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The Role Of Value And Cost In Prescription Drug Pricing

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In recent months, controversy about prescription drug prices has been in the headlines like no time since the passage of Medicare Part D. Outrage about high prices and large price increases has been directed at a wide swath of drug companies by members of Congress, candidates seeking office and many others. Some have defended pricing by suggesting that prices are set according to the value they provide to patients. Others counter that such pricing is unethical, particularly for critical/lifesaving medicines. To charge more because a product is more important to the life and well-being of a patient (a notion defined as value-based pricing) is questionable to many. Some argue that the more important the product, the cheaper and more accessible it should be.

To make sense of these arguments and to understand the role of value in drug pricing, it is important to distinguish between innovative therapies — typically protected by patents — and generics, which are copies of formerly patented products that no longer enjoy that protection. While this distinction is a bit of a simplification, given the recent development of biosimilar medicines that reference originator biologics, it is, nevertheless, a useful distinction for understanding the roles of value and cost in drug pricing.

In broad terms, it is economically desirable for the price of an innovative therapy to be driven by the value it provides to patients. In contrast, prices of generics ideally should be driven by production cost and would not typically exhibit value-based pricing. Much of the recent commentary has ignored this important distinction. Understanding it and setting public policy according to this important difference is critical to the well-being of patients today and in the future.

Pricing of Generics

After innovative products lose patent protection, subject to U.S. Food and Drug Administration approval, other companies are free to manufacture and sell generic copies of those products. Traditionally, this has led to rapid entry and price competition that drives prices down to levels near the drug's production cost. Under normal circumstances, once this has happened, substantial enduring price increases for generic drugs would not be expected.

If a local grocer were to suddenly raise the price of milk far above its acquisition cost, customers would soon go elsewhere, leading the grocer to reduce its price back to where it started. This is the type of competitive pressure that disciplines the prices of most products in the economy and forms the basis of what economists think of as "economic efficiency." It typically works the same way with generic drugs. If

the maker of a generic drug were to raise the price far above its manufacturing cost, retail pharmacies and other payers would look to other suppliers, and competition would keep prices in check. Some companies might choose to adopt higher quality standards or other costly investments that lead to somewhat higher prices reflecting their higher costs, but in order to be sustained, any cost-driven price differences among generic competitors must be valued by enough customers to justify the higher price in the mind of the payer.

There have been some high-profile exceptions to this story in the generics sector. Some companies that are the only manufacturers of certain generic drugs have raised prices substantially without encountering the type of competition that would have prevented such price increases or reversed them after a short period. Opportunities for such behavior are relatively limited. Where such pricing has happened, the root cause has a great deal to do with the lack of competition. If it were easy to get in and out of the market for a generic drug, prices would remain close to production cost, any price spikes would be short lived, and affordability concerns would largely vanish.

Pricing of Innovative Drugs

In contrast, value-based pricing plays an important role in the case of innovative drugs. When prices of new therapies treatments are tied to value, the interests of prospective patients and the companies that develop new therapies are aligned. When that link is broken, incentives are misaligned and consumers are left worse off over time.

To illustrate this, consider an important health condition for which there is presently no highly effective therapy (Alzheimer's, Zika virus, etc.), or for which existing therapies are not universally effective. Patients who currently go without effective treatments would obviously be better off if a new effective treatment became available, because unless one is developed, they have no access to treatment at any price.

Companies that might develop new medicines face choices about where to invest their (or their shareholders') money. They choose to invest based on the size and the likelihood of a payoff. This is not so different from a real estate agent engaged in the recent fad of "house flipping." The agent tries to identify properties with the greatest potential gain in value from the renovations to the property. The larger the anticipated gain, the more the agent and his or her investors will be willing to invest in a property. If they knew there were limited prospects of making a return, or more explicitly, if a rule existed that allowed them to recover nothing more than the cost of their investment, the house flipping business would be much less attractive and fewer properties would be renovated.

In the same way, if the price an innovator anticipates being able to charge for a new drug is tied to the value it will provide to patients, the company will be motivated to invest finding products that provide the most value to patients. If prices are divorced from patient value, the company's investment decisions will be driven by something else, and the most valuable patient needs are less likely to be met. In particular, if a new wonder drug is anticipated to be so essential that society it would be considered unfair or unethical to charge a price above some affordability benchmark, a company would be far less likely to make the investment needed to bring that drug to market. This problem is exacerbated in the biopharmaceutical industry by the high cost and low probability of success in the search for new treatments.

In a world where prices are divorced from value creation, and when the investment in value creation is costly and unlikely to pay off in any particular instance, it may make better financial sense for a company

to invest in something less risky and less controversial. Hence patients are more likely not to see new treatments for their most pressing concerns. A key ethical question, then, is whether consumers are better off with a value-based price for a new treatment or without the treatment at all.

Paying Value-Based Prices

Ideally, in the presence of value-based pricing, when a wonder drug is developed, patients would have insurance so they could pay a price that corresponds to the value created by the new therapy. The fundamental purpose of any type of insurance is to dampen the financial impact of high-cost/catastrophic events. When insurance properly plays its role, consumers pay a premium and perhaps a manageable copayment. In a competitive health insurance market, insurers (or their surrogates) negotiate prices for new drugs, and patient premiums and copayments are kept at manageable levels.

It is notable that such negotiations do have dramatic effects on prices paid for new drugs. For example, within the first year of the introduction of hepatitis C drugs, competitors entering the market negotiated price discounts with insurers of more than 50 percent. Those negotiated discounts are not typically seen by the general public, however, so awareness of the savings is limited. Of course, when insurance markets are not competitive, or when people do not buy or cannot afford insurance, these outcomes may not be obtained.

An Ethical Dilemma?

It is fair to ask, for patients without affordable insurance, whether it is ethical to charge a value-based price for a new "essential" therapy. In approaching that question, it is important to keep in mind that if the new therapy had not been developed in the first place, patients would not have the option of using it at all. So one must consider the baseline from which the ethical argument is made: which is more ethical, a new treatment at a value-based price, or no new treatment?

Fortunately, the tradeoff is rarely that stark. For most conditions there is another, perhaps less-desirable, treatment available, so the relevant question becomes whether the option of having the newest available treatment at a value-based price is better than living with the alternative/older technology. In considering this tradeoff, it is important to remember that the effective price of the new therapy will almost always be reduced by the introduction of competing products, and eventually will be substantially reduced by the entry of generics. So even if the newest therapy is out of reach of certain consumers today, it will not remain so.

Despite the logic of this argument, many people believe that the ethical dilemma is not solved by simply pointing out the potential gain to all people from the value represented in new treatments, or the gain to future patients when patents expire. Many still want a solution for patients who cannot afford to pay — particularly when the new medicine is critical to life or well-being — and some simply object to companies making profit from illness.

Is There a Solution?

When the ability to pay stands between a patient and a critical new treatment, it makes sense to consider the most effective and least ethically problematic way to solve the problem. The apparently simple solution of forcing the manufacturer to charge a price divorced from value imposes on all of society a burden of a lower (arguably much lower) likelihood of new treatments being developed. The

ethical problem associated with that solution is hard to see because we can't see what won't be developed in the future. That cost is nevertheless real, and according to widely accepted economic analysis, it is quite large.[1]

Alternative approaches include encouraging manufacturers to provide new products at discounted prices for those that cannot pay, and implementing public safety net programs that provide essential medicines for low-income patients. The core of these solutions are already in place. Many or even most manufacturers already have patient assistance programs for low-income patients and Medicaid provides coverage to low-income Americans, paying manufacturers the lowest prices available to any commercial buyer.

So what are the solutions to the most notable drug price concerns? For generics, it seems most sensible to address regulatory barriers to entry and exit so the problem is taken care of by competition. For innovative therapies, competition still plays a role, but that competition needs to extend to the insurance market so consumers are offered coverage that meets their needs, and prices and premiums reflect value creation. In that environment the prices of some new therapies still seem high because they will create great value. If the perceived ethical problem is that anyone is paying value-based prices, then the dilemma is more serious and a solution probably does not exist. If we want valuable new therapies, someone has to pay for them. If no one will, fewer of the health challenges that stand before us will be addressed and we will almost certainly be left without many of the advances in health that innovation promises.

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[1] See, for example, Topel and Murphy's Measuring the Gains from Medical Research, University of Chicago Press, 2003.
