Excess Prices for Drugs in Medicare: Diagnosis and Prescription

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Abstract

Excess prices for drugs in the U.S. is a persistently vexing policy problem. While there is agreement among most policy analysts that supra competitive prices are necessary to promote innovation; significant disagreements arise over how much pricing discretion prescription drug manufacturers should be permitted, and what portion of the sum of producer plus consumer surplus in the prescription drug market should be claimed by manufacturers relative to consumers and other payers.

This analysis first diagnoses the causes of the high costs in Medicare Part D. It then makes use of that diagnosis to provide a prescription for policy measures that have the potential to simultaneously reduce these costs without significantly sacrificing incentives to bring valuable new drugs to market. This paper focuses on an extremely costly component of the Medicare Part D program, the region of coverage that kicks in once a consumer has spent $4,950 on drugs in a calendar year (roughly $8,100 in total drug spending). At that point there are high levels of insurance for the consumer and reinsurance for the prescription drug plan. Consumers pay 5% of costs; plans pay 15% and the government 80%. That design generates serious inefficiencies. The significant subsidies to plans in the reinsurance region combined with the launch of unique high cost prescription drugs could be expected to lead to and has led to substantial departures from cost-effective outcomes in treatments delivered. As would be expected, spending has been growing rapidly in this so called "reinsurance region". What is less well known is that a small number of very high-cost drugs account for almost all of this growth.

Following this diagnosis, we present two, possibly complementary, prescriptions for reducing these inefficiencies. The first follows on the MedPac recommendation that the government reduce its share of risk bearing for the Part D reinsurance benefit. The second focuses on curbing price inefficiencies for those very high-cost drugs. That prescription has two components: eliminating monopolistic overpricing, and promoting the quality of drugs brought to market. It is grounded in the economics of two part tariffs, research on innovation prizes, performance-based contracts, and draws on the mechanism design literature. Such pricing could save substantially on costs without curtailing the most important R&D efforts for pharmaceuticals.

Market conditions and political forces appear ripe for significant new approaches to pricing high cost drugs in Medicare Part D. We believe that the prescription discussion here, which draws on this paper's diagnosis, identifies some promising approaches to a vexing problem.

I. Introduction

Drug pricing in the U.S. is a persistently vexing policy problem. High drug prices stress consumers, payers, employers and "budgeteers". At the same time the public demands new and better treatments, and the scientific advances that make such treatments possible.

The pharmaceutical industry insists, with merit, that delivering new improved treatments, and in some cases cures, entails high costs and risks, and that without adequate compensation, promising new drug products will not be forthcoming. Thus, there is substantial agreement across economic analyses of the prescription drug industry on a central issue: Supra competitive 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 the prescription drug business, where large research, development and human testing expenditures produce average costs that vastly exceed low marginal costs. Significant disagreements arise, however, over how much pricing discretion prescription drug manufacturers should be permitted, and what portion of the sum of producer plus consumer surplus in the prescription drug market should be claimed by manufacturers versus those who pay their prices: consumers, prescription drug plans, employers, and government.

Medicare, through its Part D optional coverage program, pays a substantial portion of the national drug bill. In 2015 the Medicare program spent $80.1 billion on the Part D benefit. Enrollees paid for 33% of that total out of pocket. The enrollee out of pocket outlays were $11.5 billion for the unsubsidized part of the premium and $15.1 billion in cost sharing for the purchase of prescription drugs (MedPac, 2017). This analysis first diagnoses the causes of the high costs in Medicare Part D. It then makes use of that diagnosis to provide a prescription for policy measures that have the potential to simultaneously reduce these costs without significantly sacrificing incentives to bring valuable new drugs to market.

The structural diagnosis focuses on an extremely costly component of the Medicare Part D program the region of coverage that kicks in once a consumer has spent $4,950 on

drugs in a calendar year (implying roughly $8,100 in total drug spending). At that point there are high levels of insurance for the consumer and reinsurance for the prescription drug plan. Consumers pay 5% of costs; plans pay 15%. Government pays the remaining 80%. In this high-expenditure region, market power, initially created by patents and now reinforced by extensive insurance, leads to extremely high drug prices. As would be expected, spending has been growing rapidly in this so called "reinsurance region", as is well known. What is less well known is that a small number of high-cost drugs account for almost all of this growth.

Insurance and reinsurance dampen the incentives to economize by either consumers or Part D prescription drug plans. Compounding the problem, the federal government is precluded by law from negotiating with drug companies. Thus, the usual restraints on prices hardly restrain. Given the severe distortions that arise in this reinsurance region, it is a place where policy innovations have the potential to significantly improve social welfare.

We first analyze current incentives in the reinsurance region and the responses by consumers and pharmaceutical plans that they induce. We then examine the resulting patterns of drug purchases and government expenditures within this region. We conclude by identifying a framework for negotiating prices that simultaneously preserves incentives for high-value innovation and allows the government to limit the extent of supra competitive prices in an area where market forces play little role.

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.

II. Diagnosis of the Problem

Medicare Part D, Structure and Consequences: The Medicare Part D program provides insurance coverage for the costs of self-administered outpatient prescription drugs. About 41 million people were enrolled in Part D coverage in 2016. To keep the program affordable, Medicare significantly subsidizes Part D coverage. In 2016, the government directly subsidized nearly 75% of the premiums that would otherwise be required of beneficiaries; beneficiaries covered the other 25% of program costs. The combination of heavy subsidies and extensive insurance to beneficiaries at time of purchase makes effective control of the cost of prescription drugs in the program highly challenging, despite mechanisms that seek to control those costs.

The Part D program relies on three components to promote the cost-effective delivery of its prescription drug coverage. First, it relies on competing private plans to hold down the prices of their inputs (drugs), insurer profits, and administrative costs. Prescription Drug Plans (PDPs) submit bids that determine the premiums they charge. Enrollees must pay a subsidized base premium ($35.63 in 2017) plus the difference between a plan's bid and the nationwide average premium. (The differential results in a reduced premium if they select a plan with a below average premium bid or an increased premium if the selected plan has a bid is above the national average.) Those premiums plus the benefit designs, formulary structures, pharmacy network and client services that the plans offer are the basis that enrollees are expected to employ when choosing a plan.

Second, Part D seeks to promote competition among prescription drug products that are offered to the plans. Prescription drug plans capitalize on such competition to obtain favorable prices for the prescription drug products that they buy. In addition, formulary design is the key tool used to foster price competition among drug manufacturers seeking to obtain favorable formulary placement (e.g., so as to offer consumers lesser cost sharing). Drug companies commonly offer rebates to plans for favorable placement on their formularies.

Third, given the difficulties that enrollees would have in choosing among complex and disparate products, and the element of market power that differentiated plans would create, Medicare defines a standardized Part D benefit design. That design sets a minimum actuarial value for prescription drug coverage in Part D. Currently it prescribes a $400 deductible, and 25% coinsurance up to a spending level of $3,700. After that, enrollees enter the so-called donut hole where they pay a substantially higher share of costs until out-of-pocket spending exceeds $4,950 (or $8,071 in total drug costs).[1] Once that limit is reached, enrollees pay 5% coinsurance, with the remaining 95% covered by a combination of the plan and the government.[2] The segment of Part D coverage beyond the $4,950 level is termed the reinsurance benefit. In that range, 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 represents a roughly 74% increase over 2007 spending levels, indicating an annual rate of growth of 7%. The growth in total program spending has been driven almost completely by the rapid growth in the reinsurance region feature of the Part D program. In 2007 the reinsurance component accounted for 25.2% of Part D per enrollee costs, in 2016 the corresponding share had soared to 56.4%. Total Medicare expenditures for reinsurance increased 4.3-fold in less than a decade. This rapid escalation has prompted policy interest in mechanisms to constrain the forces driving these changes.

Diagnosis of the problem should come before prescription. Thus, the first step is assembling the data, and analyzing the sources of this rapid escalation in costs. Both MedPac and the Department of Health and Human Services' Inspector General (OIG) have analyzed a number of the sources of spending increases in the reinsurance segment of the Part D program (OIG, 2017). MedPac has consistently reported on the experience of the reinsurance benefit.

[1] The donut hole is being phased out according to provisions in the Affordable Care Act. Currently in the donut hole for brand name drugs the enrollee pays 40%, the plan pays 10% and manufacturers provide a
[2] The standardized cost sharing is used to define the actuarial standard for each plan but plans have discretion in setting copayments and coinsurance.

Patterns and Causes of Spending: Some salient spending patterns emerge from these data and analyses. 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% of program participants entered the reinsurance segment. In 2015, 3.6 million enrollees or 9.2% of program participants made claims under the reinsurance benefit. Thus the dramatic growth in the share of spending accounted for by the reinsurance benefit did not come from 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 the price and volume of prescription growth. Its analyses show that between 2010 and 2014, 96% of the growth in reinsurance spending came from price growth. That contrasts with the non-reinsurance portion of Part D, where gross drug spending per enrollee per month and the average price for a 30-day prescription actually fell.[3] This shows that the increase in the average price of the drugs utilized by individuals in the reinsurance benefit range dramatically outpaced price increases for drugs consumed outside that range.

What explains the rapid escalation in the average price of a prescription in the reinsurance benefit range? Such price increases can come about for a number of reasons. They include the 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% of the net growth in overall invoice drug spending was due to price increases from existing branded drugs and 42% from the introduction of new products. Yet new products represent only a small fraction of drug prescriptions filled. And within that fraction, a few new products aimed at Hepatitis C drugs and some cancers accounted for the majority of the recent increase in spending in the reinsurance benefit. Their role is reflected in the escalation of the price index for Part D drugs.[4]

[3] See MedPac March 2017 Report to Congress Table 14-14.
[4] We calculated a Fisher price index for all Part D drugs that was anchored on 2007. Through 2014 the annual increase rate had been 12%.

The analysis conducted by the OIG (2017) offers further insights into these developments.[5] The OIG analysis shows a marked increase in spending associated with so-called high-priced drugs. There are a variety of definitions of high-priced drugs currently in use.[6] 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% of reinsurance benefit spending was on high-cost drugs using this definition, double the 32% figure for 2010. [7] Moreover, the percentage of beneficiaries paid under the reinsurance segment that use high cost drug has doubled from 2010 to 2015 (14% to 28**%).**

Several additional factors have been identified as contributing to 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).[8]

In sum, the Part D cost problem is largely a problem generated by high-cost drugs, and high-cost drugs are a problem largely due to the rapid escalation in their prices. What factors have led to that rapid escalation?

Drugs themselves are not the problem. And the heavy subsidy through insurance of consumers' purchases, a source of moral hazard, is not the main problem, since the elasticity of demand for most high-cost drugs is low. (For example, only people with Hepatitis C are interested in taking Solvaldi.) But when drug manufacturers have significant market power (due to lack of close substitutes) and purchases are heavily subsidized by insurance, 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. In addition PDPs have an incentive to place high cost drugs on their formularies because enrollees and their

[5] 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.
[6] CMS defines specialty or high cost drugs as those costing $600 per month or more.
[7] If the CMS definition of high cost drugs were used the 65% estimate would be higher.
[8] EGWPs are Employer Group Waiver Plans that permit an employer to contract with a Medicare Advantage plan to serve their Medicare eligible retirees in a way that coordinates Medicare Advantage with retiree health benefits.

physicians want such new products to be available to them, and Medicare is covering 80% of the cost. Moreover, plans can command higher premiums when they present richer product offerings. 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 as well as enrollees are heavily subsidized, paying respectively only 15% and 5% 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 biologic products, which have only recently been introduced. Recent evidence shows that specialty drugs like biologics now comprise 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% of the new drugs.[9]

Formulary design incentives: Given that plans carry only 15% of the cost risk in the reinsurance region, mal-incentives flourish.[10] If in addition a plan can negotiate rebates for including high-cost drugs on their formularies, as they frequently do, and if including such drugs results in beneficiaries overwhelmingly 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 grant high cost drugs favorable placement on its formulary.[11] So it is entirely possible that if a plan is deciding between a lower priced drug with no rebate and a higher priced drug that offers one, and if the latter will generally be purchased in the reinsurance region, it may opt for the higher priced drug. The combination of the rebate, the

[9] Express Scripts reports that 28% of spending in Medicare prescription drug plans stem from specialty drugs.
[10] 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 remains at a high level 10 years later and so it is likely safe to alter the risk sharing to address the inefficient incentives discussed below.
[11] For example, Medicare rules require plans to allocate a portion of the rebate to reinsurance based on the portion of plan spending above the reinsurance threshold. Even if rebates are generated by drugs that push people over the threshold.

reinsurance payment and other allocation adjustments may mean that the prescription drug plan faces lower costs from the higher priced drug.[12]The big step up in Medicare's subsidy to insurance plans, going from 0% to 80% once an insured reaches $8071 in total drug spending or $4,950 in out of pocket costs, significantly distorts incentives to plans. Not surprisingly, there have been proposals to increase the risk sharing by plans in the reinsurance region.[13] Accepting that affordability concerns require subsidizing the plans, directing subsidies to lower expenditures in exchange for reduced subsidies to higher ones, would notably reduce distortions. This type of policy change – in effect significantly leveling the subsidy schedule -- would complement other policies we discuss below. A more forceful approach would offer a risk adjusted per capita subsidy to plans, with no subsidy for drug purchases; it would reward plans fully for securing lower drug prices.[14]

Market Power and Nearly Complete Insurance, The Role of MISCs: As mentioned, the ballooning costs of Medicare Part D are largely due to high-cost drugs being consumed in the reinsurance region. Indeed, relatively small numbers of exceedingly high-priced drugs play a major role (Table 1 offers examples that are discussed below). Their prices are due to the combination of a **m**onopoly and **i**nsurance-**s**ubsidized **c**onsumption. We denote such drugs by the acronym MISC. MISCs do more than produce inefficient outcomes; they create severe political tensions. If insurers tried to control costs by keeping drugs off their formularies – and we explain below why they might not even try -- patients who need specific drugs, and their supporters, would push extremely hard to have them covered. Drug companies that seek monopoly prices, prices that can be exceedingly high given the combination of extensive insurance and understandably hyper-eager consumers, suffer severe criticisms and pressures from the press, the public, insurers and the government. In many cases they absorb these pressures, and despite them opt for high prices and the accompanying profits.

[12] For an example, see MedPac's March 2017 Report to Congress, p. 404.
[13] For a more complete discussion of this incentive issue see MedPac (2017) pages 404-405.
[14] Note that currently premiums are risk adjusted in Part D and subject to risk sharing around defined risk corridors so moving to risk adjusted capitation would increase the degree of risk borne by prescription drug plans significantly. This suggestion is similar to one made by MedPac in its March 2017 Report to Congress.

With prices decoupled from either benefits or production costs, decisions on drug development and drug pricing drift far from what a cost-effectiveness analysis would prescribe.

This constellation of forces produces outcomes that depart from valuations predicted for markets where there is competition, even if tempered by product differentiation. Drugs with equivalent health impacts and production costs sometimes sell at vastly different prices. From the manufacturers' standpoints, uncertainty reigns, a very unwelcome phenomenon, and one that discourages undertaking the development 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 products offering major improvements in the ability to treat disease (Dranove, Garthwaite, Hermosilla, 2015; Chambers et al, 2017). Thus in a world for pharmaceuticals where insurance enables MISCs to potentially thrive, as mentioned, pricing gets unmoored from the value of the drugs produced.

The combination of monopoly and nearly complete insurance produces well-known distortions. In the pharmaceutical arena, temporary monopoly power is granted by the patent system, and is reinforced by the FDA's establishment of periods of market exclusivity. The general goal of the patent system is to allow for economic profits in order to support the expenses of innovation, a justifiable second-best solution. However, the design of the patent system was developed to apply to the entire innovation economy and does not take account of special circumstances that appear in the pharmaceutical context, most importantly generous insurance arrangements. (Imagine the price consequences if the purchase of iPhones were 80% subsidized by the government so that retailers paid 15% of the price and consumers paid 5 %.)

To see the impact of having clients extensively insured in a context where a seller has considerable market power, as is conveyed for example by a patent system, consider Figure 1. (For now, to simplify, we are assuming that pharmaceutical plans operate as simple "pass throughs".) 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[15]. The profit-maximizing price and quantity under these circumstances are respectively P_0 and Q_0. Now consider the introduction of substantial insurance for consumers. The figure is drawn so that the copayment rate is 50%. (This rate, rather than the 5% actual rate in the reinsurance region, makes the graph easier to interpret.) Such insurance largely insulates consumers from the cost of care. This magnifies demand and makes it much less responsive to price. This situation is illustrated on Figure 1 through the insured demand function represented as the curve D_I. The corresponding marginal revenue curve is MR_I and the marginal cost remains as before. The graph shows substantially higher prices and sales when the MISC circumstances prevail.

If the copay is a mere 5%, the demand curve will be 20 times steeper than it would be without insurance, and ten times steeper than shown in the 50% rate in Figure 1. Berndt and Newhouse (2010) show that one likely equilibrium in a MISC environment is for the price difference between the insurance and uninsured case to be $P_I = P_0/s$ where s is the coinsurance rate. In the case of the reinsurance benefits s = 0.05 and so the difference is 20 x P_0. -- (To facilitate exposition, the initial demand curve was drawn flatter than would be expected for drugs. For similar purposes, the copayment rate was set at 50 %.)

In considering the welfare implications of the situation illustrated in Figure 1, it is important to recognize that the uninsured competitive result would imply an equilibrium quantity Q_c at a price P_c. The patent system absent insurance raises the price to P_0, while reducing quantity to Q_0. This reduces welfare in the short run in the service of dynamic efficiency, in the form of increased innovation.

Now introduce insurance to address the case of MISCs. This will compound the losses due to high prices, but will push quantities closer to the competitive outcome, Q_c. If insurance is extensive, e.g., covering 95% of the patient's cost, it will likely over correct

[15] Marginal costs have typically been assumed to be constant in the literature on drug pricing.

the quantity, implying that $Q_I > Q_c$. Therefore we identify three sets of potential net welfare losses from MISCs: excessive prices and burdens on public and private budgets, overuse of high cost drugs, and (though overuse is not able to be displayed in this diagram) distorted incentives on the types of products to bring to market.[16]

There is a second-best approach to the vast increases in prices and purchases that result from extensive insurance. The prescription drug plan itself, seeking to save on costs, could exclude a drug from its formulary, or impose a variety of restrictions that make purchase difficult. 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 plans can employ to limit the utilization of drugs. For example, in the case of psychotropic and HIV medications, protected classes have been identified to prevent plans from restricting their availability. 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% subsidy from Medicare and thus covers only 15% of the incremental cost of a prescription (recall enrollees are responsible for the other 5%).

Thus, if a plan sponsor is concerned with political pushback or enrollee pushback it has just a modest incentive to take actions to reduce access to drugs that are mostly used by individuals in the reinsurance region. What is worse, plans may wish to include such drugs as a way to attract enrollees, given that they pay just 15% of the cost, and reap 100% of any increases in premiums. 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

[16] These observations are consistent with concerns about inefficiently high R&D discussed by Garber, Jones and Romer (2006)

demand for their plan, hence with the premium they can charge and volume of enrollment.

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 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% of drug costs in the reinsurance range will significantly distort the optimal offering for a plan. Basically, when there are goods where the government picks up 80% of the tab, and other goods where it contributes nothing, a self-interested plan will surely offer those 80% goods to its clients as part of the portfolio that it offers.

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 are predominantly purchased in 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: Considerable 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 lower prices for drugs today against the

potential benefits that the promise of higher prices will allow for robust innovation tomorrow. The United States faces this tradeoff most starkly, as it is by far the world's major producer of new pharmaceuticals. Countries from Argentina and Australia to New Zealand and Zimbabwe can be cheap riders when it comes to fostering drug innovation.

Nevertheless, even in the United States, there is now broad recognition both across the political spectrum and within the health care marketplace that exorbitant pricing, particularly in 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 welfare improvements brought by an increase in the supply of new drugs. That is because it typically measures innovation as a count of new drugs independent of their contributions to improved health and well-being. Dranove et al. (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. Their empirical analysis of the demand shock created by the implementation of Part D shows that much of the increase in inventive activity occurred in areas where related treatments already existed. It also reports 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 the substantial upward demand shock that Medicare Part D produced yielded only modest gains in welfare.

Together these findings from the literature suggest the Willie Sutton approach to drug-pricing policy: focus attention on drugs where prices, hence economic profits, are highest, because that is where the money is. For those drugs, skillful intervention on pricing may be able to yield significant gains in allocative efficiency at little cost to dynamic efficiency.

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 for a small number of high-priced drugs, our MISCs, might yield equal benefits from drug innovation with much lower efficiency costs and distributional concerns due to perverse incentives?

III. Medicare Part D and MISCs

MISC drugs have three critical features: 1. Few of these products have any close substitutes at least for a number of years after they come on the market.[17] 2. Virtually all their sales are heavily subsidized through insurance. 3. The combination of monopoly or near monopoly power, combined with substantial insurance subsidy, enables MISC drugs to charge very high prices to Medicare Part D.

As implied earlier, within Medicare Part D, spending on MISCs happens overwhelmingly in the reinsurance range, as should be expected given their cost. For example, new drugs that treat Hepatitis C, cancers, and inflammatory conditions account for high levels of spending within the reinsurance benefit. Examples include Harvoni, Gleevec, Humira, Embrel, and Revlimid. Medicare Part D, in many cases, is a large purchaser of such unique products. For example in the Hepatitis C medicine category, Medicare Part D accounted for 50% of all sales in 2015 (IMS, 2016), even though that disease does not

[17] 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 bio-similars will affect the contours of competition.

disproportionately strike the elderly. Similarly, Part D accounted for about 68% of Revlimid (a drug that treats blood cancer) sales in 2015. [18]

Given Medicare Part D's role as a significant buyer, there is market power on both sides of the market for a number of MISCs paid for under the reinsurance benefit. This situation is thus a bilateral monopoly between the manufacturer and the government, albeit a set of other key players affect the demand for the end product but are substantially insulated from the price of the drugs. Those other players include doctors, who pay nothing, patients, who pay 5%, and plans, which pay 15% in the reinsurance range.

Despite its bilateral monopoly features, the MISC drug market does not behave like a typical bilateral monopoly problem, for two reasons. First, and simplest, Medicare takes no advantage of its market power, because it is prohibited from bargaining with prescription drug manufacturers. Moreover, absent new legislation, it can't duck out of its 80% subsidy of drugs purchased in the reinsurance range. This subsidy bolsters the returns to the drug manufacturers' market power.

Second, the drug market under Medicare Part D differs from the typical bilateral monopoly because the prescription drug plans stand in the middle. In a favorable world, these plans would compete with each other to secure lower prices from manufacturers – as Amazon competes with Walmart -- in order to offer lower prices to health plans, health insurers or other payers.

Matters do not work out that way. The market for Part D prescription drug plans is dominated by three large pharmacy benefit managers (PBMs). Given the quantities that these PBMs buy, they have some potential to exert a countervailing force to the pharmaceutical manufacturers, and could put downward pressure on drug prices if they had a strong incentive to do so. Unfortunately, given the 80% subsidy that they receive

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

from Medicare in the reinsurance region, prescription drug plans have little incentive to hold down drug prices. Indeed, including such drugs on their formularies, even at very high prices, given that their cost is subsidized at a 95% rate to consumers, enables the drug plans to raise their premiums.

Normally an insurance intermediary, such as a prescription drug plan (PDP), would have a strong incentive to limit coverage of expensive products. However, MISCs are overwhelmingly purchased in the reinsurance range of Medicare Part D. There, the combination of heavily subsidized consumers and the 80% subsidy of purchases from Medicare to a PDP changes, and perhaps reverses, the typical incentives. Given that the insured and the insurer are only covering 20% of the cost between them, this duo can, and in effect does, conspire against Medicare by providing coverage for MISCs.

Posit the following, to simplify: 1) The probability that an insured will have the condition for which the MISC offers treatment is p_i. 2) Insureds are risk neutral. 3) Insureds do not know their medical needs. Hence, their *a priori* demand curves deal with expectations about use, and are identical. 4) MISCs are bought only in the reinsurance range. 5) There are no administrative costs.

The figure below (Figure 3) shows the ex post aggregate demand curve for the MISC as DD among those with the condition, assuming no subsidy. The price of the MISC to the PDP is P. Given that Medicare subsidizes the PDP at 80%, P = 0.2P*, where P* is the price paid to the drug company. An insured pays P_I for the drug, where $P_I = 0.25P = 0.05P^*$. The amount Q will be demanded.

Among those with the condition, consumer surplus is the area below the demand curve and above P_I. It is shown as the region with slanted lines; that region's area is S. This quantity must be compared to the deadweight loss suffered by the duo comprised of the plan and the insured. This duo's deadweight loss arises because insureds pay less for the drug than the cost to the PDP. This deadweight loss is the dotted region, whose area is L. (Neither the PDP nor the insureds considers the cost or the deadweight loss borne by

Medicare.) The cost to the PDP from providing the MISC is the shaded region, namely Q ($P - P_I$), whose area is C.

In the figure, the area S (consumer surplus) well exceeds the area L (deadweight loss to the duo). Thus, it will be attractive for these two players to have the MISC on the formulary, and thereby exploit Medicare. The PDP can raise per capita premiums by the expected consumer surplus, of p_iS. The per capita expected cost to the PDP is p_iC. In the figure, $p_iS >> p_iC$; thus it will be worthwhile for the PDP to offer the MISC.[19] It would secure more in increased premiums than it would have to pay to provide the MISC.

It would be expected that demand for a MISC would be fairly inelastic. Holding the horizontal intercept of DD fixed, the lower the demand curve's elasticity, the greater will be the consumer surplus, and the smaller will be the deadweight loss to the duo of PDP and insureds. By contrast, the cost to Medicare – the amount demanded times its price subsidy, or $Q(P^* - P)$ -- rises as elasticity declines, since Q rises as elasticity declines.

The PBMs' own high levels of market power, hence profitability; also reduce their bargaining power against their suppliers. To see this, consider two extreme situations. In situation A there are many PBMs, who compete actively against each other. Their profit rate on sales is a modest few percent, to illustrate say 3%, 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% or 15% as an example. Given A, a 1% cost reduction would increase profits dramatically, by 25%. In B, assuming no other changes, it would increase profits by much less percentage wise; the reduction might not be worth pursuing if reducing costs entailed incurring new costs. Situation B is much closer to reality. Due to the lack of transparency in the pharmaceutical market generally, and within the Part D market in particular, it is not possible to know the profit rates of the PBMs, but what is known indicates that they are doing quite well.

[19] If DD cut the vertical axis below or only slightly above P, implying that no or few insureds valued the MISC above its cost to the PDP, then this inequality would be reversed.

Two other features of the market further weaken potential price discipline within it. First, a substantial number of Part D enrollees qualify for low-income subsidies that insulate them from the cost sharing incentives that are part of the Part D benefit design. Second, prescription drug manufacturers frequently provide consumers with drug discount coupons that serve as a counter-weight to tiered cost sharing incentives that PBMs employ to encourage the use of lower priced products.

A defining characteristic of the prescription drug market is that bringing new drugs to market entails both high costs and high risks.[20] 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, Acemoglou and Linn, 2004). Innovations are hard to procure and almost always require healthy incentives to be in place. Then why might MISCs be different?

MISCs possess three fundamental problems: 1) They may produce economic rents well in excess of those that are necessary to generate innovation incentives. See Figure 1; 2) The pricing strategy that produces these rents generates inefficiencies through the financing of subsidies for Part D and; 3) The rents that are created are haphazard, and are often only loosely connected to the benefits that the drugs provide. Thus, the provision of economic rents for many MISCs is cost-ineffective. This last observation has motivated discussion of value-based pricing, a subject that we take up below (Jayadev and Stiglitz, 2009; Towse, Garrison and Puig-Peiro, 2012).

If the drug market stayed static, that is if the drugs on the market did not change, each of these inefficiencies 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

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

advances in most areas of medical understanding, great leaps forward are likely to be available. Finally, new 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 an upsurge in the launch of new effective drugs. Figure3 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 truly innovative products were few.) Given today's potential for important new drugs, any prescription drug payment system must be sure to avoid stifling the incentives for innovation. This is especially true for the types of new drugs that have recently produced important health gains, and that are likely to sell for high prices.

Finally, problem 3 identifies the often weak connection between drug prices and "health value." Some high-priced drugs offer important clinical gains (e.g., Solvaldi, one central component for the effective treatment of Hepatitis C), but many others yield only marginal improvements, as is the case with some of the novel anti-coagulants (Eliquis). The heavy subsidies to the consumer and the Part D plans over the reinsurance range, feeds back to distort the incentives of drug companies. Those companies have almost as great an incentive to develop a drug that only ameliorates a modest impairment but still sells at an extreme price, as to develop one selling for the same price that significantly improves a life-threatening condition. The person suffering from the modest impairment, if operating in the reinsurance range, may be quite willing to pay 5% of the cost of a high-priced drug. Indeed, with the prevalent use of drug discount coupons noted earlier, consumers may even be insulated from those costs (Scott Morton, 2017). From the standpoint of society, by contrast, it would make much better sense to grant much greater profits to the drug reducing mortality as opposed to one reducing modest levels of impairment and discomfort. If such arrangements were in place, drug companies would focus on bringing drugs to market that offered great gains in quality-adjusted life years (QALYs) and would steer away from those offering merely modest gains.

IV. A Prescription: Value–Based Pricing for MISCs

The remainder of this paper focuses on the design of a framework for a negotiated value-based pricing system for drugs in the MISC category. Fortunately, though their numbers are growing, there are few MISCs, implying that a procedure that pays special attention to their pricing should be manageable.

To date, the debate on price negotiations has focused on broad-based arrangements that seemingly would cover all prescription drugs. Our reading of the evidence indicates 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 among competing drugs that are close substitutes, and favorable pricing can be realized through the negotiation of rebates or generic substitution (CBO, 2014). But with MISCs, where there are few if any substitutes and both the consumer and the plan are heavily subsidized, market function breaks down.

Our framework for negotiating prices focuses on MISCs, the major source of the excess-pricing problem, and only MISCs. Despite the modest number of drugs that fall into the MISC category, they account for a significant portion of spending for Part D, a higher proportion of the recent increases in spending, and an overwhelming portion of spending in the reinsurance region. Using CMS data for 2015 we identify a short list of drugs that are high cost (e.g., above $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. A policy that merely reined in the prices of MISCs would produce significant savings, yet would require limited administrative resources. Moreover, by restricting itself to high-priced drugs, now the source of considerable political heat, the policy might enjoy broad political support.

The fact that few drugs would be involved means that the bargaining process could be pragmatically applied solely within the Part D program. America is not a land that

welcomes price controls, or even direct government negotiations over prices, particularly given the current political climate. Thus, any effort to control a drug price would have to work through a bargaining process between the pharmaceutical manufacturers and the government, not just through a dictum on high. Moreover, the policy would and should have to recognize the trade-off between static and dynamic efficiency goals.

Elements of the Proposed Framework: Ideally, the payment framework would respond to the effectiveness of a drug, where drugs that produced more QALYs for patients would receive higher prices. In a virtuous feedback process, this would signal and incentivize drug manufacturers to strongly focus their efforts on drugs producing major health gains. Under current payment arrangements, such signals and incentives are often very weak. The result is that drug firms find it profitable to develop drugs that offer but modest improvements over those currently on the market,

Our proposal incorporates principles from the literature on paying prizes for innovation. In this case we seek to design a negotiated payment system that builds economic profit into the price of any final product that substantially improves health outcomes for its users. Thus, a drug that significantly reduces disability and/or mortality would receive a much higher price than one contributing more modestly to health.

The negotiation system would offer a per-prescription payment, updated on an annual basis. Often, information on benefits – both in terms of numbers served and average benefits per user -- will be hazy when a MISC gets included on plan formularies. Thus, data on health impacts would be collected and the payouts revisited periodically, perhaps annually. Finally, the payment arrangement would be terminated when meaningful competition came into being. This implies that a more inventive drug, one whose properties were less easy to innovate around, would end up receiving money over a longer period.

A second strand of our proposal would reduce the extreme distortions due to the 80% subsidy of the plan in the reinsurance benefit region of Part D. Following the analysis of

MedPac (2017) and others, that would require decreasing the risk borne by the government and increasing the financial risk held by the prescription drug plans in the reinsurance range. That would give PDPs a much stronger incentive to negotiate advantageous prices.

Of course, a major justification for the heavy subsidy to plans in the reinsurance range was to make premiums to the insured more affordable. Thus, if the subsidy in the reinsurance range were slashed, there would have to be increased subsidy elsewhere. Presumably, part of the original justification for putting the entire subsidy in the reinsurance range was that was where plans were most at risk.

This perception is somewhat misguided. This situation is quite unlike the usual reinsurance arrangement from the government, as say with terrorism insurance, where protection is against a single extremely costly event. The PBMs are insuring millions of clients, and the large numbers significantly spread the risks of extreme expenses of individuals in the reinsurance range.[21] [22] If anything, if pharmacy plans are to be reinsured, it should be on the basis of their total expenditures, and should not depend on what individuals spend beyond some range.

To summarize, the 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. This payment would ideally be complemented by a revision in the subsidy system for plans, removing subsidies of expenditures in the reinsurance range, and relocating those monies to subsidies elsewhere in Part D, or to direct premium subsidies.

[21] To be sure, the introduction of a new MISC drug, such as Solvaldi for hepatitis C, could represent an extreme cost event. But the preferred solution from an incentives standpoint would involve raising the per capita subsidy and employing risk adjustment to deal with differences in exposure across prescription drug plans.

[22] Rather than have 80% government subsidy in the reinsurance range and zero elsewhere, it would be preferable to have a per capita subsidy, perhaps combined with a restructured risk-adjustment mechanism and reinsurance provision. Plans would then be appropriately concerned about the prices that they paid for drugs.

Drug products subject to the mandatory negotiated payment system would be identified based on three criteria: A) They are unique products with few competitors. B) Most of their costs will be paid for under the reinsurance benefit? And C) They are likely to represent a significant claim on spending by the Part D program. Drugs that mostly meet these criteria would be identified for incorporation into 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 on-going assessment of the products in this special tier.

The pricing scheme would have three basic goals: First, it would seek to severely trim the distortions to budgets associated with drugs that tend to be priced well above even what would be their uninsured monopoly price. Second, 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 in terms of sales and after-the-fact measurements of QALY production the more highly it would be rewarded.

The scheme would be conducted with an attentive eye to the need for continuing innovation in the pharmaceutical sphere. Thus, third, pharmaceutical manufacturers would have to be adequately compensated to undertake the expensive and risky efforts required to bring new drugs to market.

We first take up the pricing goal. We need propose no alchemy in transmuting deadweight loss into Pareto superior outcomes for patients, the government and drug companies. Such possibilities typically arise within 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. A full leap in that direction, even if desirable, is beyond the scope of this essay. Moreover, as we noted above, sales or profits of a drug newly introduced to the market can only be predicted with major error. Nevertheless, the exchange of some equivalent of a lump sum payment for moderate pricing is a key component of the proposal made below. However, it should be

understood, that the size of the lump sum payment would depend on the number of prescriptions expected to be fulfilled. In practice, it would probably be paid on the actual number or prescriptions filled. The price-per-prescription would come from a declining schedule chosen at the outset through a screening process where the drug's manufacturer would have to choose among a menu of schedules on which schedule to operate. That menu would be based on the principles of mechanism design, and to be described below. The outcome is expected to give the pharmaceutical firm the equivalent of a lump sum payment in exchange for marginal cost pricing.

This type of two-part pricing solution has often been proposed for situations where patents create monopolies. Rarely are such solutions implemented, because governments rarely want to pony up the lump sum payments required, 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 necessarily 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 has good potential to elicit different government behavior, since the government is already bearing a substantial direct cost due to high drug prices, partly because of its subsidy of premiums and partly because it pays 80% of costs for enrollees in the reinsurance range. Thus, if it could get prices down, it would benefit directly. 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.[23] The pricing arrangement proposed here would add an additional dimension. It would also focus on incorporating QALYs into pricing. Future work will show how the two pricing features could be effectively combined.

We turn first to the second goal, providing incentives to bring high-value drugs to market, as indicated by the QALYs that they produce. We propose an arrangement that gives

[23] See Johnston and Zeckhauser (2009).

greater payments for drugs that deliver higher value. Thus, company X and company Y each introduce a drug that costs $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 price for X would be greater than that for Y if it realized a superior performance 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 producing lesser health gains.

The goal of this system is to determine how much to pay a drug company for producing a drug of some fixed quality, q_0, as a function of the quantity sold, n. The government will pay the company an extra amount to achieve efficiency by having the drug sell at (or relatively near to) marginal cost, as efficiency requires. We start by addressing this question as if we had perfect information. A drug is like any other commodity, the more that is sold the less is the value of the next unit. This is the benefit equivalent of a downward sloping demand curve. The fully informed government could compute the total surplus above marginal cost, the assumed selling price, for any quantity sold. Call this value, V, where $V = f(n)$, and $f' > 0$ and $f'' < 0$. We will leave aside discounting, the time value of money, to simplify exposition.

One possible solution would have the government pay the drug company the amount f(n), perhaps by paying the sum of the marginal value created in each period at the end of the period. Thus, if n_t was the total amount sold by the end of period t, the government would pay $\int_{t-1} f(n)\, dn$ to the drug company at the end of each period. Such a payment would get drug companies to produce drugs that were worth creating.

There are at least two problems with this solution. They cut in opposite directions. First, many drugs that are developed using research expenditures are never brought to market. Second, this formula would allocate the entire surplus created by the drug to the drug company. It is clear that both problems apply. It is also clear that the second outweighs

the first. No drug company could ever do better than to reap the entire surplus its drug creates.

Posit that we are going to give a drug company less than the total surplus its drug creates. This automatically thrusts us into a second-best region. Some drugs that would be worthwhile developing will not be developed. There is an inevitable tug-of-war between excessive rewards to drug companies and insufficient incentives to get valuable drugs produced. One logical cap on payments to a drug company, or at least one that would have some political appeal, would be the monopoly profits it would reap if it just sold the drug without government intervention. We will just posit that there is some cap, which would be determined both through both the political process and negotiations between government and pharmaceutical manufacturers. The cap level would trade off excessive payments against the loss of valuable drugs. The goal then is to find a relatively efficient way to reward the drug company subject to whatever cap is determined to be appropriate.

If the government had perfect information, it could just examine each drug as it arrives, and make a lump sum payment in exchange for marginal cost pricing. Unfortunately, the government will never have such information. It would have to rely on the drug company, which has far superior information about the quantity of drug that it will sell.

Now we turn to the screening problem and mechanism design. We assume that the drug company has an unbiased estimate of the quantity of the drug that it will sell. Thus, as part of its participation in this arrangement, it would announce its expected sales amount, call it n_e. The government wants to create a menu of reward schedules that induces the company to reveal that information through its choice of a schedule. Each available schedule gives the per-unit payment for any level of sales.

The figure below (Figure 4) shows a menu presenting just two schedules. In practice there would be a whole array. The solid line represents the schedule, S_{100}*, that would be chosen by a firm that expects to sell 100 units. That firm would do better than choose the alternate schedule given by the dashed line. For a firm selling 100 units, the schedule

offering the greatest total profits is S_{100}*. The dashed line shows the schedule chosen by a firm that expects to sell 110 units as S_{110}*. That schedule maximizes total profits for a firm selling 110 units.

Given this screening approach it is possible to simultaneously achieve: 1) honest reporting by the drug companies; and 2) the payment for some base level of output and incremental payment changes as quantity is increased. Here the firm selling 100 is paid $10 per unit, and is thus rewarded $1,000. The firm selling 110 is rewarded $9.70 per unit, and is thus rewarded $1,067. If it was considered advantageous to have greater output, the schedule for 110 could be shifted slightly upward to afford greater payment.[24] What is critical is that the firm selling 100 is better off on the S_{100}* schedule and the firm selling 110 is better off on the S_{110}* schedule. Thus, each firm will report honestly. As drawn, the S_{110}* schedule is simply the S_{110}* schedule shifted lower and to the right.

One of the properties of this class of screening problem is that two schedules cross precisely once, the situation shown in the diagram (Mashkin and Riley, 1984; Mussa and Rosen, 1978). It is posited that the firm producing 110 units merits a $67 increment over the firm producing 100.[25] (Adding more schedules would allow "well behaved" increments for in between quantities, such as 105, to be easily achieved.)

Matters would be more complex if, as would seem likely, there is uncertainty about the quantity demanded. Let the firm's mean estimate be m. Posit an error term, e, so that the firms actual sales are m+e. If the distribution of the error from m were known, call it h(e), there would be no problem.[26] Schedules like those in Figure 4 could still be employed.

[24] If there is uncertainty on sales, a firm might choose a schedule that does not maximize its profits for its expected sales. See footnote 26.
[25] This greater payment could be to compensate the bigger seller for more foregone profits, or to provide an appropriate incentive to develop more widely used drugs.
[26] This approach could also accommodate a situation where the error term was multiplicative, so that sales were m(1+g(e)).

The Determination of $P_{0,n}$: This analysis was undertaken for a firm offering quality q_0, where q_0 is assumed to be some minimum quality for drugs approved for compensation under Medicare Part D.[27] We designate this base payment as $P_{0,n}$., where the first subscript indicates the quality level. This payment might be made predominantly up front or simply each year as sales are made. However, if the firm declared an expected output of n, the payment schedule should not exceed the payment on S_n* at any quantity, unless the government was confident that it could claw back excess payments from the dug company.

An appropriate benchmark for $P_{0,n}$ would take into account both the expected cost of producing a new drug in its class, and the profits the drug would produce if it did not participate in this arrangement. Any tally of expected cost must include the expected costs of failed efforts to produce such a drug. That cost number might best be determined by relying exclusively on figures secured from competitor firms that had produced drugs in roughly the same class. This would avoid the problem that drug companies would simply find ways to inflate their own costs so as to increase their base payment. Given such a system, a company would not inflate its own costs, since that would merely increase the rewards to its competitors. To allow for base payments that differed by class of drug, we would have to have a different $P_{0,n}$ for each drug class i, hence $P_{0,n,i}$. In what follows, we leave aside this complication.

Of course, as mentioned, the negotiated payment would also have to take account of the profits a drug company producing a particular drug would reap. Drug companies are not in business to merely cover their costs, and they could simply not to participate in any negotiation arrangement. Any reward to profits could come from a second component of payments due to the QALYs a drug produces. There are a couple of alternative approaches that could be used to set $P_{0,n}$. One approach would adopt an approach that is commonly used in Europe. With that approach, 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

[27] This standard could merely be the standard for FDA approval, or it could be set higher.

relying on relatively available information. However, this approach would also encounter 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 pricing of a MISC.

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. Such uncertainty would attenuate innovation incentives to the benefit of no party.

Payment for Quality Produced: The second component of payment would reward drugs that produce quality above q_0. The total increment in QALYs is the sum of QALYs over all recipients that it offers over what is currently available. Information on QALYs gained would be known only roughly at the outset. Hence, it might be tallied on an annual basis. Let Q_t be the total QALY gains the drug produces through its n sales in period t. A bonus $B_t = b(Q_t)$ would be paid. It could be paid out as a lump sum at the end of the period, or it could paid on a per-unit basis using last period's experience to make an estimate for the appropriate per-unit payment, β_t for the current period, with a settling up payment, R_t, added or subtracted from the end-of-period payment. The form or precise timing of the payment is not what is critical. What is critical is to incorporate a component of payment for QALYs gained in addition to the base payment $P_{0,n}$.

The total revenues to the drug would sum across the drug, n, and over time. Therefore total revenues for a MISC would be $P_{0,n} + \Sigma_t B_t(Q_t)$ if the bonus scheme relies on annual lump sum payments. The total would be $P_{0,n} + \Sigma_t n_t*\beta_t(Q_t) + R_t$ if the bonus scheme pays predominantly on a per-unit basis. To determine present values, the period payments would be discounted.

Cost Savings Due to Discouraged Drug Development: The most direct effect of our mechanism would be reaped in the cost of drugs that came on the market and proved successful. However, there would be a second big source of savings if a plan with this flavor were implemented. Many low-value drugs that currently come on the market, and that are highly costly, would never be developed. The savings on drugs we never see might be the predominant source of savings. And society would also save on some and at times all of the R&D costs to develop some drugs.[28]

The Bargaining Process Over the Bonus and an Example: Bargaining would be bounded by a relatively low default price of $P_{0,n}$ and a requirement that ensures that innovation incentives are in place. The per-unit price, combining $P_{0,n}$ with the bonus, would be constrained to offer economic profits to firms introducing products that meet at least some minimal level of desired performance. The bargaining would focus on the size and criteria for obtaining bonus payments. The bonus schedule would be negotiated based on evidence from clinical studies, experiences in other countries, and experience with related products. The criteria for the schedule would be aligned with QALY measures, since promoting QALYs is the base objective of health policy. Such alignment would also facilitate cost-effectiveness comparisons between Medicare Part D and other health-promoting interventions. The negotiated quality schedule q would be put into place and the bonus payments would be made on a scheduled basis, perhaps yearly. This would permit new information on drug performance into the bonus schedule.

The bargaining mechanics might be considered in the context of an example. Consider a drug Z that addresses a particular type of cancer. To ease exposition, leave aside discounting. The cost of developing the drug is $1.5 billion. Assume that 15,000 people would be treated by the drug. The price per unit proposed by the manufacturer, outside of this scheme, 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, and the drug would

[28] For some drugs, it is impossible to determine if they will prove to be low value before some R&D is undertaken.

no longer be a MISC. Thus 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% of the cost of development, it would be $1.12 billion. Assume further that over the first 5 years 23 million doses were projected to be sold, and then 12 million in the next 5 years, and exclusivity would expire after 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 patients who have a defined level of positive responses to the therapy. Further assume that the bargaining fell in between the smallest and largest rebates in Medicare—perhaps 27%--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% above the full cost of drug development. Thus, a significant economic profit would still result (ignoring the second five years on patent with therapeutic competitors). This represents a notable savings to Medicare in an arrangement where profitability is based on therapeutic impact.

In practice, all costs and revenues would be computed in discounted terms. Moreover, the research and development cost would take account of failure rates. Thus, it would be doubled if half of such drugs were fully developed but never came to market.

Complementary Cost Control Mechanisms: There are numerous other potential approaches that might be used as a means to keep a lid on prices in conjunction with our proposed framework. For example, the copayment rate expected from the patient could be set to increase with price, with firms having some or full freedom to set their prices. Targeting copayments would penalize beneficiaries; given the relatively low incomes of many Medicare beneficiaries, that would be undesirable (50% of Medicare beneficiaries had incomes below $26,000 in 2016). However, if this targeting system led manufacturers to charge lower prices, beneficiaries might ultimately face lower

copayments. It is better to pay 10% of $5,000 than 5% of $12,000. In a highly sophisticated world, copayment amounts could be and would be scaled to income. The role of copayments for MISC drugs, after all, is primarily to control consumption, not to offload costs onto the insureds. 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, however, is beyond the scope of this essay.

In an extreme case a drug might be excluded from the formulary. But exclusion of a drug would harm beneficiaries and would be politically fraught.

V. Concluding Remarks

This paper was spurred by the widespread observation that drug prices are extraordinarily high in the United States, and that Medicare is responsible for a significant percentage of these costs. The diagnostic component of the paper examined the design of the reinsurance benefit in Part D of Medicare. That design generates serious inefficiencies. The significant subsidies to plans in the reinsurance region combined with the launch of unique high cost prescription drugs could be expected to lead to and has led to substantial departures from cost-effective outcomes in treatments delivered. Extremely high costs for an extremely limited class of drugs, what we label MISCs, get woefully insufficient consideration. This unfortunate situation feeds back to the innovation process. Drug companies find it worthwhile to spend vast dollars to bring forth high-cost drugs that offer only modest benefits above those of drugs already on the market. The result, being felt increasingly more with the influx of new entities on the market, are budget-busting overall expenditures on MISC drugs, some of which produce only marginal benefits.

Compounding this unfortunate situation, the prices charged under these arrangements are often multiples of what would be monopoly prices due to patents, but absent insurance. However, good news is hiding amidst these discomfiting observations. There is the potential for a quite different pricing scheme that would produce substantial gains in both

efficiency and health outcomes. Such pricing could save substantially on costs without curtailing the most important R&D efforts for pharmaceuticals.

These findings point in two policy directions. The first follows on the MedPac recommendation that the government reduce its share of risk bearing for the Part D reinsurance benefit. This would make prescription drug plans bear much more of the costs over that range. An increase on subsidies elsewhere, the least distortionary being an increased straightforward premium subsidy, would be required to keep premiums affordable.

The second focuses on eliminating price inefficiencies. It has two components: eliminating monopolistic overpricing, and promoting the quality of drugs brought to market. It led to a framework that could guide the structure of price negotiations for the relatively limited number of MISC drugs. It is grounded in the economics of two part tariffs, research on innovation prizes, performance-based contracts, and draws on the mechanism design literature.

The framework calls for identifying high cost drugs with significant market power that could be expected to be reimbursed under the reinsurance benefit of Part D. These drugs would be accepted for coverage under Part D, but only if their producers participated in mandatory negotiations. Those negotiations would focus on two main elements of the two-part tariff pricing framework. Specifically the criteria for obtaining different levels of bonus payments and the size of the bonus payments would be negotiated. Failure to either successfully complete negotiations or to reach acceptable levels of performance would result in a default price that would yield no economic profit, indeed some loss. This default feature would reward successful negotiation. The government would be constrained to offer a potential price schedule that resulted in substantially greater profits if desired health outcomes – as indicated by QALYs produced -- were achieved. Finally, the negotiated price structure would be in force only until competitive conditions emerged in a drug class. At that point, the market price would replace the negotiated price.

MISCs represent a tiny fraction of the pharmaceuticals on the market, yet they have an immense impact on spending under Medicare Part D. Indeed, due to severe incentive distortions, the responses of drug companies' to those incentives, and a Medicare Part D structure that prohibits Medicare from negotiating prices and discourages prescription drug plans from doing so, MISCs receive extreme prices and are responsible for a major portion of policy concern about drug expenditures. Those prices and expenditures merit even greater concern when those drugs yield only moderate benefits. Market conditions and political forces appear ripe for significant new approaches to pricing high cost drugs in Medicare Part D. We believe that the prescription discussion that draws on this paper's diagnosis identifies some promising approaches to a vexing problem.

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Table 1: High Cost Drugs and Reinsurance

Drug	2015 Spend (millions $)	PUPY Spend 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 Dash Board (2016)

Figure 1: Market Power and Insurance

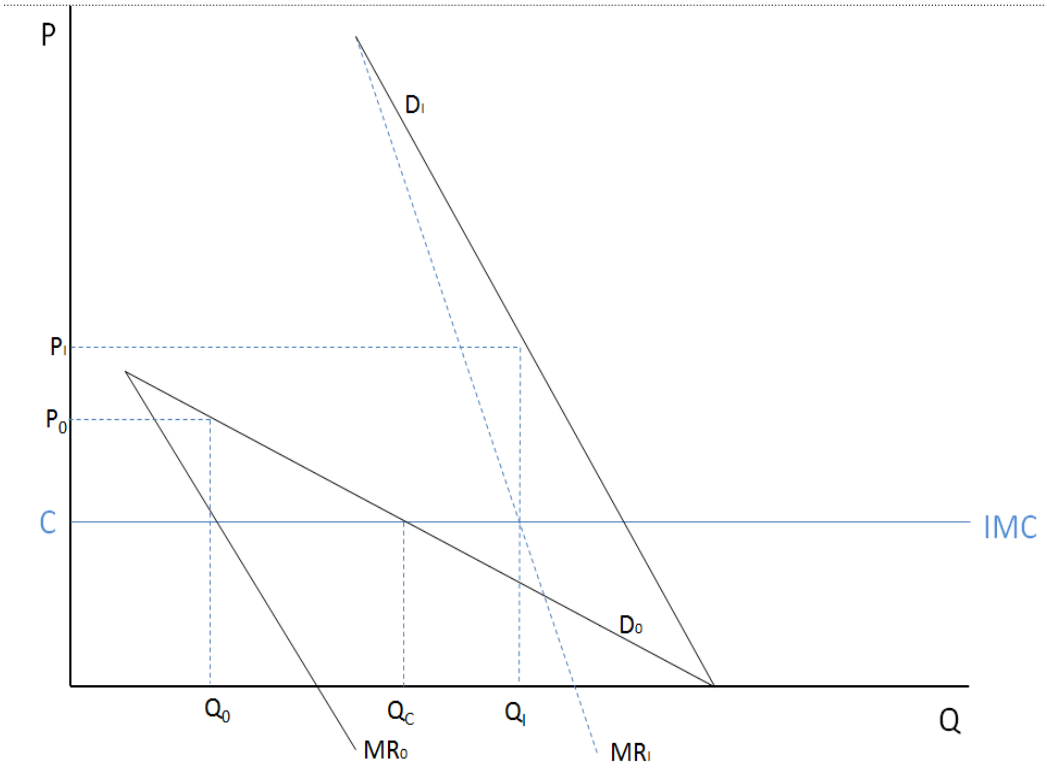

Figure 2: Trend in FDA Drug Approvals

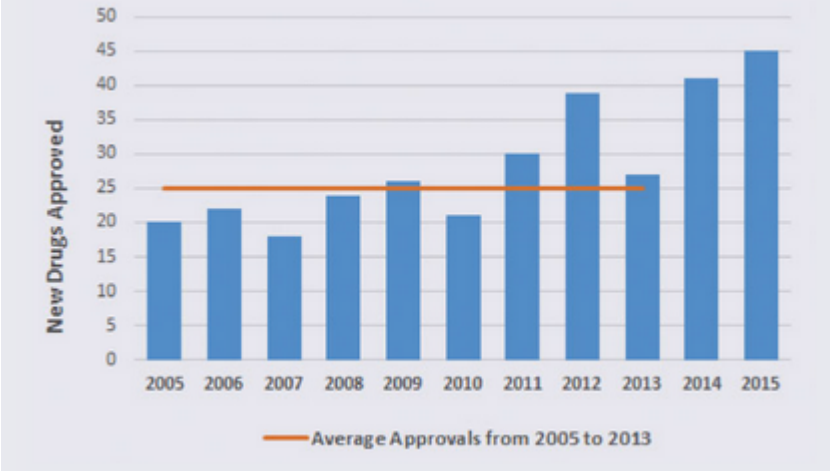

Figure 3: Prescription Drug Plan's Incentive to Cover a MISC

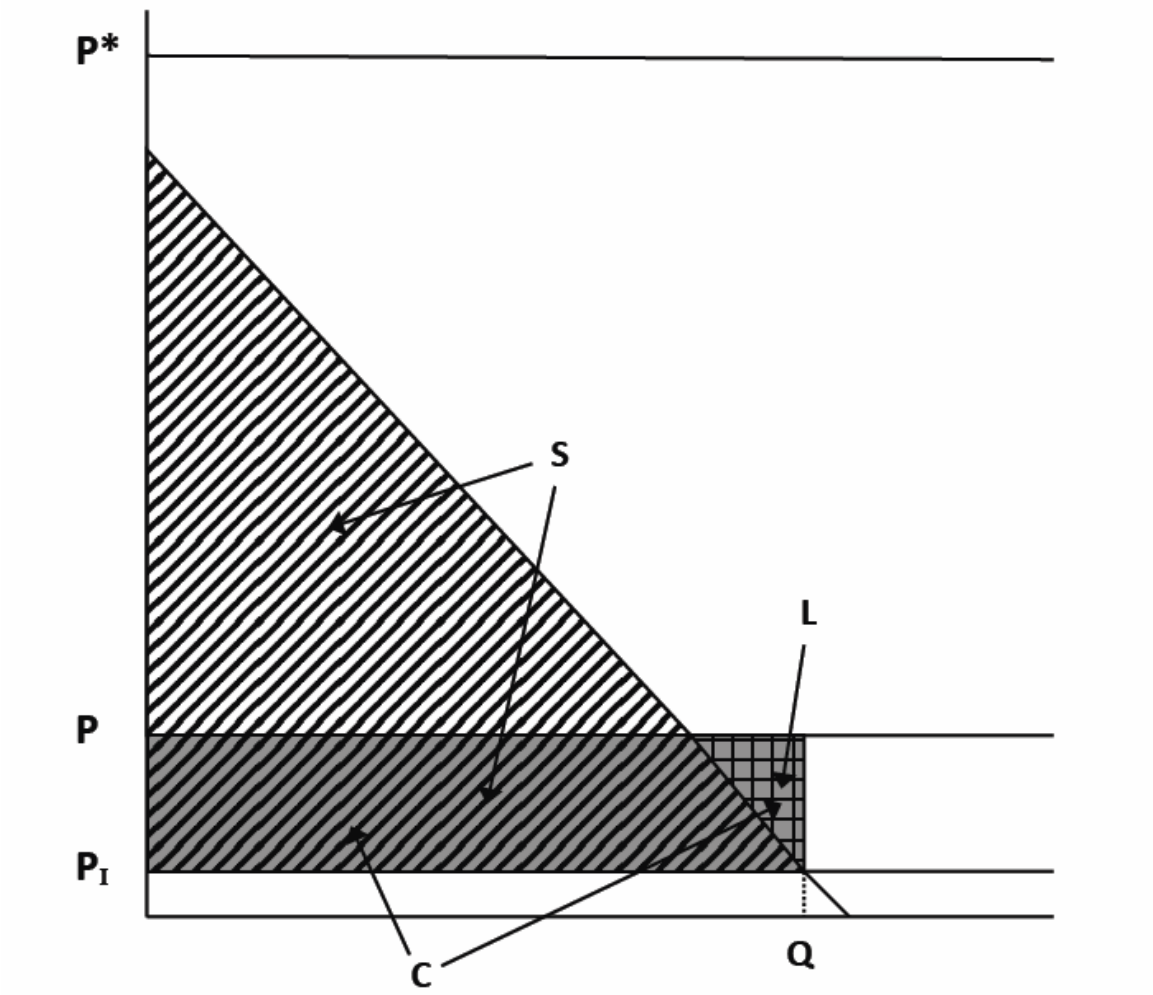

Figure 4: Price Schedule Mechanism