CITIZENS AGAINST GOVERNMENT WASTE

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Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061,
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Docket No. FDA-2019-D-5743

Draft Guidance: Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry

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

For 20 years, the Food and Drug Administration (FDA) has refused to certify the safety of imported drugs. The agency decided it was impossible to determine if the drugs were safe, consumers were being misled importation would save money, and it would open the door for devious individuals to manufacture counterfeit, adulterated, and dangerous drugs and infiltrate them into the supply chain.[i]

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."[ii]

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.[iii]

The first pathway would be a rulemaking that "would rely on the authority in the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 804 to authorize demonstration projects to allow importation of drugs from Canada."

The second pathway described in the guidance document is the subject matter of this comment. Manufacturers using this pathway would be able 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 will be called multi-market approved (MMA) drugs. While the entire effort 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.

The manufacturer must submit a supplement to a current New Drug Application (NDA) or a Biologics License Application (BLA) for appropriate and FDA-approved labeling changes. The MMA label must match the FDA-approved label utilized in the U.S. In doing so, consideration must be given to the costs involved with a variety of issues, including:

- The manufacturer attesting that the MMA product has the same active ingredients, active ingredient source, strength, and route of administration as described in the NDA or BLA;
- Dealing with and resolving the confusion involved with different proprietary names for the same drug or the same proprietary name that is being used with different drugs. This phenomenon often occurs between the U.S. and foreign markets and the new MMA label must match the FDA-approved proprietary name;
- Differentiating the MMA in an easy-to-understand way for both patients and druggists from other drugs that are not subject to the guidance;
- Registering, listing, and proposing a separate national drug code (NDC) for the MMA;
- Requirements involved for importing MMA drugs into the U.S., through the Automated Commercial Environment, or by other methods, and shipping and storage costs;
- Complying with the Drug Supply Chain Security Act, including authorizing and registering foreign partners involved with the importation of an MMA.

There is no FDA estimate for the substantial costs of compliance, which will be borne by U.S. taxpayers and U.S. consumers.

CAGW understands the concern over drug prices, but this elaborate and convoluted process will not only raise costs across the pharmaceutical market, it will invite unscrupulous actors to game the system with counterfeit drugs. CAGW continues to argue that faster generic drug approvals and the adoption of modern techniques to streamline all clinical trials and the approval process to encourage more competition will help reduce drug prices.

The administration should also act on the President's Council on 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."[iv]

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 that will effectively reduce drug prices by encouraging more competition.

Sincerely,

Thomas Schatz

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[i] Partnership for Safe Medicines, Statements Opposing Drug Importation 2000-, https://www.safemedicines.org/opposing-drug-importation-2000

[ii] 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

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

[iv] 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