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Taking on the Crisis of High Drug Prices in America®

Reference: Public Comments on FDA-2019-D-5743 for "Importation of Certain FDA-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Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry"

Submitter: Gabriel Levitt, founder and president of Prescription Justice; co-founder and president of PharmacyChecker.com

Draft Guidance: "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act"

Agencies: U.S. Food and Drug Administration

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The goal of the organization Prescription Justice is to end the crisis of high drug prices in America. Prescription drug importation is part of the solution. Prescription Justice provides information that consumers can use to reclaim personal prescription drug imports that are refused by the FDA and threatened with destruction. We appreciate the FDA's role in protecting the public from real safety risks associated with drug importation but believe that the agency can avoid overzealous enforcement that leads to confiscations of more affordable FDA-approved and foreign versions of FDA-approved drugs. Such confiscations can deprive people of life-saving medicines. The industry guidance on which you seek comments is potentially relevant to safe personal drug importation where industry can play an integral role.

Thank you for the opportunity to comment.

According to the Kaiser Family Foundation, 29% of American adults (74 million people) do not fill a prescription as directed because of cost.[1] That the U.S. tolerates cost-related medication non-adherence on such a mass scale, in which people die because of drug prices, should shock our national conscience.[2] About four million Americans import lower-cost medicine for personal use each year, and 20 million overall say they have done so at some point because the prices are much lower in other countries.[3] In doing so, they often technically violate federal law.[4] For many, they have no other choice.[5]

The main purpose of the "Importation of Certain FDA-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Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry" (the "guidance document") is to explain a pathway for drug manufacturers to

create new NDC (national drug code) numbers for foreign-made, FDA-approved drugs to help them potentially offer lower prices. Despite its narrow focus, the guidance opens the door to a larger exploration of how lawful, safe drug importation should be a part of the solution to this crisis of high drug prices. It presents opportunities for this to happen and raises questions about personal importation.

Clarify the Scope of Drug Importation as a Percentage of the Current Drug Supply

The guidance document clarifies for the public the fact that drug importation is **not** illegal. It is expressly legal under Section 801 of the U.S. Food and Drug Administration. Drug companies manufacture many medications outside the U.S. and then export them for sale at U.S. pharmacies.[6] Those exact same drugs are sold at much lower cost in other countries where they are actually made (UK, EU, India, Singapore, etc.) compared to the United States. For example, according to a report last year by the House Ways and Means Committee, drug prices in other countries are on average almost 75% lower in 11 high-income countries compared to the U.S. on 79 drugs that account for 60% of Medicare drug spending.[7] The problem is that federal law gives the drug companies a monopoly on commercial distribution within the U.S. so that they can control the price of the drug. Apparently, even if they wanted to lower drug prices, drug manufacturers face *challenges in the private market* to prevent it. Per the guidance document, they can choose to export FDA-approved drugs at lower cost, but only with a new NDC number.

In view of the above, for the public to adequately assess the scope of this opportunity for industry to charge lower prices, it is important for the FDA to clarify the percentage of finished prescription drugs currently sold in the U.S. that are foreign made (imported). For well over a decade, the FDA has stated in various public documents and testimony that 40% of prescription drugs sold in the U.S. are imported but does not give the basis for that data point.[8] In 2018 and 2019, staff at PharmacyChecker researched the country of manufacture of the 100 most commonly-dispensed brand name drugs in the U.S. (per 2015 data) and 71% of those drugs were made outside the U.S.[9]

Please clarify in your final guidance what percent of finished drugs sold in U.S. pharmacies are foreign made and provide the basis for your data.

Clarify Commercial Use vs. Personal Use Importation

Section 801(d)(1)(B) expressly applies to "commercial use" imports.[10] It does not address people who might fill a prescription in another country, such as Canada, India or the UK, and import the medicine for **personal use** when traveling back home to the U.S. This is not theoretical. As stated above, about 20 million Americans say they have imported a medicine for personal use.[11] Many of them have done so in person when traveling and via the mail. Here, I'm addressing personal imports through travel.

The guidance document identifies qualified drugs for import as "FDA-approved drugs that were also authorized for sale in a foreign country in which the drugs were originally intended to be marketed" as drugs with multi-market authorization or "MMA products" [Lines 149-151].

It is fair to conclude that a person obtaining an MMA product in a pharmacy outside the U.S. can lawfully import it as long as it is for personal, not commercial, use [re-sale]. For clarity, the aforementioned import does not relate to Section 804 of the Food, Drug and Cosmetic Act part J, which articulates Congress's direction that the FDA should use "enforcement discretion" to permit personal importation that does not present an "unreasonable risk" to the patient.[12] Under Section 804, the FDA should not only permit MMA products (FDA-approved drugs) but also allow foreign versions of FDA-approved drugs for personal use where the drug is not an "unreasonable risk." In contrast to personal imports allowed through enforcement discretion, personal imports of MMA products could be lawful not merely permitted.

One hurdle to personal importation of MMA products is that they might be deemed misbranded due to foreign labels and/or different warnings and directions for use. If the personal use importer could show possession of the U.S. label, directions for use and a valid prescription for that product, then the drug may no longer be viewed as misbranded.

Such imports would pose no additional risk to the public health. First, the public at large, by definition, would not be affected by the personal import because it cannot be re-sold. Second, the FDA affirms in the guidance document that qualified drugs "[differ] from the FDA-approved drug or FDA-licensed biological product only with regard to the [label]" [Line 161-162].

Let us examine the case of Januvia 100mg. For an American traveling in the UK, 90 pills of Januvia 100mg could be purchased for about $3/pill, compared to about $19/pill in the U.S. or $270 in the UK vs. $1,710 in the U.S. for an uninsured patient. Buying Januvia in the UK would save an American $1,440.[13] Roundtrip flights to London can be purchased for as little as $378,[14] which would leave the patient with over $1,000 in savings.

There are insulin products that could qualify as MMA products, such as Lantus Solostar, which are FDA-approved drugs made outside the United States. Clearly, Americans would want to know how they could lawfully import such medications under FDA guidance.

It is recommended that the FDA amend the final guidance to include instructions for individuals who wish to import MMA products for personal use when traveling back from Canada and other countries.

Millions of Americans buy their medicine internationally and have it mailed to them from licensed pharmacies, often ordered online.[15] Notwithstanding Congress's position in Section 804 that people should be permitted to import prescription drugs for personal use that are otherwise illegal, such as those mailed from pharmacies in other countries, MMA products imported for personal use may be legal under Section 801 as long as the importer has evidence of a prescription and the U.S. label.

Under Section 801(a), while not compelled by law to do so, the Secretary of Health and Human Services can refuse and destroy an imported prescription drug valued at $2,500 or less that is being shipped to a patient with a prescription, but cannot destroy the drug until the patient has received a letter from the FDA providing the reason for the refusal and is provided "due process" to defend the import through a

letter of testimony to the FDA.[16] In view of this guidance, if the FDA knows that an imported drug is an MMA product and the patient presents a prescription and the U.S. label to overcome the misbranding designation, then the import may be lawful.

Please clarify the FDA's opinion on whether personal imports of MMA products that are detained at an international mail facility could be released to patients who present a prescription and the U.S. label for the product.

Clarify Whether Drug Manufacturers Could Export Directly to Patients via International Pharmacy

Section 801 does not prevent drug manufacturers from exporting their products directly to consumers in the U.S. If drug manufacturers established licensed pharmacy settings in the country of manufacture in accordance with local pharmacy laws, they could conceivably accept prescription orders directly from patients, thereby cutting out the problem of intermediaries altogether. Those exported MMA products would already be labeled for the U.S.

The guidance document states: "FDA's view is that international mail is not appropriate for the importation of MMA products." That view is probably informed by real concerns and threats from counterfeit drugs and fentanyl coming through international mail facilities, but it may also pertain to the FDA deterring consumers from using the Internet for safe personal drug importation.[17] Peer-reviewed research has consistently shown that properly-credentialed international online pharmacies sell the same medication by mail to the U.S. that is available at U.S. pharmacies.[18]

International pharmacy is a real solution to cutting out middlemen, and drug manufacturers could potentially participate. If drug manufacturers were to have the responsibility for the prescription fulfillment, the drug could be tracked using advanced electronic data (AED), as called for under the STOP Act.[19] Thus, the path of a drug from the envisioned drug manufacturer-operated pharmacy to the patient would be assured. This would be the most direct path for a foreign FDA-approved drug to travel to a patient, allowing for much lower costs – with a new NDC number – and entirely preventing the opportunity for counterfeiting.

Please clarify whether a drug manufacturer could, through establishing a pharmacy in the country of manufacture, mail an MMA product directly to a patient in the U.S. with a valid prescription for the product.

Clarify the Meaning of "Challenges in the Private Market"

To restate, the main goal of the guidance document is to show drug manufacturers that they can sell their medications at lower drug prices in the U.S. if they choose to do so. The genesis of this effort, as indicated in the document, is that the FDA has "become aware" [Line 121] that some drug manufacturers would like to charge lower prices but would need to place different NDC numbers on those same drug packages to do so. Those new NDC numbers would help them overcome "challenges in the private market" [Line 123].

Ostensibly, "challenges in the private market" means that drug manufacturers are locked into contracts with third-party entities, such as pharmacy benefit managers (PBMs), in which the list drug price is fixed based on the drug's National Drug Code (NDC). That list price apparently must be charged throughout the entire U.S. market for a drug that has that NDC number on it. That same FDA-approved drug, let's say it's Januvia 100mg labeled with NDC# 0006-0277-31 by Merck Sharp & Dohme Corp, is also sold in the United Kingdom but with labeling for the UK, where it is manufactured for both markets (the U.S. and the UK). The proposed guidance allows Merck to create a new NDC # for Januvia 100mg and add the required U.S. labeling to the drug that was initially destined for sale in the country of its manufacture, the UK. That "new" Januvia is not constrained by the pricing contract of the original and can therefore be lawfully priced lower. In this theoretical example, the manufacturer may find more buyers at a lower price, perhaps in the cash, out-of-pocket market.

Please clarify in your final guidance if the aforementioned explanation is accurate and any other possible meanings of "challenges in the private market."

In considering drug importation, our goals should be to ascertain how consumers can benefit from lower drug prices available in other countries or new business models for the industry that would genuinely encourage lower drug prices. It is my hope that the comments above lead the FDA to pursue bolder initiatives on importation to help end the crisis of high drug prices in America.

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[1] Kirzinger, Ashley, Lunna Lopes, Bryan Wu, and Mollyann Brodie, *KFF Health Tracking Poll – February 2019: Prescription Drugs, Kaiser Family Foundation,* March 1, 2019, See https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ [last accessed 2/19/2020].

[2] Jones, Sarah, "Another Person Has Died After Rationing Insulin," New York Magazine, Intelligencer, July 15, 2019. See https://nymag.com/intelligencer/2019/07/another-person-has-died-from-rationing-insulin.html [last accessed 2/19/2020].

[3] Bluth, Rachel, "Faced With Unaffordable Drug Prices, Tens Of Millions Buy Medicine Outside U.S.," Kaiser Health News, December 20, 2016. See https://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-u-s/ [last accessed 2/19/2020].

[4] Ibid.

[5] Change.org petition with comments from thousands of Americans who import medicine for personal use, posted here: http://www.pharmacychecker.com/pdf/comments-by-americans-concernedsection-708-fdasia.pdf and here https://www.change.org/p/kathleen-sebelius-please-don-t-stop-americans-from-gettingmedicine-at-lower-cost-outside-the-u-s.

[6] U.S. Government Accountability Office, "DRUG SAFETY: Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections," December 10, 2019, See https://www.gao.gov/assets/gao-20-262t.pdf [last accessed 2/19/2020]. GAO-20-262T.

[7] "A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices," a report prepared by the House Ways and Means Committee Staff, September 2019. See https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf [Last accessed 10/29/19].

[8] Presentation by former FDA Commissioner Margarete Hamburg, October 8, 2010. Dr. Hamburg cites the 40% figure. See https://www.c-span.org/video/?295894-4/margaret-hamburg-remarks-counterfeit-perscription-drugs [Last accessed 10/29/19].

[9] "FDA's Drug Importation Data is Wrong," PharmacyChecker News Release, July 17, 2018. See https://www.pharmacychecker.com/news/fdas-drug-importation-data-is-wrong/: [Last accessed 10/29/19].
[10] 21 U.S.C 381(d)(1)(b) See https://www.law.cornell.edu/uscode/text/21/381..
[11] Supra note 2.
[12] 21 U.S.C 384 (j).
[13] Supra note 6.
[14] See https://www.kayak.com/flight-routes/New-York-NYC/London-LON [last accessed 2/19/2020].
[15] Supra note2.
[16] 21 U.S.C. 381(a)
[17] McAuliff, Michael, "Trump administration seizing cheaper medications from Canada and other countries," June 14, 2018, *Tarbell*. See https://tarbell.org/2018/06/trump-administration-seizing-cheaper-medications-from-canada-and-other-countries/ [last accessed 2/19/2020].
[18] Bate, Roger, "Personal Medicine Importation: What Are the Risks, and How Can They Be Mitigated?" American Enterprise Institute, September 11, 2019. See https://www.aei.org/research-products/report/personal-medicine-importation-what-are-the-risks-and-how-can-they-be-mitigated/: [Last accessed 10/29/2019].
[19] "No Holds Barred – Or Missed," July 29, 2019, Office of the Inspector General, United States Postal Service. See https://www.uspsoig.gov/blog/no-holds-barred-%E2%80%93-or-missed [last accessed 2/19/2020].