
Docket No. FDA-2019-N-5711

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I appreciate the opportunity to comment on this notice of proposed rulemaking (NPRM). Founded in 2002, and launching its website in 2003, PharmacyChecker provides consumers with online pharmacy verification and comparative drug price information to help them make the best decisions for themselves and their families on how to afford prescription drugs.

Prescription Justice was founded in 2015 to help end the crisis of high drug prices in America. Prescription Justice advocates for policies that are supported by overwhelming majorities of American voters, Republican and Democrat. They include ending the ban on Medicare negotiating drug prices; banning reverse patent agreements among brand and generic drug companies, also known as “pay-for-delay;” legalizing the importation of lower-cost, safe and effective drugs; and advocating for the use of FDA enforcement discretion to allow individuals the freedom to import affordable medications for their own care.

The FDA should be commended for its effort to create rules, pursuant to Section 804 of the Food, Drug and Cosmetic Act, that can lead to a regulated and safe channel of wholesale drug importation from Canada to help reduce cost burdens on states and consumers. The agency has created a well-thought-out roadmap for states and other non-federal entities to safely import medications directly from licensed and qualified Canadian wholesale pharmacies that charge lower prices than their U.S. counterparts.

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 this magnitude of cost-related medication non-adherence, 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 about 20 million 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 NPRM accurately and importantly distinguishes wholesale from personal drug importation (“personal importation”). Problems often related to personal importation should not be viewed as roadblocks to implementing parts (b)-(h) of Section 804, which have nothing to do with expanding personal importation.

These comments will focus on Part J of Section 804, pertaining to personal importation.
While the NPRM recognizes the importance to Americans of buying more affordable drugs outside the U.S., the FDA seems to defer actions that are not only permissible but encouraged under Section 804(J) to expand access to personally imported FDA-approved and foreign versions of FDA-approved drugs. In the NPRM’s brief coverage of personal importation, the focus is solely on the Internet and problems from “rogue online pharmacies,” in a manner that may overlook opportunities for personal importation that have nothing to do with the Internet.

Where personal importation is related to medicine orders placed on the Internet, it’s more critical than ever to harness the agency’s limited budget to tackle unreasonable risks that Americans may be taking when obtaining cheaper medicines online, while not deterring them from affordable and safe prescription drugs available in other countries through orders placed online.6

According to a report by the House Ways and Means Committee, prices on 79 drugs that comprise 60% of drug spending in Medicare are almost 75% lower in 11 high income countries compared to the U.S.7 Drug prices in Canada are actually higher than in most countries, but still far lower than in the U.S. It’s for this reason that the FDA states “that some American consumers have sought to import drugs from other countries in an effort to obtain treatments that may be otherwise inaccessible to them because of cost.”

**Part J(1) of Section 804 is Congress’s Position on Personal Importation**

The NPRM states: “FDA is not proposing to implement the personal importation provisions in section 804(jj) through this rulemaking.” The FDA’s decision doesn’t lessen the importance of Part J in protecting the current ability of Americans to obtain personal use quantities of more affordable FDA-approved and foreign versions of FDA-approved drugs from other countries. Part J is written in three sections. Section (1) does not appear to require *implementation*. It’s Congress’s declaration on what the agency “should” do. It states:

“(j)Waiver authority for importation by individuals

(1) **Declarations.** Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make such importations in circumstances in which—

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.”

The standard required to permit lawful wholesale importation, part (b)-(h) from Canada is that it “pose no additional risk to the public’s health and safety and would be expected to result in a significant reduction in the cost of covered products to the American consumer.” In contrast, the standard for permitting personal importation via enforcement discretion is purposefully not as strict, which is that it can’t represent an “unreasonable risk.” In most circumstances, personal imports of drugs that are the
same as FDA-approved or high-quality foreign versions of FDA-approved, dispensed by licensed pharmacists for patients with valid prescriptions, cannot logically be viewed as an “unreasonable risk.” That’s especially the case if the patient looking to import cannot afford the medication domestically.

**Recommendations to the FDA for adhering to Section 804 (J)(1)**

- Generally, revise the FDA’s public message that warns Americans against buying medication from foreign pharmacies where that warning may lead to even more people going without prescribed medicines due to cost.
- Provide guidance on the FDA’s website to explain the differences between rogue pharmacy websites and safe international online pharmacies.
- Ensure that Congress’s funding for agency enforcement efforts against illegal drug importation, whether to combat counterfeit drugs or opioid ingredients ordered online, does not prevent patients from obtaining personal use quantities or prescribed medicines that do not present an unreasonable risk to their health.
- Release personal drug imports that have been refused and detained at international mail facilities of non-controlled, FDA-approved or foreign versions of FDA-approved medications to patients who have provided the agency with a letter of testimony demonstrating: 1) possession of a valid prescription, 2) possession of the U.S. label relevant to consumers for that prescription, found at [https://dailymed.nlm.nih.gov/dailymed/](https://dailymed.nlm.nih.gov/dailymed/), 3) the source of the medication is a licensed pharmacy.
- Conduct an internal audit to ensure that the FDA is providing due process to patients, as required by Section 801 (21 U.S.C. 381), if their imported prescription orders are refused so that they are released to those patients who provide ample evidence to the FDA that their medicine is not an unreasonable risk.

The recommendations above are respectfully presented for the FDA’s consideration in light of what the law states the FDA should be doing pursuant to Section 804 (J)(1), and to assess if its resources are being allocated accordingly so that unreasonable risks – but not safe personal medicine imports – are curtailed.

**(J)(2) Waiver authority**

Dangers from the Internet are the only reasons given for why the agency is not implementing regulations and waivers pursuant to J(1)(2). Millions of Americans travel to Mexico, Canada and other countries each year and return with prescription medicines for their own use because the prices are much lower. In 2019, 84 million Americans traveled to Mexico and another 7 million traveled to Canada for personal use. In 2019, nearly 2.5 million Americans traveled to other countries for personal use, and they bring back prescription drugs at much lower prices for personal use when traveling outside the U.S.

Pursuant to (J)(1)(2), the agency should announce a general waiver for people who bring back medicines through travel. Alternatively, the general waiver could be specific to travel from countries known to have comparable regulation to the U.S. for drug safety.

Part (J)(2) of Section 804 looks to the FDA to grant specific waivers by regulation or on a case-by-case basis. Whereas above, in (J1), the law establishes what the FDA “should” do; (J)(2) directs what the FDA
“may” do. This means that the FDA may grant waivers to individuals to import more affordable drugs that would otherwise be prohibited. It can also establish a general regulation that individuals could use to determine the appropriateness of a personal import.

Presumably, the aforementioned waivers and regulations are what the NPRM was referring to by stating it is not implementing Part J. The FDA’s reasons fall short in clarity and appropriateness. Most conspicuously, the NPRM implies that the agency’s main reason for not “implementing” (J)(2) is due to threats from “rogue online pharmacies…that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States.”

There are many such rogue sites, as the NPRM warns, but they don’t negate the existence of safe international online pharmacies, ones that require a prescription, adhere to strict safeguards and process orders filled by licensed pharmacies, dispensed by licensed pharmacists in countries outside the U.S. Independent, peer-reviewed research has demonstrated that such pharmacies are comparable in safety to U.S. online mail order pharmacies.

Since the only reason given by the FDA for not implementing Part J was threats from the Internet, the agency should consider waivers for personal importation that are not related to the Internet. Here are some examples:

- Permit, through a new general regulation, personal imports of FDA-approved and foreign versions of FDA approved drugs through travel for patients with valid prescriptions.
- Permit, through a new general regulation, personal imports of FDA-approved and foreign versions of FDA approved drugs through the mail for patients with valid prescriptions who order directly from a licensed brick-and-mortar pharmacy by phone.
- Permit personal drug import waivers to individual patients who must apply for the waivers, including with consent from their licensed practitioners.
- Permit personal drug import waivers for specific drugs, such as insulin, so that Americans can travel to Canada and other countries with express permission to bring back life-sustaining medicines that they can afford.

These are general examples of how the agency can implement (J)(2) to expressly permit more forms of safe personal drug importation, ones that don’t include ordering medicines online.

(J)(3) Personal Importation from Canada Only

This part of section 804 is very straightforward. If implemented, Americans would be expressly permitted to import FDA-approved drug and foreign Canadian versions of FDA-approved drugs from Canada for their own use, pursuant to a valid prescription.

Part J(3) states:

“Drugs imported from Canada. In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;
(B) is accompanied by a copy of a valid prescription;
(C) is imported from Canada, from a seller registered with the Secretary;
(D) is a prescription drug approved by the Secretary under subchapter V;
(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 360 of this title; and
(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.”

The above provisions were drafted to codify common practices of safe personal importation from Canada, including by mail. However, the FDA should at a minimum, immediately, expressly permit prescription drug imports for personal use from Canada that are carried across the border. In fact, that channel of importation is not only not an “unreasonable risk” but would “pose no additional risk to the public's health and safety and would be expected to result in a significant reduction in the cost of covered products to the American consumer.”

For assurances on safety, just look to the remarks of former FDA Commissioner Dr. Scott Gottlieb during testimony before Congress in 2019:

“Canadians have safe drugs and if you go into a brick and mortar pharmacy and you purchase a drug, you’re getting a safe and effective drug. I have confidence in the Canadian drug regulatory system.”

In terms of significant savings, according to the House Ways and Means Committee price report, brand name drug prices are on average 71% lower in Canada than the United States.

The FDA is aware that people with diabetes are going to Canada to import for personal use insulin products. In one highly publicized example of a “Caravan to Canada,” it was reported that one vial of the same medication under a different name was $320 in the U.S. vs. $30 in the Canada. That’s a 90% savings: clearly significant.

Based on these simple assessments, it’s not only unreasonable but unjustifiable not to expressly permit this at the earliest time possible. An argument against this might be to point out that people are already doing this, and the FDA does not stop them. Also, in some Department of Homeland Security appropriations bills, the law specifically bans the U.S. Customs and Border Protection from stopping personal imports of FDA-approved drugs. Nonetheless, a clear policy of express permission for Americans who take insulin to get it in Canada would improve adherence to their treatments, save them money and probably save some of their lives.

**Using Advanced Electronic Data to Track Personal Drug Imports**

The FDA is rightfully concerned about opioids, opioid ingredients and counterfeit drug imports coming in through international mail facilities (IMFs). To try and stop illegal opioid imports in particular, the provisions of the Synthetics Trafficking and Overdose Prevention Act (STOP Act), which became law, included requirements mandating that advanced electronic data is provided to the U.S. Postal Service for packages coming through IMFs. That AED lets the USPS know the source of a package. Illegal opioids and non-controlled safe and affordable medicines both come in through IMFs.
Before its passage, there were concerns that requirements under the STOP Act could be misused to intercept safe, personally-imported medicines. Reporting by independent media source Tarbell appears to show that the FDA is using funding that was appropriated to help prevent illegal opioid imports to refuse and, in some cases, destroy safe imported medicines in route to patients.

FDA personnel who process refusals and destructions of personal use imported medicines sometimes document that the sender is “unknown.” AED can be employed to ensure that a personally imported medicine is obtained from a licensed pharmacy. In those cases, FDA personnel tasked with examining such imports will know the source. Thus, for example, the path of a drug from a licensed pharmacy in Canada to a patient in the U.S. could be guaranteed using AED. FDA personnel could quickly permit such imports, allowing more time to focus on intercepting packages of dangerous drugs, such as illegal fentanyl.

**Personal Drug Importation Related to the Internet**

Above, I have provided examples on how the FDA could implement regulations and/or waivers, pursuant to Section 804(J)(2) and (3) to expressly permit safe personal importation. Those regulations or waivers could specify that they do not create or confer any rights, privileges, or benefits to individuals for the purpose of buying medicines over the Internet that are then imported by them for personal use. However, the FDA should also implement regulations and waivers to either expressly permit orders on “white listed” international online pharmacies and/or provide special guidance to consumers that provide commonsense tips on how to avoid unreasonable risks when buying medication online from another country.

Part J of Section 804 provides the FDA with wide latitude on the use of enforcement discretion for personal importation, which includes the role of safe international online pharmacies. One of the main points made by the agency against Internet purchases of medicine is that rogue online pharmacies pose as safe Canadian pharmacies, but the medicines ordered are coming from outside of Canada or are being transshipped through Canada. The implication is that pharmacies in Canada are safe and orders placed online filled by Canadian pharmacies are safe, too. At a minimum, the FDA could expressly permit online orders that are filled in Canada, from licensed Canadian pharmacies.

There are many rogue pharmacy sites that pretend to be Canadian. There are also Canadian-based online pharmacies and international online pharmacies based in other countries that fill orders with pharmacies in several countries – including Canada. The safest among those are usually accredited by or members of third-party organizations, such as PharmacyChecker or the Canadian International Pharmacy Association. Such safe international online pharmacies require valid prescriptions and do not sell controlled drugs. Independent testing for over a decade of pharmacy practices and prescription drug quality has consistently demonstrated the safety of these international online pharmacies.

The FDA should provide guidance that 1) warns the public against rogue online pharmacies; 2) articulates the regulatory prohibitions on importation and the lack of FDA assurance over personally imported prescription medicine; and 3) communicates what the safer international online pharmacy options are for those who choose to personally import a more affordable medicine.
Enforcement Against International Online Pharmacies and Part J

While the FDA has taken actions against and shut down thousands of rogue online pharmacies, the NPRM confusingly brings up the case of Canada Drugs Ltd. ("Canada Drugs") – “an internet-based pharmacy corporation located in Winnipeg, Manitoba, Canada.” Canada Drugs Ltd, its owners and affiliated entities were indicted for and some plead guilty to illegal wholesale importation, in part because two batches of counterfeit Avastin drug were discovered in its supply chain, but also because it was importing misbranded FDA-approved or foreign versions of FDA-approved medicine through wholesale channels.20

In contrast, that company’s retail-facing online pharmacy, called CanadaDrugs.com, required valid prescriptions, provided patient consultations, processed prescription orders filled by licensed pharmacies for about 17 years and was never found, or accused of, selling a counterfeit or even substandard drug.21 As part of a plea bargain with the U.S. Department of Justice, Canada Drugs had to forfeit its online pharmacy sites but was granted three months during which to continue filling prescription orders for its U.S. patients.22 Presumably, the reason the FDA might have allowed that is to not interrupt the continuity of care for its patients. That decision must have been based on the recognition that those personal imports were not an “unreasonable risk.”

Unlike with personal importation, the law does not affirm that illegal wholesale importation should be permitted where it does not represent an unreasonable risk. While Canada Drugs was not indicted for intentionally selling a counterfeit drug, the severity of a counterfeit drug breaching the U.S. drug supply, especially an oncology medicine, demanded a serious effort by the FDA to hold those responsible accountable and prevent future illegal wholesale importation.

Instead of CanadaDrugs.com, the NPRM could have included an example of an actual rogue online pharmacy, such as AllMedsPharmacy.net, which advertised the sale of prescription drugs without a prescription, and, according to the FDA, was found selling counterfeit and controlled drugs directly to Americans, and without requiring a valid prescription.23 Common estimates of rogue online pharmacies in operation are in the tens of thousands, potentially as high as 70,000.24 Yet it appears that the FDA continues to spend a considerable part of its Internet-related enforcement dollars against safe personal drug importation, in some cases that have little or nothing to do with “online pharmacies.” A prime example is an FDA warning letter last year to CanaRx, a Canadian-based company that works with U.S. municipalities and other self-insured organizations by connecting their employees and retirees to licensed pharmacies in Australia, Canada and the UK.25 Such programs have operated without safety problems for over 15 years and are closed to the participating local governments and organizations.

Enforcement actions against the safest examples of personal importation, whether self-insured municipalities working with companies like CanaRx or properly credentialed international online pharmacies strongly appear to go against the direction and the purpose of Section 804(J)(1). The legislative record speaks to this point. For example, the Prescription Drug Import Fairness Act of 2000 was passed into law as Section 746 of an appropriations bill applicable to the FDA and other agencies in 2000 (H.R. 4461).26 In this law, Congress articulates these findings:

“Patients and their families sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration (‘FDA’).”

Page 7 of 11 (PharmacyChecker and Prescription Justice comments, docket No. FDA-2019-N-5711)
It’s noteworthy that these findings are the only “findings” included in the U.S House of Representative’s online publication of Section 801 of the Food, Drug and Cosmetic Act, 21 U.S.C. 381, which codifies the rules for which drugs are lawful to import, and include the only mention of the word “patient.”27

Due to this finding, three years later, in the Medicare Modernization and Prescription Drug Improvement Act of 2003, Congress amended Section 804 of the Food, Drug and Cosmetic act to include Part J, which tells the FDA unequivocally that it should allow personal importation that is not an unreasonable risk.28 More recently, The STOP Act, which added new authorities to quell illegal drug importation, included a provision to carve out protections for personal importation.29

The law gives special consideration to Americans for whom personal importation of more affordable prescription drugs is important. For Americans to effectively and safely import lower cost prescription drugs into the U.S. they must have options to do so and those should include safe international online pharmacies.

Recommendations to the FDA on enforcement actions against online pharmacies and guidance to consumers, pursuant to Section 804(J):

- Prioritize enforcement actions against rogue online pharmacies: those websites found to intentionally sell falsified drugs; not require valid prescriptions for prescription medications; make fraudulent claims; or exacerbate illegal distribution of opioids and other controlled drugs.
- Avoid enforcement actions against international online pharmacies that the FDA knows to be the safest international options available to Americans.

Enforcement discretion should be applied by the FDA to the safest international online pharmacies as well as individuals who personally import medicines. Balanced use of that discretion, and guiding consumers through public education to safe international online pharmacies will reduce the numbers of Americans who do not take prescribed medicines due to cost and protect them from rogue online pharmacies. Those actions are encouraged and in line with what is permitted under Section 804 (J).

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4 Ibid.


10 Testimony by Scott Gottlieb, MD, former FDA Commissioner, before the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related. February 27, 2019. See video at 1:34.20: https://www.youtube.com/watch?v=KZc7kA5SM5E&feature=youtu.be&t=5661 [last accessed 3/9/2020].

11 Ibid at Note 7.


14 Section 206 of H.R.244 – Consolidated Appropriations Act, 2017.


19 Ibid, see note 9.


21 Ibid.

22 See CanadaDrugs.com’s announcement


24 The FDA cites data by LegitScript in its proposed rule to implement Section 708 of the Food and Drug Administration Safety and Innovation Act of 2012, stating, “34,000 active rogue Internet pharmacies as of April 2013.” On LegitScript’s website today, you’ll see that there are 72,291 active Internet pharmacies but the percentage of those categorized as “rogue” is not readily apparent.

Page 9 of 11 (PharmacyChecker and Prescription Justice comments, docket No. FDA-2019-N-5711)
26 Public Law No: 106-387. Sec. 746. (a) Short Title.--This section may be cited as the “Prescription Drug Import Fairness Act of 2000.” See https://www.congress.gov/bill/106th-congress/house-bill/4461/text?q=%7B%22search%22%3A%22%22%5C%22Prescription+Drug+Import+Fairness+Act+of+2000%5C%22%22%7D&r=2 [last accessed 3/9/2020].