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Fairness in the trade-off between drug price regulation and investments in research and development: A survey of economists

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Abstract

One of the most important policy issues in pharmaceuticals is the tradeoff between innovation and access. High drug prices promote additional research and development while hampering access. We used the behavioral economics theory of dual-entitlement to design a survey of economists who are members of the National Bureau of Economic Research to investigate the role of fairness in the prescription United States drug market. Sixty-two percent of respondents expected that price regulation would have a large or moderate impact on research and development by pharmaceutical manufacturers. The survey respondents reported manufacturers should be compensated for the upfront investments and risks they take in the drug development process. However, they also believed that prices were impeding access, especially for low-income patients, and making it more difficult for federal state and local governments to control drug spending. Taken together, these responses represent the tension between pricing, innovation and access.

JEL Classification: D9; O31; I18

Keywords

price regulation — research and development — dual-entitlement — expert opinion — innovation — incentives

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Background

While the markets for different types of goods and services vary in many ways, one common thread throughout all sectors of the economy is the presence of tradeoffs, or the opportunity cost, of making decisions. Thus, the market for the development and sale of prescription drugs is subject to tradeoffs as well.

Our primary goal is to report the results of a survey, of expert economists, on fairness in drug pricing. We place our results in the context of the current literature on dual entitlement theory and provide perspectives on how fairness is a critical component of the larger discussion on different approaches to making the tradeoff decision.

Dual entitlement theory

The dual entitlement theory was developed in the field of behavioral economics (Kahneman et al., 1986; Xia et al., 2004) and has commonly been used to assess fairness in other sectors of the economy including housing, food and automation (Xia et al., 2004; Dickson & Kalapurakal, 1994) – applications in the healthcare sector, and more specifically pharmaceuticals, are lacking. Previously, we used dual entitlement theory as the foundation of a survey to assess the fairness of prescription drug prices (Trujillo et al., 2018).

Dual entitlement theory asserts that both sides, consumers and producers, are entitled to rights based on a reference point. There are three fundamental elements that assessment of the fairness of prices: outcomes to the participants (i.e. the value of the drug to the patient and the producers), presence of reference transactions (i.e. prices of other similar drugs), and any changing circumstances for the producer (i.e. higher production costs for the drug manufacturer). The weights of these three elements with respect to the consumer and producer's reference point determine the assessment of fairness in any transaction.

In this paper, we focus on an external component that could affect the perception of fairness - the willingness of the government to engage in some form of price regula-

tion/negotiation. There are many different types of regulation/negotiation that have been proposed in the United States and most other industrialized countries use some form of regulation/negotiation to control spending. A 2018 Council of Economic Advisors report showed that the United States provides over 70% of profits for drug companies and argued that other countries should pay higher prices (Hassett et al., 2018). A Commonwealth Fund survey comparing the public's difficulty getting access to drugs found that the United States respondent was 2-3 times more likely to say that cost was the reason they had difficulty accessing drugs than people in other countries. We wondered how economists viewed this policy discussion of higher profits leading to additional research and development and less access to the same drugs. We were also interested in the economist perceptions of fairness and willingness to use price regulation to promote greater access.

Motivation for survey

Expert opinion is often a good resource in determining the acceptability and impact of policy proposals in an area in which little experimental or quasi-experimental work can be done. In this paper, we examine the economist's views of the tradeoffs between access and innovation in the pharmaceutical market.

Our contribution

We explore this tradeoff by asking economic experts a series of questions on fairness in the prescription drug market. We conducted a survey of economists from the National Bureau of Economic Research to assess how they perceive different aspects of fairness in the prescription drug market. The survey questions attempt to identify how economists define fairness in the prescription market. The Institutional Review Board at the Johns Hopkins Bloomberg School of Public Health approved our survey. Details regarding survey implementation can be found in a published article (Trujillo et al., 2018).

We combine the survey results with a summary of the current literature examining the possible effects of implementing regulatory policies in the United States and discuss the results of our survey of economists about the tradeoff between price regulation, access and research and development.

Methods

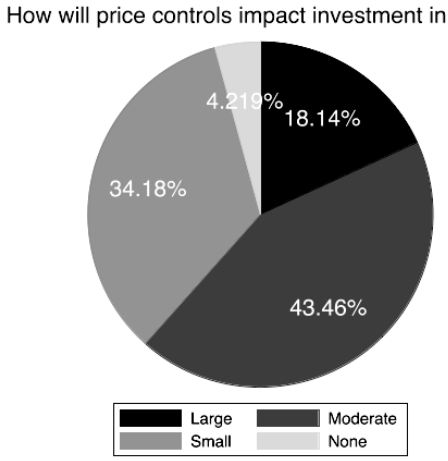
The survey has three main parts. First, we asked participants about fairness of the prices of branded prescription drugs. Second, participants were asked to explain the reasons for their assessment. Finally, we asked respondents to anticipate pharmaceutical manufacturer's reactions. These included questions about how price changes in different circumstances would affect their level of support for different policy proposals. In this section, we gauged the potential magnitude of the impact of price regulation on research and development and access.

We piloted this survey to a group of medical and public health students at Johns Hopkins University. We then identified and surveyed economists from the National Bureau of Economic Research.

Results

We had a total of 923 potential respondents and achieved a 34% response rate. Most respondents reside in the United States (98%) and the majority of the economists were affiliate with an academic institution (97%). The most prevalent field of interest in the response was health economics followed by applied economics. Finally, about 65% of respondents had a family member that is taking branded prescription medicines. While a prior report discusses the economists' responses to each of the three types of questions discussed above, this paper focuses specifically on questions that tie together investments in research and development and access to drugs – drug price served as the link between the two.

One question explained that there is "disagreement about the degree to which controlling prices for pharmaceuticals will affect investments" in research and development and asked how the respondent felt price controls would impact R&D. 62% of the economists responded that price controls would have a large or moderate impact on research and development (Figure 1).

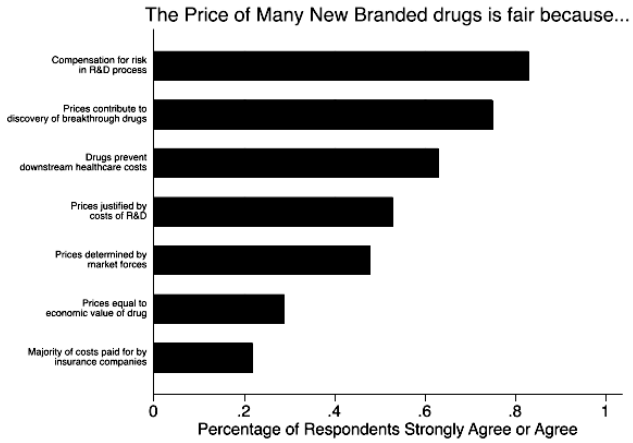


Notes: Respondents indicated the magnitude of impact of price controls on investments in research. There is some variation, however, a majority of respondents indicate a moderate or large impact.

Figure 1. Impact of Price Controls on Research Development

To assess the tradeoff between innovation and access, economists were then asked to rate their "level of agreement or disagreement" with various reasons why "some have argued that the pricing of branded prescription drugs is fair." Economists were split on this issue – about 53% agreed and 47% disagreed (Figure 2). When asked if drug companies should be compensated for the risk they take in investing in the drug development process, 84% agreed (Figure 2). Economists viewed other justifications for branded drug prices being fair as well. 75% of economists agreed that prices of

branded drugs are fair because "prices contribute to the discovery of breakthrough drugs" (Figure 4). 63% of economists agreed that branded drug prices were fair if they "prevent downstream health care expenditures" (Figure 2). Economists seem to believe that the potential for cost offsets in the future is one way of measuring the value of prescription drugs – one of the elements in the dual entitlement framework – that contributes to the assessment of fairness.

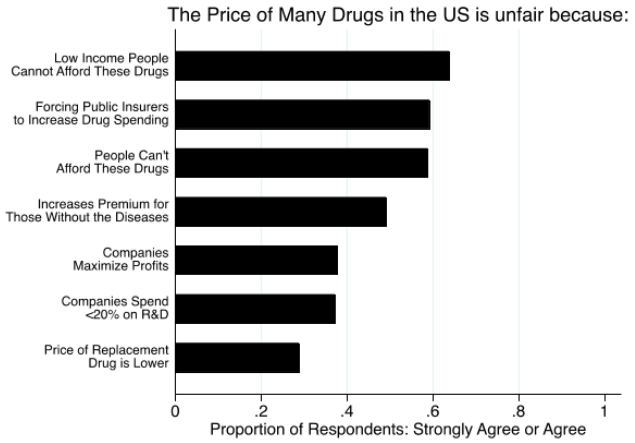


Notes: Respondents indicated their level of agreement with reasons behind "fair" drug prices. More than 60% of respondents agreed that manufacturers should be compensated for risks they take in research and development, prices contribute to the discovery of breakthrough drugs and prescription drugs can prevent downstream healthcare costs.

Figure 2. Why are prices fair?

Recent work done in the field of drug pricing policy has argued against using research and development costs as a justification (Kanavos & Reinhardt, 2003) for high drug prices. Using public filings of research and development and drug sales volume information, Yu et al. found substantial differences in prices – list prices in other developed countries are, on average, 41% of U.S. net drug prices for the 20 top-selling drugs in the United States (Centers for Medicare & Medicaid Services, 2018). Another study found that the higher prices in the United States resulted in an 'excess premium' of $116 billion in 2015 (Centers for Medicare & Medicaid Services, 2018). These researchers computed that if the 'premium' placed on the U.S. market was lowered just to match investment in R&D, it would have saved the American health care system about $40 billion in 2015 (Centers for Medicare & Medicaid Services, 2018).

We also asked economists their levels of agreement with a variety of commonly cited reasons why branded drug prices are unfair (Figure 3). Many of these reasons focus, either directly or indirectly, on the other side of the tradeoff – patient access to prescription drugs. Over 60% of economists agreed that prices were unfair because "low income people cannot afford these drugs." This highlights the varying levels of, or barriers to, access based on insurance coverage. Further, it seems to logically follow that over 50% of respondents also agreed that prices of branded drugs were unfair because they "force public insurers like Medicaid or Medicare to significantly increase drug spending." More generally, economists felt that branded drug prices were unfair because "many people" cannot afford these drugs – without any specific socioeconomic characteristics. These results show that affordability is a component of the respondents' assessment of fairness and is particularly important in the low-income population. These results, juxtaposed with the responses described above, emphasize the tension generated by this tradeoff.



Notes: Respondents indicated their level of agreement with reasons behind "unfair" drug prices. Over 50% of respondents indicated the following reasons for unfair prices: low income people cannot afford high priced drugs, public insurers are forced to increase drug spending and people in general, of all income levels, cannot afford these drugs.

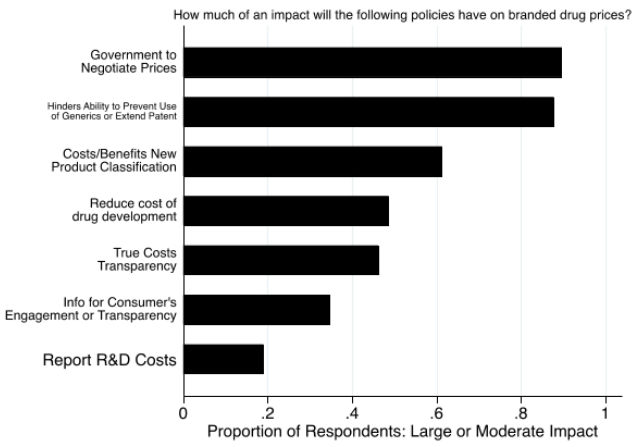
Figure 3. Why are prices unfair?

After understanding our respondents' position on fairness of the reasons for drug prices, we asked how a series of policies might impact branded drug prices in the United States (Figure 4). Providing the government with the ability to negotiate prices and preventing 'pay-for-delay' programs received the strongest support – less than 20% felt that reporting research and development costs would have a meaningful impact on drug prices. The economists' support of other policy proposals to address drug prices demonstrates that direct price controls may not be the only approach policymakers should be discussing.

Discussion

Price regulation across the Globe

Price regulation in the United States is nearly nonexistent and so it is challenging to assess in this particular setting, motivating our goals of the survey. However, many European countries, with universal or publicly funded health care systems, practice either external or internal reference pricing (Frank & Newhouse, 2008) as a form of price regulation. Reference pricing has been proposed as a form of price controls



Notes: Survey respondents indicated the magnitude of impact of various policies on branded drug prices. More than half of respondents indicated the following policies would have a moderate or large impact: allowing federal agencies to negotiate drug prices, limits manufacturers ability to employ "evergreening," and using cost-benefit information to classify new products.

Figure 4. Impact of policies on branded drug prices

in the United States as a way to help payers to secure the lowest price (Frank & Newhouse, 2008). The Centers for Medicare & Medicaid Services has proposed taking a step in this direction with the International Pricing Index model. This would essentially tiethe prices of a select number of therapeutics faced by patients in the United States to an international benchmark.

A variety of alternatives, to direct price controls, have been proposed for the American health care setting given the currently fragmented system. These include initiatives to empowering the federal government to negotiate drug prices on behalf of all public payers (Kanavos & Reinhardt, 2003; Neumann et al., 2011), advanced purchase agreements with the federal payers (CMS Newsroom, 2019), and risk-sharing agreements (American Hospital Association, 2018). Although the future of the IPI model remains in flux, CMS has proposed other mechanisms to significantly increase drug cost transparency for Medicare Advantage beneficiaries. The final rule released in the summer of 2019 requires Part D plans to provide clinicians with information on out-of-pocket costs for drugs at the point of care (Bai et al., 2019). With this additional information in hand, patients are better positioned to make well-informed decisions about their health care in partnership with their provider. The Administration's hope is that by enhancing transparency to the consumer, manufacturers will be motivated to compete on price and thereby increase the accessibility of therapies for patients. Part D plans will eventually be required to integrate this feature into electronic prescribing tools or electronic health record systems in an effort to ensure a seamless exchange of information at the time of care.

The current Administration has also proposed industry members disclose list prices of their products in any direct-to-consumer television advertisements in an effort to further empower patients to navigate the health care system. While some of our survey respondents felt efforts to increase transparency would make a substantial impact, explicit drug pricing transparency proposals regarding list prices have proven controversial (Lobo, 2019; Aleccia et al., 2019). As is the case with any policy, decision-makers must be aware of potential unintended consequences. Although manufacturers may be motivated to compete on prices, consumers may link higher prices to better quality – shifting demand towards the more expensive therapy.

We continue to see innovative efforts towards payment for medical products. States have some more flexibility and continue to work with CMS to find alternative approaches to increase patient access to therapies. Several states have acquired the necessary waivers from CMS to develop and implement outcome-based contracts (OBC) – those in which the payment for a particular therapy is contingent upon achieving a predefined set of outcomes (Washington State - Health Care Authority, 2019). Specifically, Oklahoma and Michigan have finalized OBCs for three therapies with three separate manufacturers.

Louisiana and Washington have taken payment reform a few steps further. With the help of supplemental rebate arrangements facilitated by CMS, these states have entered into subscription-type payment models that take a population health approach to increasing access and improving health (Greene & Padula, 2017). Each state has entered into a state-specific arrangement with manufacturers of direct acting antivirals for the treatment of Hepatitis C (HCV). These arrangements include an annual, predefined expenditure cap for the state that effectively reduces the unit price of the drug. Beyond the expenditure cap, states face close to zero cost for additional units of therapy. The redistribution of risk across the stakeholders realigns incentives to increase access to curative therapies like those available for HCV. Each model includes several common features – the state of Washington, however, has proposed additional public health initiatives to facilitate enhanced surveillance efforts (Freed et al., 2020). Although there is no one-to-one comparison of advanced purchase agreements sometimes found in international settings, these models represent an overall trend towards value-based payment in the American health care system. An anti-price gouging bill, to stymie 'unconscionable' increases in drug prices had briefly gone into effect in early 2017 in the state of Maryland (Gagnon & Wolfe, 2015). While 4th U.S. Circuit Court of Appeals put this on hold in 2018, it represents another unique legislative approach to address the issue of rising drug prices. Drug importation into the United States continues to be a point of debate in the national health care system discussion (Baker, 2013).

Effects of price controls on economic and clinical outcomes

Researchers have simulated the consequences of price controls in specific healthcare settings. For example, some have shown that Medicare Part D could accrue substantial savings if it secured the same prices as Medicaid or the Veteran's Administration (VA) (Frakt et al., 2012; Moreno et al., 2017; Vernon, 2015; Lieberman & Gisburg, 2019). In the short-term, Medicare would see these savings in the form of reduced drug prices. However, Vernon argues that you need to consider the long-term cost to patients of decreased innovation that may not be immediately obvious in his discussion of static versus dynamic efficiency (Verb, 2019).

The IPI model provides a timely example of these tradeoffs. During its open comment period, CMS received input that highlighted both the short-term advantages and long-term disadvantages (Lieberman & Gisburg, 2019). While at first glance, it may seem to level the playing field for patient access to therapies in the United States, the proposal has received pushback. Models suggest varying degrees of impact on prices, in both directions, given the limited group of therapeutics that it includes. Many have cautioned that this may have a chilling effect on investments in innovation or research and development by the pharmaceutical industry given that the American taxpayer often subsidizes these efforts through the prices they pay (Fellows & Hollis, 2013). Others have outlined the hurdles likely to stagnate the implementation of this proposal in the US health care system given the way drugs are paid for (Mazzucato, 2015). A notable unintended consequence of this proposal includes increases in prices abroad to adjust for lower prices in the United States. Although the magnitude of this adjustment will depend on price elasticity in each market, this may reduce any potential savings from the IPI model.

This tradeoff highlights the need for a discussion from a fairness perspective. The third element of the dual entitlement theory provides a good framework within which to ask this question – how to determine if producers and consumers gain benefit from a particular product or marketing decision. Economists have simulated these long-term effects on innovation and subsequent life expectancy. Moreno et. al found that using VA level pricing would save Part D plans between $0.1 trillion and $0.3 trillion in lifetime drug spending for those born between 1949-2005. Others have found annual savings of similar magnitude to Medicare Part D (Frakt et al., 2012; Moreno et al., 2017; Vernon, 2015; Lieberman & Gisburg, 2019; Verb, 2019). At the same time, others have found that price setting in Part D could reduce the introduction of new drugs by nearly 25% and therefore reducing life expectancy for those born between 1991-1995 by almost 2 years.

While manufacturers often use their R&D costs to justify future drug prices, it is important to note that those investments are sunk costs (Fellows & Hollis, 2013) and are only minimally relevant to pricing a drug once it is approved for use and marketing (Kanavos & Reinhardt, 2003). This key economic concept also plays a role in the fairness argument about policy tradeoffs. If investments in innovation are defined as sunk costs, is it fair to pass on those costs to the consumer? However, at the same time, drug companies must incur nearly all sunk costs prior to applying for FDA approval and only a small percentage of drugs successfully make it to the market (Mazzucato, 2015). The differential timing of the investments and benefits exemplify Vernon's argument above.

The results of our survey showed that economists, unlike the general public, do not perceive research and development costs to serve as a valid justification for rising drug prices (Figure 3). However, the government, through agencies like the National Institutes of Health (NIH), provides some of the funds for basic science research and pharmaceutical manufacturers fund the subsequent clinical trials required for FDA approval.

If a significant portion of the development of novel therapies is federally funded, using taxpayer dollars, is it fair for pharmaceutical manufacturers, who provide the resources to bring the product to market, to justify their high prices based on their investment in research and development? (Mazzucato, 2015). We explored these justifications in our survey on fairness and found that economists believed drug companies should be compensated for the risks that they take. Almost 40% of respondents agreed (Figure 3) that drug prices were 'unfair' because manufacturers spend less than 20% of their budget on R&D, while a substantial portion is spent on marketing or advertising. These two assessments of fairness are in some tension with each other. The benefits to the producer and consumer are realized at different points in time and so assessing fairness in this context is complicated by the dynamic nature of the transaction, but highlighted by the third element of the dual entitlement theory.

Direction for future research

Given how unique the American health system is, future research should consider these defining aspects of the care setting. By choosing to cover certain drugs, insurers send signals to manufacturers regarding where they should invest their research dollars given that there is a market for those products. The magnitude of the signal, given the available resources to the payer, might explain why certain companies invest in certain therapeutic areas. Each payer's resources are generated from different sources – private insurers from premiums paid by its beneficiaries and public payers from taxes. Future research could incorporate how public payers, in particular, and the taxpayers that fund them, may influence an individual's assessment of fairness.

The type of innovation – the disease area – should also be considered when making fairness assessments. For example, a drug for a chronic condition, such as hypertension, will be taken everyday for the rest of a patient's life. However, a treatment regimen for an infectious disease, like Hepatitis C, is completed once and the patient is cured. With a cure, in subsequent years, the manufacturer can expect their profits to

decline and so from the producer's perspective, this is incorporated into their reference point used to assess the fairness of the price.

Conclusions

The tradeoff between access and innovation is at the root of this policy debate. We approached this issue from the perspective of fairness given the short-term and long-term consequences of drug pricing policy decisions. Pharmaceutical manufacturers, as the producers and sellers of a product, have a right to generate a profit, while the unique type of product they create entitles patients, or the consumers, to affordable prices. While our survey was one approach to better understanding the fairness of these tradeoffs, we found that many have simulated the implications of various approaches to price regulation.

One notable limitation in our study is the focus on economic perspectives. In order to enact any piece of legislation, we must assess the policy from a political standpoint and determine whether or not there is an appetite for such substantial changes in the way the pharmaceutical market functions. Our survey demonstrated that economic experts in the United States do believe that direct price controls would significantly impact investment in R&D – and the majority agrees that manufacturers should be compensated for the risk they take in this process. It follows that we need an approach that preserves the incentive to invest in drug development while maximizing access to affordable drugs. Mechanisms by which to achieve these goals simultaneously are available, have been widely discussed and could be adapted for the American setting.

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