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www.afgazad.com afgazad@gmail.com

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BY DEAN BAKER
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Time to End Patent Monopolies

For several years the opioid crisis has been recognized as a major national catastrophe. Millions of people have become addicted to the new generation of opioid drugs. In many cases, this addiction has led to the destruction of families, job loss, crime, and suicide. At the peak of the crisis in West Virginia, the hardest hit state, the death rate from overdoses alone, was more than 41 people per 100,000. This is more than 70 percent of its fatality rate from the pandemic, as of mid-December. And this doesn't count deaths due to crime or opioid-related health conditions. Opioids are a big part of the story of the state's drop in life expectancy over the last quarter century.

The crisis did not just happen by chance. As we now know, drug manufacturers and distributors made large amounts of money pushing their drugs. The actual process of pushing opioids by Purdue Pharma, Johnson & Johnson, and their distributors has been well-documented. While the patent monopoly meant the price of Oxycontin, the most widely marketed drug among the new generation of opioids, was far higher than generic versions, this big profit margin gave Purdue Pharma and others an enormous incentive to push their drugs.

In particular, they misled doctors and the public about their addictiveness. They hired hundreds of salespeople to promote their drugs as widely as possible, with no concern whatsoever about abuse of their drugs. As a result of a series of recent legal actions, leading manufacturers and distributors have now paid or agreed to pay tens of billions of dollars to compensate individuals and communities for the harm done by their drugs.

While the devastation caused by the opioid crisis and the ensuing legal actions have received considerable attention, this important part of the picture has been completely missing. There has been essentially zero discussion of the incentive that government-granted patent monopolies gave these companies to push their drugs.

The basic point is a simple one: Patent monopolies allow companies to sell drugs at prices far above the free-market level. This is intentional. In order to give drug companies the "incentive" to invest in the development of new drugs, we give them a 20-year patent monopoly, which allows them to sell their drugs at prices far above what they would sell for if they faced generic competition.

These monopolies are the reason that many drugs are so expensive. It is rare that it actually costs much money to manufacture and distribute a given drug. When a drug is selling for thousands or even tens of thousands of dollars, it is almost always because its manufacturer holds a patent monopoly. When these drugs are subject to generic competition, they can often sell for less than 1 percent of the patent protected price.

Furthermore, if a company can sell a drug at a markup of several thousand percent thanks to a monopoly, it has enormous incentive to market it as widely as possible. This will often mean concealing evidence suggesting that a drug may not be as effective as claimed, or is actually harmful, as was the case with the opioid crisis.

The opioid crisis was an extreme case, but instances where drug companies have paid large settlements in response to claims they misled doctors and the general public about the safety or effectiveness of their drugs are not rare. To take another famous example, the drug giant Merck paid billions of dollars in a settlement over allegations that it concealed evidence that its arthritis drug, Vioxx, was dangerous for people with heart conditions.

We could see the problem of drug companies lying to push drugs as an unfortunate, but unavoidable, aspect of the drug development process if there was no alternative to relying on patent monopolies to finance the development of new drugs. But in fact there are alternative mechanisms, as we in fact just witnessed with Moderna's rapid development of an effective vaccine against the coronavirus.

As part of Operation Warp Speed, the federal government paid Moderna more than $900 million, fully covering the cost of its pre-clinical research and clinical trials. While the government also gave Moderna patent rights to its vaccine, it effectively paid for the full research and development costs upfront.

This is an important precedent, since it shows that direct public funding can be an effective way to support the development of new drugs. This should really not be a surprising story. The government already spends over $40 billion a year financing biomedical research through the National Institutes of Health (NIH). This money is almost universally regarded as a smart investment, as it has led to many great breakthroughs in medicine. In fact, the discovery of the coronavirus spike protein in 2016, which is the main building block for both the Moderna and Pfizer vaccines, was achieved thanks to NIH funding.

But most NIH funding is directed toward more basic research than was the case with the Moderna vaccine. The pharmaceutical industry has long pushed the view that, although the government could very effectively support basic biomedical research, if it turned to actually

developing drugs or vaccines itself, we would effectively be throwing money in the toilet because the government cannot effectively direct funding for later stages of drug development.

This was in spite of the fact that there have actually been many important drugs developed largely on NIH grants. Still, the Moderna vaccine gives us a new and very prominent example of how the government can effectively finance the direct development of a drug or a vaccine. Of course, if we are directly funding drug development there is no point in also granting patent monopolies, and PhRMA's main argument falls apart. The logic of direct funding is that all findings would be fully open so that any manufacturer could make them. There are better and worse ways to construct financing mechanisms, but obviously direct funding can provide an alternative to patent monopolies. (I discuss this issue in chapter five of ***Rigged***—it's free.)

In additional to allowing drugs to be available as cheap generics from the day they are approved, direct funding can also allow for open-source research. This would mean that results from pre-clinical research, as well as clinical trials, would be posted on the web as soon as practical. This would allow researchers to build on one another's successes and learn from their failures. This sort of open research was touted by scientists in the early days of the pandemic as a factor allowing much greater understanding of COVID-19 than otherwise would have been the case.

It would be great if the Moderna example allowed the country to engage in a serious debate on the best way to finance the development of new drugs and explicitly consider alternatives to patent monopolies. But if we are to have this debate, we have to be able to talk honestly about the problems with patent financing. This means acknowledging the perverse incentives provided by patent monopolies, and that has included the incentive to push opioids onto patients even when the drug companies knew they were so highly addictive.

Unfortunately, this obvious link between the opioid crisis and the pharmaceutical patent system has never featured in discussions of the crisis to date. Maybe the developments we've witnessed as a result of the pandemic will finally open our eyes and allow for a real discussion of the role that patent monopolies played in worsening this crisis in the context of a much broader debate about their merits more generally as a mechanism for financing the development of drugs.

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***Dean Baker** is the senior economist at the Center for Economic and Policy Research in Washington, DC.*