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Prescription Drug Procurement and the Federal Budget

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INTRODUCTION

As policymakers continue to wrestle with concerns over the federal budget and deficit following the unsuccessful efforts of the Joint Select Committee on Deficit Reduction, the challenge of obtaining major budget savings from the nation's major public health insurance programs, Medicare and Medicaid, remains. It has become clear that health care spending and the growth of health care spending are central causes of the federal budget imbalance (CBO, 2011). Part of the shared premise of Democrats and Republicans is that wasteful public spending on health care can be identified and redirected away from government with relatively little harm to people served by public programs or to the functioning of the economy. The level of waste and inefficiency in American health care has been estimated to range from 20 percent to 40 percent of health spending.[1] Yet there are important disagreements about what is unnecessary and inefficient spending and the consequences of scaling back in certain areas. The policy challenge is to realize such savings in a manner that minimizes the harm done to vulnerable Americans and to the long-term productivity of the health sector.

One area that has been the subject of interest and debate relates to public spending on prescription drugs. Several recent proposals, including that of the National Commission on Fiscal Responsibility and Reform (the Simpson-Bowles Commission), take aim at the way that the government purchases prescription drugs.[2] The proposals focus on a number of specific measures that seek to, among other things, affect the nature of competition in prescription drug markets, and intervene in price determination when competition appears not to be working.

This paper identifies areas where the government (or private plans on its behalf) may be paying for drugs in a context where market forces may not be working so as to produce efficient prices: specifically, for drugs provided to Part D enrollees receiving low-income subsidies, and the market for drugs that are unique and/or biologics. After reviewing the ways in which market forces are constrained from operating efficiently, the paper examines three proposals to address areas of limited competition which could yield federal savings: 1) extending Medicaid drug prices to Medicare Part D beneficiaries that receive low-income subsidies; 2) establishing a system of temporary administered prices in market segments where there are unique drugs under both Part B and Part D of Medicare; and 3) accelerating competition from generic biological products, known as follow-on biologics.

[1] www.economist.com/blogs/dailychart/2011/06/us health care spending
[2] Legislation filed by Congressmen Waxman and Stark and Senator Kohl have also taken aim at realizing budget savings by changing the way government buys and pays for prescription drugs. The Medicare Drug Savings Act (H.R. 2190) claims to offer savings of $120 billion over 10 years, while Prescription Drug Cost Reduction Act claims savings of more than $140 billion over 10 years.

BACKGROUND

How Drug Prices Are Determined in Medicare

Medicare covers prescription drugs under two separate parts of the program. Part B covers drugs that are primarily administered in physicians' offices, hospital outpatient departments, and dialysis clinics (typically injectable drugs).[3] Part D covers outpatient prescription drugs provided by stand-alone prescription drug plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs). The drug purchasing and pricing strategies in each part are different and can be subject to different types of market inefficiencies.

Medicare Part D

Medicare Part D established a new private-plan marketplace for prescription drug coverage for Medicare beneficiaries in 2006. The program relies on competition for enrollees to promote premium competition that in turn creates incentives for Part D plans to be careful purchasers. One of the promises of Part D was that, by linking elderly and disabled beneficiaries with Part D plans, Medicare could benefit from bargaining power of larger and more sophisticated purchasers. Drug plans were to build on the purchasing strategies that had been adopted in the private sector, in particular the emergence of the pharmaceutical benefit management (PBM) industry and its use of formularies and benefit design to steer utilization towards lost-cost (generic and "preferred" brand-name) drug products.

Part D plans, like other private sector purchasers, have greater success in obtaining lower prices when there is robust competition between drugs. If multiple drugs are therapeutic substitutes, the insurance plan can typically obtain a favorable price by steering purchasing volume to particular products over others in response to price offers from manufacturers (CBO, 2002; Newhouse, 2004; Frank and Newhouse, 2008). When there are generic substitutes available for brand-name drugs, direct substitution of "chemical carbon copies" results in lower prices and spending for the same drug product. Part D plans use such purchasing strategies to determine prices. This represents a substantial departure from the take-it-or-leave-it administered pricing used by Medicare for all Part B drugs and 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.[4]

Medicare Part B

Drugs purchased under Medicare Part B, in contrast, make use of administered prices in much the same way that Medicare pays for most medical care. Because physicians typically administer most Part B drugs, they are reimbursed for the purchased drugs to be administered to their patients at Medicare's established prices. Medicare Part B sets payment levels for drugs based on reports of average sales price (ASP) from pharmaceutical manufacturers. Patients are required to pay a 20 percent coinsurance rate under Medicare for Part B drugs (along with many other medical services), but the vast majority of

[3] Medicare also pays for prescription drugs dispensed during a hospital stay as part of the Prospective Payment System for inpatient hospital care.
[4] 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.

beneficiaries have some form of supplemental insurance coverage that helps pay their share of the total cost (e.g. Medicaid, Employer, or Medigap) (MedPAC, 2011).

Medicare Drug Spending

Overall, spending on prescription drugs represented about 18 percent of total Medicare spending in 2009, an increase from about 5 percent in 2005, the year before the Part D benefit took effect (MedPAC, 2011). In 2009 there were roughly 28.7 million people enrolled in Part D at some point during the year. About 18.7 million were in stand-alone plans while 10 million were in Medicare Advantage Plans. Total spending for Part D was $73.9 billion in 2009 (including Part D plan payments and enrollee copayments), of which $54.6 billion (73.8 percent) was spent for drugs used by enrollees in stand-alone PDPs. The average spending per prescription (including plan and enrollee liability) was $60 for Part D enrollees in stand-alone PDPs (MedPAC, 2011).

Approximately 9 million Medicare beneficiaries received drugs covered under Part B in 2009.[5] Spending for prescription drugs under Part B in 2009 amounted to about $17.6 billion.[6] Drugs to treat cancer are 7 of the top 10 drugs with respect to spending provided under Part B. In addition, the 7 drugs with the highest Part B spending were biologic drugs, as opposed to small-molecule drugs (MedPAC, 2011). Biological drugs are created using biological processes, whereas small molecule products rely on chemical synthesis. Biologics frequently make use of living cells to create therapeutic products like vaccines, blood products and recombinant proteins.

While the addition of the Part D benefit in 2006 greatly expanded Medicare's role in paying for prescription drugs, the overall annual rate of growth in national drug spending has been declining for the past 10 years (IMS, 2011; CMS OACT, 2012). In 2010, drug spending grew at a rate of 2.3 percent in nominal terms compared to about 17 percent in 2001. Spending on traditional small molecule drugs grew at a mere 0.5 percent in 2009, compared to 6.6 percent for biological products. The downward pressure on spending increases in recent years has been driven by several important factors, such as the slow-down in the development and launch of new branded small molecule products, patent expirations in many blockbuster drugs, and rapid penetration by low-cost generic competitors (typically 80 percent within 6 months of patent expiration).

However, the development of new biological products accompanied by extended periods of protection from generic competition is putting upward pressure on drug prices. This is illustrated by the fact that the three products with the largest volume spending increase for drugs overall in 2010 were all biological products. Moreover, the leading therapeutic class with respect to spending growth was cancer drugs, where biologics play a disproportionate role. Finally, biological products are heavily represented among new brand launches in 2010.

Purchasing Performance

The Medicare Modernization Act of 2003 (MMA) altered the formula for establishing the administered prices called for under Medicare Part B by setting prescription drug prices at 106 percent of Average Sales Price (ASP). ASP is based on actual transaction prices, and therefore represents a weighted

[5] This figure was estimated from tabulations from the Medical Expenditure Panel Survey (MEPS).
[6] MedPAC (2011), A Data Book: Health Care Spending and the Medicare Program, Chapter 10, June. MedPAC estimates $11.1 in physician offices drug spending, $3.5 billion in hospital outpatient departments, and $3 billion in dialysis clinics.

average of the supply prices received by the manufacturer net of price concessions (such as discounts and chargebacks). The ASP data do not include so-called performance rebates, which are price concessions granted by manufacturers to purchasers based on the volume of sales of a particular or group of drugs. Performance rebates are quite prevalent in the private marketplace. The result is that providers can typically purchase Part B drugs for prices below the Medicare established fee, meaning that Medicare is essentially overpaying when the actual purchase price is less than the ASP-based administered price (MedPAC, 2006).

The results of the Part D approach to purchasing prescription drugs suggest that it has generally performed well with respect to prices paid for the large number of drugs where competition between therapeutic or genetic rivals occurs. In particular, Medicare beneficiaries that had previously purchased drugs in cash because they had no drug coverage faced lower prices (before applying coverage provisions that further lowered out of pocket obligations) as a result of being enrolled in Part D plans that were negotiating prices on their behalf (Frank & Newhouse, 2008; Berndt & Newhouse, 2010). At the same time, as expected, the volume of prescriptions dispensed to this population expanded. It is also clear that PDPs have acted on their incentives to be careful purchasers by taking advantage of important patent expirations and making use of newly available generic substitutes for brand-name prescription drugs (Aitken & Berndt, 2011). This has resulted in reductions in the costs of a number of important therapies. For example, generic entry has been largely responsible for the 40 percent reduction in the cost of lipid regulators and the 60 percent decline in the cost of ACE inhibitors. Moreover, during the period 2000 to 2009 there was a 63 percent increase in the dispensing rate for generic products in the U.S. overall. Generic penetration in Part D was estimated by the Congressional Budget Office (CBO) at 65 percent in 2007 and is likely to be higher today (CBO, 2010).

The question of the impact of the design of Part D on overall spending on pharmaceuticals is less clear. Strong claims have been made that the competitive market for prescription drug plans "has proven to be a dramatic success in controlling prescription drug costs (because) actual Part D costs have been in the vicinity of 40 percent below the Congressional Budget Office's initial ten year estimate" (Holtz-Eakin & Ramlet, 2011). The inference here is based on treating the projections of CBO as if they represent an empirically established long-run trend that was disturbed by the new policy. That is decidedly not the case. Establishing projections for large new spending programs is known to be difficult. In 2003, the Part D program was seen by CBO as posing an especially challenging prediction problem. As the CBO director at the time, Douglas Holtz-Eakin, noted: "Because the new prescription drug program represents a major departure from what currently exists, there is a great deal of uncertainty about its budgetary impact…" (CBO, 2002). Therefore, calling actual spending levels that are below projected levels that were not based on any established historical trend "savings"(Antos and King, 2011), as many have done, is misleading. A more accurate term for the difference between actual and projected savings in this case would be forecast error, not generally something that results in celebration.

Areas of Limited Competition in Drug Procurement in Medicare

This section focuses on the areas in which limited competition results in higher prices paid by Medicare than might be obtained in a well-functioning market, thereby resulting in inefficient spending. Specifically, there are inefficiencies associated with the cost of purchasing drugs for low-income subsidy (LIS) recipients and with the prices paid by Medicare and beneficiaries for so-called unique and/or biologic drugs purchased under Parts B and D. Three proposals to address these inefficiencies are

discussed, each of which is projected to achieve federal savings with few undesirable effects on the pharmaceutical markets.

Changing Prices Paid by Medicare for People that Receive a Low-Income Subsidy

The Issue: Prior to 2006, when Part D was implemented, Medicare beneficiaries who also qualify for Medicaid (the so-called dual eligibles) received drug coverage under Medicaid, and therefore had drugs purchased for them under Medicaid's "best price" rebate system. Under this system, Medicaid receives either the "best private price" at which a manufacturer sells a drug or a price 23.1 percent below the average manufacturer price for that drug, whichever is lower.[7] Thus, a manufacturer that negotiates a lower price for any payer must offer that price to Medicaid. This requirement creates an incentive for manufacturers to be less willing to grant rebates to private insurers.

When Medicare Part D was implemented, purchasing of drugs for dual eligibles was automatically shifted from Medicaid to Medicare prescription drug plans, and a new low-income subsidy (LIS) program was created to provide additional financial assistance with Part D plan premiums and prescription drug cost sharing to duals and other low-income beneficiaries. Beneficiaries who qualify for the full amount of assistance through the LIS program pay no premiums and only very modest cost sharing ($1.10/$3.30 for generics, $2.60/$6.50 for brand-name drugs in 2012, depending on income). Dual eligibles and other low-income Medicare beneficiaires, now 10.9 million people, are among the sickest and highest-cost beneficiaries, with disproportionately high drug use and spending. LIS recipients account for 38 percent of all Part D enrollees but roughly 76 percent of Medicare beneficiaries with more than $6,100 in prescription drug spending in 2009 (MedPAC, 2011).

As described earlier, Part D private plan sponsors (or pharmacy benefit managers on their behalf) negotiate with pharmaceutical manufacturers to obtain rebates and discounts on behalf of each sponsor's enrollees. The evidence to date suggests that when drug coverage for dual eligibles switched from Medicaid to Medicare, the prices for their drugs increased significantly (Frank & Newhouse, 2008). This appears to be the result of lower rebates under Part D plans than Medicaid, according to a recent analysis by the Inspector General of the U.S. Department of Health and Human Services (Office of the Inspector General, 2011). Because dual eligibles and other LIS recipients account for a disproportionate share of spending under Part D, the prices paid for their prescriptions have important fiscal effects for Medicare.

Dual eligible and other LIS recipients are also disproportionate users of drugs in "protected classes" under Part D, a designation which limits the capacity of Part D sponsors to negotiate lower prices on these drugs, because they are required by law to include these drugs on the formulary. Historically, drug spending by dual eligibles has been concentrated in certain classes of drugs: antipsychotics, ulcer drugs, antidepressants, antihypertensives, and anticonvulsants (Bagchi, Esposito, & Verdier, 2007). With all dual eligibles now enrolled in Medicare Part D plans, this pattern of drug use and spending is significant because of a specific requirement that all Part D plans provide all Part D-covered drugs in certain "protected" classes — classes that are of clinical concern because restricting access to them may have life-threatening consequences, and patients with a given condition need to have access to multiple drugs in the class. The designation of protected classes means that the use of formulary design to steer demand is limited by regulation — a fact that reduces PDPs' bargaining power with manufacturers.

[7] The Patient Protection and Affordable Care Act of 2010 increased the minimum rebate percentage from 15.1 percent of the average manufacturer price (AMP) to 23.1 percent of AMP, effective January 2010.

Thus, Part D sponsors can neither limit the range of products offered nor – in the case of utilization of drugs in protected classes by LIS enrollees – can they use cost sharing provisions (e.g. tiering) to steer utilization in ways that enhances their bargaining power.

Currently, the protected classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosupressants — a list that includes three of the classes with the highest spending by dually eligible and other LIS beneficiaries. Dual eligibles are also disproportionate users of the other protected classes (e.g. antiretrovirals).

The Proposal: One way to address concerns about the inefficiencies in Medicare drug spending for dual eligibles and other LIS Part D enrollees would be to allow drugs purchased for these enrollees to receive the Medicaid rebate, rather than the price negotiated by Part D plans, thereby lowering the price Medicare pays for drugs used by this population. This would achieve savings in an area where Part D sponsors have limited capacity to drive market share. In fact, CBO estimates that there would be net savings of over $100 billion over 10 years if the Medicaid Part D drug rebate system were adopted for Part D LIS enrollees (CBO, 2011).

Three main objections have been lodged against this proposal.

- Applying the Medicaid rebate to Part D LIS recipients could reduce financial returns on research-and-development (R&D) investments so that companies would not make adequate investments in developing new products (Antos & King, 2011).
- Linking Medicare prices to best private prices, including Part D LIS rebate prices, would create incentives for drug companies to offer fewer rebates to private payers, such as employers, and possibly to launch new drugs at higher prices (Holtz-Eakin & Zhong, 2011).
- Paying Medicaid prices for drugs purchased on behalf of LIS beneficiaries would result in higher prices for other Part D recipients (Holtz-Eakin & Ramlet, 2011).

The first two concerns are logical potential consequences of the proposed policy. Whether they are the likely result is a matter that can be subjected to some empirical examination. The third concern is inconsistent with profit-maximizing behavior on the part of prescription drug manufacturers and does not seem like a logical potential outcome of the proposed policy. Each of these objections is discussed in turn.

Impact of Medicaid Rebate on R&D: Evidence from Antipsychotic Drugs

To investigate the likely impact of paying Medicaid prices for Part D LIS enrollees on R&D, an examination was conducted of R&D activity in the market for antipsychotic drugs, a class of drugs that is one of the protected drug classes under Part D and that prior to 2006 was disproportionately reliant on Medicaid as a source of revenue, accounting for over 70 percent of sales (Duggan, 2005). The hypothesis is that if Medicaid prices were too low to induce a robust R&D effort, one would expect this class of drugs to display low levels of drug development activity. (For a more in-depth analysis of drug development in antipsychotics see Frank and Seiguer, 2008)

This analysis used data obtained from Adis International's Research and Development Insight (RDI) dataset to examine drug development activity during the period that coincided with the implementation of the rebate provisions under Medicaid for a class of drugs used disproportionately by Medicaid

recipients.[8] This dataset represents one of the most complete compilations of drug development data available, and is continuously updated by Adis researchers.[9] RDI contains molecule-level data (that is, the compound that makes up the active ingredient of a particular medication), including the dates of transitions between phases of development, details on pre-clinical and clinical trial outcomes, ownership changes, molecular-mechanism and patent information. The database tracks each molecule at the level of a clinical indication (e.g. schizophrenia or metastatic breast cancer). For example, within the "Affective Disorders" therapeutic area, there are a variety of indications, including depression, eating disorders and bipolar disorders. The RDI dataset is the most comprehensive source of information on drug development; while it misses some R&D activity, it is used extensively by researchers and industry experts to describe general patterns in R&D.

Table 1 shows the activity by pharmaceutical companies in the area of antipsychotics R&D between 1994 and 2005, confirming a significant level of activity related to the development of drugs that are used disproportionately by Medicaid beneficiaries. Products are grouped by the receptor sites targeted by the drugs under investigation (that is, the specific biological mechanism that the drug aims to affect). The data indicate that 107 drugs were in development during the 1994-2005 period.[10] While development was highly concentrated in the large pharmaceutical firms, with about half of all drug development taking place in eleven firms, overall, 67 firms had at least one molecule in development. During this same period, 62 drugs were being tested at a Phase I (the first stage of human testing) level or higher, of which 32 (52 percent) were suspended or discontinued, and the remainder were approved for marketing, as shown in **Table 2**. This level of activity for anti-psychotics did not differ from overall industry activity during that time period, an era when R&D was considered robust.

To put these figures into context, there were a total of 26 new drugs approved for marketing by the FDA in 2010 across all drug classes – compared to 30 new drugs approved for marketing for in the antipsychotics class between 1994 and 2005. Among those newly approved in 2010, there were four drugs that target arthritis, an area acknowledged to be one of active development. Some other active areas of current (2010) research and development include the dementias, where there are currently 90 drugs in development. In addition, there are 54 drugs in the antipsychotic category that target schizophrenia. This figure is comparable to what occurred during the period when government-set administrative prices were the dominant source of revenues.

Together these data suggest that the 1994-2005 period was not a time of low R&D activity in the area of antipsychotic medications – which one would expect if the Medicaid rebate stifled innovation for drugs used disproportionately by Medicaid enrollees. To the contrary, the antipsychotic market has been characterized by a high level of development activity, a high failure rate, a mix of "me too" and innovative products and some blockbuster products, similar to therapeutic areas that do not rely heavily

[8] Adis markets a pharmaceutical information database [www.adis.com]. It is the data base used most frequently by the industry to track industry wide R&D activity. PhRMA uses the Adis data base to produce its publications on R&D activity in the industry. Adis tracks drug development by monitoring the scientific literature, presentations at scientific meetings, company press releases and internet sources.

[9] The database goes back to 1984, although the bulk of the data encompasses the post 1994-period. Adis has various criteria for the inclusion of drugs in their database. In general, priority is given to drugs which have a novel target, structure, or mechanism of action or represent a new therapy. If a company is developing a novel formulation of the drug, which has the potential to provide some benefit over existing formulations, this drug will be included in the database. Separate profiles are created for existing drugs when another company intends to develop it for an entirely new indication.

[10] The most populated target over the study period has been the mixed dopamine D2 receptor agonists and antagonists with 27 drugs (molecules) in development. These include molecules aimed at the dopamine D2 receptor as well as other dopamine receptors and serotonin receptors. Partial dopamine D2 receptor antagonists and agonists accounted for another substantial area of research interest, as did research on the dopamine D4 receptor.

on Medicaid as a source of revenue. Specifically, in comparing the pre-Part D to the post-Part D period, there is no evidence of an increase in innovative activity for antipsychotic drugs. When comparing the class of antipsychotics to other drug classes that are less reliant on Medicaid, it displays innovative activities comparable to drug classes with high levels of innovative activity. These findings are inconsistent with the claim that Medicaid prices inhibit R&D effort to the point that new innovative products would not be forthcoming relative to other therapeutic areas that are not so reliant on Medicaid revenue. In the end, the price-determination mechanism used in practice does not appear to be the deciding factor in innovative activity in the anti-psychotic class.

This assessment is consistent with conclusions reached by CBO. CBO argued in a 2011 budget options report, in an assessment of paying for drugs purchased for beneficiaries receiving an LIS using Medicaid prices, that the President's ideas "would not significantly reduce the incentive to develop 'breakthrough drugs' because those drugs could be launched at prices high enough to largely offset the rebate."[11]

Private Payer Prices

The second argument against the Medicaid drug rebate proposal for Part D LIS enrollees concerns distortions in the prices paid by private purchasers as a result of the rules governing the Medicaid "best price" method of price determination. Research by Scott-Morton (1997) identified the fact that regulating Medicaid prices by linking Medicaid to the best private price inhibits the granting of rebates by manufacturers. The empirical evidence suggests that in fact, some small distortion in private prices does occur as a result of the Medicaid rules. However, Scott-Morton (1997) concludes that the incentive effects of Medicaid pricing incentives "are visible, though small." She estimates that, on average, prices for drugs that face generic competition increased by 4 percent because of the Medicaid rebate provision.

It is important to note that since Scott-Morton conducted her study, the rate of generic penetration has increased dramatically, such that 80 percent of sales shift from branded to generic products within six months of patent expiration. The implication is that the number of branded sales will be lower today than in 1991 and so the impact of any price increases will be smaller. The central policy question is: are these price distortions large enough to offset the savings realized in a segment of the market where prices currently exceed those that would result in a well-functioning market? Scott-Morton's estimates, together with the changes noted in the market for prescription drugs, suggest that they would not be. CBO's analysis of the budgetary savings from this proposal is consistent with this view (CBO, 2011).

Prices for Other Part D Beneficiaries

Holtz-Eakin and Ramlet (2011) extend the analysis offered by Scott-Morton (1997) to an area not covered by her research, when they state the following: "Such an impact [of the Medicaid rebate on private payer prices] would likely be felt in the employer based insurance market, as well as in government programs including Part D." The first part of the statement made by Holtz-Eakin and Ramlet was addressed in the previous section in the discussion of concerns about the impact on private payer prices. The second part of their statement suggests that not only will there be price distortions in private markets but that other Part D beneficiaries will also pay higher prices.

[11] The net effect on the long-run budget depends on the market share of the new products that enter and the degree of competition between newer products and incumbents. Breakthrough drugs would likely command a relatively high price, while additional "me too" products much less so.

The implications here are two fold. First, they imply that a formula that explicitly excluded Part D will affect Part D prices. It is not clear what such a mechanism could be. Second, they imply that manufacturers are not pursuing profit-maximizing prices for Medicare Part D plans. Because Part D prices are excluded from the Medicaid formula, the assertion by Holtz-Eakin and Ramlet imply that manufacturers could have set Part D prices higher than they do under "current law" but chose not to, thereby leaving money on the table. The notion that the industry consciously has been pricing so as not to maximize profits flies in the face of decades of economic analysis of the industry and Holtz-Eakin and Ramlet own conception of this industry. Therefore this concern does not likely pose a meaningful risk to the effectiveness of the Medicaid drug rebate proposal.

Unique Drugs

The Issue: 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), and also to the specific approach to determining the administered prices under Part B. Recall that Part B has a 20 percent coinsurance (though many beneficiaries are insulated from this due to supplemental coverage) and uses average sales prices that are largely based on information from insured populations. Unique drugs arise in two ways: new products with important therapeutic advantages, which are introduced into existing therapeutic classes of drugs, and unique products that arise from the creation of new therapeutic classes.[12] Significant market power can arise in either case.

In recent years, unique drugs like biological agents have seen high growth in prices and spending. These products make claims on both Part B and Part D of Medicare. IMS (2011) reports that price increases for patent-protected brands had a 6 percent contribution to overall spending growth in 2010. For example, Lucentis and Lantus were two of the three drugs with the highest increase in spending growth in 2010. Oncologic drugs Avastin, Herceptin and Rituxan have also seen high rates of spending growth. A major issue with biologics is that they remain unique for longer periods of time. While that will change somewhat now that an abbreviated pathway for biosimilars has been set out in the Patient Protection and Affordable Care Act of 2010, those provisions still call for a 12-year exclusivity period. This is important because biological products represent an increasing share of new product launches and are expected to be a driver of Medicare drug spending in the future.

The cost implications for Medicare are significant. Medicare Part B spending for anti-cancer monoclonal antibodies alone was estimated to exceed $2 billion in 2009 (Leonard, et al., 2011). Part B spending for "sole source" cancer-related drugs (those directly used to treat the cancer plus those that address side effects of treatment) exceeded $3 billion in 2009 (MedPAC, 2011). Forty-three percent of the $11 billion spent on the top 10 Part B drugs (ranked by level of spending) in 2009 administered by physicians were sole source products, many of them biological agents.

Biologics and other unique drugs have similar cost implications for Part D. In Part D, classes with little generic or branded competition include drugs to treat asthma and chronic obstructive pulmonary

[12] Previous work has 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, & Frank, 2007). That number has markedly dropped in most of the first decade on the 21st century, with only five such drugs in the entire four-year period between 2000 and 2004, or just one per year. In 2010 there were 10 innovative products launched (IMS, 2011). 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 there are some recent examples, including Forteo and Prolia that treat osteoporosis, Plavix, which treats heart disease, Provenge for prostate cancer and Gilenya for multiple sclerosis.

disease agents, platelet aggregation inhibitors, and cognitive disorder therapies. These accounted for roughly $10 billion in spending in 2009 (MedPAC, 2011). Overall, biological products accounted for about 6 percent of Part D spending in 2007. For Part D cancer-related drug spending on biologics alone, outlays are estimated at about $1 billion in 2009 (Leonard, et al., 2011).

Why unique drugs pose a problem for Medicare

When the MMA was being debated it was expected that the existence of unique drugs 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, & Frank, 2007). Second, there is substantial cost sharing below the catastrophic coverage 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). Evidence and practice to date, however, suggests that the impact has been more significant than anticipated.

As a result of the standard Part D benefit design, enrollees do not face the full price of drug products for large ranges of spending. In 2012, beneficiaries who are not covered by the LIS face coinsurance of around 25 percent up to $2,930 in spending, followed by a gap in coverage where they are responsible for 50 percent of the cost of brands and 86 percent of the cost of generics until they have spent $4,700 out of pocket, after which they are protected against 95 percent of additional costs. Drug plans are potentially in a weak bargaining position because they have limited ability to redirect demand away from unique products, and there would surely be strong political pressure not to allow plans to leave such unique (and presumably superior) products off the formulary. Some negotiation pressure is created by the use of "specialty tiers" in drug formularies. But overall, 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.[13]

Furthermore, PDPs incentive to bargain on price for unique drugs is limited because they share much of the high-cost risk with the government and patients. With the government having responsibility for 80 percent of the costs of spending above the catastrophic level and the enrollee responsible for 5 percent, Part D plans face only a 15 percent liability at the high end of spending. Because Part D plan sponsors share the cost with the government and enrollees, 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. 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 or a market where consumers pay the full price of a good, as is the usual case outside of health care.

There are indications that drug prices for unique drugs have responded accordingly. Early on in the Part D program, some significant price changes during the first half of 2006 that were reported by manufacturers of brand-name prescription drugs occurred for relatively unique drugs with had high shares of elderly buyers. Examples include Plavix, Forteo, and Evista, all of which were reported to have experienced significant gains in prices. Research by Frank and Newhouse (2008) compared brand-name drugs with high shares (55 percent or more) of elderly purchasers and brand-name drugs with relatively

[13] That is, the regulations on allowable formularies, which are set on clinical grounds, may well require coverage of the drug.

low shares (35 percent or less) of elderly purchasers from among the brand-name drugs among the top 50 in sales. This research showed that the drugs sold to the elderly grew at a faster rate after August of 2004 and that that trend continued into 2006.[14]

Thus, it appears that the enhanced market power of the manufacturer alongside the insurance coverage created by Part D (which also exists in Part B) creates minimal incentive or opportunity to achieve price concessions that would have fiscal benefits for the federal government and enrollees. This has the potential to create a distributional imbalance in the direction of offering substantially greater economic "rents" (i.e., a form of what are commonly called excess profits) 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 and the federal budget.

The Proposals: There are a number of ideas for addressing the spending levels that stem from the excess market power of unique drugs. One is to permit the government to negotiate when drugs are unique and Medicare is a major purchaser.[15] Another approach would be to shorten the exclusivity period for biological products from 12 years to 7 years as a means to accelerate the injection of competition from follow-on biological products. Under both types of proposals, it is believed that when there are unique drugs where Medicare purchases a large amount of the product, the proposals would yield budget savings with little or no loss in social efficiency.

Frank and Newhouse (2008) advanced the idea of a system of binding arbitration for establishing a set of temporary administered prices of unique drugs in the period until competition from either generic (biosimilar) or therapeutic products occurred. Such temporary administered prices would focus on drugs that are both unique and where the federal government is a large purchaser of the product. The binding arbitration would only be triggered when both conditions were present. These temporary administered prices would apply to both Part B and Part D. Such a system would have to be mindful of the costs of R&D in the biologics area and assess whether prices remain at levels that offer a reasonable return to the risk investments. In essence, this proposal allows the government to pool the purchasing power across Part D plans and Part B to strengthen its hand in leveraging lower prices for unique drugs. Furnishing a complete projection of the savings stemming from temporary use of administered prices is beyond the scope of this paper, but if assuming even modest impacts of arbitration on prices, in the range of 10 percent to 15 percent, the savings could exceed $6 billion over 10 years.

Another approach would be to shorten the exclusivity period for biological products from 12 years to 7 years as a means to accelerate the injection of competition from follow-on biological products. This proposal was considered in deliberations over the 2010 health reform law and was recently proposed by the Obama Administration in the President's Fiscal Year 2013 budget. This proposal requires that the biological product be approaching the latter part of its exclusivity period. It is important to note that the biologics will have had the benefit of exclusivity for the term of their patent, with a guarantee of a minimum of 7 years of market exclusivity. In addition, it is expected that the approval process for follow-on biologics will not be as rapid and simple as is the case currently for generic non-biologic agents. The implication is that there will be ample time for manufacturers to recoup their R&D investments in biological products.

[14] 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.
[15] Senator Kohl makes some related suggestions in a recent letter (dated October, 13, 2011) to the Joint Select Committee on Deficit Reduction.

The Office of Management and Budget (OMB) estimates that reducing the exclusivity period for biological products that have lost patent protection would save $3.8 billion over 10 years (OMB, 2012). CBO (2008; 2011) estimates that biosimilar prices would be about 40 percent lower than their branded counterparts. To highlight the significance of the potential savings, it has been reported that biologic products with about $10.4 billion in annual sales will face patent expiration between 2012 and 2015. In addition, biologics with more than $10.5 billion in yearly sales will have their patents expire between 2014 and 2018 (Grabowski, Long, & Mortimer, 2011). It is important to note that over time these savings would grow as more biologic products lose patent protection and ultimately exceed the 7-year window of exclusivity (Grabowski, Long, & Mortimer, 2011).

CONCLUSION

Competition in prescription drug markets has been shown to generate downward pressure on prescription drug prices. Both therapeutic and generic competition can affect drug prices. Generic competition has been shown to drive large and rapid declines in prices following patent loss, while the effects of therapeutic competition have been more modest.

The Medicare program and its beneficiaries frequently benefit from competition in prescription drug markets. The design of Part D offers opportunities to promote competition and to benefit from competition, but this paper has shown that in couple of key areas, competition is quite limited. One case is where steps to protect vulnerable population results in limiting the bargaining power of purchasers, such as in the case of drugs in the protected classes. A second case is where drugs are unique and where regulatory institutions may create barriers to generic competition even after patent expiration.

When such circumstances arise, there are policy measures that can be taken to limit excessive payments to drug manufacturers that can produce budget savings for the federal government. The policy responses to these situations range from using Medicaid prices, to encouraging more rapid competition from follow-on biologics, to the use of temporary administered prices when competitive solutions are not available. Together, these ideas offer the potential for well over $100 billion in savings over 10 years and continued growth in savings thereafter, which could be especially welcome in a time of fiscal strain on the Medicare program and the federal budget overall.

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TABLE 1: TARGETS OF ANTIPSYCHOTIC DRUGS UNDER DEVELOPMENT, 1994-2005

Molecular Site Targeted	Number of Molecules in Development	Molecular Site Targeted	Number of Molecules in Development
Adenosine receptor	1	Glycine	1
Alpha 2 Adrenoreceptor	1	Glycine-mixed	2
Benzodiazepine receptor	1	Neurotensin	1
Calcium channel	2		
Cannabinoid receptor	3	Norepinephrine	1
Cholecystokinin	3	Opioid receptor	8
Dopamine D1 receptor	9	Opioid receptor-mixed	3
Dopamine D1 receptor- mixed	4	Phosphodiesterase	1
Dopamine D2 receptor	16	Phospholipase	1
Dopamine D2 receptor- mixed	27	Potassium channel	1
Dopamine D3 receptor	8	Serotonin 1 receptor	5
Dopamine D3 receptor- mixed	1		
Dopamine D4 receptor	12	Serotonin 2 receptor	9
Dopamine D4 receptor- mixed	2	Serotonin 2 receptor-mixed	2
Dopamine receptor	8	Serotonin 3 receptor	8
Dopamine receptor- mixed	2	Serotonin 7 receptor	1
G protein-coupled receptor	2	Serotonin receptor	1
Glutamate	5	Undefined	18

NOTE: Glutamate includes AMPA and NMDA as subtypes

TABLE 2: HIGHEST STAGE OF DEVELOPMENT FOR MOLECULES IN SAMPLE

Stage of Development	Number of Molecules
Pre-Clinical	15
Phase I	6
Phase II	10
Phase III	3
Filed for approval/registered	1
Launched	9
Suspended/Discontinued, Phase Unknown	1
Suspended/Discontinued, Pre-Clinical	93
Suspended/Discontinued, Phase I	12
Suspended/Discontinued, Phase II	11
Suspended/Discontinued, Phase III	9
Withdrawn	1

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