**Testimony before the House Oversight and Government Reform Committee**

**"Medicaid Rebates, the Economics of the Pharmaceutical Industry, and the Medicare Part D Program"**

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

## 1. Industry Background

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

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

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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 rise or fall over time. The same number of dollars spent in different decades will result in a different number of NDAs due to the state of basic medical knowledge.

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

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

## 2. Medicaid Rebates

The Medicaid programs of the various states receive rebates from manufacturers whose drugs are dispensed to Medicaid enrollees. These rebates were established in the Omnibus Budget Reconciliation Act of 1990. The motivation for the rebates was to lower the net cost of prescription drugs to the government without reducing payments to pharmacies. Instead, a state Medicaid program reimburses a pharmacy for a prescription dispensed to a Medicaid enrollee. Then the manufacturer of the drug pays the state Medicaid program a rebate, which lowers the net price to the Medicaid agency. There are two components to Medicaid rebates on branded drugs: the basic rebate and, in some cases, an inflation adjustment.[3] For brands the basic rebate is the lower of a) a flat rate (currently 15.1%) of the Average Manufacturer Price (AMP) or b) the difference between AMP and the best, or lowest, price offered to any private buyer. For example, if a manufacturer offers an HMO a price that is more than 15.1% below its AMP, that price would be a "best price" and sales to all 49 Medicaid programs[4] would get that same discount. Even if the manufacturer sells to only one customer at a very low price, that price triggers a large discount for all the sales of that drug that the manufacturer makes to all state Medicaid programs. One can immediately see that the existence of the best price component of the rebate makes it expensive for manufacturers to give discounts to some buyers. When discounts are expensive, firms tend either to eliminate discounts, or not give as many. In turn, this means prices rise for many buyers, as does the average price. This experience was documented by the GAO and other government agencies when the Medicaid rebate was first introduced, and Congress amended the rebate statute to exempt sales to certain governmental agencies from the best price provision.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**7. Rebates lower the cost of Part D**

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