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

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

International Drug Price Comparisons

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

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

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

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

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

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

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

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

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

Who Enrolled in Part D

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

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

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

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

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

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

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

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

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

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

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

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

Who Entered The Doughnut Hole

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

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

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

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

Who Left the Doughnut Hole

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

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

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

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

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

Life in the Doughnut Hole

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

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

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

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

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

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

Medical Implications

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

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

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

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

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

- 7% switched medications

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

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

When Did They Enter the Doughnut Hole?

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

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

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

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

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

Prices of Generic Versus Brand Name Drugs

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

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

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

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

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

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

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

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

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

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

When Drug Companies Raise Their Prices For Brand Name Drugs

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

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

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

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

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

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

Drug Price Increases

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

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

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

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

The 50% Deal With PhARMA

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

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

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

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

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

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

Implications for Beneficiaries

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

Implications for Medicare

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

I would be happy to answer any questions.