TERRY Health

Pharma Mini Briefs

January 25, 2024

Why Florida's Drug Importation Plan Won't Work

by Richard Jackson, Scott McKibbin, Brian Septon, and Munzoor Shaikh

Earlier in January, the FDA approved Florida's plan to import lower-priced brand-name prescription drugs from Canada. The plan, which is the first of its kind to receive FDA authorization, would allow the state to purchase the drugs from Canadian wholesalers, ship them to selected pharmacies in Florida, then dispense them to state-administered health programs, including Medicaid. According to Florida, the plan will save the state over $175 million a year in drug spending once fully implemented. Several other states have applied, or are planning to apply, for FDA approval of similar drug importation plans.

At first glance, the logic behind wholesale drug importation seems compelling. Americans spend nearly twice as much per capita on pharmaceuticals as Canadians do, with much of the difference attributable to the lower prices that the Canadian government negotiates with U.S. pharmaceutical companies. Individual Americans have long been able to import drugs from Canada and enjoy the savings. Why shouldn't states be allowed to do the same thing on a larger scale? It seems like a painless fix, which may explain why it's one of those rare issues that enjoys bipartisan support these days. The previous administration set the ball in motion by directing federal agencies to develop enabling regulations, and the current administration followed up by instructing the FDA to work with states that have proposed drug importation programs.

The problem is that it's not a painless fix, and in fact may not be a fix at all. As a practical matter, wholesale drug importation is unlikely to deliver the savings that its advocates claim it will. And if it somehow did result in large-scale savings, the perverse reality of how global pharmaceutical pricing works means that it might have a chilling effect on the development of new drugs. High U.S. drug prices are a real problem that calls for real solutions. Wholesale drug importation is not one of them.

The Perverse Reality

Let's start with why state plans like Florida's won't work as advertised. To begin with, Canada has already announced that it will shut down wholesale drug exports to the United States if it determines that Florida's plan would put its drug supply at risk. Given that the entire population of Canada is not even twice that of Florida, this is a real danger—and it would become an even bigger one if the FDA approves other state plans. On the other hand, if Canada does allow wholesale drug exports to proceed,

U.S. pharmaceutical companies may limit the sale of drugs to Canada. There is plenty of precedent for this kind of maneuvering on the part of pharmaceutical companies. In the European Union, one of whose bedrock principles is the free movement of goods between member states, pharmaceutical companies routinely restrict the supply of drugs to members with lower prices in order to stem their resale to members with higher prices.

Beyond these practical obstacles, two more fundamental concerns are sometimes raised about wholesale drug importation, one of which is legitimate and one of which is baseless. The baseless concern is that it would put patient safety at risk. Any country from which we are likely to import drugs, whether it is Canada or a member of the European Union, has drug safety regulations in place that are every bit as robust as ours. Indeed, because of the way other countries package drugs, theirs may be even safer than ours are. In most OECD countries, drugs are directly packaged at manufacturing facilities into the same containers that consumers ultimately pick up at the pharmacy. In the United States, most drugs are packaged into large drums, whose contents may be repeatedly repackaged into smaller containers along the distribution chain. At each step, there is an opportunity for adulteration or counterfeiting that doesn't exist in other countries.

The legitimate concern is that wholesale drug importation might reduce U.S. pharmaceutical innovation. To see why, it is necessary to understand how the industry works. Developing new drugs is an expensive and lengthy process, with estimates of total R&D spending ranging from $0.8 billion to $2.3 billion for each new drug successfully brought to market. R&D spending by U.S. pharmaceutical companies now amounts to about 25 percent of their revenues, compared with an average of 3 percent for all companies in the S&P 500. Most drug compounds that pharmaceutical companies investigate never make it to clinical trials, and of those that do only about 10 to 15 percent ever make it to market.[1] This in turn means that the industry must recoup its R&D costs from sales of the few that do.

Thus we arrive at the perverse reality that explains cross-country differences in pharmaceutical pricing. Other countries are able to negotiate (or in some cases dictate) lower prices than we pay in the United States precisely because pharmaceutical companies are able to charge higher prices in the United States. Those companies can still make a profit selling drugs at lower prices in Canada, France, or the UK because, once drugs have been developed, the marginal cost of manufacturing another batch is typically small. But the decision to develop new drugs in the first place depends at least in part on the expectation of being able to recoup R&D costs in the U.S. market, which happens to be far and away the world's largest. If every country, including the United States, paid the same low price, there would be less innovation.

Experts disagree about how great the risk is, but few believe there is no risk at all.[2] Over time, the R&D of large pharmaceutical companies tends to rise and fall along with their revenues, which obviously are affected by the prices they can charge. Nor

---

[1] CBO, *Research and Development in the Pharmaceutical Industry* (Washington, DC: CBO, April 2021).

[2] See, among others, CBO, *Research and Development in the Pharmaceutical Industry*; Steven M. Lieberman, Paul B. Ginsburg, and Kavita K. Patel, "Balancing Lower U.S. Prescription Drug Prices and Innovation—Part 1" (Washington, DC: Brookings Institution, November 24, 2020); Santiago G. Moreno and David Epstein, "The Price of Innovation—The Role of Drug Pricing in Pharmaceutical Innovation: A Conceptual Framework," *Journal of Market Access and Health Policy*, 7:1 (March 20, 2019); and OECD, *Pharmaceutical Pricing Policies in a Global Market* (Paris: OECD, 2008).

is it just "Big Pharma" whose R&D might be squeezed if U.S. drug prices were to fall substantially. So would small biomedical companies, which account for a large share of new drugs and an even larger share of the drug pipeline. These small companies, many of which have no current revenue at all, rely heavily on venture capital to finance their R&D, and the expectation of a lower return on investment would make this more difficult to raise. Anyone who doubts that pricing policies can affect drug development should consider the experience of Europe, which once led the world in pharmaceutical innovation but now lags far behind the United States.

A Serious Approach to Reform

None of this is to say that pharmaceutical pricing in the United States is efficient or fair, or that as a nation we should acquiesce in paying inflated drug prices. The current pricing system is riddled with waste and subject to costly gaming, and fixing it will require far-reaching reforms. A serious approach to reform would begin by considering the following measures:

- **Restrict Marketing.** U.S. pharmaceutical companies spend vast amounts of money marketing their products. Indeed, according to some estimates they spend even more on marketing than they do on R&D. Pharmaceutical marketing takes many forms, including the distribution of free samples to physicians by "drug reps" and direct-to-consumer marketing, mainly in the form of television and online advertising. Many developed countries restrict or ban marketing to physicians and only one besides the United States, New Zealand, allows direct marketing of prescription drugs to consumers. The United States should consider limiting these practices as well.
- **Rethink Distribution.** Pharmacy Benefit Managers (PBMs), which act as middlemen in the pharmaceutical distribution system, are supposed to save healthcare payers money by negotiating rebates from drug companies and discounts from pharmacies. Many industry analysts believe that the reality is just the opposite and that they greatly add to total costs. The PBM industry is characterized by opaque contracts that make the actual flow of funds difficult to track. It is also highly concentrated, often making those contracts a "take it or leave it" proposition. For both of these reasons, it is ripe for reform.
- **Leverage Cost-Benefit Analysis.** Many developed countries make extensive use of cost-benefit analysis in determining which drugs should be included in formularies and how they should be priced relative to alternatives. We don't. Clinical trials in the United States typically benchmark the efficacy of new drugs against placebos, rather than clinical markers or competing therapies, as is common practice in other countries. Moreover, the FDA's drug approval process makes no attempt to quantify the value of health outcomes, for instance by calculating the number of additional quality-adjusted life years (QALYs) a new drug can be expected to give a patient. Making greater use of cost-benefit analysis in pharmaceutical pricing would not only save money, it would also help to push new drug development in directions that are the most likely to improve society's overall health.
- **Curtail "Evergreening" Practices.** Pharmaceutical companies routinely engage in regulatory end runs designed to reset the patent clock and delay the introduction of lower-priced generics and biosimilars. Known collectively as "evergreening," these practices, which include the minor rejiggering of chemical compounds and delivery methods, often result in extended patent protection for drug formulations that have little or no additional therapeutic benefit. These practices should be curtailed. While patent protection is essential to reward

innovation, drug companies should not be allowed to reap windfalls by gaming the rules. The best solution may be to push for global harmonization of patent rules through the WTO or other international organizations. Global harmonization would put a stop to the gaming that occurs in the United States, while also helping to ensure that R&D costs are more equitably shared worldwide.

- **Increase Public R&D.** Public investment in basic science, especially through the National Institutes of Health (NIH), is critical to pharmaceutical innovation. Increasing public investment could help to ensure a healthy drug pipeline in a future healthcare financing environment which, one way or the other, is likely to be increasingly sensitive to price and focused on value. More public-private partnerships along the lines of Operation Warp Speed, which accelerated the development of COVID-19 vaccines, may also be helpful in developing new drugs, particularly in areas, such as antimicrobial resistance, where the financial incentives for pharmaceutical companies to invest in R&D are weaker.
- **Improve the Efficiency of Private R&D.** New and evolving technologies, from AI (which can determine which drug compounds are most promising) to digitalization (which can allow remote clinical trials), have the potential to make drug development more efficient and less costly. Public policy should do what it can to encourage their adoption and diffusion. Some new drugs now also come with tests designed to determine whether they are appropriate for a given patient. Here too there is considerable potential for pharmaceutical savings, which can accrue not just from lowering unit prices but also from limiting the volume of drugs consumed.

While all of this will help, one more critical step is needed. Rather than authorizing states to pursue quixotic drug importation plans, the federal government should focus on getting other countries to pay for more of U.S. pharmaceutical R&D, which amounts to over two-thirds of the total pharmaceutical R&D spending of all OECD countries.[3] We have tried this approach with NATO spending, and it is beginning to work. We could use trade negotiations to encourage fairer burden sharing in pharmaceutical spending, too. The case for doing so is not only compelling on economic grounds, but also on equity grounds. It is one thing for the United States to subsidize pharmaceutical consumption in low-income countries. It is quite another to subsidize it in other rich countries. Eliminate the vast subsidy we are paying to the rest of the rich world and, over time, the savings will show up in family, employer, and government budgets.

An Entirely Different Story

Individual Americans who travel to Canada to fill their prescriptions or have drugs shipped to them by Canadian mail order pharmacies are exploiting a loophole in today's perverse global pharmaceutical pricing system. While importing drugs on a personal and retail basis works, wholesale drug importation is an entirely different story. Unless and until we resolve the global pricing differential problem, trying to push a much larger share of U.S. pharmaceutical consumption through the loophole will risk unravelling the whole system. If we did resolve the global pricing problem, wholesale drug importation would of course be unobjectionable. But then again, it would also be unnecessary.

The issues surrounding U.S. drug pricing are both complicated and controversial, and we are aware that the arguments and recommendations we have made in this issue brief will challenge the assumptions of some of our readers. In subsequent issue briefs we will dig deeper into drug pricing reform and how it is likely to affect

[3] OECD, *Health at a Glance 2023* (Paris: OECD, 2023).

manufacturers, payers, providers, and other healthcare system participants. We may also look at related issues not mentioned here, including Medicare drug price negotiation, cost shifting, generic drug pricing, and chronic drug shortages. Please stay tuned for more from Terry Health.

To learn more about Terry Health and how our interdisciplinary team of problem solvers can help your organization succeed in a rapidly evolving healthcare environment, contact us at insights@terrygroup.com.