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Abolish The FDA. It Does Patients More Harm Than Good

Kalman Knizhnik

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Lost in the country's inevitable descent into single-payer health care is the role the federal government plays in the skyrocketing prices of both over-the-counter (OTC) and prescription medications. While the rising premiums, increasing out of pocket costs, and deteriorating quality of service resulting from Obamacare are the direct consequence of its economic incoherence, the rising costs of many, if not all, medications are largely the result of the lack of competition in the pharmaceutical industry.

Although some may argue that "big pharma" greedily increases prices to benefit from the suffering of chronically and terminally ill patients, there remains the question of why so few cheaper alternatives are offered on the market. After all, in the wake of Mylan's Epi-pen fiasco, prescriptions for the generic and competitor brands increasedby nearly 25 percent in the first two months of 2017. "Big pharma" can be as greedy as they want, but why is there not just a slightly smaller "big pharma" coming along to provide a slightly cheaper product and steal all of the slightly bigger "big pharma" profits?

The chief culprit in driving up prices is, as is typically the case, the federal government's well-intentioned attempt to regulate the OTC and prescription medicine market via the Food and Drug Administration (FDA).

Where We Got the FDA

Initially formed in 1906 by President Theodore Roosevelt, the FDA in 1938 was given authority by the Federal Food, Drug, and Cosmetic Act (FDCA) to oversee the safety of these types of products. In this role (Tenth Amendment be damned), the FDA is responsible for approving drugs to treat various diseases.

The FDCA was passed after an improperly prepared medicine caused the poisoning and deaths of more than 100 people. Since then, knowing that OTC and prescription drugs are FDA-approved has given millions of patients the confidence that the medications they use for treating their conditions have been 1) shown not to kill people and 2) proven to be not ineffective.

This is, of course, a perfectly natural concern for all patients who are not knowledgeable about the intricacies of the chemical structure of each of the pills they have to take over the course of their lifetimes. The questions "Will this kill me?" and "Am I wasting my money on something that does not work and may give me horrible diarrhea instead of treating my ingrown toenail?" are valid and crucial to address. So it is understandable that the statement "Abolish the FDA" may meet scorn from patients who have come to rely on the peace of mind provided by the FDA's stamp of approval.

Nevertheless, perhaps more important than repealing Obamacare is curtailing the FDA's regulatory oversight. If medications were to become significantly more affordable, health care spending may take up far less than nearly 20 percent of gross domestic product. Despite promises to cut 75 percent of regulations, President Trump has not yet indicated that FDA regulations will be among those.

Consider a World Without the FDA

To understand why the FDA has caused so much irreparable harm to countless patients, it is helpful to consider a world without the FDA, which was the case for the more-than-century after America's founding. In such an environment, pharmaceutical companies need not prove their product is effective or even harmless in double-blind controlled trials consisting of several phases.

Consider an arbitrary disease that significantly affects a patient's quality of life such that he tries to relieve his condition medically. In the absence of an FDA, four possible outcomes are likely: 1) Pharmaceutical companies produce drugs that are ineffective and have terrible side effects, 2) Pharmaceutical companies produce drugs that are effective but have terrible side effects, 3) Pharmaceutical companies produce drugs that are ineffective and don't have terrible side effects, 4) Pharmaceutical companies produce drugs that are effective and don't have terrible side effects. For completeness, let's include "death" as a terrible side effect.

The possibility of outcomes other than 4) is, ostensibly, why the FDA was created. But now the thought experiment becomes: suppose, in the absence of the FDA, the worst-case scenario 1) occurs. In such a case, why wouldn't the pharmaceutical company quickly go out of business, since—especially in today's consumer-review-driven era—the profits from such drugs will be minimal to nonexistent as patients realize that they are being sold snake oil? What patient would want to purchase something that doesn't work and causes extra suffering?

If we suppose instead that the slightly less harmful, but nevertheless undesirable scenario 3) occurs, the effect will be the same. If the drug is ineffective, consumers will have absolutely no incentive to buy it. Drugs produced under scenarios 1) and 3) will quickly leave the market and be replaced by drugs produced under scenarios 2) and 4).

Already the role of the FDA is called into question. If ineffective and harmful drugs would be quickly removed from the market by a lack of demand, and pharmaceutical companies would have no incentive to produce them, what is the purpose of the FDA checking that drugs are not ineffective and harmful?

The FDA Makes Errors, Too

An obvious response is to say that many patients will experience terrible side effects (including death) before news of the drug's adverse side effects or ineffectiveness reaches the general public. Indeed, the FDCA was passed precisely because of such an event, when an improper formulation caused the deaths of hundreds of people.

This argument is misleading for two reasons. First, there is evidence that the FDA is not even good at what it does, frequently approving drugs before being forced to recall them over safety concerns. A recent study found that, between 2004-2014, the FDA recalled more than 4,000 drugs, nearly 10 percent of which carried significant health risks, including death. So clearly such drugs do make it to the market, however briefly, even with FDA oversight.

The bigger issue, however, is that the FDA's extensive and expensive approval process takes a huge unseen toll on human lives. An eight-year delay in the FDA's approval of a single drug, Provenge, was estimated to have cost 82,000 lost life years. While the FDA may be effective at preventing highly visible death and illness due to poisoning and other adverse side effects, there is a hidden cost to the approval process, and this far outweighs the visible cost (economically, though not necessarily politically).

Developing a treatment for such conditions is prohibitively difficult, due to the multi-billion dollar price tag associated with getting FDA approval.

Another argument that can be made against the thought experiment above is that plenty of medications are already being sold that are completely ineffective and frequently have terrible side effects, yet they seem to not be cycled out of the market in spite of their lack of effectiveness. This would seem to suggest that scenarios 1) and 3) above could well occur even without an FDA, and that therefore the FDA is useful in reducing the number of such ineffective medications available.

This is true, insofar as some conditions are currently incurable and untreatable because of their complexity or rarity. Medications for such conditions will continue to be ineffective even in the absence of the FDA because the medical field has not yet learned how to treat them. But developing a treatment for such conditions is prohibitively difficult, due to the multi-billion dollar price tag associated with getting FDA approval for the treatment.

If drug X, typically used to treat condition Y, is discovered to be effective at treating previously untreatable condition Z, the FDA requires the company that produces this drug to put it through several phases of testing before it approves of using X to treat Z. But if the company cannot afford the price tag associated with the approval process, the treatment will languish, and ineffective medications will remain on the market. In the absence of the FDA, such a treatment will make it to market far sooner and stimulate further research into treatment for condition Z. This is economics 101.

A Dead Person Ain't Buying Pharma's Stuff Any More

Assuming that people will suffer terrible side effects without FDA oversight requires believing that pharmaceutical companies will not do their due diligence in testing their products. In fact, the opposite would be true. The greatest profits come from producing a product that people buy because it alleviates their suffering. Patients will discontinue buying drugs if they are dead or incapacitated by the drugs' side effects or ineffectiveness, leading to huge losses for the company.

To protect against such a scenario, it would behoove pharmaceutical companies to research the efficacy and potential harmful effects of their products. As an example, movie studios frequently audience test their movies and adapt to feedback before putting out the finished product because they want to be sure that the audience will enjoy it. In the case of OTC and prescription medication, critically, this would happen without the FDA requiring this testing, and companies would continue to test their product until they were certain that it would return a profit.

As a result, scenarios 2) and 4) above are the most likely outcomes in the absence of the FDA. Either the drug is effective and does not cause any side effects, or the side effects are less harmful than the condition the drug effectively treats, giving the patient enough of an incentive to continue purchasing the product.

The Costs of Getting Drugs to People Really Matter

Crucially, the costs a pharmaceutical company incurs in testing their product will invariably be lower if they are not forced to meet the FDA's arbitrary requirements. A study by Tufts University found that the cost of getting a drug approved by the FDA is a staggering $3 billion, up from $1 billion (inflation adjusted) in 2003. As a result, the cost of these drugs must be set high enough to not only make a profit on the drug just produced, but also to afford research and development on future projects.

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This has resulted in skyrocketing prices for consumers, whether directly if paying out-of-pocket or indirectly in the form of higher insurance premiums. If pharmaceutical companies do not need to spend nearly as much money on proving that their products are not ineffective or harmful, they will be able to lower the prices of most medications.

A typical response may be that companies will be disinclined to lower their prices, even for effective medications, since patients have no other options but to purchase what are, in many cases, life-saving drugs. Yet without the $3 billion price of FDA approval, cheaper alternatives would soon find their way to market as competitors realize that there is a demand for the product.

This process will take time, yes. Patients may initially pay way more than the medication costs to produce until there is a viable alternative. But most patients are currently paying far more than is necessary for their medication anyway, and the ability of cheaper products to quickly enter the market, which the FDA currently suppresses, provides the potential for rapidly lowering drug prices.

The FDA Keeps People from Getting Effective Treatment

Many would argue that the FDA provides patients the opportunity to have enough information to consent to taking serious medications. But, as Cato Institute economist Arnold Kling argues, "Patient consent is not the focus of the FDA at all. You do not need an FDA to enforce the patient's right to consent. In fact, you can argue that the FDA acts contrary to patient consent, because it tells people what drugs they cannot have even if they are fully aware of the evidence regarding the risks of the drugs and the data on the drugs' effectiveness."

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In contrast, there are many examples of the FDA refusing to approve drugs that patients consent to try in order to treat their conditions. The FDA has refused to approve potentially life-saving treatment for ovarian cancer, has refused to approve domperidone despite its proven efficacy in improving lactation, has not approved fecal matter transplant procedures to treat inflammatory bowel disease despite approving it for the treatment of C. Difficile (although even that may be short-lived), forced one American campus to wait for approval for a European meningitis vaccine that it already granted to another American campus, and has performed many other shenanigans that prevent fully informed patients from trying certain treatments even when all else has failed.

The sad story of the Epi-pen debacle is an unfortunate example of the competition of the free market being unable to operate because of regulatory oversight. The FDA recently approved Symjepi, a competitor to the Epi-pen, which will be significantly cheaper than Mylan's version. Had Symjepi been approved several months earlier—or, better yet, if it did not even require approval—Epi-pen users would not have had to pay $600 for their medications.

All of the arguments above are basic free-market economics. Those who believe that the FDA is serving a vital role in keeping harmful medicine from the market need to adequately answer this: what incentive do pharmaceutical companies have to produce drugs that don't work or cause such serious side effects that patients would choose to discontinue their use?