CITIZENS AGAINST GOVERNMENT WASTE

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March 5, 2020

Food and Drug Administration
Dockets Management Staff (HFA-305)
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Docket No. FDA-2019-N-5711
Proposed Rule: Importation of Prescription Drugs

Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in the federal government. CAGW was founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson to implement the recommendations of President Ronald Reagan's Private Sector Survey on Cost Control, also known as the Grace Commission.

Comment

Since 2000, the Food and Drug Administration (FDA) has refused to certify the safety of imported drugs for many good reasons. On December 26, 2000, then-Secretary of Health and Human Services Donna Shalala said in a letter to President Bill Clinton with regard to the Fiscal Year 2001 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, that while the law allowed prescription drugs to be imported from certain countries, it could only be done if the "reimportation process poses no additional risk to the public's health and safety and that it will result in a significant reduction in the cost of covered products to the American consumer." Due to "serious flaws and loopholes" in the law, she said it was "impossible for me to demonstrate that it is safe and cost effective" to import drugs from other countries.[i]

In his "questions for the record" testimony before a November 17, 2015 Senate Committee on Health, Education, Labor, and Pensions nomination hearing as FDA commissioner, Robert Califf, M.D. said, "Authorizing importation would compromise the closed drug distribution system in the United States and undermine these laws, thus making it easier for unapproved drugs, which may include counterfeit or other substandard drugs, to reach American patients putting their treatment at risk. FDA is concerned that the risks of unapproved products from foreign sources outweigh any potential cost savings. We are also concerned that adverse events flowing from importation of such unapproved products could lead to diminished confidence in FDA-approved products."[ii]

On May 14, 2018, Health and Human Services (HHS) Secretary Alex Azar reiterated the FDA's opposition when he said, "the last four FDA commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from, say, a counterfeit factory in China. The United States has the safest regulatory system in the world. The last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved. … Many people may be familiar with proposals to give our seniors access to cheaper drugs by importing drugs from other countries, such as Canada. This, too, is a gimmick. It has been assessed multiple times by the Congressional Budget Office, and CBO has said it would have no meaningful effect."[iii]

Despite well-documented concerns and economic analyses, the Trump administration announced in December 2019 that it would allow the importation of drugs intended for foreign markets through two potential pathways in a supposed effort to provide safe, lower cost drugs to consumers.[iv]

One pathway is a guidance document for manufacturers that would allow them to import versions of FDA-approved drugs that they sell in foreign countries into the U.S. The administration says manufacturers could "potentially" be allowed to offer a lower price than their current distribution contracts require. These products would be called multi-market approved (MMA) drugs. CAGW wrote a comment in opposition to this policy because while it is supposed to bring down drug prices for Americans, any reasonable review of the guidance raises serious questions on how that would be accomplished and whether the potential savings make the entire effort worthwhile.[v]

The other pathway, which is the subject of this comment, would be a rulemaking that "would rely on the authority in the Federal Food, Drug, and Cosmetic Act section 804 to authorize demonstration projects to allow importation of drugs from Canada."

Under this proposal, the FDA would create Section 804 Importation Programs (SIPs), which would be authorized by the agency but managed by the states or other non-federal governmental entities and their co-sponsors, like pharmacists or wholesalers. The SIP would decide what drugs would be imported from Canada, but these drugs would have to be approved by both Health Canada's Health Products and Food Branch and the FDA.

The SIP would choose the foreign seller in Canada and the importer in the United States. The importation proposed regulation attempts to maintain a "closed" supply chain by requiring that each drug a SIP chooses for importation "would be limited to three entities, *i.e.* one manufacturer, one foreign seller, and one importer." Once the SIP proves it can import drugs safely under the regulation, it will be allowed to work with additional sellers and suppliers, however maintaining the same one manufacturer, one seller, and one importer for each drug.

This will create an anti-competitive atmosphere and little incentive to keep drug prices low. After all, there will be a cost for both the foreign seller and the importer to be compliant to supply chain security requirements. These requirements include "ensuring that a section 804 serial identifier (SSI), the alphanumeric serial number unique to each package or homogeneous case, is affixed or imprinted to each package and homogenous case of the drugs" and the

importer would have to "ensure that a product identifier meeting the requirements of section 582 of the FD&C Act (21 U.S.C. 360eee-1), the product identifier that includes a National Drug Code, a unique alphanumeric serial number, lot number, and expiration date, in both human- and machine-readable format, which is affixed or imprinted to each package or homogenous case of the drugs. The importer would also have to maintain records linking the product identifier affixed or imprinted on a package or homogenous case to the SSI that the foreign seller assigned."

In addition to these requirements, the importer would have to submit a pre-import request to the FDA at least 30 days in advance of the scheduled arrival and receipt at a Customs and Border Protection port of entry authorized by the FDA. Testing would also be required by the manufacturer or a qualifying laboratory, which must follow the manufacturer's testing protocols to assure the drug is authentic and has not degraded, as well as other statutory requirements, like confirming the labeling or relabeling is correct, all of which will create additional costs for the imported drug.

There are also post-importation requirements that will necessitate additional outlays, like analyzing the cost savings to American consumers and providing all the data to the FDA. Adverse events, medication errors, field alerts, and similar information must be reported to the manufacturer and the FDA. And if a recall is warranted, it will be the SIP's responsibility to have a written procedure in place and manage the recall.

The proposed rule clearly demonstrates that few states or entities are going to be able to manage this complicated procedure and save their citizens money, but they will waste valuable tax dollars in trying. There is no estimate in the proposed regulation on how much the extra procedures will cost in comparison to the estimated savings. Any information provided is dubious because there are too many unknowns.

Even if a state government or other entity is able to develop an importation program, unscrupulous actors can easily take advantage of the program and develop a fake Canadian drug website to entice unsuspecting citizens to purchase their "state approved" counterfeit drugs.

The regulation also ignores clear objections by Canadians that they are not interested and do not plan to send their price-controlled drugs to entities in the United States.

In July 2019, Reuters reported that according to obtained documents, "Canada opposes any U.S. plans to buy Canadian prescription drugs that might threaten the country's drug supply or raise costs for its own citizens, officials have told U.S. authorities, in a new setback to the Trump administration's efforts to tackle high drug prices." Shipments to the U.S. could cause shortages for their citizens and Canadian officials are making Canada's position "clear" to U.S. federal and state officials that the country would "take action to ensure Canadians have uninterrupted access to the prescription drugs they need."

At a January 17, 2020 hearing before the Washington State Senate Committee on Health and Long Term Care, Canada's Best Medicines Coalition Chairman John Adams testified about importation bills that have been introduced in a variety of states to purchase price-controlled

drugs from his country. He said his coalition of 28 nonprofits advocate for Canadian citizens to have timely access to medicines that are safe and effective and that his nation of 38 million does not have a large enough pharmaceutical supply for U.S. citizens, particularly since Canada is already experiencing drug shortages.[vi]

An opinion piece in the January 16, 2020 Canadian ***Financial Post*** stated that drug manufacturers "are unlikely to permit their Canadian wholesalers or distributors to undercut their prices in the U.S. by exporting drugs that they have supplied specifically for the Canadian market. Indeed, the wholesalers may be contractually prohibited from exporting any product they purchase from manufacturers" and the Canadian "federal government has already vowed to protect Canadians' drug supplies and access to medication."[vii]

Drug shortages, across many classes, have been a consistent problem in Canada for several years so it seems very likely there will be no drugs coming south from our neighbor to the north. Furthermore, importing drugs from Canada, or any other country that has socialized medicine, is simply importing their price controls.[viii]

CAGW understands the concern over drug prices, but this expensive, elaborate and complex process will not lower costs for Americans. It will invite deceitful actors to take advantage of any importation system that may be implemented and attempt to flood the market with dangerous counterfeit drugs. Some will get through and will either seriously harm a patient or do nothing to help their medical condition.

CAGW continues to argue that faster generic drug approvals and the adoption of modern techniques to streamline all clinical trials and the approval process will encourage more competition and reduce drug prices.

Instead of wasting time and money on dangerous and faulty importation programs, the administration should vigorously implement suggestions offered in the President's Council of Economic Advisers February 13, 2020 report, "Funding the Global Benefits to Biopharmaceutical Innovation." It points out one of the major problems with drug costs is global free-riding on U.S. biopharmaceutical research and development. The report states, "We find that if free-riding abroad was reduced, then the United States could institute domestic pricing policies that could save its patients and taxpayers $194 billion a year … without sacrificing the flow of new treatments."[ix]

The administration should abandon this expensive, unworkable, and dangerous importation "gimmick." Doing otherwise will tie up valuable FDA resources that could be used to speed up drug approvals, which will effectively reduce drug prices by encouraging more competition.

Sincerely,

Thomas Schatz

[i] *Congressional Record*, 107 Congress, 2 Session, Vol. 148, No. 97, Daily Edition, Page S6910, July 17, 2002, https://www.congress.gov/congressional-record/volume-148/senate-section/page/S6910.

[ii] Senate Health, Education, Labor, and Pensions Hearing on the Nomination of Robert Califf to Serve as FDA Commissioner Testimony, November 17, 2015, P. 47, https://www.govinfo.gov/content/pkg/CHRG-114shrg97694/pdf/CHRG-114shrg97694.pdf.

[iii] Health and Human Services Secretary Alex M. Azar II, "Remarks on Drug Pricing Blueprint," May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[iv] U.S. Food and Drug Administration News Release, "Trump Administration takes historic steps to lower U.S. prescription drug prices," December 18, 2019, p. 47, https://www.fda.gov/news-events/press-announcements/trump-administration-takes-historic-steps-lower-us-prescription-drug-prices.

[v] Citizens Against Government Waste, "Draft Guidance: Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry," February 21, 2020, https://www.cagw.org/sites/default/files/pdf/Comments%20on%20Importation%20of%20Certain%20FDA-Approved%20Prescription%20Drugs%20MMA_0.pdf.

[vi] Best Medicines Coalition Chairman John Adams Testimony, Washington State Senate Health & Long Term Care Committee, January 17, 2020, https://www.tvw.org/watch/?eventID=2020011130.

[vii] *Financial Post*, "Why Canada Won't End Up as the Drugstore to the U.S.," January 16, 2020, https://business.financialpost.com/opinion/why-canada-wont-end-up-as-the-drugstore-to-the-u-s.

[viii] Ross McLaughlin, *CTV News*, Vancouver, Canada, https://bc.ctvnews.ca/drug-shortages-cause-problems-for-canadians-1.4522599.

[ix] The Council of Economic Advisers, "Funding the Global Benefits to Biopharmaceutical Innovation," February 2020, https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf.