Testimony for the Senate Finance Committee

"Prescription Drug Pricing and Negotiation: An Overview and Economic Perspectives for the Medicare Prescription Drug Benefit"

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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.

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[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

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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".

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