Simplifying and Accelerating President Trump's Pharmaceutical Pricing Plan with Parallel Imports

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President Trump, on May 12, 2025, announced a plan to "equalize" pharmaceutical prices in the United States and other developed countries using the concept of "most favored nation". He explained this meant that pharmaceutical companies in the United States would be "asked" to charge prices for their products equal to the lowest price charged in any developed country. This is a variation on the theme of "reference pricing" which is used in many countries where the domestic price of a pharmaceutical product is established through comparison to a basket of prices charged for the same drug in comparable countries.

President Trump combined his proposal for most favored nation pricing with the idea of eliminating the middleman and selling pharmaceuticals directly. This could significantly lower the end price of pharmaceuticals to US programs such as Medicare and Medicaid and could particularly help those without prescription insurance plans. This proposal was short on details. But, on the whole, it is difficult to quarrel with a proposal to eliminate a costly part of the pharmaceutical distribution chain which is highly concentrated in a few companies.

President Trump started on a soft note saying that enforceable action would be taken if the pharmaceutical companies resisted. It was disconcerting that President Trump's announcement resulted in sharp gains in the share prices of the major Pharma companies. Assuming the market has a degree of wisdom, this reflects a common understanding that making a voluntary request to the pharmaceutical industry is not likely to yield major concessions. Ultimately, executive and legislative action will need to be taken.

The pharmaceutical companies have been successful in defending their pricing interests in the federal courts. They argued, and the Supreme Court agreed, that advertising and promoting drugs is protected essentially the same way as pure political speech. The prior Trump Administration's proposal to require pricing transparency in commercial advertisement was struck down for the lack of sufficient legislative authority. The pharmaceutical companies will do everything they can, including in the courts, to delay price controls.

Over the past decades innumerable bills have been introduced in Congress aimed at controlling pharmaceutical prices. These bills die in Committee, or on the floor. President Trump noted that the pharmaceutical lobby was and remains powerful. Pres. Biden, a good friend to the pharmaceutical industry, introduced a plan to negotiate the price of certain drugs purchased by the federal government (directly or indirectly), but this is a limited effort.

There is an existing alternative to asking the pharmaceutical companies to lower their prices. It might benefit from one or two legislative tweaks, but even that may not be necessary.

In 2017, the US Supreme Court resolved a long-running battle in favor of international exhaustion of patent rights, a doctrine that permits so-called "parallel importation" of patented medicines. The technical details are not so important for present purposes. Essentially this means that when a US-patented pharmaceutical product is sold anywhere in the world the patent owner cannot prevent a buyer from importing that product into the United States by invoking their US patent. The patent has been "exhausted" by the first sale abroad. Parallel importation of patented medicines has been around in Europe for a long time, going back to the 1960s. It allows the free movement of pharmaceutical products within the European market. But the pharmaceutical companies fought against allowing parallel importation into the United States.

Up until 2017, what prevented a patented drug from being imported into the United States as a parallel import is that the US patent owner could invoke its patent to prevent the importation, even if the product was produced and sold by its own affiliate overseas. Its patent rights were not exhausted by an overseas sale. Also, there was a special rule enacted by Congress that prevents the "reimportation" of prescription drugs if they are manufactured in the United States and sent overseas, unless the originator consents to reimportation.[i]

Now, in principle, if the same pharmaceutical is priced at $3 US (or its currency equivalent) in Europe, and $6 in the United States, someone can buy the product at the lower price in Europe, import and supply it in the United States. In many parallel import situations, private traders "buy low" in the first sale, and "sell higher" in the importing country, earning some part of the difference between markets as profit. This is classical price arbitrage. But there is nothing that requires a parallel importer to be a profit-seeking enterprise. The US federal government, a state government authority, or a hospital system can purchase pharmaceutical products and forego an arbitrage profit on importation. (And it could well be that a company like Amazon or Costco with considerable experience in parallel importing could lower prices in the United States through low-margin resales.) It is foreseeable that pharmaceutical companies already selling in the United States would need to lower their prices to match the prices of the imported products.

Patents, however, are not the only barrier. As of now, the FDA interprets its statutory authority to approve drugs for importing and marketing in the United States in a very restrictive way. Even if the same pharmaceutical product is manufactured under the authority of the same pharmaceutical company in Europe and the United States, the European-manufactured product can be imported into the United States by a third party only if it is imported pursuant to a US FDA approval of the European product. This serves the interests of pharmaceutical originator companies whose products are introduced in the United States, and who want to prevent lower-priced imported versions of their products from competing with their own higher priced US versions.

Two decades ago Congress directed the FDA to study importation of prescription drugs from Canada. The FDA concluded that supply chain security risks would not be offset by costs savings, and it declined to recommend allowing such imports. More recently the FDA, under mandate by Congress, created a program under which it would approve drug importation from Canada subject to the formulation by State or Tribal authorities of

programs (so-called SIPs) the FDA deemed adequate to protect US consumers. In January 2024, the FDA approved the first of such plans for Florida.

But this arrangement still imposes limitations that make importation difficult to function as a control on prices. By limiting importation from a single country – Canada -- that has a population much smaller than that of the United States, it creates problems for the Canadian government because the pharmaceutical industry will not supply additional products to Canada if it believes they are destined for the United States market. It is a much more limited implementation of parallel importation than is possible. Congress and the FDA together set up a program that was destined at best to be marginally effective.

In the world of pharmaceuticals there will always be regulations. Still, a straightforward program allowing parallel importation from any developed country (including, e.g., Australia, Canada, the EU/EEA, Japan, New Zealand, Switzerland and the United Kingdom) would be relatively easy, particularly because drug regulatory authorities in these countries and their pharmaceutical distribution networks (e.g., their supply chains) are comparable to those in the United States. Whether produced in Europe or in the United States, the facility where the drug is manufactured should have been inspected by the FDA or its European counterpart already recognized as comparable by the FDA.

No one wants to discount the importance of securing pharmaceutical supply chains, but importing pharmaceutical products manufactured and placed on the market in Europe does not entail a security risk greater than buying products manufactured in Indiana. There is no evidence that European consumers of pharmaceutical products are injured by these products because of security issues. Moreover, and this is no small matter, a substantial portion of the pharmaceutical products -- particularly generics – that US consumers purchase in the United States are made in India, China, Israel, or other foreign countries, and imported into the United States. Foreign generic companies submit regulatory dossiers to the FDA showing that the drugs they manufacture have the same chemical composition as previously approved products. Unless there is a patent holder trying to prevent the introduction of the generic product, this is straightforward approval process because the generic producer is relying on the clinical trial assessment that accompanied the FDA's original "branded drug" approval.

If the Trump Administration is serious about reducing unnecessary regulation and lowering prices for American consumers, it could start by having the FDA streamline the process for approving parallel importation of lower-priced originator pharmaceuticals from Europe. This appears largely a matter of how the FDA chooses to interpret its own statutory authority. It should not require additional congressional legislation. Yes, Congress specifically legislated to direct the FDA to allow imports from Canada, but this was because the FDA had resisted doing that. The FDA could have done this under its existing authority.

Expanding the implementation of FDA rules, any pharmaceutical product approved for commercial sale in the United States could be purchased in one of the designated countries and imported into the United States by a registered parallel importer. Registered parallel importers would need to demonstrate to the FDA their compliance with appropriate supply chain controls. A product exported from Europe might need an additional barcode put on the package so that it can be more easily identified within US tracking systems, and it might

need some additional information on the label, which could include that it was exported from Europe. Assuming that a federal, state or other buyer was not seeking to make a profit, prices for the imported products would be equivalent to the prices charged in the foreign markets, plus perhaps a modest increment for transport and warehouse costs.

The originator pharmaceutical industry in the United States will attempt to block the FDA from approving expanded parallel imports. Americans who do not think twice about buying prescription drugs when they are traveling in Europe will be told that those drugs are unsafe to import into the United States. The companies will say that prices in the United States will not go down because the middlemen will take their cut. But middlemen are not needed. Federal, state and hospital system purchasers can employ parallel import agents. The originator companies will say that US innovation will suffer because their profits will be lower. That is what they said when the Supreme Court rejected their plea to block parallel imports in 2017. If we can never reduce pharmaceutical company profits, pharmaceutical prices will never go down!

With low-priced parallel imports from developed countries, the United States would achieve the objective proposed by President Trump of paying prices "equal" to those paid in other developed countries, even if not always the lowest price among those countries.

This is where the second element of this approach comes in. Left to their own devices, the pharmaceutical companies will attempt to limit products made available outside the United States to prevent parallel importation. They could accomplish this by contracting with purchasers, making it a breach to resell products. Or they can strictly limit the quantity of products they distribute abroad so there is no surplus available for export to the United States, thereby acting to prevent price competition with products on the US market. These types of practices are used by pharmaceutical companies doing business in Europe to restrict parallel imports within the EU.

The US federal government must make clear that it is unlawful under US antitrust laws for companies doing business in or with the United States to limit the availability of pharmaceutical products being sold in foreign markets for purposes of preventing price competition within the US market. Companies must meet demand, including demand for products destined for parallel importation, assuming they are not physically constrained in production capacity, so that imported products can effectively compete on price with domestic products. Companies must not attempt to contractually prevent product reselling. (Production constraints should not be a "real" problem.)

Congress could specifically legislate that limiting the availability of pharmaceutical products within or outside United States territory for purposes of restraining price competition is an antitrust violation, civil and criminal. Such legislation may not, strictly speaking, be necessary because agreements to limit output to raise or maintain prices, or to abuse a monopoly position, generally should constitute a violation of the Sherman Act (depending on the market situation and behavior, either Section 1 or 2). The fact that anticompetitive activity may be taking place outside the territory of the United States should not make a significant difference since this activity would have a direct, foreseeable and substantial effect in the United States, and therefore would establish a cause of action within the United States. The reason for suggesting legislation is to provide clear guidance to the

courts since using antitrust litigation to clarify rules may be inefficient. Clearly defined legislation would aid antitrust prosecution.

Going back to where we started, President Trump announced plans to reduce US pharmaceutical prices by asking pharmaceutical companies to charge the same prices in the United States as their lowest prices in developed country markets. This request for seemingly voluntary concessions by the pharmaceutical industry is unlikely to have much practical effect unless and until it is accompanied by legislation and/or executive action. The major pharmaceutical companies based in the United States will fight against mandatory rules, and up until now they have successfully forestalled major action to control drug prices.

My proposal, to extend parallel importation already permitted by US intellectual property law, court rulings and to a limited extent by FDA regulations, is intended to accomplish the objective in a simplified way; that is, through bypassing the need for additional action by Congress in terms of pharmaceutical pricing. The FDA can decide that pharmaceutical products produced in any developed country market can be parallel imported into the United States provided some basic guidelines on supply chain management are followed. The federal government, state governments, hospital chains and so forth can purchase lower-priced drugs outside the United States and import them into the United States. The parallel imports program would not be limited to Canada, and it would not require the type of elaborate administrative structures that have been created by the FDA for the initial State parallel import plans. Pharmaceutical products put on the market in Europe can be purchased there and imported into the United States. US prices will go down. If pharmaceutical companies respond by restricting the availability of products sold outside the United States, they will be guilty of US antitrust violations.

[i] 21 USC §381(d).