Goodman Institute
Turning Ideas Into Policy

Monopoly is the problem.
Competition is the soloution.

Why Are Drug Prices So High?

Why are pharmaceutical prices so high while the prices of so many other items we buy are low and even falling? One reason is a lack of competition. Drug companies typically have a monopoly on the drugs they sell, and monopolists charge higher prices than they would if they had to compete.

The solution seems straightforward. If we want lower drug prices, we need more competition and there are at least three ways to get it: (1) reduce the FDA's power to keep drugs off the market; (2) allow more over-the-counter sales of drugs; and (3) allow pharmacists to prescribe drugs.

Let's look at each of these in turn.

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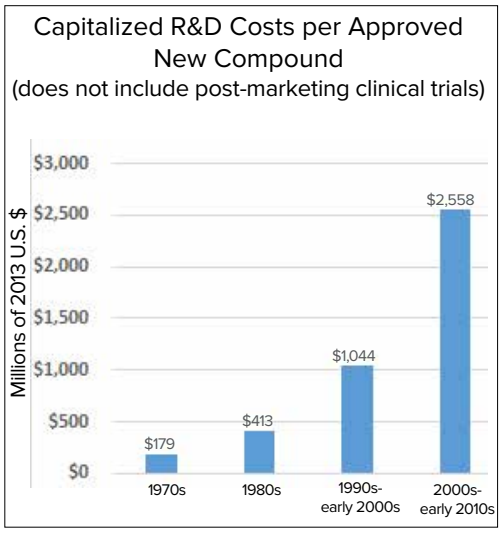
Reducing the FDA's Power to Keep Drugs off the Market

Patent law gives drug companies a legal monopoly for 20 years on the drugs they create. The prospect of a legal monopoly gives drug companies an incentive to create more, and better, drugs. Can we get both more drug development and lower drug prices without disturbing patent law? Yes. To do so, we must curb the Food and Drug Administration's power to keep drugs off the market.

Safety vs. Efficacy.

The FDA has monopoly power over new drugs. It keeps new drugs off the market for years, not months. Ask people why the FDA should have such power and they will likely say they're worried about potentially unsafe drugs. But the biggest holdup in getting drugs to market is not how long it takes to show that they're safe, but rather the time and expense needed to show, to the FDA's satisfaction, that they are efficacious for particular uses.[i] Approximately 35% of drug development costs are for safety testing, while 65% are for efficacy testing.[ii]



Economists have shown[iii] that the cost to get one drug to market successfully is now more than $2.8 billion. This cost has been

growing at 7.5 percent per year,[iv] more than doubling every ten years. Most of this cost is due to FDA regulation. Some potentially helpful drugs don't ever make it to market because the cost the company must bear is too high. Drug companies regularly "kill" drugs that could be effective[v] because the potential profits, multiplied by the probability of collecting them, are less than the anticipated costs. One of us has helped kill drugs for brain cancer, ovarian cancer, melanoma, hemophilia and other debilitating conditions. Imagine a drug for melanoma that never got on the market due to FDA regulation. In a sense, its price is infinite because it can't be purchased. Reduce FDA regulation so that it gets on the market, and the price falls from "infinite" to merely "high." If you had melanoma, which would you rather have: no drug or a high-priced drug that treats it?

If we simply went back to pre-1962 law, the FDA could still require proof of safety, but would not be able to require evidence on efficacy. This one change would allow drugs to be developed faster — often as much as 10 years faster. Market success would establish efficacy. Could there be ineffective drugs? Sure. But as doctors and patients learn, such drugs would disappear over time. This is nothing new; doctors and patients regularly evaluate drugs for efficacy. Clinical trials often show that perhaps only 20 percent, 40 percent, or 60 percent of patients benefit. Even when the FDA finally approves the drug as "safe and efficacious," doctors must still evaluate the drug to find out how efficacious it is for each particular patient. In practice, an FDA certification of efficacy is just a starting point.

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"Off-Label" Uses of Drugs.

Who would want to take a drug that has not been shown, to the FDA's satisfaction, to be effective? Almost everyone. Many drugs have off-label uses. These are uses that doctors have found effective for a particular use but that the FDA has not approved for that use. According to WebMD, "More than one in five outpatient prescriptions written in the U.S. are for off-label uses."[vi] Tabarrok[vii] cites studies showing that 80 to 90 percent of pediatric patients are prescribed drugs for off-label uses.

As is well-known in the medical establishment, off-label prescribing is legal and widely practiced. Indeed, Congress, the National Institutes of Health, Medicare, the Veterans Administration, and the National Cancer Institute all encourage it. Consider gastroparesis, a poorly understood upper gastrointestinal disorder in which the contents of the stomach do not move efficiently into the small intestine. Diabetics are particularly susceptible to this condition. The FDA has approved only one drug to treat it: metoclopramide. But doctors have found that, for some patients, an antibiotic called erythromycin reduces nausea, vomiting, and abdominal pain. Erythromycin is not FDA-approved to treat gastroparesis. But it works. Moreover, off-label uses in oncology account for as much as 90 percent of all cancer treatments. For some diseases, like AL amyloidosis, there are no approved medicines. Not a single one. So what do doctors do? They use medicines developed to treat related diseases, such as multiple myeloma, even though they and their patients would prefer medicines that treat AL amyloidosis directly.[viii]

There are also widely used grandfathered drugs that pre-date the FDA's regulations.

Nitroglycerin has been used successfully for 130 years as a vasodilator to treat heart conditions such as angina and chronic heart failure. Aspirin — the one-cent miracle drug — was never tested and approved by the FDA. How could it have been? The FDA didn't exist in 1899.

The widespread practice of off-label use means that our proposal is not as radical as it sounds at first. If it makes sense to allow people to use safe drugs for off-label uses, then it also makes sense for them to use safe drugs that the FDA has not approved for any use.

"Me Too" Drugs.

When faced with the thought of more pharmaceuticals on the market, people often talk disdainfully[ix] about "me-too drugs" — that is, drugs that are similar to and compete with existing drugs. But Chevrolet is a "me-too Ford." And, after Chevrolet entered the automobile market, the price of a given quality Ford fell. With more me-too drugs, prices would be lower. Far lower. Saying that a product is "me-too" amounts to saying that its existence increases competition. That's good, not bad.

Not all patients respond to all drugs. In addition to their competitive benefit, "me-too" drugs are important because they give doctors and patients other therapy choices.

Curbing the FDA.

There are a few ways to go about curtailing the FDA's power. The most extreme would be to have the FDA serve as an information agency rather than a gatekeeper. Companies that wanted to sell drugs without FDA approval could do so if the label said clearly, in big letters, "This drug has not been approved by the FDA." Consider two groups of patients and doctors: (1) those who insist on only FDA-approved drugs, and (2) those who are willing to trust other sources of information. Under our proposal, the first group would be no worse off; they would not change their behavior. But the second group, those of us who rely on other information sources, would, by our own standards, be better off. Moreover, given the prevalence of off-label uses, there is reason to think a large majority of the population would be in the second group. Regardless of which group each person is in, people will still need to personally test every drug prescribed by their physician to ensure that it is safe and effective *for them*.

Another way to cut the FDA's power would be to revert to pre-1962 law and end its power to require efficacy for particular uses, or "indications." This would cut as much as a decade and hundreds of millions of dollars off the development process. We could also require the FDA to approve any drug that has already been approved by one of its counterparts in developed countries.[x]

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Allowing Over-The-Counter Sales.

Another way to get lower prices is to allow more over-the-counter sales. OTC drugs are typically cheaper. OTC proton pump inhibitors and H2 antagonists, for example, are priced at about 10 percent of their prescription versions.[xi] The main reason: consumers, spending their own money out-of-pocket, are more price-conscious than health insurers. Moreover, simply comparing OTC prices with Rx prices substantially understates the saving.

The reason is that consumers save time and money by being able to avoid a visit to the doctor.

Merck & Co. tried three times to get the FDA to approve an Rx-to-OTC switch for its statin Mevacor (lovastatin). After the third rejection, the company gave up.

Allowing Pharmacists to Prescribe Drugs.

At the time prescriptions are refilled, the pharmacist is often ideally suited to inquire about whether the drug is working and whether there are side effects. Pharmacists often know more than physicians about drug interactions and they often have more experience observing them. This is why many other countries' governments give pharmacists far more authority to prescribe than we do in the United States.

The solution to this could be a continuum. At one end would be drugs for which instructions on the package plus common sense are all that are needed for patients to make good decisions. Common cold and allergy remedies are examples. At the other end of the continuum are cancer drugs where the choice of drug therapies requires highly specialized knowledge and continuing medical observation on the part of highly trained specialists. Most people would want doctors making these prescribing decisions.

In the middle of the continuum are conditions for which pharmacists typically have as much knowledge as, or even more knowledge than, physicians have about optimal drug therapies. Examples include conditions for which no medical diagnosis is needed (e.g., most contraceptives) or where the condition has already been diagnosed, and both the condition and its treatment are routine and ongoing (e.g., many chronic illnesses).

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[i] David R. Henderson and Charles L. Hooper, "Markets Can Determine Drug Efficacy," Forbes, July 8, 2009. At: http://www.forbes.com/2009/07/08/waxman-fda-bill-efficacy-opinions-contributors-biologic-drugs.html

[ii] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, " The price of innovation: new estimates of drug development costs," Journal of Health Economics, Journal of Health Economics 22 (2003) 151–185, Table 5.

[iii] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the pharmaceutical industry: New Estimates of R&D Costs," Journal of Health Economics, Vol. 47, May 2016: 20-33. At: http://www.sciencedirect.com/science/article/pii/S0167629616000291

[iv] Joseph A. DiMasi, "R&D Cost Study Briefing," Boston, MA, November 18, 2014. At: http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf

[v] Charles Hooper, "Obama and the 'Drug Killer'", Forbes, October 31, 2008. At: http://www.forbes.com/2008/10/30/obama-drug-medicine-oped-cx_ch_1031hooper.html

[vi] Kelli Miller, "Off-Label Drug Use: What You Need to Know," WebMD, 2009 at: http://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know#1

[vii] Alexander T. Tabarrok, "Assessing the FDA via the Anomaly of Off-Label Drug Prescribing," Independent Review, Vol. V, No. 1, Summer 2000: 25-53. At: http://www.independent.org/publications/tir/article.asp?articleID=240&issueID=21

[viii] This paragraph covers some of the same ground that we covered in David R. Henderson and Charles L. Hooper, "To Increase Innovation and Make Drugs More Affordable, Deregulate," Journal of Clinical Pathways, September/October 2015. At: http://www.journalofclinicalpathways.com/increase-innovation-and-make-drugs-more-affordable-deregulate

[ix] Bruce Friedman, "How Pharmaceutical Companies Fool Consumers with Me-Too Drugs," January 7, 2013. At: http://labsoftnews.typepad.com/lab_soft_news/2013/01/how-pharmaceutical-companies-fool-consumers-with-me-too-drugs.html

[x] See Daniel B. Klein, "Drug-Approval Denationalization," Library of Economics and Liberty, April 6, 2009. At: http://www.econlib.org/library/Columns/y2009/Kleindrugapproval.html

[xi] "Using the Proton Pump Inhibitors to Treat Heartburn and Stomach Acid Reflux: Comparing Effectiveness, Safety, and Price," Consumer Reports, Updated July 2013. At: https://www.consumerreports.org/health/resources/pdf/best-buy-drugs PPIsUpdate-FINAL.pdf

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