The Future of the Pharmaceutical Industry: Beyond Government-Granted Monopolies

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Abstract: Just as tariffs lead to economic distortions and provide incentives for corruption, so do patent monopolies on prescription drugs, except the impact is often an order of magnitude larger.

Introduction

We all know the story of why tariffs are bad. By raising the price of a product 10 or 25 percent (the typical range for tariffs among wealthy countries), in addition to raising the costs to consumers, the tariff also leads to bad outcomes in the form of corruption and wasted resources. For example, the tariffs that the Trump administration imposed on imported steel led to major battles over exemptions from these tariffs by various steel users.[1] There is always the risk that these exemptions will be decided based on political, rather than objective economic, criteria.

In public debates the distortions associated with patent monopolies are rarely seen as comparable to the distortions resulting from tariffs, but they are nonetheless of the same type. Patents typically raise the price of a protected drug thirty or forty-fold above the free market price and, in some cases by more than 100-fold. For example, when the Hepatitis C drug sofosbuvir was selling for almost $50,000 in the United States, a generic version was available in India for less than $400.[2] This is equivalent to tariffs of several thousand percent or even more than 10,000 percent.

Just as businesses take steps to avoid trade tariffs, drug manufacturers take steps to abuse patents. The large gap between the patent monopoly price and the free market price encourages a wide range of rent-seeking behavior, which has substantial economic costs as well as public health consequences.

The most troubling form of rent-seeking behavior in the pharmaceutical industry is misrepresenting the safety and effectiveness of drugs in order to maximize monopoly profits. Since drug companies have access to their data, and no one else does, they are often able to get away with these sorts of misrepresentations. They are helped by the fact that they can use a portion of their monopoly rents to pay for and promote statements of researchers and doctors touting the benefits of their drugs. The most notorious case of misrepresentations to promote drugs is with the new genera-

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tion of opioids, where several major manufacturers were alleged to have deliberately downplayed their addictiveness in order to promote sales.

The drug companies also try to maximize their monopoly profits by using lobbying expenditures and campaign contributions to enlist the support of politicians, who can then support favored treatment for drugs in public programs like Medicare and Medicaid.[3] They may also put in place laws or rules which require private insurers to pay excessive prices for drugs of little value.

Drug companies further utilize strategies to forestall generic competition.[4] They also often file patents of dubious validity. In these battles with generic manufacturers there is a fundamental asymmetry.[5] The brand manufacturer is fighting to be able to sell the drug at the monopoly price whereas the generic company is looking to sell the drug at the free market price. In this context, the brand manufacturer has an enormous advantage since they have so much more at stake.

Patent monopolies also distort the research process itself. Drug companies will often spend large amounts of money developing drugs that essentially duplicate existing drugs, with the hope of getting a portion of the patent rents. While it is generally of some benefit to have multiple treatments available for a condition (some people may react poorly to a specific drug), in general, research money would be better spent on developing drugs for conditions where there is no effective treatment. There is also relatively little money devoted to developing treatments for conditions that primarily affect lower income people both in the rich countries and the developing world.

These are well-known reasons for why patent monopolies have negative consequences in the prescription drug market. However, precisely because patent monopolies give so much power to the pharmaceutical industry, it is difficult to envision a direct attack at the federal level on the patent-financed development of drugs. As an alternative, there are steps that can be taken at the state or local level, or by private non-profits, to try to undermine the system.

Working Around U.S. Patent Monopolies

Since the United States is the only wealthy country in the world that gives drug companies virtually unchecked patent monopolies, this means drug prices are considerably higher than in any other country.[6] This creates enormous opportunities for savings by getting around U.S. monopolies and allowing patients to get drugs at lower prices elsewhere. This means either bringing lower cost foreign drugs into the United States or having patients in the United States go overseas to take advantage of lower cost drugs.

Importing drugs into the country is the more efficient route, since it is much cheaper to transport drugs than people. However, large-scale importation is blocked by federal law, and even importation for personal use is illegal.[7] (The Health and Human Services Secretary does have the authority to allow importation from Canada). As a practical matter, the Food and Drug Administration has generally opted not to take enforcement measures against patients who import modest quantities of drugs (less than a three-month supply) for personal use.[8]

While state and local governments may run into legal obstacles if they were to directly promote importation, for example by keeping a list of high-quality mail-order pharmacies in other countries, they could take more modest measures which would almost certainly be within the law. For example, they could publish price lists showing the relative cost of drugs in the United States and a range of other countries. This would simply be providing information that allows people in the United States see how much more money they pay for drugs as a result of unchecked patent monopolies.

This is in fact the sort of action that could be undertaken by any organization and promoted by state and local governments who want to better inform their

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citizens on why drug prices are high. Specifically, if there were one website that catalogued prices for various drugs in countries around the world, any state or local government would be able to have this information posted on their own website to broaden public awareness of the price differences. If, based on this information, people decided to seek out lower cost drugs from other countries, that would be entirely their own choice.

The other route, of sending people to other countries to take advantage of lower drug prices, is considerably more costly, but may still make sense in the context of the large price differences for many important drugs. With the cost of many drugs in the United States 100 times or more above the cost of generic versions in other countries, it may be possible to pay for a patient's travel, including a family member, and still save money on the cost of treatment.

The simple arithmetic suggests that such situations may not be rare. For example, the list price for the Hepatitis C drug Solvaldi was originally $84,000. High quality generic versions were available in India for less than $1,000.[9] If two round-trip airfares cost $6,000 and accommodations could be arranged for $100 per night for a 3-month course of treatment, this would mean total travel expenses of $15,000. With savings from buying the drug in India of $80,000, this would allow for net after-travel savings of more than $65,000. This could be split by a state government health insurance program (Medicaid, SCHIP, or public employee insurance) and the patient.

States could also structure their insurance regulations and liability rules to facilitate this practice among private insurers. This would mean setting up guidelines, presumably with some list of approved providers in other countries, with whom insurers could arrange care. It could also adjust rules on malpractice to ensure that patients had clear recourse if something goes wrong with their treatment.

This not simply a hypothetical scenario. Utah, one of the most Republican states in the country, has put in place a system where it will pay patients, who are insured through its public employee health insurance program, to fly to San Diego and cross into Tijuana and buy drugs there. The state insurance plan will cover the transportation cost and give the patient $500 for their troubles.[10] This is not being done to make a political point, this is being done to save the state money. In 2019, 20 patients took advantage of the program for a savings to the system of $500,000. Both patients and the system's managers were very satisfied with the program.[11]

If this option proves popular with patients, it is likely that the state will look to expand it and that other states will also follow this path. In addition to saving money, allowing people the option to travel to countries where drugs are much cheaper is also a way to drive home the point that drugs don't have to be expensive. This realization is likely to be increasingly important as more people find themselves in a situation where they or a family member need a drug with an extremely high price in the United States.

While the industry has raised safety issues, regulatory agencies in many countries are at least as stringent as the Food and Drug Administration in ensuring quality. Using designated pharmacies should ensure that patients traveling abroad will be getting drugs that are safe and effective.

Towards Patent-Free Drugs

It would be a huge step forward if drug companies had more difficulty charging high patent-protected prices for their drugs. But this is only part of the long-term story for cleaning up the prescription drug market. While the industry exaggerates the costs associated with developing drugs, it is costly to bring a drug through the development process, clinical testing, and the FDA approval process. If drug companies are not allowed to charge some premium over a free market price, they will be unable to recoup these costs. If we are going to continue to develop new drugs, but not have drug companies don't rely on patent monopolies to finance their research, we will need some alternative source of research funding.

In the long-run the federal government would ideally pick up the cost, either through a system of direct funding that could look like an expanded National Institutes of Health or a patent buyout system under which the government would buy up drug patents and place them in the public domain so new drugs could be sold as generics.[12] However this sort of transformation of funding mechanisms is not likely to happen any time soon, since the pharmaceutical industry would likely use its full power to block the transformation of a system that is hugely profitable for it. In the meantime, there are possibilities for incremental progress either through the actions of state governments or private philanthropies.

In the case of state governments, a large amount of research at public universities is already directly or indirectly supported by state governments. States could look to increase this funding with the idea that the drugs developed would be available to the states' residents at generic prices. This would mean that any manufacturer could produce the drug to sell to the state's residents. The state could make this a condition for research at state supported universities. In order to allow it to recoup the costs of the research,

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the research could still be patented with the drugs developed selling at patent protected prices elsewhere. (Existing pharmaceutical companies could be contracted to market the drug outside of the state.)

Having low prices in one state, or a consortium of states, if several states agreed to act collectively, will naturally lead people to come to these states to take advantage of the low prices. That has the disadvantage of reducing the potential profits from selling the drug at the patent protected price in other states and countries. At the same time, it does help to both make the new drug available to a larger group of people at a low price, and it also helps to drive home the point that government intervention in the form of patent monopolies is the reason drug prices are high. In short, the outcome of people flocking to a state that pays for research to take advantage of its low drug prices should not be viewed as something to be feared.

There also is the advantage of a state paying for research that it can be a model for disclosure of results. This is especially important for clinical trials. While there have been efforts to increase disclosure of information on clinical trials in recent years, the fact is most drug companies only make available the most minimal information about their outcomes. At present, they only disclose summary results of their trials.

Ideally, there should be a full breakdown of the results for each patient, subject to the limits required to ensure anonymity, that would allow any researcher to independently analyze the results of the trial. This would allow researchers to determine not only the effectiveness of the drug in aggregate, but also to assess differences by sex, age, prior health conditions, and other factors. This is actually now being done with the YODA project, which does provide detailed data to researchers on the outcomes of clinical trials.[13] One major manufacturer, Johnson and Johnson, is now providing its data through this channel.

There is no legitimate reason that this information should be kept secret. The fact that it is generally not public is a serious impediment to doctors trying to determine the best treatment for their patients. If universities used public funds to carry through clinical trials, they could be required to have full disclosure. This would be a benefit for those seeking a full analysis of these trials, but also provide a benchmark that could be used to demand more disclosure from industry funded trials.

The other potential source for funding the development of new drugs is philanthropic organizations. In this case, there is the advantage that there is no need to show a direct return for the money spent. In principle, an organization devoted to public health would be advancing its goals by directly funding research that led to the availability of important new drugs at a low cost.

There is already precedent for this sort of philanthropic support with the Drugs for Neglected Diseases Initiative.[14] DNDI has developed a number of effective new drugs and treatments on a budget that is less than has been estimated as the cost for developing a single drug in the United States. These treatments have benefited tens of millions of people in the developing world. It would be a small, but tremendously important step, to rely on philanthropic contributions to develop drugs that would be produced as generics in the wealthy countries.[16]

It is worth mentioning that most of DNDI's work has been devoted towards developing new uses of existing drugs or modifications of existing drugs, as opposed to developing altogether new drugs. However, this fact does not undermine the importance of its example.

First, if we can achieve substantial health benefits from exploring new uses of existing drugs, then we absolutely should want research in this direction. The fact that companies may not be able to get a patent for new uses discourages such research under the current system. The other point is that DNDI researchers have been able to innovate without the motivation of patent monopolies. This should help undermine further the rather odd notion that pharmaceutical research can only be properly motivated with the lure of patent monopolies.

If even a small number of successful drugs could be developed with philanthropic support, it could provide an incredibly powerful example. It would be a blunt reminder that drugs are cheap to produce, it is only patent monopolies and related protections that make them expensive. Also, as with state supported research, in the case of drugs developed with philanthropic support, all results could be put in the public domain, including the raw data from clinical trials.

Conclusion: The Waste and Corruption from Patent Monopolies in Prescription Drugs Offers Opportunities

In spite of its corruption and inefficiency, it would be difficult politically to directly challenge the patent system for financing prescription drug research at the federal level. However, the fact that drug prices in the United States are so far above their free market price offers enormous opportunities for smaller scale attacks on the system.

These attacks can take two main forms. The first involves facilitating the purchase of drugs outside the United States. Since patent protected drugs in the United States can typically be purchased at far

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lower prices in other countries, there are large potential gains from either bringing foreign drugs into the United States or sending patients overseas to take advantage of lower priced drugs.

The other form of attack is directly supporting the development of new drugs that can then be sold at generic prices from the day they are approved by the FDA. This can be done either by state governments, which already fund a substantial amount of research through their university systems, or by a private philanthropy. In the former case, it should be possible to design mechanisms that would allow the state to recover its additional spending through lower prices to its residents, as well as a share of patent rents for drugs sold elsewhere.

In both cases, the example of new drugs being developed outside the patent system, and then sold at generic prices, should be an important model for an alternative system for supporting drug development. The fact that the current system does such a poor job of meeting health needs provides a large amount of room for improvement.

Note

The author has no conflicts of interest to declare.

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