Testimony of:

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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.

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[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.

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[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

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[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]

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[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.

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