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ISSUE BRIEF

Establishing a Two-Part Drug Pricing System to Promote Value-Based Pricing and Innovation

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Executive Summary

Value assessment frameworks, such as the one used by the Institute for Clinical and Economic Review (ICER), assume that a centralized organization or agency is necessary to determine the value of medicines. But central planning is incapable of determining the value of any good or service, especially a good as complicated and important as innovative medicines. Central planners can only impose price controls, they can never accurately estimate how 300 million Americans value the benefits from new and innovative medicines. The prices of medicines will only reflect how patients value them by establishing an efficient market process.

Recognizing this reality fundamentally alters how policymakers should approach the problem of ensuring that the prices for drugs reflect their value. Instead of focusing on value assessment frameworks and cost effectiveness models, policymakers should focus on creating efficient drug markets and eliminating the obstacles that make it difficult to determine whether drug prices reflect their value. Necessary reforms include making drug prices more transparent and ensuring that rebates paid by manufacturers are benefiting patients rather than industry middlemen. Reforms should also create a more efficient process for pricing the value of innovation as distinct from pricing the value of safely producing and distributing innovative medicines. Implementing a two-part pricing system is a contracting reform that can establish prices that separately reflect the value for medicines' innovation services and the value for medicines' production services.

Under the two-part pricing system developed in this paper, the first price would be an access fee for innovative medicines, established via a negotiation between insurers and manufacturers. Insurers would pay the access fee on behalf of their beneficiaries. Once paid, the fee would ensure that all people covered by the insurance plan can access the drug and only need to cover the costs associated with the profitable production, transportation, and distribution of safe and efficacious medicines. These costs are much lower than the costs of innovation and are the second price of the two-part pricing model.

"Implementing a two-part pricing system is a contracting reform that can establish prices that separately reflect the value for medicines' innovation services and the value for medicines' production services.

Efficiently pricing innovation

The demand side of the market for innovation (or R&D services) is represented by the insurer because innovation is expensive and individual patients face unknown risks that will require medicines that still have expensive innovation costs associated with them. The purpose of health insurance is to cover the financial consequences from these types of unknown but expensive health care risks. Since the costs of R&D services are an insurable event, patients are the indirect consumers of R&D services by being the direct consumers of insurance services. Consequently, it is the insurers who are responsible for covering the costs associated with the R&D services.

Since insurers are acting as the agents on behalf of patients (the principals), it is essential that the insurer's interests are aligned with their beneficiaries. Reforms that empower patients to choose between alternative insurance options and address the many perverse incentives of the current insurance system will help make certain that the incentives of insurers will reflect the interests of the insured when negotiating the access fees with manufacturers. So long as the incentives of the insurers and their beneficiaries are aligned and prices are transparent, the negotiations between insurers and manufacturers of innovative drugs will be efficient.

On the demand side, health insurers are purchasing the right to access the innovative drugs on behalf of their beneficiaries. Transparent prices, coupled with the sophistication and size of the major health insurers (with the top ten health insurers representing more than 50 percent of the market),[1] creates leverage for the insurers during the access fee negotiations. Due to this leverage, health insurers will be able to effectively represent how patients value the array of innovative medicines.

With respect to the supply-side of the market, innovative manufacturers are selling access to their patented innovations. The market exclusivity granted to the manufacturers, coupled with the clinical efficacy of the drugs, provides counter-leverage for the manufacturers and enables manufacturers to effectively represent the supply-side cost considerations of developing new and innovative drugs.

When combined, the bulk purchases made by the payer counterbalances the leverage created by the manufacturers' product exclusivity, creating an efficient negotiation process between the suppliers and demanders in the marketplace. When patients value manufacturer drug portfolios more highly, those manufacturers will be in a better position to negotiate higher access fees. Manufacturers that offer a portfolio with less value, or innovative drugs that face more branded competitors, will be in a weaker bargaining position with respect to establishing the access fees. The push-and-pull between these negotiations, when supported by an insurance market that accurately reflects how patients value these innovations, will tend toward prices that reflect value. In fact, this type of price discovery process is the only way for patients' subjective value to be reflected in prices.

Depending on the negotiation, the access fee negotiated by the innovative manufacturer and insurer could cover a single medicine, a select group of medicines, or the entire innovative manufacturer's portfolio. There are important advantages that arise by setting the access fee based on the manufacturers' portfolio of drugs because manufacturers innovate across a wide range of drug candidates. Therefore, connecting the negotiation to a manufacturer's portfolio better connects the access fee (revenues for the manufacturers) to the manufacturers' costs. From the patient perspective, patients do not know which R&D services they will need. Therefore, patients will value having access to many innovative drugs. Pricing based on the portfolio of drugs helps ensure broad access for patients.

Another important consideration is how to address the large purchases made by the government sector. Since a competitive market process requires two private organizations to negotiate with one another, when the federal and state government purchase innovative medicines through Medicare, Medicaid, and the Veterans Administration, the formulas already used by Medicare Part B should be applied. These formulas tie Medicare Part B's costs to the average price of the drugs that the private sector has negotiated. In this way, federal and state governments will benefit from the private negotiation process, and the negotiation process will remain efficient, allowing it to establish prices that reflect the underlying value of the innovative R&D services.

Efficiently pricing production and distribution

The second price in the two-price model will cover the much lower production and distribution costs associated with safely manufacturing, wholesaling, storing, and retailing the medicines. The current pricing in the market for generics exemplifies the expected per-prescription costs for most chemical-based medicines patients will purchase at the pharmacy counter. The costs for medicines with higher production costs (such as biologics) would likely be higher. These costs will be generally covered by patients and will only have insurance implications should expenditures exceed certain out-of-pocket thresholds, which can arise when patients require many medicines, or the drugs have exceptionally expensive production and distribution costs.

For drugs that still have exclusivity, one concern with respect to ensuring that the per prescription fee does not exceed the value of the production services is the lack of competition. Generic prices reflect the production costs due to the discipline created by a competitive marketplace, which is lacking when a drug has exclusivity rights. Offsetting these concerns, the robust generic marketplace serves as an effective benchmark to highlight unjustifiable discrepancies between the production price of innovative drugs and the production price of generic drugs.

Additionally, to the extent insurance coverage has out of pocket maximums, insurers have an incentive to ensure that their beneficiaries are charged a competitive per prescription fee, otherwise the insurer's costs will be adversely impacted. The separate prices for innovation and production could incent alternative industry structures that create competition. For instance, the developers of innovative medicines could find it more profitable to outsource the actual production of their innovations, which could establish competition in the production of the medicine even as the innovator receives compensation for the rights to access these innovative drugs.

The Benefits Enabled by A Two-Part Pricing Model

Establishing a transparent two-part pricing system creates several important benefits that include:

- Creating a market process that efficiently values the price of innovation.
- Establishing a per-prescription fee (e.g., prices patients pay when they receive their medicines) that reflects the value of safely producing and distributing efficacious medicines.
- Creating positive incentives for manufacturers to streamline their R&D processes because the companies that can innovate more efficiently will be directly rewarded for these efforts through more profitable access fees.
- The elimination of the "emergency scenario" where patients need a medicine immediately and are, consequently, in no position to serve as an effective demand side of the market.
- Establishing competitive prices that can more easily adjust to new realities such as the discovery that a new medicine can also efficaciously treat other diseases, or the introduction of new competitor branded/biologic products.
- Managing the risks associated with drug affordability more efficiently by incorporating the costs of innovation into patients' insurance premiums, which directly mitigates patient financial risks. Instead of patients being exposed to a nontransparent share of the innovative costs when they receive their medicines, which can lead to significant affordability problems, the costs of innovation are diversified across the insured population. Consequently, the two-part pricing model directly addresses the problem of drug affordability.
- Mitigating the risks of paying the high costs of innovation will also reduce other inefficiencies that are pervasive in the health care industry. For instance, the problem of patients not adhering to their prescribed medications increases overall health care spending and decreases patient health outcomes. By eliminating the high costs that patients can face when purchasing their medicines, the two-part pricing model eliminates an important driver of the drug adherence problem.

Ultimately, fundamental price reforms such as implementing a two-part pricing model for innovative drugs are necessary because an efficient market process is the only way to ensure that prices accurately reflect value. Prices that reflect value as determined in a competitive market are essential for ensuring that medicines are as affordable as possible while also maintaining the incentive for continued innovation.

Introduction

Part I of *Quantifying the Wrong Value* demonstrated that ICER's cost effectiveness models are inherently flawed. Their results provide precisely quantified estimates that do not accurately reflect value. Part I also noted that ICER raises a fundamentally important question: How can we ensure that the prices for medicines efficiently reflect their value to patients?

Answering this question is challenging because value is inherently subjective and difficult to directly measure. For most products, this question is not pertinent because prices set in competitive markets naturally tend toward value,[2] but the beneficial dynamics created by competitive markets do not currently exist for medicines.

ICER's premise is that this beneficial competitive process cannot exist because health care is different. Patients who require innovative medicines need these drugs regardless of the price and this dire need prevents the typical market process from connecting prices and value. The natural conclusion from this assertion is that a centralized authority needs to use value assessment frameworks and cost effectiveness studies in order to dictate the value of drugs.

Not only is this argument meritless, but cost-effectiveness analyses are incapable of accurately quantifying how 300 million Americans subjectively value their medicines, as Part I of this series demonstrated. Centralized organizations can only impose price controls; they cannot declare which prices accurately reflect value. Only an efficient market process can ensure that prices reflect value and drugs are as affordable as possible while still maintaining a strong incentive for continued innovation.

The Inefficiencies Separating Price from Value

A market process is efficient when both prices and information are transparent, and the incentives of consumers and producers are properly aligned. When this occurs, consumers will spend their money when the value they place on the product equals or exceeds its price. Producers, on the other hand, will only sell goods when the price is high enough to make their efforts worthwhile. Since producers are only selling the product if the returns are sufficient to cover the costs, and consumers are only buying the product if they value the product more than it costs to produce, prices in competitive markets reflect value. Furthermore, resources are not wasted producing goods whose cost exceeds their value, which is ultimately growth detracting.

The market for apples exemplifies this beneficial process. On the supply-side, apple growers spend money purchasing the apple grove, caring for the trees, harvesting the apples, and sending the apples to market for consumers to purchase. These costs, and the mark-ups to cover the cost of distribution, wholesaling, and retailing, are built into the price of apples. On the demand side, consumers will purchase apples if they value them more than they cost. Consequently, the prevailing price (say $1.00 per pound) is a lower-end estimate on the value that consumers place on apples – consumers who value apples at more than $1.00 per pound will still purchase apples at the prevailing price, but are getting a particularly good deal (e.g., value to them is even greater).

A relatively efficient price for apples develops because prices are transparent, consumers can accurately communicate their desires to producers, and producers are able to accurately convey their costs and the unique attributes of their products to consumers. This efficient market process leads to an apple price that roughly conveys value. In comparison, the current market process for purchasing innovative medicines is rife with inefficiencies that make it difficult to know whether prices reflect value.

An Ineffective Method for Pricing Innovation

To see why our current system is ineffectively pricing innovation it is important to understand that it costs $2.9 billion and takes 10 to 15 years to discover and develop one new drug, an extraordinarily long, risky, and costly endeavor.[3] Once these investments have been sunk into the process, the cost to produce the medicine is relatively cheap. Since efficient markets price products based on production costs,[4] not sunk costs, the prices that would emerge in a competitive market are insufficient to cover the costs of innovation.

To overcome this problem, the government grants innovators exclusivity in the marketplace for a set period. Exclusivity provides innovators with an ability to price their drugs above the costs of production and creates an opportunity for innovators to recoup their capital costs. This system makes sense.

However, while exclusivity is necessary to incent innovation, a better pricing system is necessary to establish an efficient price discovery process that will ensure that prices reflect the value of an innovation. This point is essential. Just like with the market for apples, or any other product, the only way that prices for innovative medicines will reflect their underlying value is if these prices are determined in a competitive market. To the extent that drug prices may not currently reflect their underlying value, it is because the current pricing system is thwarting an efficient market process from forming.

These inefficiencies include the complex and opaque pricing system. Transparent prices are the *sine qua non* of an efficient price discovery process, but the current drug pricing system is complex and opaque.[5] For instance, many cost-effectiveness analyses use a drug's announced list price as a reflection of its value because list prices are readily available. However, as they have developed, list prices are not designed to reflect the costs of drugs to the health care system. List prices are simply the opening bid that starts a complicated negotiation process between manufacturers and pharmacy benefit managers (PBMs) on behalf of insurers.

> "...The current market process for purchasing innovative medicines is rife with inefficiencies that make it difficult to know whether prices reflect value.

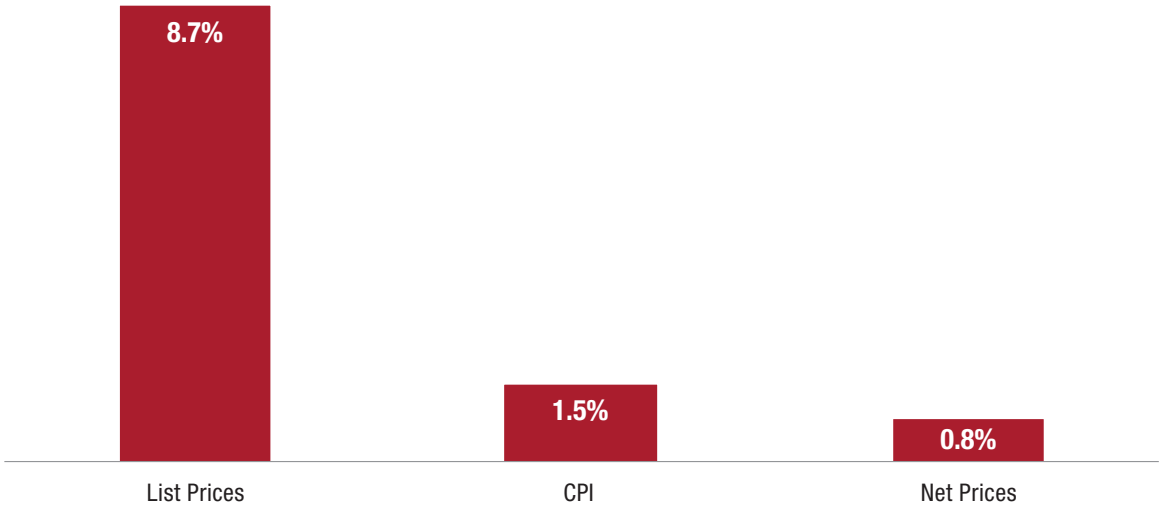
Drug prices minus the value of concessions paid to PBMs and insurers equals drugs' net prices. The net prices reflect the manufacturer's revenues and therefore reflect the cost of the drug to the health care system. Net prices are difficult to measure because there is a lack of transparency regarding the total dollar amount of concessions that are offered to specific PBMs for specific drugs. Estimates for net prices do exist, however, as well as more certain data on the total aggregate dollar value of concessions paid.

If concessions were small and not growing, the growth trends in gross and net prices would be similar. However, this has not been the case. Research shows that the growth in concessions has been accommodated by an equivalent growth in gross prices, leaving net prices flat. Sood, Ribero, Ryan, and Van Nuys (2020) examined the association between rebates and list prices finding,

> that for drugs without generic competition, rebates and list prices move together roughly dollar-for-dollar, resulting in a relatively steady net price. Because manufacturers of brand drugs with a generic equivalent have less market power, a $1 increase in rebates corresponds to a less-than-$1 increase in list price, and a declining net price.
>
> Our finding that increased rebates are positively associated with increased list prices supports the notion that PBMs' demand for rebates is at least partly responsible for increasing list prices.[6]

The differing growth trends between list prices and net prices is visualized in Figure 1. It shows the average annual growth in list prices and net prices between 2013 and 2020 and compares this growth to the average annual growth in inflation as measured by the consumer price index (CPI). Figure 1 confirms that, for the health care system overall, there is a significant drug affordability problem only if the prices of drugs are wrongly measured by list prices – prices grew 8.7 percent annually during this time period compared to a mere 1.5 percent growth in inflation. However, measuring prices based on the more appropriate net price demonstrates the exact opposite – prices for drugs are growing slower than overall inflation. These data confirm that there is no affordability issue for drugs from a health care system perspective.

Figure 1
Average Annual Growth in Drug List Prices, Net Prices and Consumer Price Index 2013 - 2020



Source: Author calculations based on Drug Channels Institute data

The problem of "which price" gets more complicated because we have not yet accounted for the distribution of the costs between patients and insurers. From a patient perspective, an alternative way to view the price of drugs is based on the out-of-pocket expenditures required to purchase the medicine.

Out-of-pocket costs are affordable for many patients; however, the price opacity creates affordability problems for certain patients because patient co-insurance costs are typically based on the list prices not the more systemically relevant net prices. As a result, the extreme growth in list prices for expensive specialty drugs is causing out-of-pocket costs to grow excessively for these patients. Therefore, the opaque pricing system has enabled excessive growth in list prices, which then drive-up patient out-of-pocket costs and create an inappropriate shifting of costs on to patients.

Without considering the value-based pricing issue, addressing the opaque pricing environment in order to improve drug affordability is an important policy priority. Such reforms should move the market toward a net pricing model and require that patients directly benefit at the pharmacy counter from all concessions offered by manufacturers through lower drug costs and all co-insurance costs should be based on these actual market prices.

In addition to these well-known issues of price opacity, the current pricing system makes it difficult for prices to reflect value because it essentially bundles two different goods into one price. Price bundling occurs when complimentary goods are sold as a package. Fast food meal deals exemplify the practice. A meal deal combines the individual components (the sandwich, fries, and a drink) into one bundled product that sells at a discount to each product's stand-alone price. The practice offers consumers a discount if they purchase the bundle rather than each component alone, enhancing the cost-effectiveness of the meal. The bundle offers producers an opportunity to enhance profits by encouraging more total sales.

In the case of innovative drugs, the two goods that are being bundled together are compensation for the capital costs associated with developing the innovative medicine (innovation services) and compensation for physically producing the medicine (production services). Since the physical medicine (e.g., the pill or infusion drug) reflects the culmination of both services, it seems natural to have one price for both services. However, there are fundamental differences between the R&D services and the production services that make it more difficult to accurately value both when these prices are bundled together.

Starting with the innovation services, while innovation costs are expensive, it is unknown whether a person will require an innovative medicine (defined as a drug that is still within its exclusivity period) in any given year. Since people do not know if they will require an innovative medicine in any given year, everyone faces this unknown risk sometime in the near (or distant) future.

The major reason to purchase insurance, including health insurance, is to enable the insured person or entity to transfer the financial risk associated with a low-probability/high-cost event to the insurer for a pre-determined fee. The possibility that a person will be prescribed medicines that have large innovation costs associated with them is precisely this type of situation. Health insurance diversifies these risks across the entire insured population, and then the insurer assumes the costs for the sub-population that requires the expensive medicines, subject to the terms of the insurance contract.

"While insurers are better positioned to serve as the consumer in the innovation services market, this is not necessarily the case for the drug's production services market.

This reality demonstrates that, from the patient perspective, when R&D services need to be purchased, it is more efficient for most patients to purchase insurance and rely on the insurer to pay for the costs. This implies that patients are not the direct consumers of R&D services, but only indirect consumers by being direct consumers of health insurance services (or, as is common in the current employer-based system, having their employers serve as the direct consumer of insurance services on their behalf). Since insurers are now the party that is financially responsible for covering these costs, it is more efficient for insurers to fulfill the role of the R&D services consumer.

While insurers are better positioned to serve as the consumer in the innovation services market, this is not necessarily the case for the drug's production services market. Production costs are significantly less than the cost of innovation; how much cheaper depends on the type of medicine. Small molecule drugs (or chemical compounds) are generally cheap to produce, which explains why 92 percent of generics are filled for $20 or less.[7] Based on data from IQVIA, $102.3 billion were spent on 3.8 billion generic prescriptions in 2019 – an average cost of $26.94 per generic prescription, see Table 1.

Table 1
Total Generic Prescriptions, Spending, and Spending per Prescription, 2019

		VALUE	UNITS	SOURCE
(1)	Total Generic Spending	$102.3	billions	IQVIA
(2)	Total Generic Units	3,796.0	millions	IQVIA
(3)	Cost per Generic	$26.94		(1) / (2)

Source: Author calculations based on IQVIA data

In most cases, the financial risks associated with production costs of $26.94 per prescription are manageable. The risk that a patient will have to cover the costs associated with the production services of a drug (often less than $20) is, generally, not an insurable event. This difference is material when it comes to establishing an efficient market mechanism for establishing prices that reflect value.

Before discussing the implications, it is important to note that the costs of production could still raise some insurance implications. Patients face unaffordable financial risks should they require many generic medicines that, when taken as a total bill, sums to a large cost. Some medicines will also have substantial production costs associated with them that could sum to a large cost. The purpose of health insurance is also to cap patients' financial exposure to these financial risks.

However, unlike covering the costs of innovation, the issue is the scale of the purchases. The current healthy competitive market for generics that account for 90 percent of all prescriptions filled at a pharmacy counter demonstrates that the prices for medicines will generally reflect value when only production costs need to be considered.[8] Generic prices generally reflect the value of production due to the relatively low costs of production (in comparison to the high costs of innovation) and the ability of patients (as a group) to be effective consumers. Since paying for the production services is not an inherently insurable transaction, patients can serve as an effective consumer (demand-side) in these markets. Insurance services for some patients can become an issue due to the volume of purchases, but from a value-based pricing perspective, these are secondary considerations.

Pricing models that explicitly recognize the two different services being purchased when patients are prescribed innovative drugs – innovation services and production services – can enable a more efficient price discovery process. The result will be prices that reflect value (value-based pricing).

One potential mechanism for establishing this beneficial process, which is developed in this paper, is a two-part pricing system. Two-part pricing systems are quite common in the economy. Take the ticket price for a sporting event as an example. People will pay money in order to watch their favorite team play, but then pay again on a per use basis for the food and drinks they consume. This pricing is efficient because it reflects two different services that are being provided by the team owner – the enjoyment of watching their favorite team versus the enjoyment of the food or drink while in the stadium. Further, the two-part pricing system prevents people from shirking on paying for watching their team by coming to the stadium but not purchasing anything to eat or drink. Alternatively, it enables people who just want to enjoy watching the game or enjoy only a small amount of food or drink to not pay for services they will not use.

A Two-Part Pricing Model to Enable Efficient Value-Based Pricing

Applied to the drug market, a two-part pricing system would establish separate prices for medicines' innovation services and production services. It should be noted that creating an efficient market for innovation services is the essential outcome for enabling value-based prices to emerge. The purpose of the suggested two-part pricing system developed below is to demonstrate how creating an efficient market for innovation services enables value-based prices to emerge. Alternative market structures for achieving this goal also exist, and perhaps achieve this goal more efficiently. Eliminating the current pricing inefficiencies in order to establish an efficient market process is the only way to ensure that the prices for innovative medicines reflect their value.

If the entrance fee model is followed, then a two-part pricing system would begin with a negotiation between the insurers and manufacturers to establish the access fee for the innovative medicines that insurers would pay on behalf of their beneficiaries. With an access fee agreed upon, when people purchase an insurance plan, the plan would provide them with access to the approved innovative drugs. The negotiated fee would be paid by insurers and enable all people covered by the plan to access the drug and only be responsible for paying the production costs associated with the medicine.

Since the demand side of the market for R&D services is represented by the insurer acting as the agent for their insured beneficiaries (the principal), it is essential to avoid any principal-agent problems – where the principal's actions do not accurately reflect the agent's interests. Toward this goal, reforms that empower patients to shop between alternative insurance options are essential, which should also include fundamental reforms to the health insurance system to address its many perverse incentives. With the ability to change plans, people will be able to communicate their access preferences to the insurers. Insurers that offer access to too few innovative drugs would lose customers, as would insurers that are too expensive because they offer access to too many innovative drugs that patients do not value.

Through this interaction, insurers and policy holders would establish insurance premiums that reflect how patients value innovation. Put more formally, the incentives of the insurers are aligned such that the insurer is reflecting the interests of the insured when negotiating the access fees with manufacturers. In this case, the revenues from the annual premiums would provide the resources that insurers can use when negotiating the price of the access fee with manufacturers.[9] Since health insurers are sophisticated and large purchasers, with the top ten health insurers representing more than 50 percent of the market,[10] insurers will have sufficient leverage during the access fee negotiations to accurately represent the interests of the insured.

With respect to the innovative manufacturers, the essential service they are selling to insurers is access to their patented innovations. The market exclusivity granted to the manufacturers, coupled with the clinical efficacy of the drugs, provides counter-leverage for the manufacturers and enables them to effectively represent the supply-side cost considerations of developing new and innovative drugs.

During the negotiations, the bulk purchases made by the payers counterbalances the leverage created by the manufacturers' product exclusivity, creating an efficient negotiation process between the suppliers and demanders in the marketplace. When patients value manufacturer drug portfolios more highly, those manufacturers will be in a better position to negotiate higher access fees. Manufacturers that offer a portfolio with less value, or innovative drugs that face more branded competitors, will be in a weaker bargaining position with respect to establishing the access fees. The push-and-pull between these negotiations, when supported by an insurance market that accurately reflects how patients value these innovations, will tend toward prices that reflect value. In fact, this type of price discovery process is the only way for patients' subjective value to be reflected in prices.

Depending on the negotiation, the access fee negotiated by the innovative manufacturer and insurer could cover a single medicine, a select group of medicines, or the entire innovative manufacturer's portfolio. There are important advantages that arise by setting the access fee based on the manufacturers' portfolio of drugs rather than on an innovative drug-by-drug basis. For instance, manufacturers are innovating across a wide range of drug candidates. Therefore, connecting the negotiation on a manufacturer's portfolio better connects the access fee (revenues for the manufacturers) to the manufacturers' costs. From the patient perspective, patients are not necessarily sure which drugs they will need. Therefore, there is value for patients when they can access the widest possible number of innovative drugs. Pricing based on the portfolio of drugs helps ensure broad access for patients.

Since a competitive market process requires two private organizations to negotiate with one another, the access fee negotiation has not addressed a large purchaser of innovative medicines – federal and state government purchases of innovative medicines through Medicare, Medicaid, Veterans Affairs, and other government programs.

Allowing the government to negotiate prices will, inevitably, lead to price controls, which inhibits the goal of establishing value-based prices. This problem can be solved by applying the formulas already used by Medicare Part B and other drug programs. These formulas tie Medicare Part B's costs to the average price of the drugs that the private sector has negotiated. In this way, the federal and state governments will benefit from the private negotiation process, and the negotiation process will remain efficient, allowing it to establish prices that reflect a medicine's underlying value.

What has not been paid for yet is the production costs of the drug – or the second price in the two-part pricing model. Since drugs with large R&D service costs have had these costs covered, the per prescription fee covered by patients should only reflect the much lower production costs associated with obtaining the chemicals or producing the biologic processes, and manufacturing the drug safely. It would also need to include the costs for safely wholesaling, storing, and retailing the medicines.

> "Eliminating the current pricing inefficiencies in order to establish an efficient market process is the only way to ensure that the prices for innovative medicines reflect their value.

The current pricing in the market for generics exemplifies the expected per-prescription costs for most chemical-based medicines patients will purchase at the pharmacy counter. The costs for medicines with higher production costs (such as biologics) would likely be higher and could also have insurance implications should expenditures exceed certain out-of-pocket thresholds. Unless the out-of-pocket thresholds are exceeded, these transactions would not require any additional interaction with the insurer – patients could directly purchase the drug with cash from the pharmacy.

For drugs that still have exclusivity, one concern with respect to ensuring that the per prescription fee does not exceed the value of the production services is the lack of competition. Generic prices reflect the production costs due to the discipline created by a competitive marketplace, which is lacking when a drug has exclusivity rights. There are many pathways for ensuring that the per prescription fee only reflects the marginal costs of production, however.

First, the robust generic marketplace serves as an effective benchmark to highlight unjustifiable discrepancies between the production price of innovative drugs and the production price of generic drugs. Second, to the extent insurance coverage has out of pocket maximums, insurers will have an incentive to include stipulations regarding the per prescription fee that their beneficiaries will pay to ensure that the insurer's costs are not adversely impacted by any excessive pricing. Third, the separate prices for innovation and production could incent alternative industry structures that create competition. For instance, the developers of innovative medicines could find it more profitable to outsource the actual production of their innovations, which could establish competition in the production of the medicine even as the innovator receives compensation for the rights to access these innovative drugs.

Pricing Innovative Medicines Under a Two-Part Pricing Model – A Hypothetical Example

To get a sense of how this two-part pricing model would work, consider the financials and market incentives for a typical access fee negotiation between an innovative manufacturer and an insurer.

The incentives of the supply-side

The pertinent costs from the innovative manufacturer's perspective are the capital costs associated with R&D. Covering its cost of capital is typically not the explicit strategy of any company in any industry. However, just like with any business, pharmaceutical companies must earn sufficient revenues to cover its costs of capital. If this can be achieved, then the company will stay in business. Any company that cannot cover its costs of capital will, eventually, cease operations. Therefore, while perhaps not an explicit pricing strategy of any individual company, pricing to cover a company's cost of capital is an economic necessity. Based on this logic, covering its estimated cost of capital is a convenient benchmark for the access fee that manufacturers are required to earn.

> "There are important advantages that arise by setting the access fee based on the manufacturers' portfolio of drugs rather than on an innovative drug-by-drug basis.

The cost of capital for R&D expenditures is significantly higher than the research and development outlays spent to develop the innovative drug. The cost of capital must also compensate investors for the long time period it takes to develop a new pharmaceutical product and the risks that the investors must bear regarding whether the pharmaceutical research program will succeed. The risks associated with pharmaceutical innovation include the potential the new drug will not be effective, that it will be unsafe even if it is effective, or the pharmaceutical therapy is not commercially viable even if it is effective and safe.

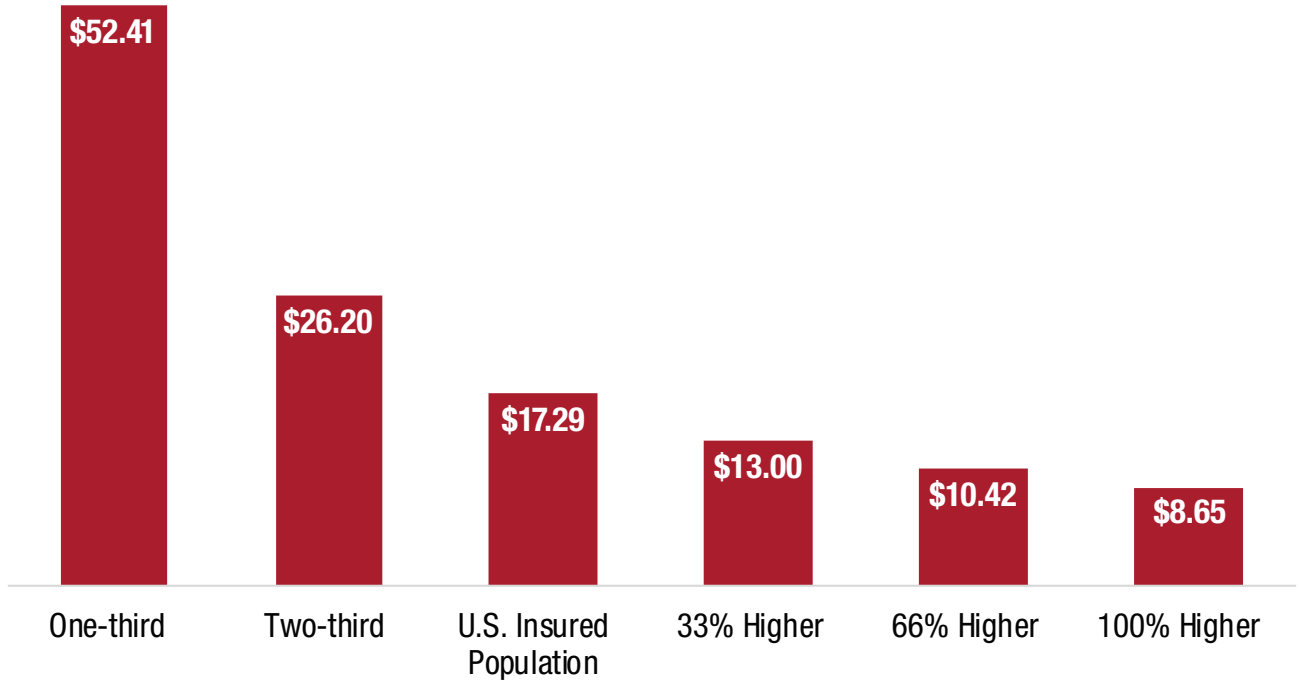
With respect to the manufacturer's cost of capital, it takes the average innovative pharmaceutical manufacturer between 10 and 15 years to develop each innovative drug in its portfolio. They also spend billions of dollars on R&D for each successful drug (including the costs for failures). In addition to the direct expenditures, the time value of money and the large risks of failure are essential components of a company's capital costs, which can be measured based on the industry's weighted average cost of capital (WACC).

While the manufacturer's assumed goal is to cover its cost of capital, the value of the drug and the capital costs of developing drugs will vary, which is one advantage of negotiating the fee over a portfolio of drugs rather than a single drug. Assuming a portfolio of 10 drugs, R&D expenditures of $3.0 billion per drug, a WACC of 4.74% (the industry's estimated WACC as of March 2021),[11] and the typical 11.5 years of remaining patent protection when each innovative drug comes to market,[12] covering the manufacturer's capital costs requires $5.0 billion in revenues a year for a portfolio of 10 innovative drugs.[13]

If the access fee is established based on a fixed fee per insured person, then the proposed per beneficiary access fee will depend upon the number of covered lives that the manufacturer believes will ultimately have access to the innovation. Based on the size of the insured market in the U.S. (289.6 million people with private or government insurance), an annual access fee of $17.29 per insured person per year would be sufficient to cover the cost of capital across a portfolio of 10 drugs. An assumption of reaching a smaller share of the insured market would cause the access fee to be higher in order to still cover the $5.0 billion in capital costs.

As Figure 2 demonstrates, if only one-third of the current insured population were provided access, the access fee would need to be $52.41 to still recoup the $5.0 billion in capital costs. However, spreading the costs of innovation to other countries would lower the necessary access fee further. If the potential population were double the current U.S. insured population, the necessary access fee would fall to a bit under $8.65 to still recoup the $5.0 billion in capital costs.

Figure 2
Access Fee per Beneficiary Across Alternative Assumed Beneficiary Market Sizes



While the cost of capital is a useful benchmark, there are other important value considerations from the manufacturer's perspective. Some drugs will provide effective cures for awful diseases, extend patients' lives, improve patients' quality of life, and/or significantly reduce other health care expenditures. Other drugs may provide fewer of these benefits. The expectations of these health and financial benefits are also an important part of the negotiation process between the manufacturers and the insurers and could raise the possibility of including "outcomes-based" contract clauses into the access fee. Depending upon the manufacturer's evidence regarding these issues, the actual proposed access fee could vary from the values presented in Figure 2.

These other important value considerations also increase the benefits from basing the access fee on a portfolio of drugs rather than setting the fee on a drug-by-drug basis. When set over a manufacturer's portfolio of drugs, the quality of life and impact on other health care costs are averaged across many drugs. Just like holding a portfolio of stocks diversifies against individual risks, allowing investors to earn the average return of the market, diversifying across a large number of drugs creates greater certainty that the average quality of life and cost benefits will more closely reflect the industry average. This improved certainty increases the ability of the negotiators to set the access fee that properly values these other important value considerations.

The incentives of the demand-side

On the demand-side of the negotiation, the insurer's goal is to provide their beneficiaries with access to the drugs they value but not overpay for this access, which is paying an access fee that exceeds the value that their beneficiaries are willing to pay. Based on the portfolio of 10 drugs, an insurer would be willing to pay the proposed access fee (e.g., $17.29 per beneficiary) if:

- Patients valued the portfolio enough such that the insurer could raise premiums to pass along the additional $17.29 access fee without losing beneficiaries, which is an indication that patients value these innovations at that price and/or,
- Paying this fee (and thus being able to offer their beneficiaries access to these innovative drugs) improves the insurer's ability to attract beneficiaries due to the high value they place on having access to these drugs.

Separate from these justifications, insurers will also have an incentive to pay the access fee without a need to raise premiums (or only partially raising premiums) due to the potential impact that covering the drug could have on other health care costs that insurers must pay. Take the costs associated with drug nonadherence that insurers are currently bearing as an example of this potential justification.

As summarized by Viswanathan et. al. (2012), nonadherence to medicines increases total U.S. health care costs between $100 billion and $289 billion annually.[14] On a per insured person basis, nonadherence costs are between $345 and $998 annually. The out-of-pocket costs that patients must pay are an important driver of this problem. According to a February 2020 surescripts survey, "over half of patients reported that they had not taken a medication because it was too expensive".[15] Paying an additional $17.29 per beneficiary will improve patients' incentives to adhere to their prescriptions because patients will have lower out-of-pocket expenditures when they are purchasing their medicines. To the extent this leads to a meaningful reduction in non-adherence costs, costs that are 20 to 58 times greater than a $17.29 access fee, paying the access fee without raising premiums could make financial sense for insurers.

Based on the premiums that the insurer is able to charge, the estimated loss of customers from not being able to offer their insured patients the portfolio of drugs, and the estimated impact on total health care costs, the insurer will assess what access fee they are able to offer. Depending on the insurer's assessment, this could lead to accepting the fee, or negotiating for a smaller fee than proposed by the manufacturer.

It is important to note that insurers that pay too much for the drug, or fail to keep premiums as low as possible, will be offering an uncompetitive insurance service and will start losing beneficiaries. Additionally, insurers that find ways to keep costs more competitive or provide patients with access to a broader, more preferred, portfolio of medicines will gain beneficiaries. As a result, the access fee has more efficiently aligned the insurer's incentives with that of the patient, and is, consequently, able to accurately express how patients value medicines. When combined with the incentives of manufacturers (as the supply-side), the two-part pricing model creates a competitive market process (e.g., negotiation) that will tend toward prices that reflect the value of new medical innovations.

Setting the per-prescription fee paid by the patient

While these negotiations establish prices that reflect the value of innovation, they have not established value-based prices for the actual production and distribution of the medicine. This is the purpose of the second price of the two-part pricing model, or the per-prescription fee paid by the patient at the pharmacy counter or infusion center. With the need to pay for innovation services alleviated, the per-prescription fee will reflect the marginal costs of producing the drug, which are the prices that emerge in competitive markets. These prices will tend toward the value of safely producing and distributing the drug being purchased. Unlike with the access fee, the per prescription fee will apply to drugs that have exclusivity rights and drugs that do not have exclusivity rights.

Based on the average costs for a generic medicine sold over the counter, this per prescription fee, paid by the patient when they purchase their medicines, would average around $27 per prescription. For infusion drugs that have more expensive production costs, the prices would be higher; however, without having to cover the costs of innovation – including the capital costs associated with biosimilars that could be priced as part of the access fee negotiations – the value-based per prescription fee would still be significantly lower.

The Benefits Created by a Two-Part Pricing Model

There are several important benefits from establishing a two-part pricing model.

The most important benefit, which is the raison d'etre of the policy, is the better alignment of the interests of insurers, patients, and innovative manufacturers through the access fee negotiations process. This process, when based on transparent prices, balances patients' subjective valuations of current and prospective innovations with the actual cost of innovation. Further, the access fee eliminates the "emergency scenario" where patients need a medicine immediately and are, consequently, in no position to serve as an effective demand side of the market. The result is an efficient market process that establishes prices that reflect the value of innovation.

As emphasized throughout this paper, this market process that accurately conveys patients' subjective value and the manufacturer's actual capital costs is the only way to ensure that the resulting prices will accurately reflect value. Prices that reflect value as determined in a competitive market are essential for ensuring that medicines are as affordable as possible while also maintaining the incentive for continued innovation.

Furthering the benefits, competitively established prices can more easily adjust to new realities such as the discovery that a medicine can efficaciously treat other diseases, or the introduction of new competitor branded/biologic products. By making the cost of innovation the explicit subject of a balanced access fee negotiation, the two-part pricing model also creates positive incentives for manufacturers to streamline their R&D processes because the companies that can innovate more efficiently will be directly rewarded for these efforts through more profitable access fees.

It is not just the price of innovation that will reflect its value under the two-part pricing model. The per-prescription fee (e.g., prices patients pay when they receive their medicines) will also reflect its value-added, which is the production and distribution of medicines that are safe and efficacious.

Establishing a competitive process that enables prices to reflect their value also addresses other problems afflicting the health care system. Perhaps most importantly, the two-part pricing model manages the risks associated with drug affordability more efficiently. Specifically, by incorporating the costs of innovation into patients' insurance premiums, the pricing model directly mitigates patient financial risks. Instead of patients being exposed to an opaque share of the innovative costs when they receive their medicines, which can lead to significant affordability problems, the costs of innovation are diversified across the insured population. Consequently, the two-part pricing model directly addresses the problem of drug affordability by appropriately categorizing the expensive innovation costs as an insurance transaction.

Mitigating the risks of paying the high costs of innovation will also reduce the problem of patients not adhering to their prescribed medications. As discussed above, the problem of nonadherence creates up to $289 billion in unnecessary health costs, and subjects patients to avoidable health risks and complications. Since the high costs that patients can face when purchasing their medicines is an important driver of this problem, appropriately incorporating the innovation costs into an insurance transaction under a two-part pricing model alleviates one important driver of the nonadherence problem. With patients facing lower costs when they require innovative medicines, it is likely that the amount of medicine nonadherence will decline, which will have beneficial impacts on the quality of patients' health and reduce overall health care spending.

The two-part pricing model also addresses incentive problems that afflict the health care sector. Paramount among these are the improvements to the doctor-patient relationship. Take the impact on the prior authorization issue – the need for doctors to get the approval of an insurance company before they can prescribe a medicine to their patients – as an example. The use of prior authorizations has increased significantly, mostly due to non-clinical reasons such as cost management. These non-clinical uses of prior authorizations impose large bureaucratic burdens on providers and plan sponsors, and exposes patients to unnecessary health risks.[16] Under an access fee model, however, the insurer's costs are not tied to the additional use of an innovative medicine. Consequently, there is no longer any incentive to use prior authorizations to manage costs. Total systemic health care costs will decline as a result, while also improving the doctor-patient relationship and the overall health care quality for patients.

Conclusion

The premise of this paper is that, regardless of the product or service, the only way to ensure that prices reflect value is through an efficient market process. Applied to the current pharmaceutical and biopharmaceutical markets, there are many inefficiencies that are currently preventing an efficient market process from emerging. However, these inefficiencies are not innate to the drug market. Instead, by implementing alternative market structures, coupled with essential policy reforms that promote greater price transparency, an efficient market process for valuing drug innovations and valuing the safe production and distribution of pharmaceutical products is possible.

This analysis describes a two-part pricing model to demonstrate the improved incentives from such a system, as well as to illustrate how this system will tend toward value-based prices for drugs. These results are a stark contrast with the inherent inability of centralized organizations to use cost-effectiveness models to accurately value medicines, which was reviewed in the first paper in this series.

Despite these realities, research into value-based frameworks continue to emphasize how to improve the methodology that a centralized organization can employ to determine medicines' value-based prices. However, this analysis argues that such analyses should be abandoned in favor of research that examines how to minimize the current market inefficiencies in order to empower an efficient market process for pricing drugs.

Endnotes

1 Price S "Largest Health Insurance Companies of 2021", https://www.valuepenguin.com/largest-health-insurance-companies#:~:text=Also%20known%20as%20covered%20lives,insurance%20plan%20with%20that%20provider.&text=For%20example%2C%20your%20company's%20benefit,Medicare%20and%20retirement%20plans. (Accessed May 17, 2021).

2 More precisely, the prices will reflect the value of the marginal consumer. For all other consumers that purchased the product, the value they received from the product will exceed the price, making the price an even better deal.

3 DiMasi JA, Grabowski HG, and Hansen RW "Innovation in the pharmaceutical industry: New estimates of R&D costs" *J Health Econ.* May 2016; 47:20-33.

4 Technically, based on marginal costs.

5 For a more detailed discussion of the problems created by the current complex drug pricing system and potential reforms to address these inefficiencies see: Winegarden W "Improving Market Efficiencies Will Promote Greater Drug Affordability" Pacific Research Institute: Center for Medical Economics and Innovation, January 2020, https://www.pacificresearch.org/wp-content/uploads/2020/01/DrugAffordability_F.pdf; Winegarden W "Reforming Rebates Will Improve Drug Affordability" Pacific Research Institute: Center for Medical Economics and Innovation, September 2020, https://www.pacificresearch.org/wp-content/uploads/2020/09/DrugRebates_F.pdf.

6 Sood N, Ribero R, Ryan M, and Van Nuys K "The Association Between Drug Rebates and List Prices" USC Schaeffer White Paper, February 11, 2020, https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.

7 "Secure Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report" Association for Accessible Medicines" September 2020, https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf.

8 "Medicine Spending and Affordability in the United States" IQVIA, August 2020.

9 While not discussed for tractability purposes, patient access and adherence to innovative medicines can reduce expenditures in other health care services, such as fewer hospital stays or emergency room visits. These potential savings, while not part of the premiums, are derived from providing patients with more efficient access to innovative medicines.

10 Price S "Largest Health Insurance Companies of 2021", https://www.valuepenguin.com/largest-health-insurance-companies#:~:text=Also%20known%20as%20covered%20lives,insurance%20plan%20with%20that%20provider.&text=For%20example%2C%20your%20company's%20benefit,-Medicare%20and%20retirement%20plans. (Accessed May 17, 2021).

11 http://pages.stern.nyu.edu/~adamodar/.

12 Lichtenberg FR and Duflos G "Time Release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public" Center for Medical Progress at the Manhattan Institute, October 2009.

13 For a detailed discussion of these issues see: Winegarden W "The Economics of Pharmaceutical Pricing" Pacific Research Institute, June 2014, https://medecon.org/wp-content/uploads/2019/03/PhamaPricingF.pdf.

14 Viswanathan M et al. "Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States" *Annal of Internal Medicine,* December 4, 2012, https://www.acpjournals.org/doi/10.7326/0003-4819-157-11-201212040-00538.

15 "Prescription Price Transparency and the Patient Experience" surescripts, February 2020, https://surescripts.com/docs/default-source/pressrelease-library/2020_price-transparency_data-brief-patient-survey.pdf.

16 Popovian R, Winegarden W "An Estimate of the Net Benefits from Prior Authorization Policies in the U.S." *Health Sci J.*, April 2021, 15 No. 4: 833.

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