, and a location, and get a price. The trouble is that we want to know the prices of lots of drugs in lots of locations. We can write a program to get them all for us, but it occurred to me that the spreadsheet or database that answers the questions on the website would have all that data already in one place and organized in some logical fashion.

My question is therefore whether I might be able to obtain a piece of the dataset (particular drugs on particular dates) directly from you, which I would use only for research purposes. Kelly Merriman told my research assistant that the data were not commonly available to people who asked for them, but also suggested contacting you in case you could make an exception for us. I hope you are able to do this as the data are not secret in any way, and we want to use them for research only; it seems the efficient thing to do. Also, since we would pay the programmer with NSF money, we would also be saving the government this duplicative spending!

Thank you very much for considering my request. Please feel free to email or phone if you have any questions for me.

Sincerely yours,
Fiona Scott Morton

-----Original Message-----
**From:** REESE, Donald W. (CMS/OESS)
**Sent:** Wednesday, September 06, 2006 9:19 AM
**To:** Scott Morton, Fiona
**Subject:** RE: question

I sorry Fiona. I do not have the authority or ability in providing the information you requested in your email.

Donald W. Reese, PharmD, MBA
LCDR, USPHS
Pharmacist

Medicare Drug Benefit Group
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244
410-786-6691

---

**From:** Scott Morton, Fiona
**Sent:** Wednesday, September 06, 2006 10:17 AM
**To:** REESE, Donald W. (CMS/OESS)
**Subject:** RE: question

Mr. Reese,
Thanks for the quick reply. Does someone else have the authority?
Fiona

---

**Fiona M. Scott Morton**
Professor of Economics and Strategy
Yale School of Management
Box 208200
New Haven, CT 06520-8200
U.S.A.

v: ++1.203.432.5569
f. ++1.203.432.6974

---

Fiona,
I believe similar requests have not been honored this year. You can email your inquire at this url web page..

http://www.cms.hhs.gov/NonIdentifiableDataFiles/09_PrescriptionDrugPlanFormularyandPharmacyNetworkFiles.asp#TopOfPage

You will need to scroll to the bottom of the web page and click on "Submit Feedback".

Don

**United States Senate Committee on Finance Hearing**
**Prescription Drug Pricing and Negotiation:**
**An Overview and Economic Perspectives for the Medicare Drug Benefit**
**January 11, 2007**

**Questions Submitted for the Record**
**Dr. Fiona M. Scott Morton**

**Chairman Baucus**

*Question for Dr. Scott Morton:*

1. I'm concerned by reports that seniors are paying astronomical amounts for certain drugs, but we don't have an easy way of looking at what beneficiaries are paying, do we? How could we better improve our understanding of the prices that plans are having beneficiaries pay for drugs?

The prices that beneficiaries pay for their drugs are readily available on the CMS website, planfinder, if you only want to see a few prices. If you want to collect many prices and analyze them for research or policy purposes, you are out of luck. CMS will not provide those data to researchers in any format except individually off the website. You need to program a 'crawler' to ask for the drug you want and record the website's answer and ask again for the next drug. This is very time-consuming and limits the amount of data that can be gathered from the CMS website. This, in turn, limits effective research on the topic of what prices seniors are paying for their drugs, which, it seems to me, is a very important topic.

> Similarly pharmaceutical manufacturers make claims about the tremendous research and development costs of new drugs. Do we know how much drug companies actually spend on research and development? Is that publicly reported? Do you have estimates or do we have no way of knowing?

Publicly-traded firms, those colloquially known as "big pharma" do report expenditures on R&D in corporate filings. However, another important source of R&D is in the biotech area where much of the action is private start-ups. Almost all of their funding, as I understand it, goes to R&D in their efforts to develop a useful product. Some of those products are licensed and sold by big pharma, so the prices they charge feed into the R&D of the biotech sector. It would be much more difficult to calculate a total R&D number from the biotech sector because of the many small, private firms involved.

*Questions for Dr. Scott Morton and Mr. Haislmaier:*

1. One of the main reasons for designing the drug benefit as a private market with competing plans, each with their own formulary, rather than a government benefit with one formulary, was to offer seniors greater choice. However, it seems to me that the plans have a major advantage over seniors. Seniors are required to choose a plan once a year during an open enrollment period while the drug plans can change their formularies at any time. Under pressure, CMS issued guidance that plans should "grandfather" for the remainder of the year any drug a beneficiary took before the plan's formulary change. However, it still allows plans to change formularies for enrollees that weren't on the affected drugs. Can this type of asymmetry distort the market? If so, how? Or is it just unfair?

This issue seems potentially important and underexplored. Plans can change formularies and change prices during the course of the time the beneficiary is locked in. We want beneficiaries to shop for plans that are the best deal for them, ie, that have the lowest prices on the drugs they take. If both the preferred drug and the price that is charged for it can change during the course of the year, then seniors can make what look like good decisions and then not reap the benefits. Possibly some PDPs are developing reputations for being plans that do not change during the course of the year and seniors will come to understand these reputations and purchase accordingly. Perhaps some PDPs are engaging in bait-and-switch techniques. Once again, this would be easy to study with a large sample of drug prices from all plans each month, but we cannot do so because CMS will not provide the data. If indeed this is a problem, one policy response might be to forbid prices from being raised or formularies from being changed during the enrollment year, provided an exception was made for the entry of a generic. When a generic enters a market, a PDP might well want to increase the price or co-payment, or change formulary status, on the imitated brand AND its therapeutic substitute to encourage use of the generic.

2. Prices for single-source drugs can be astronomical. Yet, you have cautioned against interfering in prices for these drugs because they may be truly innovative. However, I know that the federal government funds a significant amount of the basic science research that leads to privately manufactured and sold drugs. The drug companies may further develop and test the drugs, but government is paying for a significant amount of the legwork. Senators Snowe and Wyden proposed that the Secretary of HHS should take steps to negotiate prices for drugs developed with a significant amount of publicly funded research. What do you think of this idea?

Some R&D is so basic – namely it is not clear at all what sort of commercial application would result, if any – that no for-profit firm would undertake that R&D. This work is appropriately funded by taxpayers, and it may be difficult to link to particular drugs due to its fundamental nature. However, for more applied R&D, I think it is perfectly reasonable for the taxpayer to want some return. However, I would build the lower price

into the license of the intellectual property (as universities are getting good at doing), rather than arbitrarily lowering prices ten years later on a finished drug. If the patent licensing terms on innovations funded by NIH are known up front, a firm can sensibly decide to pursue investment in the drug or not, according to its forecast of profits.

**Senator Grassley**

*Question for Dr. Scott Morton:*

1. How would negotiation work for single source drugs?

   Some people want to have the government negotiate prices on single source drugs. How do you think that type of negotiation would go? What impact might this might have on the availability of those types of drugs?
   What kind of therapies are we talking about here and what would the Secretary have to do to have any leverage over manufacturers to get lower prices?

First, it is difficult to know what set of drugs is being referred to in the first question. In the hearing at which I testified and in this question, you refer to "single-source drugs." These are drugs that have no generic alternative (whether they are still on patent or not). As I indicated in my testimony, many of these drugs face competition from therapeutic substitutes and PDPs are able to acquire these drugs at reasonable prices. Thus, I feel negotiation would be largely superfluous and availability of drugs with therapeutic substitutes is now, and would continue to be, very good.

The Snowe-Wyden bill refers to negotiation for single-source drugs without therapeutic equivalents. This is confusing terminology because "equivalent" usually means exactly the same and therefore refers to a generic drug. If this is the case, then see the paragraph above for my answer to the question.

The context of the bill suggests to me that the authors mean "without therapeutic substitutes." This group is indeed difficult to grapple with because the innovator has come up with a drug that is novel and much better than any existing therapy. The therapies that fall in this category are drugs that are first in a class, such as Viagra, and drugs that match particular patient profiles but not others, such as some chemotherapy drugs. Note that over time, both of these types of drugs often experience entry of therapeutic substitutes.

PDPs must cover a novel drug and consumers are insured and are therefore not price sensitive. In this setting, we have no constraints on price. A negotiation between the manufacturer of such a novel drug and the government would not have an impact unless the government were permitted to set a price for the drug, or exclude it from some substantial fraction of the market. The latter would naturally reduce the availability of the drug. The former is a strong step away from the market mechanism which characterizes

the rest of the Part D program, and, while it provides leverage, it will also decrease investment in new drugs which could have a large negative impact on society.

In my testimony I suggested cost-effectiveness studies for high-expenditure drugs. I feel this step could provide more precise knowledge of the value of the drug in comparison to the previously available options and would give the private sector, PDPs, and CMS some sense of whether the manufacturer was wildly over-pricing its product or legitimately charging for a large improvement in health. Perhaps revelation of this information would itself change prices, and if not, guidance from CMS on a appropriate formulary might succeed in creating price competition.

**Senator Rockefeller**

*Question for All Witnesses:*

1. The essential difference between the Medicare pricing framework that Democrats envisioned and what was actually signed into law is that our proposals would have put Pharmacy Benefit Managers (PBMs) at risk for performance.

   In other words, payment to PBMs would have been on a per-script basis and according to factors such as keeping costs low for beneficiaries, filling prescriptions on time, using comparative effectiveness studies to determine covered drugs, offering generics, and effectively communicating plan changes to beneficiaries.

   Under the prescription drug law, plans hold all the power, but bear little profit risk for failing to meet certain performance standards. This is despite the massive subsidies provided to plans by the federal government.

   If Congress were to put prescription drug plans at greater risk for achieving standards like the ones I just mentioned, wouldn't that also be an effective way to achieve savings for seniors?

Making PDPs bear risk will cause them to work hard to avoid attracting expensive enrollees, namely those who are very sick. This is because the very sick use lots of drugs, and if the PDPs are not compensated for each drug the enrollee needs, but instead are given an average payment, then they will lose money on the very sick. (This makes the sick "bad risks" which you quoted from my testimony.) PDPs will make money on the healthy enrollees, and so will attempt to enroll them and avoid the sick. The way a plan avoids sick enrollees is to design a formulary, or set prices of drugs, to make their plan unattractive to the very sick. For example, a plan might omit cutting-edge HIV drugs from its formulary, which would make someone with HIV try to find a better plan. However, all plans would be doing something similar, and so the patient with HIV would not be able to find a plan with generous drug coverage for HIV. Thus, the quality of care

(availability of drugs) for the very sick will fall. I am belaboring this point because it was made clear to me in the hearing that you, Senator Rockefeller, care a great deal about the welfare of low-income, often dual-eligible, enrollees in the Part D program. Your policy change, as expressed in this question, will lower the quality of care the program provides those individuals. However, it will also likely save the program money.

Currently, the program insulates the PDP from the cost of covering enrollees with expensive illnesses by subsidizing the costs of those enrollees. As you note in this question, one could certainly change the program to make PDPs bear more risk, and I advocated this in my written testimony – in fact you quoted this section of my testimony at the hearing. If PDPs bore the cost of providing medications for the very sick, they would exert more effort in reducing costs of expensive medicines. This would reduce the cost of the Part D program. However, keep in mind the tradeoff of lowering quality of care for the sickest.

**Senator Hatch**

*Question for All Witnesses:*

1. Timing of Negotiation: I am concerned that the timing of government negotiation may not be consistent with the Part D bidding process. Under current regulation, 2008 bids for Prescription Drug Plans (PDPs) and Medicare Advantage plans (MA-PDs), which include premiums and benefits, are due on June 4, 2007. Even if legislation requiring government negotiation was enacted tomorrow, it seems unlikely that the Secretary of HHS could negotiate drug prices for the roughly 4,300 Medicare covered drugs in time for plans to renegotiate with manufacturers before submission of 2008 bids. Do you think a requirement to adjust bids mid-year will create substantial administrative problems for the Part D program and for seniors covered under Part D?

Yes. Additionally, the secretary might not obtain prices that are lower than prices obtained by some PDPs. If so, the PDPs would be in the position of changing only some prices and not others.

2. Reduction in Private Negotiation Ability: It is unclear how HHS negotiation will affect private plan negotiations over discounts, dispensing fees, and formularies. The HHS negotiated price may or may not be the lowest price given that HHS will not use a formulary and will negotiate on behalf of fewer members than some Pharmacy Benefit Managers (PBMs). I am concerned that drug manufacturers may use the HHS negotiated price to refuse to give private plans better discounts. Do you share my concern that government negotiation could actually reduce private plans' ability to get bigger discounts from drug manufacturers, or in other words, that the result of government "negotiation" could actually be to establish a floor rather than the intended ceiling on prices?

Yes, this could occur particularly if the secretary of HHS used private knowledge of PDP acquisition prices to attempt to negotiate with manufacturers. If a manufacturer gave a good price to one PDP for a particular reason (the PDP would generate substantial additional market share for the manufacturer, for example) and the secretary attempted to use that price as a goal for his or her negotiations, it would provide a strong incentive for manufacturers not to give PDPs discounts, but create the 'floor' you mention in your question.

3. Cost-Shifting: If government negotiation were successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost-shifting to small businesses and working families in the private insurance market?

Economic analysis of price-setting does not indicate that a lower price on one drug would be cross-subsidized by higher prices on other drugs. Prices are as high as manufacturers can profitably set them at all times. However, the negotiation mechanism you outlined in question 2 could function in the private market also if the secretary had information about private prices and used those in negotiations. This would drive up small business and working family prices.

**Senator Crapo**

*Questions for Dr. Scott Morton, Dr. Anderson, and Mr. Haislmaier:*

1. We know that large PBMs, such as Advance PCS (75 million covered individuals), Medco Health Solutions (65 million) and Express Scripts (57 million) have significant market power and are larger than Medicare. How can a government agency, working on behalf of 22.5 million seniors, match the purchasing power of a very large, very experienced industry working on behalf of hundreds of millions of Americans? How can we expect savings?"

We cannot, unless HHS is willing to exclude drugs from coverage under Medicare or set prices administratively.

2. Some have talked about non-interference as if it is a Republican creation. Isn't it true that in 1999 President Clinton offered this language in his Medicare proposal and Senator Daschle included this provision in his Medicare bill? And isn't it true that this provision was embraced by Democrats, some of my colleagues here included, as the best way to contain cost and protect patient access to prescription drugs? What has changed? Given the data that has been published since the implementation of the program I would suggest the case for the noninterference clause has strengthened.

I am sorry, but I am not qualified to answer this question.

3. If government negotiations happened to be successful on certain drugs, would drug manufacturers simply increase their prices in other federal and non-federal programs to offset revenue losses in Medicare? Do you think government negotiation of drugs in Medicare could result in cost-shifting to small businesses and working families in the private insurance market?

See my answer above to this same question.

**Senator Pat Roberts**
**Statement for the Record**
**Finance Committee Hearing: Prescription Drug Pricing and Negotiation: An Overview and Economic Perspective for the Medicare Prescription Drug Benefit**
**January 11, 2007**

As a new member of this committee, I first want to thank the Chairman for calling this hearing today to discuss this important issue. I also want to thank the panelists who have taken their time to share their perspectives—this hearing has been very informative.

I want to start out by saying that I support lower drug prices for our seniors. This is one of the biggest concerns I hear from seniors all across my home state of Kansas and I agree that getting these folks the drugs they need is critical, especially in our rural areas. In fact, I don't think you'll find a senator here today or in the U.S. Senate who doesn't want lower drug prices for his or her constituents.

However, I also don't want to do anything that will harm our seniors down the road, especially in terms of limiting access to life-saving drugs and medications. This is why I have strong concerns with a "federal price negotiation" scheme and have voted against proposals to strike the "non-interference" language Congress put into the Medicare Modernization Act in 2003.

I think it's easy to say that we should let the federal government negotiate for lower drug prices. It's a great sound bite. But, I think we need to be honest with seniors with what is at stake if the federal government steps in and takes over drug price negotiations for Medicare.

Let me talk about my first concern: restricted access to drugs. Many people point to the Veterans Administration and ask why can't the federal government negotiate for Medicare like they do for the VA? It's a great question and several members have discussed this today. Let me hit on a few of these points: the VA drug program restricts patient access to medicines and relies on a limited number of VA pharmacies or mail order.

I repeat: the VA drug program restricts patient access to medicines and relies on a limited number of VA pharmacies or mail order. It is estimated that the VA formulary or "drug list" contains only 38% of the drugs approved in the 1990s and 19% of the drugs approved since 2000. In addition, nearly 80% of prescriptions in the VA program are distributed through the VA mail order system.

Well, this would certainly be bad news for our seniors and local pharmacists back home. Over the past year, seniors have had access through the Medicare drug benefit to nearly any drug they need at an affordable cost. I doubt many of these seniors in my hometown of Dodge City or any other community in Kansas would now welcome limited access to their necessary medicines.

The local pharmacists should also cry foul if any model for Medicare relies almost exclusively on mail order. In Kansas, our local pharmacists are the backbone of our rural communities and serve the majority of our senior population.

Often times, seniors and their local pharmacists have known each other for years. Seniors trust their pharmacist and prefer to get their prescriptions in their community. I doubt many seniors would appreciate the federal government telling them they could no longer choose to go to their local pharmacy and instead had to get their drugs through the mail.

I also have deep concerns about disrupting the private competition model that has proven very effective over the past year in regards to Medicare Part D. I agree there have been problems with the new Medicare drug program, especially with the initial implementation of the benefit. During the few several weeks of the new program, my office was bombarded with phone calls from seniors who had trouble accessing their plans.

Thankfully, we were able to work with CMS to get these problems resolved and now seniors are saving money and they're satisfied with the benefit. Seniors are saving an average of $1200 per year on their drug costs and independent analysis have shown that 80% of beneficiaries are satisfied with their Medicare drug plan.

Premiums under Medicare Part D have also been lower than expected. This year, premiums will average $22 per month for seniors, over 40% less than was originally projected under the benefit. In addition, the Part D net cost to the federal government is also lower than expected. On Monday, the official Medicare actuaries announced that the net 10-year cost of Part D has dropped by $189 billion over the original budget window used when the MMA was enacted. That is a *30 percent drop* in the actual cost compared to the projection.

This shows that private companies competing with each other is the best way to keep costs low and save seniors and the government significant money.

I think we should also be concerned about the potential distortion a federal price setting or negotiation model would have in the U.S. Since the Medicare population comprises nearly 40% of our drug market, any federal price setting or negotiation model could potentially significantly impact our drug market and possibly raise prices for others, such as working families, small businesses or near-retirees not yet eligible for Medicare.

A negative impact might also be seen on research and development for life-saving prescription drugs, as briefly mentioned in testimony here today. A recently published report suggests that "negotiating" drug prices by the federal government would produce a decline in investment in new drug R&D of about $10 billion a year, costing a loss of 5 million expected life-years annually.

I know these numbers seem a bit farfetched. However, I do believe that the impact on drug research and development—whether large *or* small—must be a consideration when discussing price negotiation because I am not willing to take a chance on adversely affecting innovation and lifesaving cures. We owe it to not only our seniors, but all Americans to ensure continued access to these necessary prescription drugs.

In closing, I think we need an open and honest debate as to what is the right approach to lower drug costs. However, I don't want to be in the business of providing false hope and empty promises to seniors through federal price negotiation. Our seniors deserve a fair debate, not a sound bite.

**Statement for the Record**
**SFC Hearing on Medicare Price Negotiation**
**Senator Jay Rockefeller**
**January 11, 2007**

Thank you, Chairman Baucus. Let me begin by acknowledging the work of the outgoing Chairman, Senator Grassley. Chuck and I have worked together on a number of important issues. He was always a fair Chairman, even on issues where we disagreed, and I appreciate that.

I would also like to welcome our new members and say how excited I am to work with each of you, under the leadership of our distinguished Chairman, to conduct the business of this Committee.

Mr. Chairman, I want to thank you for holding this important Medicare hearing today. In doing so, you have set an important tone for the future work of this Committee. I am sure that I am not alone in expressing my frustration that this Committee has not done more oversight since the passage of Medicare prescription drug law. Medicaid is another area where oversight by this Committee is long overdue. And, I'm sure we could all list a few more topics.

My point is that you are starting this Committee off on the right foot. I applaud your efforts, and I am looking forward to working with you to fulfill the Committee's ongoing oversight responsibilities.

The topic of today's hearing – Medicare price negotiation – has become a political hot-button issue. However, for the seniors in my home state of West Virginia, prescription drug affordability is not a political issue, but an issue of survival. It is about whether this drug benefit allows seniors to go to their local pharmacies and purchase the prescription drugs they need, when they need them and at an affordable price. For many seniors in my state, Medicare's current prescription drug program does not meet those objectives.

The 43 million people who participate in the Medicare program depend on the federal government to seek the best deal possible – they depend on Medicare's ability to negotiate to get the most for their hard-earned dollars. However, the Medicare law expressly prohibits the federal government from negotiating with drug companies to lower prescription drug prices. I believe this is wrong.

Price negotiation has been enormously successful for the Department of Veterans Affairs and state Medicaid programs. So, it is unclear to me why opponents of price negotiation believe Medicare should be any different.

Yes, it is true that Democrats also prohibited the ability of Medicare to negotiate in legislative proposals offered prior to passage of the Medicare drug benefit. But, I would say to my colleagues that our position on this issue has evolved in response to needs of Medicare beneficiaries who are not getting the benefit they need and deserve.

I would also remind my colleagues that there was an essential difference between the Medicare pricing framework that Democrats envisioned and what was actually signed into law. Our proposals would have put Pharmacy Benefit Managers (PBMs) at risk for performance. In other words, payment to PBMs would have been on a per-script basis and according to factors such as keeping costs low for beneficiaries, filling prescriptions on time, using comparative effectiveness studies to determine covered drugs, offering generics, and effectively communicating plan changes to beneficiaries. Under the prescription drug law, plans hold all the power, but bear little profit risk for failing to meet certain performance standards. This is despite the massive subsidies provided to plans by the federal government. There is no question in my

mind that the Medicare prescription drug pricing and risk structure needs to be adjusted to protect seniors.

Some argue that allowing Medicare to negotiate would have an adverse impact on pharmaceutical research and development. We have heard this argument many times before. We heard it when we created the Medicaid rebate program in 1990 and we heard it again when we created the Department of Veterans Affairs prescription drug program in 1992.

Opponents of both programs argued that these approaches amounted to government price control and would limit pharmaceutical R&D. However, they fail to mention that both programs gave pharmaceutical manufacturers broad authority to reap billions in profits from guaranteed populations – Medicaid recipients and Veterans – in exchange for reasonable program discounts and rebates. I would also remind my colleagues that, while the federal government has held up its end of these contractual relationships, drug companies often have not. States have had to sue many times in order to get the federally required Medicaid rebates. And, pharmaceutical manufacturers had consistently failed to include the cost of so-called "authorized generics" in the Medicaid best price rebates – a problem Congress successfully worked to remedy as part of the Deficit Reduction Act.

The Medicare prescription drug benefit similarly allows drug companies to reap billions of dollars in profits, this time from 43 million seniors and individuals with disabilities, without a guaranteed trade-off in savings like those achieved in Medicaid and the VA. This does not seem rational, and I am hopeful that the witnesses here today will shed some light on this notion that the net effect of any new federal prescription drug program that includes reasonable savings for consumers necessarily reduces pharmaceutical research and development.

Another area that I hope the panelists here today will address is the prescription drug cost burden on our seniors relative to the rest of the population. Federal entitlement programs exist for vulnerable populations – our veterans who have defended this nation in times of war, working families who rely on Medicaid to meet their health care needs, and seniors who have worked their entire lives and deserve to enjoy their golden years. Yet, opponents of Medicare price negotiation argue – just as they did with Medicaid and the VA – that prices for other payers would rise. Well, I would ask my colleagues why seniors should be left to pay the highest prices for drugs in this country? I don't believe they should. I believe they should have the same protections against high prescription drug costs as Medicaid recipients and veterans.

Finally, a point about the impact of price negotiation on Medicare prescription drug formularies. Some have argued that the difference between the VA drug benefit and the Medicare drug benefit is that Medicare beneficiaries have more choices. I disagree with that assessment. First, choices are not meaningful without access. The Department of Veterans Affairs provides a generous prescription drug subsidy so that veterans can get the prescription drugs they need when they need them. There is no annual deductible requirement, co-payments are only $8 for each 30-day supply of medication, and there is no large gap in coverage for which veterans are on the hook for 100 percent of their prescription drug costs. So, in actuality, veterans have consistent access to the prescriptions they need.

Second, the VA limits its formulary to only include those drugs that have well-researched, well-documented clinical evidence demonstrating a cost-effective benefit to the patient population. The result of this comparative-effectiveness approach is that the VA is able to deliver safe, high-quality health care while keeping costs low for veterans. It is why the VA was able to protect patients from the adverse effects of Vioxx. The VA never included the drug on its national formulary because of concerns about the drug's safety. I, for one, would like to see that type of evidence-based approach in Medicare, instead of an approach, like the one we have

today, that could expose Medicare beneficiaries to unsafe prescription drugs or "me-too" drugs sold at a higher price without a new and innovative clinical benefit.

I also want to make it clear that necessary prescriptions which are not on the VA's formulary – and are requested by a physician – can be ordered through VA's solid non-formulary process. These approvals are reviewed by an approving official, and, according to the GAO, many VA prescribers report that approvals are made within hours or minutes.

If veterans aren't happy with their drug access and pricing, it is news to me and to the VA. Yesterday, the Department of Veterans Affairs announced the results of a survey done by an independent reviewer of customer satisfaction. For the seventh straight year, the Department of Veterans Affairs has received significantly higher marks than the private health care industry. VA's marks keep going up – with ratings for outpatient care at eight points higher than in the private sector.

In closing, there are tough considerations that have to made, and the Medicare price negotiation debate is not as simple as whether the language says the Secretary of HHS "shall negotiate" or "may negotiate." However, the prospect of protecting seniors from high prescription drugs costs – costs many seniors struggle to pay – means that we must do something and soon. Price negotiation is an accepted and successful practice in other areas of our health care system, and I think we must find a way to make it work in Medicare.

I thank the Chair.

**Statement of Hon. Olympia J. Snowe**
**Senate Committee on Finance Hearing**
**Prescription Drug Pricing and Negotiation: An Overview and Economic Perspectives for the Medicare Prescription Drug Benefit**
**January 11, 2007**

Good morning. I would like to thank Chairman Baucus for holding this hearing so we can consider the issue of negotiation in managing the cost of our seniors' prescription drug benefit.

We have seen landmark progress over the past few years as – *at last* – our seniors have a prescription drug benefit on which they can rely. This has not come without difficulty. This benefit which is certainly not all it *could* or *should* be, nor was its troubled implementation. Yet today seniors are saving substantially on their prescription drugs and we see reports that *four of five* enrollees are pleased with the assistance they are receiving.

It is undoubtedly the help they are getting which has resulted in such satisfaction. Because the confusion, the complexity, and often a lack of oversight on the plans have created some serious consumer issues which we will continue to address. But today the issue before us is the cost of prescription drugs in the plans, and that is certainly one which concerns me and so many here today, and millions of our constituents as well.

Over three years ago the Congress was given a price tag for this benefit that was simply unrealistic. Recognizing an absence of cost management, I joined with my colleague Senator Wyden to address escalating costs. Today, some say all is well, as we hear that the estimated cost of the benefit declined somewhat from a peak estimate of about $720 billion over ten years. Yet I must note that some of the *reasons* for that reduction are too quickly glossed over. Enrollment is *lower* than it was estimated to be as more Americans chose to stay in private coverage. We also saw this past year that we failed to reach many of those *low income seniors* who most needed help. Today as seniors enter their first full year of coverage, we will see a more realistic year – particularly in terms of more beneficiaries facing the donut hole.

We have heard estimates that the average senior is saving an average of $1000 per year. But we should ask *how* that savings is being achieved. And the discovery by many seniors – when they reached the donut hole – that the purchase cost of medications actually increased compared to what they were paying prior to enrolling in Part D – that should be a red flag that we may not be seeing the purchasing power of seniors harnessed for the savings they deserve.

Back in 2005 the Medicare Actuary had estimated that drug plans would negotiate a discount of about 15 percent off undiscounted retail prices. So last year we were curious – just how were they doing in Maine? My staff compared prices for the top 24 medications used by seniors and found that our plan prices for those medications averaged *less than 12 percent* below the price any senior could already obtain, *by simply walking into a retail pharmacy*. That is not even using membership or association discounts, or using an on-line pharmacy like Drugstore.com – where seniors could obtain better prices. That result – finding a single senior could do better than a plan – is certainly disappointing.

That points to a system that is working well in terms of *subsidy*, but *not* well in terms of negotiation. But we are told that the cost of the benefit is lower, and that premiums were stable this year. Yet if you ask what *standalone* drug coverage actually costs this year...CMS will tell

you that those premiums have *gone up about 10 percent*. Not unlike increases in the deductible, the size of the donut hole, and out-of-pocket expense. And as Senator Wyden and I learned from the GAO reports we have received, the prices of drugs used by seniors have inexorably increased since 2000 at 2 to 3 times the inflation rate.

So the costs of this program will remain a concern. Most of envisioned that not only would the *taxpayer* contribute to helping seniors with drug expenses, but we would realize real savings from lower prices on prescription drugs.

That is why Senator Wyden and I proposed to achieve some balance in the public-private partnership which is Part D today. That means that the HHS Secretary should have a proper role in negotiation. *Negotiation, not price setting.*

What I believe most of us desire to do is give the present system the best tools to achieve success. That means that the Secretary must have an oversight role. He should be examining performance and pointing out where plans need to improve. But today if he noticed a product on which poor discounts were being achieved, he would be accused of interference if he pointed that out. And if a plan reported intransigence, he could not respond. That makes no sense. It serves neither taxpayers nor beneficiaries.

Our legislation rescinding the "non-interference" clause and directs the Secretary to negotiate for any necessary fallback plan, and in addition, to respond to requests for help from plans which cannot obtain reasonable negotiation.

We have added two additional areas in which the Secretary must negotiate. First as the CBO has stated that negotiation of *single-source* drugs could yield savings, our legislation directs the Secretary to engage in negotiation regarding those unique products. We also know that some drugs exist because the taxpayer provides substantial support to see them developed. The public deserves a fair price on those products it made possible, so the Secretary should weigh in in those cases.

These are reasonable ways to help plans succeed, and to protect both beneficiaries and taxpayers within the public-private partnership on which this benefit rests.

So Mr. Chairman, I appreciate this opportunity to discuss of how effective negotiation can help us manage costs. Our constituents have called to us to see that the cost of Part D is managed responsibly. I look forward to working with you and the Committee to achieve that.

Thank you.

› Home
About NIH OTT
· Current Issues
· International Technology Transfer
· Organization
· Statistics
· Directions
· Career Opportunities
· Success Stories
· Presentations and Articles
› Licensing & Royalties
› CRADAs & MTAs
› Forms & Model Agreements
› Policy
› FAQs
› Contact Us

## Licensing & Royalties

### FDA Approved Products Developed with Technologies from the NIH Intramural Research Program

**FDA Approved Products Developed with Technologies from the Intramural Research Program at the** National Institutes of Health

| Licensee | Product | FDA Approval Date / First Commercial U.S. Sale |
|---|---|---|
| Berlex Laboratories | Fludara® | 18 April 1991 / 1991 |

A DNA polymerase inhibitor (fludarabine) that has been shown to have potent activity in the treatment of B-cell leukemia. This compound is a cancer chemotherapeutic drug, 2-F-araA.

| | | |
|---|---|---|
| Bristol Myers Squibb | Videx® | 09 Oct 1991 / 1991 |

A treatment of HIV infection with ddI. Selectively inhibits the replication of HIV by interfering with a critical element known as reverse transcriptase. Because of being better tolerated or having a different pattern of toxicity than other treatments, patients may find it useful in either individual or combination treatment therapy.

| | | |
|---|---|---|
| Hoffmann LaRoche | Hivid® | 19 Jun 1992 / 1992 |

A treatment of HIV infection with ddC. Inhibits the replication of HIV by interfering with the critical enzyme reverse transcriptase. Patients find it useful in either individual or combination treatment therapy.

| | | |
|---|---|---|
| Bristol Myers Squibb | Taxol® | 29 Dec 1992 / 1996 |

An improved method for administering Taxol® (paclitaxel) has significantly improved the treatment of cancerous tumors, particularly advanced stage epithelial ovarian and breast cancers. Paclitaxel is a compound derived from the bark of the Western Yew tree.

| | | |
|---|---|---|
| MedImmune Inc. | NeuTrexin® | 17 Dec 1993 / 1994 |

A treatment using trimetrexate as an anti-parasitic agent for infection. Infections due to Toxoplasma gondii and Pneumocystis carinii, as seen in AIDS patients are extremely refractory to standard therapy can be effectively treated by administering this drug.

RETURN TO TOP

| | | |
|---|---|---|
| GlaxoSmithKline | Havrix® | 22 Feb 1995 / 1997 |

A vaccine from the isolation of Hepatitis A virus strain HM-175. Hepatitis A is probably the most widespread of viral hepatitis diseases and is an endemic childhood disease in the underdeveloped countries of the world.

| | | |
|---|---|---|
| Janssen Pharmaceuticals | SPORANOX® Oral Solution | 21 Feb 1997 / 1997 |

Oral formulation of the anti-fungal agent itraconazole that is used for the treatment of painful and debilitating fungal infections of the esophagus and mouth, commonly called thrush. Itraconazole is solubilized for this application through coupling with hydroxy-propyl-cyclodextrin, a molecular inclusion complex.

| | | |
|---|---|---|
| Protein Design Laboratory / Hoffman LaRoche | ZENAPAX® | 10 Dec 1997 / 1998 |

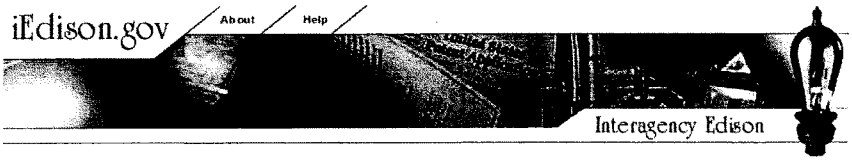
A humanized monoclonal antibody used for the prevention of acute kidney transplant rejection. This recombinantly produced antibody achieves its immunosuppressive properties by binding to the alpha (or Tac) subunit of human interleukin-2 (IL-2) receptor that is expressed on the surface of activated lymphocytes.

| | | |
|---|---|---|
| MedImmune Inc | Synagis® | 19 Jun 1998 / 1998 |

A monoclonal antibody used for the prevention and treatment of serious lower respiratory tract disease by respiratory syncytial virus (RSV). RSV is the most common cause of pneumonia and bronchiolitis in infancy and early childhood. Synagis is the world's first monoclonal antibody licensed by the FDA for any infectious disease.

| | | |
|---|---|---|
| Baxter Pharmaceuticals, formerly North American Vaccine, Inc. | Certiva™ | 29 Jul 1998 / 1998 |

A combined diphtheria, tetanus and acellular pertussis vaccine for use in infants and children. A special process that reduces local and systemic adverse events commonly associated with traditional whole-cell DPT vaccine administration has detoxified the acellular pertussis component of this vaccine. Certiva™ is the first pediatric vaccine introduced into the U.S. market by a new independent vaccine producer in over ten years. (Manufacturer has withdrawn the product from the market)




## Report of FDA Approved Commercial Products Involving NIH Extramural Support

Items listed on this page have been identified as having involved NIH extramural support that helped to further the research and development of these final products. Although each product may have multiple funding sources and may include multiple technologies, the products are listed because NIH extramural support was also identified as being involved.

Please note that the time for development of a successful FDA approved drug, from basic research and initial identification of a potential candidate compound through to FDA approval, can range from 5 years to 15 years.

| Commercial Name | FDA Approval Type | FDA Approval Number | NIH Support |
|---|---|---|---|
| Active Contact System | | | HD036154 |
| Bexxar | Biologic | BL 125011/0 | CA042768 |
| | Biologic | BL 125011/0 | CA056794 |
| Estramet | | | CA022795 |
| FluMist | Biologic | BL 125020/43 | AI005053 |
| | Biologic | BL 125020/43 | AI052564 |
| | Biologic | BL 125020/43 | AI072521 |
| Lyrica | Drug | 021446 | NS015703 |
| Menostar | Drug | NDA# 021674 | AG005407 |
| ONTAK | Biologic | 1258 | AI012500 |
| | Biologic | 1258 | AM016684 |
| ProKera (TM) | Medical Device | K032104 | R01 EY006819 |
| Trusopt & Cosopt | | | EY002227 |
| Zolinza | Drug | NDA 21-991 | CA057227 |

| Commercial Name | Support |
|---|---|
| Emtriva | AI026055 |
| | AI028731 |
| Epogen | |
| Kaletra | AI027220 |
| Neupogen | |
| Norvir | AI027220 |
| Procrit | |
| Taxol | |
| Truvada | AI026055 |
| | AI028731 |
| Xalatan | EY000333 |
| | EY000402 |
| Zerit | CA028852 |

COMMUNICATION

---

**Prescription Drug Pricing and Negotiation: An Overview and Economic Perspectives for the Medicare Prescription Drug Benefit**

**Hearing**
**Before the**
**Committee on Finance**
**United States Senate**
**January 11, 2007**

**Statement Submitted by the Academy of Managed Care Pharmacy**
**100 North Pitt Street**
**Suite 400**
**Alexandria, Virginia 22314**

## ACADEMY OF MANAGED CARE PHARMACY

### Reliance on Medicare Part D Plan Sponsors to Negotiate Prices with Pharmaceutical Manufacturers

The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 5,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Academy supports continuation of the current statutory requirement that Medicare Part D drug benefit plan sponsors negotiate with pharmaceutical manufacturers to secure low drug prices and opposes legislation that would transfer that responsibility to the federal government. The Academy supports the current structure of the Part D benefit that relies on the concept that drug price concessions are best achieved by negotiations by participating drug plan sponsors who themselves are motivated by the competitive need to provide the most cost-effective and clinically appropriate drug benefits possible.

The Academy believes that the needs of patients and the ability of health care professionals to provide quality, safe and affordable health care are best served by having the government promote effective competition and encourage the use of innovative management techniques by purchasers, rather than directly intervening in competitive activities or engaging in micro-management of otherwise functioning markets. The Academy also believes that the use of proven managed care strategies as part of an integrated program to provide a prescription drug benefit are working to give Medicare beneficiaries access to the medications they need in an effective and affordable manner.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which established the Part D drug benefit, is structured so that Part D plan sponsors negotiate prices with pharmaceutical manufacturers on behalf of Medicare beneficiaries. Section 1860D-11 (the "noninterference" provision) of MMA expressly forbids the Secretary of Health and Human Services (HHS) from negotiating with pharmaceutical manufacturers for the price of prescription drugs on behalf of Medicare beneficiaries and from establishing a list of preferred drugs.

*The Academy believes proposals to repeal the noninterference provision would introduce consequences that must be thoughtfully considered before action is taken. It is important to note that the price of a drug is only one factor affecting the continued long term viability of the program.*

**1. The Medicare Part D drug benefit program is working.** The competitive model on which the Part D program was designed created incentives for qualifying plan sponsors to negotiate significant price discounts and provide the drug benefit as efficiently as possible. These

incentives have proven to be strong and effective. The structure of the Part D drug benefit program offers beneficiaries a broad choice of options so that they can select a plan that offers the medications they need through pharmacies convenient to them. The plans offered under Part D are designed to attract enrollees through clinically sound formularies, affordable premiums and low cost-sharing requirements. The results are impressive:

- Almost 23 million enrollees in the program
- Monthly premiums averaging $24 per month in 2006 are anticipated to be approximately $27 in 2007, both amounts significantly lower than originally projected
- Survey after survey indicates that the overwhelming majority of beneficiaries are satisfied with the program in terms of out-of-pocket costs, savings and the range of plans that offer access to the medications they need.

The ability of plan sponsors to effectively negotiate with pharmaceutical manufacturers to secure price concessions through well-established management tools has clearly been a major factor in the successful launch of the Part D program. Giving the federal government the authority to negotiate drug prices would remove one of the principal competitive tools for managing the benefit available to drug plan sponsors.

*In view of the program's success, there is no justification for switching from a model in which a diversity of private purchasers negotiate with manufacturers to one in which the government makes specific, universal purchasing decisions. Making such a fundamental change in the Medicare drug benefit after only the first year poses its own risks to beneficiaries and the Medicare program and could undermine the long term success of the program.*

**2. Authorizing the federal government to negotiate the purchase price of drugs under the Medicare Part D program would inappropriately separate price negotiation from the formulary development process.** AMCP supports the use of appropriately designed formularies as quality-enhancing, cost-effective managed care pharmacy tools. As outlined in the consensus document *Principles of a Sound Drug Formulary System*, formulary systems are complex structures that are dependent on a variety of components whose interaction result in patients having access to the medications they need in a cost-effective, affordable manner. Effective use of formularies has mitigated the increase in the cost of medications without sacrificing patient access to necessary therapy, including access to medically necessary non-formulary drugs.

A formulary should only exist as part of a formulary management system, where formulary management serves as an integrated patient care process that enables health care professionals to work together to promote clinically sound, cost-effective pharmaceutical care. Formularies are developed in the context of an ongoing decision-making process in which medication experts determine which drugs meet the clinical needs of a defined patient population, taking into account scientific evidence relating to effectiveness and safety.

Due to the diversity of medications on the market and the continuous introduction of new medications, a formulary must be a dynamic and continually revised document. Decisions on which drugs are included on a formulary are made by pharmacy and therapeutics (P&T) committees. P&T committees are responsible for developing, managing, updating and administering a formulary. P&T committees are comprised of primary care and specialty

physicians, pharmacists and other health care professionals. In order to keep a formulary current, P&T committees meet regularly to objectively appraise, evaluate and select drugs for the formulary and to review and update the appropriateness of a formulary system in light of new drugs and new indications, uses or warnings affecting existing drugs.

P&T committees' evaluations of medications are based first on safety and efficacy and then on cost-effectiveness. It is commonplace in the private sector for a P&T committee to determine clinically whether a drug under consideration for inclusion on a formulary *must be* added to the formulary, *may be* added to the formulary, or *should not be* added to the formulary. Once a therapeutic decision is made to add a drug to a formulary, price negotiations begin. Price or cost should never be the sole factor underlying P&T decisions.

Authorizing the federal government to negotiate prices for medications provided by Part D plan sponsors inappropriately separates the therapeutic evaluation from cost-effectiveness considerations. It would be easy to foresee a situation where the federal government would negotiate a low price for a medication that Part D sponsors have decided not to add to their formularies based on safety reasons. If the product is publicly listed as the lowest cost drug in its class, Part D sponsors may have no alternative but to add that medication to formulary based on public and government-driven demand. In such a situation, cost considerations would be overriding clinically sound therapeutic decision making which can jeopardize patient care.

Additionally, the federal government's imposition of a standard price for drugs under Part D would greatly impair the ability of Part D plan sponsors to design a competitive benefit offering that integrates clinically sound, evidence based medication choices with delivery systems and co-payment alternatives that provide beneficiaries with substantive choice. The ability of Part D sponsors to negotiate formulary placement and the price of drugs with manufacturers is a driving force in the Part D program's success in achieving the premium levels it offers beneficiaries and the government.

The Academy believes that the formulary decision-making process that has proven successful in the competitive private sector should continue to be the basis for the purchase of drugs under the Medicare Part D program.

**3. The assertion that the federal government would secure significantly lower prices from manufacturers compared to those being secured by drug plan sponsors under the current Part D structure is open to serious question.** As noted above, plan sponsors under the current law's competitive structure have strong incentives to negotiate the deepest possible discounts. In addition, the overwhelming majority of plan sponsors participating in the Part D program have an established track record in the private sector of successfully negotiating prescription drug discounts for large populations. The nonpartisan Congressional Budget Office (CBO) has stated that repealing the noninterference provision would have a negligible effect on federal spending, because the federal government would not be able to negotiate significantly lower prices than the prices obtained by private plan sponsors charged with that responsibility. In an interview, Michael O. Leavitt, secretary of Health and Human Services, said, "I don't believe I can do a better job than an efficient market."

**4. Even if, in the short term, the government was able to secure prices lower than the plan sponsors have been or would be able to do in the future, there are longer term adverse consequences that must be taken into consideration.** Requiring the Secretary to directly negotiate with pharmaceutical manufacturers would likely result in de facto price controls: The term "negotiate" is not applicable in the context of the Medicare drug benefit as it implies some comparative equity among the parties. Allowing the federal government itself to directly "negotiate" on behalf of almost 23 million Medicare beneficiaries would result in government setting prices, as pharmaceutical manufacturers would have little choice but to accept what the government offers. Examples are easily found in other parts of the Medicare program, in which the federal government's approach has been the imposition of rigid pricing schedules for provider services under Medicare Parts A and B.

**5. The experience of the Department of Veterans Affairs (VA) in negotiating discounted prices is often cited as an example of the types of discounts that might be available to Medicare should the Secretary of HHS negotiate on behalf of Medicare beneficiaries.** It is true that the VA purchases pharmaceuticals at prices lower than the average obtained by Medicare drug plan sponsors. However, there are substantial differences between Medicare and the VA that draw into question whether this is an appropriate benchmark for comparison.

The VA is able to hold prices down because there is a comparatively limited network of VA pharmacies. Three-quarters of its prescriptions are delivered by mail, through a dedicated arehouse and distribution network. The VA, through its health care system, both purchases and distributes prescription drugs. In contrast, the Medicare program is an insurer that pays for care that is delivered to covered beneficiaries at a myriad of sites by a myriad of professionals operating without a centralized system's oversight and guidance.

Two fundamental factors operate in tandem and are unique to the VA:

- **The closed system of patient care under the VA system.** The VA is a direct provider of health care. Its physicians, pharmacists and other health care providers reach consensus on patient protocols for therapy, including prescription drugs. The fact that patients obtain full health care services through the VA's integrated system fosters collaboration among those providing care to the veterans and adherence to the VA formulary. Information released by HHS estimates approximately 40 percent of covered veterans are also enrolled in the Part D program; this suggests that some veterans are enrolling due to limitations of the VA formulary.

- **The federal statutory ceiling price available to the VA and the statutory authority granted to the VA to purchase drugs under the Federal Supply Schedule.** The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) introduced the Medicaid best price practice. The provision made it illegal for a manufacturer to sell a medication to any other purchaser at a price less than what it charged Medicaid. The ramifications for the VA were immediate and profound: the VA lost its price advantage, and prices increased significantly for the VA, just as they did in the private market. Congress responded by enacting the Veterans Health Care Act of 1992, which not only exempted the VA from the best price requirement, but established a system of price ceilings and

authorization for the VA to purchase drugs off the federal supply schedule. This not only reinvigorated the VA's ability to use market tools to negotiate lower prices, but it also imposed a statutory price ceiling on VA drug purchases of 76% of the nonfederal average manufacturer price, and allowed the VA to access Federal Supply Schedule prices, if lower. Much of the VA's comparative price advantage comes from the 'price control' elements of this pricing scheme.

*CONCLUSION*

To expediently provide a national program based on widely employed best practices in the private sector, the MMA was structured upon a competitive approach that would encourage vigorous competition among qualifying private drug plan sponsors. The twofold objectives were to serve the medication needs of Medicare beneficiaries with maximum flexibility for patients, plus manage the cost requirements of the federal government. In giving drug plan sponsors the responsibility for administering the new Part D prescription drug benefit, Congress cited the success of private sector managed care organizations in using a broad range of innovative and integrated strategies to effectively manage prescription drug benefits for given patient populations — including the securing of price concessions from manufacturers and the use of clinically appropriate formulary systems, based on standards outlined in the law.

*Neither a clinical nor financial case has been made to justify fundamentally undermining the structure established by MMA. Accordingly, AMCP opposes repeal of the noninterference provision.*

****

○