February 27, 2023

Dan Solis
Assistant Commissioner for Import Operations
U.S. Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA), Office of Importation Operations (OIO)
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Re: Importation of Prescription Drugs from Outside the United States and Canada

Dear Mr. Solis:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers.

It has recently come to our attention that certain companies are partnering with health plans to implement "alternative funding programs" whereby plan enrollees' prescription medications are imported from outside the United States and Canada. Therefore, we are asking for a meeting with your office to discuss:

(1) The risks these programs pose to the health and safety of consumers;

(2) Whether our understanding is correct that these alternative funding programs are inconsistent with federal laws, regulations, and policy on importing medications from outside the United States and Canada; and

(3) If our interpretation is correct, what actions FDA could take to help protect consumers, including enforcement actions or updating current guidance to clarify that importation via alternative funding programs is illegal.

I. Third-Party Companies are Partnering with Health Plans to Import Consumers' Prescription Drugs from Canada and Other Countries

Health plans are partnering with companies, often referred to as "specialty medication programs," to develop alternative funding programs. Under an alternative funding program, the third-party specialty medication program determines whether a consumer's prescription medication is funded, or otherwise available at a lower cost, through a source other than the plan – i.e., an alternative funding source.[1]

[1] Angela Maas, *Industry Experts Question Alternative Funding Companies That Carve Out Some Specialty Drugs, 'Abuse Charities,* https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/.

Alternative funding sources can include commercial copay assistance programs, charitable assistance programs, and international importation.[2] International importation can include importation from Canadian pharmacies and other international pharmacies.[3] For instance, one company has stated in a promotional video:

> Since many of the medications [the company] sources come from Canada, it may take seven to ten days for your medications to arrive. If your order contains a temperature sensitive medication, you should receive your package within three to five days if you're available to sign, or six to eight days if you have opted out of signing. For overseas orders, you can expect your package to arrive within four to five weeks.[4]

Thus, this and similar programs appear to import drugs from both Canadian pharmacies and entities in other foreign countries.[5] The drugs being imported under these programs are generally also available in the United States and FDA approved. However, it is our understanding that such imported drugs may be manufactured in facilities that have not been inspected by the FDA.

As explained below, third-party specialty medication programs are using both Canadian pharmacies and entities in other foreign countries to import prescription drugs in a manner that is inconsistent with federal laws, regulations, and policy.

II. Laws, Regulations, and Agency Policy Related to Drug Importation

The federal Food, Drug, and Cosmetic Act (FDCA) limits the types of drugs that may be imported in the United States to help ensure that the domestic drug supply is safe and effective.[6] It is illegal under the FDCA to import non-FDA approved drugs, including "foreign versions" of FDA approved drugs.[7] Congress implemented this prohibition to protect consumers from internationally developed drugs that are not vetted for safety in accordance with FDA's standards.[8]

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[2] Angela Maas, *Industry Experts Question Alternative Funding Companies That Carve Out Some Specialty Drugs, 'Abuse Charities,* https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/.

[3] Aimed Alliance, *Essential Health Benefits, Importation, and More – Do You Know the Risks?,* at slide 28 https://aimedalliance.org/wp-content/uploads/2023/01/Aimed-Alliance-Non-EHB-and-Alternative-Funding-Schemes-Presentation.pdf; SHARx, *How Long Will It Take to Get My Medication?,* https://www.youtube.com/watch?v=pPFObSLiCL0.

[4] SHARx, *How Long Will It Take to Get My Medication?,* https://www.youtube.com/watch?v=pPFObSLiCL0.

[5] SHARx, *What are considered high-cost drugs,* https://www.sharxplan.com/what-is-a-high-cost-med/#:~:text=These%20would%20include%3A%20Insulin%20(most,Xolair%2C%20and%20MANY%20More; Payer Matrix, *Drug List – Powered by Payer Matrix,* https://centriqbenefits.com/wp-content/uploads/sites/399/2021/11/Member-Facing-Drug-List.pdf.

[6] HHS, *HHS Task Force on Drug Importation,* http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf.

[7] FDA, *CDER Small Business and Industry Assistance: Import and Export of Human Drugs and Biologics,* https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-small-business-and-industry-assistance-import-and-export-human-drugs-and-biologics.

[8] FDA, *Personal Importation*, https://www.fda.gov/industry/import-basics/personal-importation#whatis .

Limited exceptions to the general prohibition on drug importation include FDA's personal importation policy and federal regulations permitting importation of prescription drugs from Canada under certain circumstances, as explained in more detail below.[9]

Regardless of whether a new drug is manufactured in the United States or in a foreign country, the drug must comply with the FDCA prior to being marketed in the United States. For example, it must be approved by the FDA, produced in FDA-inspected plants operating in accordance with current good manufacturing practices, and labeled with all required information.[10] As such, any entity that intends to import prescription drugs for human use into the United States must ensure that the drug satisfies these requirements.[11]

A. FDA's Personal Importation Policy

While importing unapproved prescription drugs is illegal, FDA's policy on importing prescription drugs for personal use recognizes that there may be circumstances in which the FDA may exercise enforcement discretion with respect to illegal importation.[12] The personal use policy, set forth in FDA's Regulatory Procedures Manual and endorsed under the FDCA, provides that an individual may be permitted to import an unapproved prescription drug for personal use if:

1. The product is not used to treat a serious condition, such as the use of an over-the-counter treatment (OTC); or
2. The product is used to treat a serious condition; and
    a. The product is needed to treat the serious condition and the medication is not available in the United States;
    b. There is no commercialization or promotion of the drug to U.S. residents;
    c. The drug does not represent an unreasonable risk;
    d. The individual importing the drug affirms in writing that the product is for personal use;
    e. The quantity is not more than a 3-month supply; and either:
        i. The consumer provides contact information for the U.S. doctor providing treatment with the drug; or
        ii. The consumer provides evidence that the product is for continuation of a treatment begun in a foreign country.[13]

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[9] Federal law also permits FDA-approved drugs that are manufactured domestically and exported abroad to be "re-imported" by manufacturers or HHS under rare circumstances, such as re-importation for emergencies and product recalls. HHS, *HHS Task Force on Drug Importation,* http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf; Meredith Freed, Tricia Neuman, and Juliette Cubanski, *10 FAQs on Prescription Drug Importation,* https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/.
[10] HHS, *HHS Task Force on Drug Importation,* http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf;
[11] *Id.*
[12] *Id.*
[13] FDA, *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions,* https://www.fda.gov/media/71776/download; 21 U.S.C. § 384(j)(1).

The FDA has exercised enforcement discretion in these circumstances under the justification that this conduct does not pose an unreasonable health risk, and it is typically for small shipments in terms of both size and value. In light of the relatively minor nature of personal importation, the FDA is more concerned with commercially shipped drugs, as commercially shipped products are more likely to have a widespread impact on the health and safety of consumers.[14]

B. Section 804 Importation of Prescription Drugs from Canada

Section 804 of the FDCA permits importation of *eligible* prescription drugs, from *Canada* by a State, Indian Tribe, or for certain pharmacists or wholesale distributors.[15] FDA finalized a rule in 2000 to implement the Section 804 importation program.[16] All prescription drugs are eligible for this program except (1) controlled substances; (2) a biological product; (3) an infused drug; (4) an intravenously injected drug; (5) a drug inhaled during surgery; (6) an intrathecally or intraocularly injected drug; (7) a drug that is subject to REMS; and (8) a drug that is not a "product" for purposes of section 582 of the FDCA.[17] To import prescription drugs into a state under this exception, the state's law must allow such importation; and the eligible importing entity must receive a Section 804 program approval in accordance with the procedures set forth in the final rule.

III. Importation by Alternative Funding Programs is Inconsistent with Federal Laws, Regulation, and Policy

Drug importation through alternative funding programs is inconsistent with the FDCA, FDA's personal importation policy, and the final rule on Section 804 drug importation from Canada. First, to the extent that such programs source drugs manufactured in non-FDA-inspected facilities, they violate important safety and effectiveness protections set forth in the FDCA.

Second, when a consumer is enrolled in an alternative funding program, the importation activity cannot satisfy FDA's personal importation policy. Specifically, individuals seeking to use the prescription drug do not personally import the drug in a manner anticipated under FDA's policy (e.g., via mail or internet order, or via personal baggage after foreign travel). Rather, a company applies for importation on behalf of the consumer. Typically, once a health plan partners with a third-party specialty medication program, the program will contact the consumer, obtain their personal information, identify the alternative funding program the consumer is eligible for, and enroll them in that

[14] FDA, *Regulatory Procedures Manual,* at p. 21. https://www.fda.gov/media/71776/download.
[15] 21 U.S.C. § 384.
[16] FDA, *Importation of Prescription Drugs,* https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs.
[17] FDA, *Importation of Prescription Drugs,* https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs.

program (i.e., international importation).[18] The operation of these importation schemes is the exact situation the FDCA, FDA personal use policy, and FDA regulations aim to avoid – widespread importation of unapproved and unregulated prescription drugs that create unnecessary risks to consumers' health and safety.

In addition, even if these programs were considered a form of personal importation, the type of prescription drugs they are importing fall outside the scope of FDA's policy because they are used to treat serious or chronic conditions, are typically already available in the United States (through legal pathways), and consumers are receiving more than a three-month supply (or are repeatedly refilling up to three-month supplies). Notably, these programs may classify a wide range of prescription drugs as eligible for alternative funding. One program defines all high-cost prescriptions ("any medication that has a cost of at least $350 per month") as an eligible prescription.[19] This definition of high-cost drugs does not require that the medication be unavailable in the United States, and it explicitly includes prescriptions drugs such as Avastin, an injectable cancer treatment; and Remicade, an infusion treatment; both of which are available in the United States.[20]

Finally, only six states (VT, FL, ME, CO, NM, NH,) have laws permitting prescription drug importation from Canada; however, none of these states have received a Section 804 program approval.[21] Moreover, these third-party specialty medication programs are targeting medications that are explicitly prohibited under this exception. For instance, one employer was provided a monthly break down of how their prescriptions where obtained, and this included an international importation of "Humalog Vial" an infusion treatment.[22] Therefore, alternative funding programs cannot justify importation of prescription drugs from Canada via the Section 804 importation regulations.

IV. Unregulated Importation is Dangerous to Consumers

The United States has consistently worked to develop strategies to lower health care costs for consumers. However, cost reduction should not come at the expense of consumers' health and

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[18] Payer Matrix, *Payer Matrix Program Overview*, https://docs.bartonccc.edu/humres/HRBenefits%20and%20Discounts/Benefits/Health%20Plan%20Open%20Enrollment%20Links/BCCC%20Payer%20Matrix%20Overview%20%20FAQs%20-Combined%20(002).pdf.

[19] *Introducing the Sharx Program*, https://www.waukeshacounty.gov/globalassets/administration/human-resources/benefits/intro-letter.pdf.

[20] *Introducing the Sharx Program*, https://www.waukeshacounty.gov/globalassets/administration/human-resources/benefits/intro-letter.pdf; Forbes, *How Alternative Funding Programs Can Ease The Cost Burden of Specialty Drugs*, https://www.forbes.com/sites/forbesbusinesscouncil/2021/10/13/how-alternative-funding-programs-can-ease-the-cost-burden-of-specialty-drugs/?sh=107fe21b595b.

[21] Meredith Free, Tricia Neuman, and Juliette Cubanski, *10 FAQs on Prescription Drug Importation*, (July 28, 2021), https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/#:~:text=Several%20states%2C%20including%20Florida%2C%20Vermont,for%20prescription%20drugs%20from%20Canada.

[22] Aimed Alliance, *Essential Health Benefits, Importation, and More – Do You Know the Risks?*, at slide 30, https://aimedalliance.org/wp-content/uploads/2023/01/Aimed-Alliance-Non-EHB-and-Alternative-Funding-Schemes-Presentation.pdf.

safety. The FDA has recognized that importing medications raises the risk of quality assurance deficiencies; counterfeit potential; presence of untested substances; unsupervised use; labeling and language issues; and lack of information from importation sources.[23] As such, it is imperative that all importation activities comply with federal laws, regulations, and policies to ensure safety and effectiveness.

While some individuals may elect to import their medications from Canada, this is intended to be a *personal choice*, not a mandate from a health plan. When a health plan partners with a third-party specialty medication program, the third-party program contacts the consumer and tells them they must enroll in the third-party specialty medication program, or they will be responsible for a 30 percent to 100 percent co-insurance that will not count towards their deductible or annual limit on cost-sharing. By structuring these programs in a highly coercive way, consumers are left with no option but to enroll in these programs. Consequently, this also means they are unable to object to their medication being imported from outside the United States – this is not the *personal choice* the FDA was trying to protect under the personal importation policy.

V. Conclusion

For the reasons provided above, Aimed Alliance requests a meeting with the FDA to discuss our interpretation that drug importation by alternative funding programs is inconsistent with federal laws, regulations, and policy; the impact of mandated importation on the health and safety of consumers; and how the FDA might focus its efforts to protect consumers from these schemes.

Sincerely,

Ashira Vantrees, Esq.
Counsel at Aimed Alliance

[23] FDA, *Imported Drugs Raise Safety Concerns*, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/imported-drugs-raise-safety-concerns.