# A FRAMEWORK FOR NEGOTIATION IN PART D OF MEDICARE

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## I. INTRODUCTION

Drug pricing in the U.S. is a persistently vexing policy problem. Budgeteers, consumers and payers are all stressed by the pressures of high drug prices. At the same time, the public demands new and better cures. The pharmaceutical industry insists that delivering new treatment and cures requires compensation for the high costs and risks entailed in development of new drug products. There is substantial agreement across economic analyses of the prescription drug industry that supracompetitive prices (prices that exceed those that would result from a competitive market), and/or other forms of payments to producers, are necessary to promote innovation in a high fixed cost-low marginal cost business like prescription drugs. Policy disagreements in large part center on how much pricing discretion prescription drug manufacturers should be permitted, and how much of any surplus in the prescription drug market should be claimed by manufacturers versus consumers and other parties.

In this paper, we focus on one set of circumstances in the Medicare Part D program, where market power, conveyed initially by patents, but reinforced by the insurance system itself, is most likely to result in extreme price distortions. That distortion is greatest within the reinsurance benefit in the Part D program, namely when clients of prescription drug plans have already spent a considerable amount on drugs in a year. As we will discuss, this is a segment of the Part D benefit where spending has been growing rapidly and where high-cost drugs account for most of the growth.

It is also one where incentives to economize that face consumers and Part D plans are strongly dampened, because Medicare Part D pays the reinsurance. Compounding the problem, the federal government is precluded from negotiation with drug companies. Thus, the usual restraints on prices hardly restrain. For these reasons and because of the evidence about the shape of the trade-off between profitability and innovation effort, a policy focus on the reinsurance benefit of Part D is a place where policy adjustments can significantly improve social welfare.

We first analyze the extant incentives. We then propose a framework for negotiating prices that at once preserves incentives for innovation while allowing the government to limit the degree to which supracompetitive prices prevail in the absence of market forces.

The paper is organized into four sections. Section II provides some background on the Part D program and on the nature of the policy problem related to the reinsurance benefit. Section III focuses on the problem of extreme market power in the reinsurance benefit range, and offers a framework for targeted temporary price negotiations. Sections IV and V present concluding observations.

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## II. BACKGROUND: THE PROBLEM

The Medicare Part D program provides insurance coverage for the costs of self-administered outpatient prescription drugs. 41 million people were enrolled in Part D supported coverage in 2016. The Part D program relies on two modes of competition to promote the cost-effective delivery of prescription drug coverage to Medicare beneficiaries. First, it relies on competing private plans to provide coverage to Medicare beneficiaries. These plans submit bids that determine the premiums they charge. Enrollees must pay a premium that reflects the average nationwide premium plus the difference between a plan's bid and the nationwide average. (The adjustment can be a reduction below or an increase above the national average.) Those premiums plus the benefit designs, formulary structures, pharmacy network, and client services the plans offer are the basis that enrollees are expected to employ when choosing which plan to join.

Second, Part D seeks to promote competition among prescription drug products. Prescription drug plans capitalize on such competition to obtain favorable prices for the prescription drug products they buy. In addition, formulary design is used to create price competition among drug manufacturers seeking to obtain favorable formulary placement (e.g., lesser cost sharing by the patient).

Medicare defines a standardized Part D benefit design to set a minimum actuarial value for prescription drug coverage in Part D. The current design prescribes a $400 deductible, and 25 percent coinsurance up to a spending level of $3,700. After that, enrollees enter the so-called donut hole where they pay 100 percent of costs until out-of-pocket spending exceeds $4,950.[1] Once that limit is reached, enrollees pay five percent coinsurance, with the remaining 95 percent covered by the plan. This last segment of the Part D benefit is termed the reinsurance benefit. Within the reinsurance benefit, the 95 percent plan payment is covered 15 percent by the plan itself, and 80 percent by the government (Medicare). Thus, the government pays the bulk of the costs for high-cost users; enrollees are close to fully insured.

MedPac reports that government spending on Part D of Medicare reached $80.1 billion in 2015 (MedPac, 2017). This amounts to a roughly 74 percent increase over 2007 spending levels, indicating an annual rate of growth of seven percent. The growth in total program spending has been driven by the rapid growth in the reinsurance feature of the Part D program. In 2007, the reinsurance component accounted for 25.2 percent of Part D per enrollee costs, and in 2017, the corresponding share had soared to 56.4 percent. This vast escalation has prompted policy interest to constrain the forces driving these changes. MedPac and the Department of Health and Human Services' Inspector General have conducted analyses of some of the sources of spending increases in the reinsurance segment of the Part D program (OIG, 2017), and MedPac has consistently reported on the evolution of the reinsurance benefit.

Together those data and analyses reveal some salient spending patterns. One key finding is that while the number of beneficiaries reaching the reinsurance benefit has increased by about 57 percent between 2007 and 2015, the share of Part D enrollees entering the reinsurance coverage segment of Part D has remained quite stable over time. In 2007, 2.3 million enrollees or 9.5 percent of program participants entered the reinsurance segment. In 2015, 3.6 million enrollees or 9.2 percent of program participants

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1   The donut hole is being phased out according to provisions in the Affordable Care Act.

made claims under the reinsurance benefit. Thus, the dramatic growth in the share of spending accounted for by the reinsurance benefit was not due to growth in the share of enrollees making claims against that segment of the Part D benefit. MedPac (2017) parceled out the growth in reinsurance spending between price and volume of prescriptions growth. Its analyses show that between 2010 and 2014, 96 percent of the growth in reinsurance spending was due to price growth. That contrasts with the patterns of growth for the non-reinsurance portion of Part D, where average price actually fell. Thus, increases in the average price of the drugs utilized by individuals in the reinsurance benefit range dramatically outpaced price increases for drugs generally.

This suggests that growth in the average price of a prescription in the reinsurance benefit appears to be a main driver of the rapid growth in spending. Such price increases can come about for a number of reasons, including introduction of new high priced products, price increases from existing products and compositional changes in the mix of drugs used. A recent analysis of overall U.S. spending growth by IMSHealth (2016) indicates that about 44 percent of the net growth in invoice drug spending was due to price increases from existing branded drugs and 42 percent from the introduction of new products. New products aimed at Hepatitis C drugs and some cancers have accounted for the majority of the recent increase in spending in the reinsurance benefit. This is reflected in notable increases in the price index for Part D drugs.[2]

The analysis conducted by the OIG (2017) offers some insights into the source of the price increases.[3] The OIG analysis shows a marked increase in spending associated with so-called high-cost drugs. There are a variety of definitions of high priced drugs currently in use.[4] The OIG defined high-cost drugs as those costing $1,000 per month or more. Its analysis of Medicare Part D claims shows that, in 2015, 65 percent of reinsurance benefit spending was on high-cost drugs, double the 32 percent figure for 2010.[5] Moreover, the percentage of beneficiaries paid under the reinsurance segment that use high cost drug has doubled from 14 percent in 2010 to 28 percent in 2015.

Several additional factors have been identified as underpinning the growth in spending under the reinsurance benefit. They include the "shrinking" of the donut hole, the growth in employer group waiver plans (EGWPs) and a slight increase in the number of prescriptions per enrollee per month (MedPac, 2017).

Medicare Part D covers outpatient prescription drugs that are self-administered. Part D relies on two types of competition to control prescription drug costs: competition among Prescription Drug Plans (PDPs) and the PDPs themselves using formulary placement to promote price competition among prescription drug products. Competition for favorable placement on formularies works reasonably well when there are either generic or multiple similar therapeutic competitors in a market. This is as would be expected, given that we have the rough equivalent of a market that is functioning reasonably.

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2   We calculated a Fisher price index for all Part D drugs that was anchored in 2007. For 2013 and 2014 the annual increase rate jumped to over 12 percent.

3   It is important to note that there are differences between the estimated spending levels in the OIG and MedPac analyses for 2015. Nevertheless the large spending patterns are quite consistent.

4   CMS defines specialty or high cost drugs as those costing $600 per month or more.

5   If the CMS definition of high cost drugs were used the 65 percent estimate would be higher.

Drugs themselves are not the problem. And the heavy subsidy through insurance of consumers' purchases – the promoting source of moral hazard – is not the main problem. But when drug sellers have significant market power (due to lack of effective substitutes) and purchases are heavily subsidized by insurance, vastly excessive prices can result, and have resulted. Finally, the heavy subsidy of purchases by PDPs when their clients are in the reinsurance range dramatically reduces their incentive to fight for lower drug prices. The challenge of this "triple whammy" is the focus of this essay.

As the data referenced earlier highlights, much of the problem of excessive pricing lies in the Part D reinsurance region. That is where insurance plans and enrollees are heavily subsidized, paying, respectively, 15 percent and five percent of the cost. Neither party has a strong incentive to combat market power. Under those circumstances, traditional market forces cannot be expected to be effective. Price discipline is lost. That is the situation for high-cost drugs that are relatively unique, such as the many recently introduced biologic products. Recent evidence shows that specialty drugs like biologics are making up an increasing share of new products. As noted, a substantial portion of the growth in total pharmaceutical spending from 2014 to 2015 was due to the launch of new drugs (IMS Institute, 2016). Specialty drugs accounted for 75 percent of the new drugs.[6]

Formulary design incentives: Given that plans carry only 15 percent of the cost risk in the reinsurance region, malincentives flourish.[7] If a plan can negotiate rebates in the context of high cost drugs that result in beneficiaries making claims on the reinsurance benefit, then the combination of a high price, a sizable rebate, rules about allocation of rebate dollars, and low risk sharing in the reinsurance scheme can create an incentive for a plan to provide high cost drugs a favorable placement on formularies. So it is entirely possible that if a plan is deciding between a lower priced drug with no rebates and a higher priced drug, it may opt for the latter. The combination of the rebate, the reinsurance payment, and other allocation adjustments may mean that the prescription drug plan faces lower costs from the higher price drug. The big step in Medicare's subsidy to insurance plan purchases, going from zero percent to 80 percent once an insured reaches $4,950 in drug expenditures, significantly distorts incentives to plans. Not surprisingly, there have been proposals to increase the risk sharing by plans in the reinsurance region.[8] Even providing subsidies for lower expenditures in exchange for reduced subsidies to higher ones would be a move in the right direction. This type of policy change – basically a twisting of the subsidy schedule – is necessary to promote competition and to complement the other policies we discuss below.

Market Power and Nearly Complete Insurance: We term the combination of a monopoly with insurance-subsidized consumption by the acronym MISC. MISCs do more than produce inefficient outcomes: they create severe political tensions. Insurers try to control demand by keeping drugs off their subsidy lists. Patients who need specific drugs push to have them covered. Drug companies that pursue monopoly pricing – prices that can be exceedingly high given the combination of insurance arrangements and eager consumers – suffer severe pressures from the press, the public, insurers and the government. Decisions on drug development and drug pricing drift far from what a cost-effectiveness analysis would prescribe.

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6   Express Scripts reports that 28 percent of spending in Medicare prescription drug plans stem from specialty drugs.
7   In an effort to reduce the risks and to promote participation in the Part D program the government decided to bear most of the risks. The participation rates by plans remain high 10 years later and so it is likely safe to alter the risk sharing to address the inefficient incentives discussed below.
8   For a more complete discussion of this incentive issue see MedPac (2017) pages 404-405.

Manufacturers must guess the tradeoff between extra profits from high prices and the potential bad publicity and political pressures that they produce.

This constellation of forces produces outcomes that depart from valuations predicted for competitive markets. Drugs with equivalent health impacts and production costs can sell at vastly different prices. From the manufacturers' standpoints, uncertainty reigns, discouraging the production of valuable new drugs. In fact, manufacturers appear to respond to demand shocks, such as the growth in the size of markets, by bringing to market products that represent modest changes in treatment capabilities as much as major improvements in the ability to treat disease (Dranove, Garthwaite, Hermosilla, 2015). Thus in a MISC world for pharmaceuticals, pricing gets almost unmoored from the value of the drugs produced.

The combination of monopoly and heavily subsidized insurance for both the insured and plans produces known distortions. In the pharmaceutical area, temporary monopoly power is granted by the patent system and also by the FDA's establishment of periods of market exclusivity. The patent system in general is aimed at producing economic profits in order to spur innovation. However, the design of the patent system is applied to the entire innovation economy and does not take account of special circumstances that appear in the pharmaceutical context, most importantly generous insurance arrangements.

## Figure 1: Market power and insurance
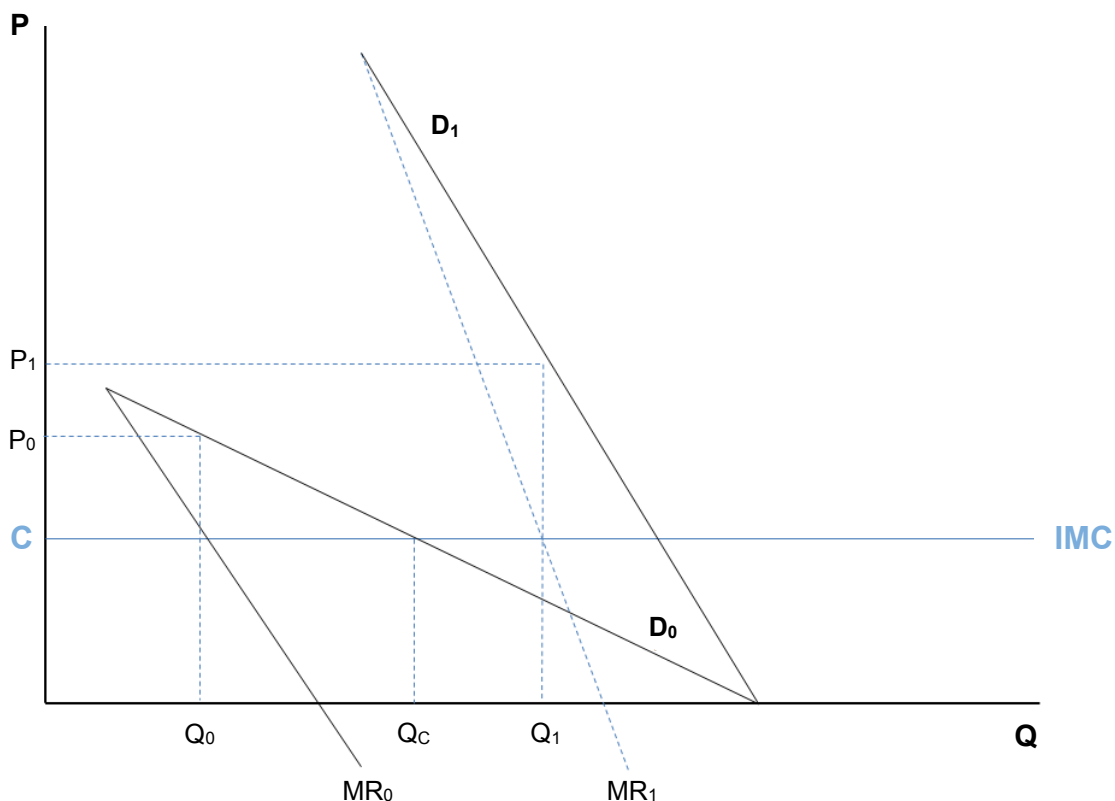


To see the impact of imposing nearly complete insurance in the context where a seller has market power – as is conveyed, for example, by a patent system – consider Figure 1. It displays the standard profit-maximizing monopolist's output and pricing decisions for drugs first where there is no insurance. The demand function is reflected by $D_0$, the marginal revenue schedule by $MR_0$ and the constant marginal cost

curve is the horizontal line C MC.[9] The profit-maximizing price and quantity under these circumstances are, respectively, $P_0$ and $Q_0$. Now consider the introduction of nearly complete insurance for consumers. Insurance serves to insulate consumers from the cost of care. This magnifies demand and makes it much less responsive to price. This is illustrated on Figure 1 through the insured demand function represented as the curve $D_1$. The corresponding marginal revenue curve is $MR_1$ and the marginal cost remains as before. The graph shows substantially higher prices and sales under the MISC circumstances. If the copay is a mere five percent, the demand curve will be 20 times steeper than it would be without insurance. Berndt and Newhouse (2010) show that one likely equilibrium in a MISC environment oocurs when the price difference between the insured and the uninsured case is $P_1 = P_0/s$, where s is the coinsurance rate. In the case of the reinsurance benefits s = 0.05, and so the difference is $20 \times P_0$.

In considering the welfare implications of the situation illustrated in Figure 1, it is important to recognize that the patent system absent insurance serves to restrict quantity to the level denoted by $Q_0$. This reduces welfare in the short run as dynamic efficiency, in the form of increased innovation, is improved. The uninsured competitive result would imply an equilibrium quantity $Q_c$. Therefore, the presence of insurance with market power stemming from patents offers a correction to the restricted supply of drugs that would result. Figure 1 highlights the likely "over correction" shown as $Q_1 - Q_c$. Therefore we identify three sets of potential net welfare losses: excessive prices and burdens on public and private budgets, distorted incentives on the types of products to bring to market, and overuse of high cost drugs.[10]

There is a second-best approach to the vast increase in price and purchases that would result. The health plan itself, seeking to save on costs, could exclude a drug from its formulary, or find a variety of mechanisms to make it hard to secure. After all, the plan will ordinarily be paying for the drugs. There are three impediments to this "solution." First, the government restricts the tools that can be employed by plans to limit utilization of drugs. For example, in the case of psychotropic and HIV medications, protected classes have been identified to prevent plans from taking such actions. In the protected classes, prescription drug plans are required to list and cover all drugs in the therapeutic class. Plans are also required to list at least two drugs on their formularies for each of the non-protected therapeutic classes. Second, plans may suffer significant pushback from their enrollees, including a substantial loss of enrollment, if they do not cover key drugs. Third, once patients are in the reinsurance region, the plan gets an 80 percent subsidy from Medicare and thus covers only 15 percent of the additional cost of a prescription (recall enrollees are responsible for the other five percent). Thus, if a plan sponsor is concerned with political pushback, enrollee pushback, or merely attracting enrollees, it has just a modest incentive to take actions to reduce access to drugs that are mostly used by individuals in the reinsurance region. This third factor helps explain why so much of the recent problem has occurred with drugs being consumed in the reinsurance region. Individuals are relatively unconcerned with their costs. The individuals' pharmaceutical plans are also relatively unconcerned with their costs, but vitally concerned with the demand for their plan, hence the premium they can charge.

Distorted Incentives for the Pharmaceutical Plan: So as to focus on the incentives for the pharmaceutical plan, we leave aside at the outset moral hazard on the part of the insured. Take an extreme case where individuals stand behind a veil of ignorance and know neither the illnesses they will confront nor the drugs

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9    Marginal costs have typically been assumed to be constant in the literature on drug pricing.
10    These observations are consistent with concerns about inefficiently high R&D discussed by Garber, Jones and Romer (2006).

they will need. Moreover, assume that they are effective expected utility maximizers. Simplify also and assume that the pharmaceutical plan has the power to determine what drugs are on its formulary, what copayments and coinsurance it will charge depending on total expenses and the drug purchased, and what premiums it will charge. A rational plan will compete by choosing effectively on each of these dimensions. The fact that Medicare picks up 80 percent of drug cost in the reinsurance range will significantly distort the optimal offering for a plan. Basically, when there are goods that you can provide for 15 cents on the dollar, whereas other goods cost you dollar per dollar, and you will be offering a portfolio of goods, you should make the goods that are cheap to you cheap to your customers as means to attract them.

Accordingly, drug plans, following normal competitive instincts, should be generous in covering drugs that are disproportionately purchased in the reinsurance region. Assuming this to be the case, quite contrary to deterring the use of the very high cost drugs that move patients to the reinsurance region, plans may even foster access to such drugs.

These dynamics suggest that a company producing a drug that is relatively unique and thereby has few if any close competitors, and that treats a significant medical condition, will have a strong incentive to price that drug so that it is more likely to fall under the reinsurance benefit. Analyses of the composition of the reinsurance benefit support this characterization of the prevalence of MISCs in the reinsurance benefit region.

Static versus Dynamic Efficiency: The policy debate on drug pricing has centered on questions of static versus dynamic efficiency—that is, how the trade-off should be made between offering consumers low prices for drugs today against the potential benefits that flow from robust innovation tomorrow. This problem is of particular concern to the United States, as it is by far the major producer of new pharmaceuticals in the world. Nevertheless, even in the United States, there is now broad recognition across the political spectrum and within the health care marketplace that exorbitant drug pricing, particularly the pricing of new drugs, has become a significant policy issue.

The evidence on the relationship between profitability and innovation is clear: expected profitability is positively associated with higher spending on research and development (R&D) and the number of new drugs marketed, as measured by the number of new molecular entities. Classic studies by Scherer (1982, 2001) and more recent work by the Congressional Budget Office (2006), Acemoglou and Linn (2004), Dubois et al (2014) and Yin (2008) establish that relationship empirically. Recent evidence also shows that the effect of profitability on the supply of new drugs diminishes as profitability grows (Dubois et al, 2014).

The empirical literature offers only limited insights about the resulting welfare improvements stemming from the increased supply of new drugs. That is because it measures innovation as a count of new drugs independent of their contributions to improved health and well-being. The work of Dranove and colleagues (2015) focuses on indicators of the potential changes in welfare that arise as new drugs are brought to market due to increases in expected profitability. Based on the empirical analysis of the demand shock created by the implementation of Part D, they find much of the increase in inventive activity occurred in areas where there were existing related treatments. They also report little increase in the number of products designated by the FDA as "novel." While these indicators are crude, they led the authors to conclude that there were likely only modest gains in welfare stemming from the substantial upward demand

shock produced by Medicare Part D.

Together these findings from the literature suggest that focusing attention in areas where the price distortions and economic profits are largest may be those where careful intervention may be able to yield significant allocative efficiency gains at the expense of few dynamic efficiency losses.

Before proceeding, we should make clear that the key question is not whether the current patent system is net beneficial for pharmaceuticals, but rather, whether adjustments to reimbursement arrangements might yield equal benefits from drug innovation with much lower efficiency costs due to malincentives. As we make clear below, we are confident that such beneficial adjustments are possible.

In the remainder of this paper, we focus on offering a framework for a temporary negotiated value-based pricing system for drugs in the MISC category.

## III. MEDICARE AND MISCs

### A. Elements of the policy problem

Many high-priced drugs have few, if any, close substitutes, at least for a number of years after they come on the market. New drugs that treat Hepatitis C, cancers, and inflammatory conditions account for high levels of spending within the reinsurance benefit and many of the leading products in those classes that meet the definition of high priced drugs face little competition.[11] Examples include Harvoni, Gleevec, Humira, Embrel, and Revlimid. Medicare, in many cases, is a large purchaser of such unique products. For example, in the Hepatitis C medicine category Medicare Part D accounts for 50 percent of all sales (IMS, 2016). Likewise, Medicare accounted for about 68 percent of Revlimid (a drug that treats blood cancer) sales in 2015.[12] The implication is that there is potential market power on both sides of the market for a number of drugs paid for under the reinsurance benefit.

Structurally, this superficially resembles a bilateral monopoly problem with a set of other key players that affect the demand for the end product but are substantially insulated from the price of the drugs. They include: doctors, who pay nothing; patients, who pay five percent; and plans, which pay 15 percent in the reinsurance range. Though this may be seem similar to a bilateral monopoly problem, it does not behave like the typical bilateral monopoly problem. That is because Medicare does not take advantage of its market power position. There are two reasons for this. The first and simplest reason is that Medicare is prohibited from bargaining with prescription drug manufacturers. Moreover, absent new legislation, it can't duck out of its 80 percent subsidy of drugs purchased in the reinsurance range. This subsidy reinforces the returns to the drug manufacturers' market power.

The second major difference between the drug market under Medicare Part D and the typical bilateral monopoly is that there are prescription drug plans standing in the middle. In theory, prescription drug plans would compete with each other to secure lower prices from manufacturers and thus be able to offer lower

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11    The competitive dynamics differ somewhat between small molecule and biological products. In the case of small molecule drugs the Hatch-Waxman Act provides a well-developed pathway for generic drug competition. The case for biologicals is quite different and it will be some time before we understand how biosimilars will affect the contours of competition.

12    This may be an underestimate. We used payments for Revlimid in the reinsurance benefit of Part D and divided that by the total sales reported by Celgene in 2015.

prices to health plans, health insurers, or other payers. The market is dominated by three large PBMs. Clearly, they buy sufficient quantities to have potential as a countervailing force to the pharmaceutical manufacturers and to thereby hold down drug prices. Unfortunately, such potential countervailing power is not used effectively. As mentioned earlier, the incentives facing prescription drug plans in connection to drugs purchased under reinsurance benefit notably reduce their incentives to bargain.

The PBMs' own high levels of market power, and hence profitability, also diminishes their bargaining power against their suppliers. To see this, consider two extreme situations. In situation A, there are many PBMs, which compete actively against each other. Their profit rate on sales is a modest few percent, just enough to make it worthwhile to be in business. In situation B, a few PBMs essentially control the industry. This concentration enables them to reap substantial profits on sales, say 10 percent or 15 percent as an example. Given A, a one percent cost reduction would increase profits dramatically, by 25 percent if they were originally making three percent. In B, assuming no other changes, it would increase profits by much less. Situation B is much closer to reality. Due to the lack of transparency in the pharmaceutical market generally, and with the Part D market in particular, it is not possible to know the profit rates of the PBMs, but it is generally believed that they are doing quite well.

Despite these factors, someone might inquire: But why should the PBMs not make conscientious efforts to hold down the prices that they pay any way? Cheaper prices should enable them to charge less for their services, hence secure more clients. The answer is that there is a powerful force on the other side: heavily-subsidized patients who push hard to get drugs, particularly those possessing unique capabilities. And, as we have just seen, given their heavy subsidy in the reinsurance range, PBMs cannot be expected to do what pharmaceutical plans would normally do: strongly discourage the use of high-priced drugs, and fight manufacturers to reduce prices of those drugs.

A defining characteristic of the prescription drug market is that bringing new drugs to market entails high costs and high risks.[13] The implication is that the development of new treatments for illnesses that threaten the health of the public represent a central measure of success of the industry (Scott Morton and Kyle, 2012). Innovations are hard to procure and almost always require healthy incentives to be in place. There are three fundamental problems with MISCs: 1) as Figure 1 demonstrates, they may produce economic rents well in excess of those that are necessary to generate innovation incentives; 2) the pricing strategy that produces these rents generates inefficiencies through the financing of subsidies for Part D, and; 3) The rents created are haphazard, and little connected to the benefits that the drugs provide. Thus, the provision of economic rents is cost-ineffective. This last observation has motivated discussion of value-based pricing, a subject that we take up below.

If the drug market stayed static – that is, if the drugs on the market did not change – these three problems would wither away. Patents would expire, generics would enter the market place, and competition would move prices back towards marginal cost. But merely waiting to have the problem wither away is not an option. Technological progress in pharmaceuticals is an urgent priority to help conquer disease. And given rapid advances in most areas of medical understanding, great leaps forward may be available. Finally, new

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13  While there is enormous debate about exactly how high the costs of bring new drugs to market, there is no evidence to suggest that on average the costs are do not involve hundreds of millions of dollars.

scourges, such as the Zika virus, are appearing, and could be devastating if there were no new drug and vaccine development.

Not surprisingly, given the pace of medical advances, recent years have seen a reinvigoration of new effective drugs being launched. Figure 2 shows the upward trend and recent acceleration in the number of new active substances introduced into the marketplace in the years 2005-2015. (Interestingly, in the prior decade, the trend was flat and the number of truly innovative products was low.) This means that any prescription drug payment system must be conscious not to stifle the incentives for innovation. This is especially the case for new, high cost drugs that have recently produced some important health gains.

## Figure 2: Trend in FDA drug approvals



Average approvals from 2005 to 2013

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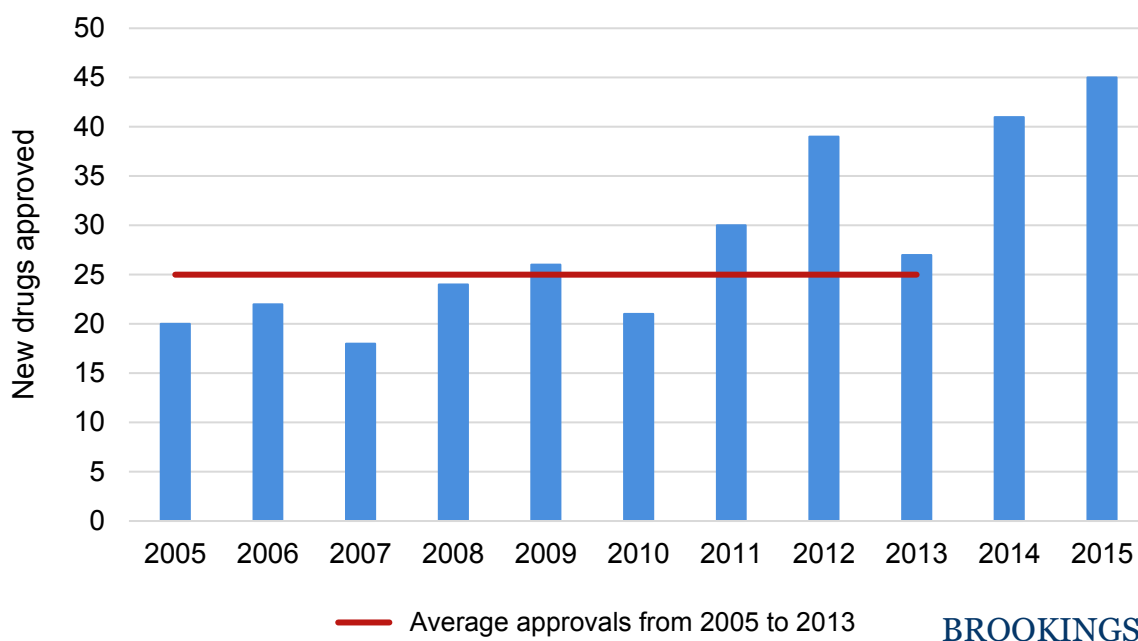
Finally, problem 3 addresses the often weak connection between drug prices and "health value." In some cases, high-priced drugs offer important clinical gains (e.g., Solvaldi), but in many other cases, the improvements are marginal. The heavy subsidies to the consumer and, over some range, the Part D plans themselves, feeds back to distort the incentives of drug companies. They have almost as much incentive to develop a highly expensive drug that ameliorates a modest impairment, as to develop one that significantly improves a condition that produces much disability or mortality. The person suffering from the condition that produces the modest impairment, if operating in the reinsurance range, may be quite willing to pay five percent of the cost of a high-priced drug.

However, from the standpoint of society, it would make much better sense to grant much greater profits to the drug improving conditions with high rates of disability and mortality than one reducing modest levels of impairment and discomfort. If this were understood to be the norm, drug companies would focus on bringing drugs to market that offered greater gains in QALYs.

## B. Towards a negotiated value-based pricing system for MISCs

The debate on price negotiations has focused on broad-based negotiations that seemingly would cover all prescription drugs. Metaphorically, it is pursuing community punishment for the crime of excess drug pricing rather than targeting the prime perpetrators, the sellers of high-priced drugs. Our reading of the evidence is that within Part D, in most cases the market functions reasonably well. Sometimes, straightforward competition among similar products works in its normally effective fashion. Where MISCs are not important parts of drug sales, Part D plans can steer beneficiaries between competing drugs that are close substitutes and favorable pricing can be realized through the negotiation of rebates (CBO, 2014). But with MISCs, market function breaks down. MISCs represent the confluence of unique products and extensive insurance to both patients and plans over the reinsurance range.

### Table 1: High cost drugs and reinsurance

| Drug | 2015 spending (millions of $) | PUPY spending 2015 |
|---|---|---|
| *Atripla* | $589 | $20,959 |
| *Copaxone* | $1,382 | $50,048 |
| *Enbrel* | $1,385 | $27,116 |
| *Gleevec* | $1,232 | $81,151 |
| *HP Acthar* | $504 | $162,370 |
| *Harvoni* | $7,030 | $92,846 |
| *Humira* | $1,662 | $29,277 |
| *Imbruvica* | $592 | $57,653 |
| *Revlimid* | $2,077 | $68,217 |
| *Solvadi* | $1,318 | $89,217 |
| *Trifedera* | $875 | $46,578 |
| *Xtandi* | $791 | $46,751 |

*Source: CMS Medicare Drug Spending Dashboard (2016).*     BROOKINGS

Our approach focuses on creating a payment framework for negotiation that makes MISCs the target of policy. Only a modest number of drugs meet the characteristics of a MISC. They are high-cost drugs and they account for a significant portion of spending for Part D, and a higher proportion of the recent increases in spending. Using CMS data for 2015, we identify a short list of drugs that are high cost (e.g. $1,000 per month), incur high levels of Part D program spending (over $500 million), and have few close substitutes. Table 1 offers examples of such drugs. The implication is that a policy to control drug pricing that was triggered by MISC features would have the potential to produce significant savings, yet be readily administered. Moreover, by restricting itself to high-priced drugs over a limited time span, the policy might enjoy more political support.

The fact that the number of products meeting these conditions is small suggests that the bargaining process could be pragmatically applied within the Part D program. Given the current political climate, any effort to control a drug price would have to come through a bargaining process, not just through a dictum

on high. Thus, the bargaining arrangements would have to be designed to ensure that manufacturers participated in the bargaining process. In addition, the policy would have to recognize the trade-off between static and dynamic efficiency goals.

Ideally, the payment framework would help to signal the effectiveness of a drug. Current payment arrangements rendered such signals very weak in many cases.

Our proposal borrows from the literature on paying prizes for innovation. In this case, we seek to design a negotiated payment system that would build economic profit into the price of the final product if it substantially improved health outcomes for its users. This means constraining government negotiators to prices that provide for economic profits when significantly improved health outcomes are realized. Thus, the aforementioned drug that would have important impacts on disability and mortality would receive a much higher price than the one addressing moderate levels of impairment and discomfort. Often, information on benefits will be somewhat hazy when a MISC gets included on plan formularies. Updated information can be used to alter a payment arrangement. Thus, data on health impacts would be collected and the payouts revisited periodically. Finally, the payment arrangement would be terminated when meaningful competition came into being. To promote this rapid return to competitive behavior would require altering the incentives in the reinsurance benefit of Part D. Following the analysis of MedPac (2017) and others, that would entail decreasing the risk borne by the government and increasing the financial risk held by the prescription drug plans. In that way, as soon as there was meaningful competition among prescription drug products, the plans would have a strong incentive to negotiate advantageous prices. This also implies that the competitive conditions in the market would be monitored closely.

A key parameter in the payment system and a point of negotiation will be an annual payout made for producing a product that advances the health of the public, and that is sold to Medicare Part D plans at an agreed-upon price.

Critics have often focused on the patent system's downside of encouraging monopoly pricing. And it has long been observed that, if the government paid the patent owner a lump sum in exchange for pricing closer to marginal cost, a substantially more efficient outcome would be achieved. Such schemes have not been implemented because the government, concerned with its own expenditures, has not been willing to pay such lump sums. But Medicare Part D presents a quite different situation. Medicare itself ends up paying for a large proportion of the cost of high-priced drugs. Thus, in theory it should welcome an arrangement where it paid the lump sum, and also saved money on drug pricing.

## C. Elements of a pricing system

Drug products subject to the mandatory negotiated payment system would be identified on three criteria:

    A) To what extent are they unique products with few competitors?
    B) How likely are they to be paid for under the reinsurance benefit?
    C) Do they represent a significant claim on spending by the Part D program?

Drugs that score high on these criteria would be identified for application of the negotiated payment system. As such, they would be treated as if they were a special drug tier that was uniform across all

prescription drug plans. The prescription drug plan's responsibility would be to pay claims and produce data for ongoing assessment of the products in this special tier.

The pricing scheme has two basic goals. First, it would seek to provide incentives for drug manufacturers to produce drugs that create significant value, as measured by QALYs produced. Moreover, the better a drug performs, the more highly it would be rewarded. Second, it would seek to severely trim the distortions to budgets associated with drugs that are priced multiples above even their uninsured monopoly price. Yet, given the need for continuing innovation in the pharmaceutical sphere, this second goal would have to be pursued subject to a constraint; the pharmaceutical manufacturers would have to be adequately compensated to undertake the expensive and risky effort to bring new drugs to market.

We take up the second goal first. We need propose no alchemy in transmuting deadweight loss into Pareto superior outcomes for patients, the government and drug companies. This is a typical situation with a high fixed cost and low marginal cost industry. In theory, the government could give the drug companies a lump-sum payment equal or somewhat greater than the profits they would otherwise earn in exchange for a price equal to marginal cost. Matters will not be quite so neat, but the exchange of a fixed payment for moderate pricing is a key component of the proposal made below. This type of two-part pricing solution has often been proposed for situations where patents create monopolies. Rarely are they implemented, because governments rarely want to pony up the lump-sum payments, despite the fact that social welfare would be improved. (Governments do not appear to value consumer surplus dollars nearly as highly as government expenditure dollars; that is, they do not follow cost-benefit prescriptions.) This is especially the case when the volume of treatments purchased is variable and outside the control of the purchaser.

However, Medicare Part D is quite different, since the government is already bearing a substantial cost from high drug prices, partly because of its subsidy of premiums and partly because it pays 80 percent of costs for enrollees in the reinsurance range. Thus, if it could get prices down, it would be a major direct beneficiary. To implement such a two-part pricing scheme would be a major step. For now, we just mention it as a possibility and note that Australia has long used such a scheme in pricing pharmaceuticals covered by its government plan.[14] The pricing arrangement proposed here would be more modest in scope. Its prime focus would be on incorporating QALYs into pricing. Future work will show how the two pricing features could be readily combined.

Thus we return to the first goal, providing incentives to bring high-value drugs to market. We propose an arrangement that gives greater payments to drug companies that produce higher-value drugs. Thus, company X and company Y each introduce a drug that cost $1 billion to create, but company X's drug provides far more QALYs per unit consumed than does Y's. Both companies would receive a per unit price, but that for X would be greater than that for Y if its greater performance was realized in practice. The objective in offering such higher payments to the more beneficial drug is to feed back to drug companies' decisions from the outset about which drugs to develop. The high health impact drug would, other factors equal, yield greater rewards to the drug company than would the drug addressing conditions with lesser impairments.

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14   See Johnston and Zeckhauser (2009).

The mechanism that we will employ would make two components to the yearly payment: a common per unit payment, $\alpha C$, and a bonus payment, b, that would also be distributed per unit retrospectively. Thus, $\alpha$ would be calibrated at some percentage less than one of the development cost, say 75 percent. The total bonus would be an increasing amount depending on the QALYs created. Thus, total revenues would attend to: development costs; number of people using the drug, n; and the average QALY gain each person received, q. The standards for identifying "good performances" and the bonus that would accompany achieving desired performance levels would be a key focus of negotiation between government and industry.

The yearly "per unit" pricing framework can be implemented as a simple contract following the model of McAfee and McMillan (1989):

$$P_t = P_{0t} + b_t(q)$$

Where t indexes time in years; P is the full per unit price; $P_0$ is the default or base price that would be paid if no agreement could be reached on the other parameters or if the desired outcomes were not achieved; q is the quality or outcome schedule that would trigger various bonus payments; and b is the per unit bonus payment. The total revenues sum across people using the drug (n) and over time. Therefore, total revenues for a MISC would be:

$$\Sigma_t\, n_t\, [P_{0t} + b_t(q)] = \text{Revenue over the time interval T}$$

The key feature of the base price is that it must cover some substantial portion of the expected costs of product development. The base price must be set high enough so that it covers most costs of development but low enough so that it does not generate economic profits to firms producing products that do not result in desired levels of health outcomes and low enough so that firms have an incentive to engage in negotiations over q and b.The base price therefore serves as a commitment device.

There are a number of approaches that can be used to set $P_0$. One such approach is commonly used in Europe. That is, new drugs prices are guided by referencing prices in other countries or in similar drugs that have been launched either in the home country or in similarly situated nations. This method has the advantage of relying on relatively available information. This approach carries a number of difficulties. If the Medicare program in the context of the size of the U.S. market adopted that type of approach, it would distort incentives about launch locations and timing. Moreover, if the U.S. were the original launch site, then there would be little guidance for the prices of MISCs.

A second approach would rely on an ad hoc rate setting process. Such a system would largely follow processes such as those used by Medicare in setting most other health care prices. That approach runs the risk of creating more uncertainty about prices and not being guided by either bargaining considerations or the costs of developing different kinds of drugs. This would serve to attenuate innovation incentives.

The third approach that we favor would set $P_0 = \alpha C$, where C is the expected development costs for a drug in a particular therapeutic class and $\alpha$ is the percentage of costs (development costs) that would be covered by the base payment. Under this approach to setting the base price, the government would decide first how to measure C and then at what level to set $\alpha$. In general, in order to avoid moral hazard in

development, the government would define C with respect to the average cost of developing a type of drug (e.g., human growth hormones). That would be based on evidence from the domestic and international industry. By structuring this with respect to development costs, it recognizes differences in the effort needed to develop different types of drugs. Because the base price is set out on a per unit basis, an estimate of expected volume would be made and the base price calculated on a unit basis. The volume would be revisited after launch and the base price possibly adjusted. The share of costs would be selected so that in expectation firms would be moderately below breakeven without taking into account outcome-based bonuses.

There are other potential commitment parameters that might be used, such as a coinsurance related to price proposals (e.g., imposing higher copayments on patients for higher price offers) and, in extreme cases, exclusion from the formulary. Targeting copayments would penalize beneficiaries and would be undesirable given the relatively low incomes of many Medicare beneficiaries. However, if this targeting system led manufacturers to charge lower prices, beneficiaries might ultimately face lower copayments. It is better to pay 10 percent of $5,000 than five percent of $12,000. In a highly sophisticated world, copayment amounts could be and would be scaled to income. The role of copayments, after all, is primarily to control consumption, not to offload costs onto the insured. Thus, moving a person with a $25,000 annual income from a $10 to a $30 copayment for a drug might be as effective as moving a $75,000 income person from a $50 copayment to a $150 copayment. The subject of income-based copayments is beyond the scope of this essay.

The extreme option of exclusion from the formulary is politically fraught and, again, harms beneficiaries.

Bargaining would be bounded by a low default price of $P_0$ and a requirement that ensures that innovation incentives are in place. The government would be constrained to pay a bonus so that P would result in economic profits to firms introducing products that meet at least some minimal level of desired performance. The bargaining would focus on the criteria for obtaining bonus payments and the size of those payments. The outcome measure schedule or target would be negotiated based on evidence from clinical studies, experiences in other countries, and the experience with related products. Because companies have private information about outcomes and population targets, there are likely gains from bargaining. The government would bring its own research and data gathering to the negotiation. Required government access to some elements of company data might also be required to enter into negotiations. The outcomes would be aligned with QALY measures so that the targets could be assessed with respect to cost-effectiveness or outcome studies across other disease areas. The negotiated quality schedule q would be put into place and reconciled within a defined time period (e.g., yearly) and bonus payments then made.

The bargaining mechanics might be considered in the context of an example. Consider a drug Z that addressed a type of cancer. The present discounted cost of developing the drug (including the time value of money) is $1.5 billion. Assume that 15,000 people would be treated by the drug. The price per unit proposed by the manufacturer is $265. Each person is typically administered 310 doses per year for this condition. Thus, the person per year cost proposed would be $82,150. We expect that, after 5 years, two therapeutic competitor drugs will enter the market. Over the first five years on the market, the present discounted revenues implied by the proposed price would be nearly $4.3 billion. If the base or default price

were set at 75 percent of the cost of development, it would be $1.12 billion. Assume further that, over the first fiive years, 23 million doses would be sold and then 12 million in the next five and exclusivity would expire after a total of 10 years. This implies a default price of $32 per dose. The government and the manufacturer would then negotiate over the outcome standard that would be the basis for bonus payments and the level of those payments. For simplicity, assume there is an agreed upon threshold based on the percentage of positive responses to the therapy. Let's now assume that the bargaining fell in between the smallest and largest rebates in Medicare, perhaps 27 percent; this would imply a bonus of about $161 per unit if the outcome target were met and a transaction price of $193. The implied payout over five years would be $3.14 billion, 209 percent above the discounted full cost of drug development that takes account of both failure rates and the time value of money. Thus, a significant economic profit would still result (ignoring the second five years on patent with therapeutic competitors). This represents notable savings to Medicare in an arrangement where profitability is based on therapeutic impact.

## IV. CONCLUDING REMARKS

In this paper, we have explored a specific type of market and regulatory failure: the design of the reinsurance benefit in Part D of Medicare. We focus our attention on this institution because we believe that when the reinsurance design is in force in conjunction with the launch of a unique high cost prescription drug, there are potentially substantial departures from cost-effective outcomes in treatment. Moreover, the design of the Part D reinsurance benefit drives a wedge between the market valuations and the social benefits of a drug. Thus, the budget and welfare losses are potentially large. Moreover, we show that the prices charged under these arrangements are likely multiples of the uninsured patent monopoly price. These observations suggest that there is the potential for altered pricing at little risk to the desired level and composition of R&D efforts for pharmaceuticals.

The policy direction we propose consists of two elements. First is a suggestion that follows on a MedPac recommendation that the government reduce its share of risk bearing for the Part D reinsurance benefit and that prescription drugs plans be given a substantial increase in their share of the financial risk for the reinsurance benefit. Second, we offer a framework that would guide the structure of price negotiations. It is grounded in the economics of two part tariffs, research on innovation prizes and performance based contracts. The framework calls for identifying high cost drugs, with significant market power that would largely be reimbursed under the reinsurance benefit of Part D. These drugs would be accepted for coverage, but there would be mandatory participation in Medicare and the negotiation would focus on two main elements of the two part tariff pricing framework. Specifically, the criteria for obtaining different level of bonus payments and the size of the bonus payments would be negotiable. Failure to either successfully complete negotiations or to reach acceptable levels of performance would result in a default price that implied no economic profit. The feature rewards successful negotiation. The government would be constrained to offer a potential price schedule that resulted in supranormal prices (economic profits) if desired health outcomes were achieved. Finally, the negotiated price structure would persist only until competitive conditions were established in a drug class; afterwards, the market price would replace the negotiated price.

MISCs represent a tiny fraction of the pharmaceuticals on the market. Yet, due to severe mal-incentives and the responses to them, they represent a major portion of policy concern about pharmaceutical pricing. Extremely high prices for drugs create even greater concern when those drugs yield only moderate benefits. Market conditions and political forces appear ripe for significant new approaches to Medicare Part D pricing for MISCs.

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