March 1, 2024

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Aimed Alliance ("Petitioner") submits this Citizen Petition under the Federal Food, Drug and Cosmetics Act ("FD&C Act") to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") issue a guidance document, as outlined in 21 CFR 10.115, pertaining to third-party companies[1] that partner with employer-sponsored health plans to import prescription drugs from outside the United States, also known as alternative funding programs. Specifically, this petition seeks clarification and definitive guidance on three key aspects:

1. An interpretation and clear position statement regarding whether third-party companies that partner with employer-sponsored health plans can legally require employees to import their prescription drugs from outside the United States;
2. An interpretation and clear position statement regarding whether third-party companies that partner with employer-sponsored health plans can import prescription drugs on behalf of consumers enrolled in an alternative funding program; and
3. An explanation of existing reporting pathways for individuals and organizations to notify the FDA of instances where entities engage in such unauthorized practices.

Such guidance is essential for promoting transparency, regulatory compliance, and the protection of public health. By addressing this conduct, the FDA can better fulfill its mandate to safeguard consumers and ensure the integrity of pharmaceutical drug products and supply chains.

On February 27, 2023, Aimed Alliance sent a letter to the FDA seeking clarity on the agency's stance regarding the legality of drug importation via alternative funding programs.[2] In response to Aimed Alliance's letter, the FDA expressed concern about the risks associated with the importation of unapproved drugs and misbranded drugs.[3] Despite affirming its commitment to allocating resources towards identifying and addressing companies involved in such importation practices, alternative funding programs continue to operate without accountability. Therefore, to effectively address these importation practices and mitigate potential risks to public health, it is imperative for the FDA to issue a definitive position statement on alternative funding programs and the use of international importation programs as a cost-saving measure for health

[1] Third-party companies, also referred to as alternative funding vendors, are the companies that run and operate alternative funding programs. The alternative funding program is the logistical mechanism used for importing prescription drugs from outside the United States.
[2] Aimed Alliance, *Letter to FDA February 27, 2023,* https://aimedalliance.org/wp-content/uploads/2023/03/Aimed-Alliance-Letter-to-FDA-February-2023.pdf.
[3] FDA, *Response to Aimed Alliance Dated April 14, 2023,* https://aimedalliance.org/wp-content/uploads/2023/04/FDA-Response-to-Aimed-Alliance-Meeting-Regarding-Illegal-Importation-of-Prescription-Drugs.pdf.

plans. As explained herein, such regulatory action is necessary to safeguard consumers from potential hazards of receiving unapproved, misbranded, and illegally imported prescription drugs.

I. Action Requested

The Petitioner asks the FDA to issue a guidance document that offers both an interpretation and a clear position statement concerning importation activities conducted by alternative funding programs. The Petitioner asks that this guidance differentiate the legality of personal importation and FDA-approved state importation programs, from the prescription drug importation practices conducted by third-party companies importing prescription drugs on behalf of consumers with employer-sponsored health insurance. Additionally, the Petitioner requests an explanation of the existing reporting pathways available for individuals and organizations to promptly notify the FDA of instances where entities engage in such practices.

Alternative funding vendors employ coercive tactics that compel enrolled individuals to import their specialty medications from Canada and other overseas countries.[4] These prescription drug importation methods involve the programs acting as intermediaries between foreign pharmacies and eligible employee-sponsored health plan beneficiaries to facilitate the dispensing of prescription drugs to enrolled employees.[5] However, as explained below, based on Aimed Alliance analysis these practices fail to meet the criteria outlined in FDA's personal importation policy as consumers are coerced to import their specialty drugs through these programs, with the programs themselves applying for importation on behalf of consumers.[6] Moreover, based on Aimed Alliance's analysis these importation practices are not permissible under Section 804 of the FD&C Act.

However, because the FDA has not explicitly stated this conduct is not within the scope of the personal importation policy or Section 804 of the FD&C Act, alternative funding vendors publicly claim that their practices are consistent with federal law.[7] Given this discrepancy and the recent approval of Florida's drug importation program, which may exacerbate the confusion surrounding the legality of different importation practices, there is a need to distinguish permissible forms of international importation from those that are prohibited. Providing this clarification will help protect consumers from potentially receiving unapproved, misbranded, and illegally imported prescription drugs.

II. Statement of Grounds

A. Third-Party Companies Partner with Health Plans to Import Consumers' Prescription Drugs into the United States

[4] Aimed Alliance, *Alternative Funding Programs: The Cost Saving Measure that Could Cost You* (2023), https://aimedalliance.org/wp-content/uploads/2023/03/AA-AltFunding-FactSheet-March2023-FINAL.pdf.
[5] *Id.*
[6] *Id.*
[7] *See* ElectRx, *FDA Response* (Mar. 2, 2023), https://electrx.com/index.php/fda-response/; PassRx, *FAQs*, https://gopassrx.com/faq/.

Health plans are partnering with companies, often referred to as alternative funding vendors, who manage "alternative funding programs" and "specialty medication programs."[8] Alternative funding programs are designed to help employer-sponsored health plans lower prescription drug spending by sourcing prescription drugs from outside the conventional health plan framework.[9]

When a health plan partners with an alternative funding program, the program directs the health plan to exclude specific high-cost drugs, from its covered drug formulary by designating the medications as non-essential health benefits (non-EHBs).[10] Consumers are informed that in order to access their medication they must enroll in the plan's alternative funding program run by the third-party vendor. [11] Given the prescription drug's non-EHB designation, consumers are told failure to enroll in the program will result in them bearing 100 percent of the drug's cost. Consequently, due to the coercive nature of these programs, plan enrollees are essentially compelled to enroll in the alternative funding program.[12] Once enrolled, the alternative funding program then assesses the patient's eligibility for alternative funding sources, which may include international importation, commercial copay assistance programs, and charitable and patient assistance programs.[13]

In the case of international importation, alternative funding programs acquire prescriptions from employees and coordinate the fulfillment of prescription drugs through a foreign pharmacy.[14] This process may involve importation from Canadian pharmacies, as well as other international sources.[15] The foreign pharmacy will then directly deliver the medications to the plan beneficiary in the United States.[16]

Programs like these import drugs not only from Canadian pharmacies but also from various entities in other foreign countries.[17] For instance, one alternative funding vendor

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[8] Aimed Alliance, *How a Loophole in the Patient Protection and Affordable Care Act Can Impact Access to Your Necessary Treatments* (2022), https://aimedalliance.org/ wp-content/uploads/2022/07/Aimed-Alliance-Non-EHBFact-Sheet-FINAL-1.pdf.

[9] Alliance for Patient Access, *The High Costs of Alternative Funding Programs* (Jun. 2023), https://allianceforpatientaccess.org/wp-content/uploads/2023/06/AfPA_High-Costs-of-Alternative-Funding-Programs_June-2023.pdf.

[10] Aimed Alliance, *Alternative Funding Programs: The Cost Saving Measure that Could Cost You* (2023), https://aimedalliance.org/wp-content/uploads/2023/03/AA-AltFunding-FactSheet-March2023-FINAL.pdf.

[11] Aimed Alliance, *Alternative Funding Programs: The Cost Saving Measure that Could Cost You* (2023), https://aimedalliance.org/wp-content/uploads/2023/03/AA-AltFunding-FactSheet-March2023-FINAL.pdf.

[12] *Id.*

[13] Petitioner recognizes copay assistance and exploitation of patient assistance programs and charitable assistance programs is outside the scope of FDA's authority. Therefore, this petition asks the FDA to solely address the use of *international importation* by alternative funding programs. *Id.*

[14] 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-FundingSchemes-Presentation.pdf; SHARx, *How Long Will It Take to Get My Medication?* (Jan. 12, 2021), https://www.youtube.com/watch?v=pPFObSLiCL0.

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

[16] *Id.*

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

explains, "[s]ince many of the medications [company] sources come from Canada, it may take seven to ten days for your medications to arrive."[18]

B. FDA's Laws, Regulations, and Policies on Prescription Drug Importation

The FD&C Act prohibits the importation of unapproved drugs, including "foreign versions" of FDA-approved drugs.[19] This prohibition enacted by Congress aims to shield consumers from internationally developed drugs that do not undergo the rigorous safety evaluations and supply chain precautions mandated by the FDA.[20]

The FDA and the Department of Health and Human Services, however, have provided two pathways to allow importation of certain prescription drugs that were originally intended for foreign markets: FDA's personal importation policy and Section 804 programs.[21] Upon importation, the FDA will assess compliance with requirements regarding registration, listing, approval, drug labeling, and adherence to current good manufacturing practices (cGMP), to ensure the integrity and safety of imported drugs.[22] Consequently, it is the Petitioners understanding that importation outside these two narrow carveouts is considered a violation of federal law.[23]

i. FDA's Personal Use Policy

FDA's personal use policy, outlined in the FDA's Regulatory Procedures Manual and sanctioned under the FD&C Act, stipulates that an individual may be granted permission 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:

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

[19] Dep't. of Health and Human Serv., *HHS Task Force on Drug Importation* (Jan. 26, 2005), https://www.aging.senate.gov/imo/media/doc/hr135rc.pdf.

[20] U.S. Food & Drug Admin, *Personal Importation*, https://www.fda.gov/industry/import-basics/personal-importation#whatis.

[21] Dep't. of Health and Human Serv., HHS Task Force on Drug Importation (Jan. 26, 2005), https://www.aging.senate.gov/imo/media/doc/hr135rc.pdf.; Meredith Freed, et al., *10 FAQs on Prescription Drug Importation* (Jul. 28, 2021), https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/.

[22] U.S. Food & Drug Admin., Letter to Aimed Alliance (Apr. 14, 2023), https://aimedalliance.org/wp-content/uploads/2023/04/FDA-Response-to-Aimed-Alliance-Meeting-Regarding-Illegal-Importation-of-Prescription-Drugs.pdf.

[23] U.S. Food & Drug Admin., *Human Drug Imports*, https://www.fda.gov/media/133688/download.

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.[24]

ii. Section 804 Importation

Section 804 of the FD&C Act authorizes the importation of eligible prescription drugs from Canada by entities such as states, Indian Tribes, and specific pharmacists or wholesale distributors.[25] Under this program, the FDA may consider and potentially authorize Section 804 importation program (SIP) proposals submitted by states or Indian tribes to permit the importation of specific prescription drugs *from Canada*, provided that the SIP demonstrates a substantial reduction in costs for American consumers without imposing additional risks to public health and safety.[26]

All prescription drugs are generally eligible, with specific exceptions, namely: (1) controlled substances; (2) biological products; (3) infused drugs; (4) intravenously injected drugs; (5) drugs inhaled during surgery; (6) drugs intrathecally or intraocularly injected; (7) drugs subject to REMS; and (8) drugs not classified as a "product" under section 582 of the FD&C Act.[27]

To import prescription drugs under Section 804, the state's laws must allow for such importation.[28] Additionally, the eligible importing entity must secure Section 804 program approval.[29] This involves submitting an importation program proposal to the FDA for review and authorization. These proposals must follow all procedures and provide the necessary information as mandated by the FD&C Act and FDA's regulations.[30]

C. Alternative Funding Program's Prescription Drug Importation Programs Violate FDA's Laws, Regulation, and Policy

Drug importation methods utilized by alternative funding programs are not within the scope of the FD&C Act, Section 804, or FDA's personal importation policy.

a. Personal Importation Policy

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[24] U.S. Food & Drug Admin., *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions*, https://www.fda.gov/media/71776/download; 21 U.S.C. § 384(j)(1).
[25] 21 U.S.C. § 384.
[26] U.S. Food & Drug Admin., *Importation of Prescription Drugs*, https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs.
[27] *Id*.
[28] National Conference of State Legislatures, *State Drug Wholesale Importation Programs* (Feb. 28, 2023), https://www.ncsl.org/health/state-drug-wholesale-importation-programs.
[29] U.S. Food & Drug Admin., *Importation of Prescription Drugs*, https://www.federalregister.gov/documents/2020/10/01/202021522/importation-of-prescription-drugs.
[30] *Id*.

Mandates by employer-sponsored health plans and alternative funding programs that employees receive their prescription drugs from a foreign pharmacy do not satisfy the criteria for legal importation outlined in FDA's personal importation policy.

In contrast to traditional personal importation methods, like mail or internet orders, where a consumer is independently seeking out a lower-cost alternative for their medication, alternative funding programs involve companies mandating and applying for importation on behalf of consumers. This includes alternative funding programs contacting consumers who are prescribed importation-eligible prescription drugs, identifying a foreign pharmacy, and ordering the medication on the consumers behalf.[31] These practices are inconsistent with the FDA's personal important policy, which is designed to allow *individuals* to import their prescription drugs from Canada. This policy was never intended to mandate importation as a widespread cost-saving measure for employer-sponsored health plans.

Even if categorized as a form of personal importation, the prescription drugs imported by alternative funding programs fall outside the scope of FDA's policy, as they are intended for treating serious or chronic conditions; are readily available in the United States;[32] and may include certain medications, like injectables, that are prohibited under the policy. Examples of medications imported under an alternative funding program include prescription drugs like Avastin, an injectable cancer treatment, and Remicade, an infusion treatment. Both of these medications are accessible in the United States and fall outside the *type* of prescription drug permitted to be imported under the policy.[33]

Lastly, it is essential to recall the *intent* of the FDA personal importation policy—to allow *individuals* to access medications from Canada, under the premise that singular individuals importing their medications would not flood the market with unsafe or unauthorized drugs. However, the use of the personal importation policy by alternative funding programs poses precisely this risk. These companies are importing thousands of drugs on behalf of individuals, thereby creating the exact type of prescription drug importation that both the FDA and Congress intended to prohibit under the FD&C Act.

b. Section 804

Alternative funding programs' importation practices do not meet the criteria for legal importation outlined in Section 804 of the FD&C Act for several reasons. As explained above, to

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[31] Aimed Alliance, *Letter to FDA Re: Importation of Prescription Drugs from Outside the United States and Canada* (Feb. 27, 2023), https://aimedalliance.org/wp-content/uploads/2023/03/Aimed-Alliance-Letter-to-FDA-February-2023.pdf; Aimed Alliance, *Alternative Funding Programs: The Cost Saving Measure that Could Cost You* (2023), https://aimedalliance.org/wp-content/uploads/2023/03/AA-AltFunding-FactSheet-March2023-FINAL.pdf.

[32] Some alternative funding programs adopt a broad classification, considering all high-cost prescription drugs eligible for alternative funding and define "high-cost" prescriptions as those with a cost of at least $350. These programs often do not require the medication to be unavailable in the United States. *See e.g.* Sharx, *Introducing the Sharx Program*, https://www.kellerisd.net/cms/lib/TX02215599/Centricity//Domain/88/2022-23/22_12Dec/Benefits_Rx_SHARxIntro.pdf.

[33] *Id.*; Forbes, *How Alternative Funding Programs Can Ease The Cost Burden of Specialty Drugs* (Oct. 13, 2021), https://www.forbes.com/sites/forbesbusinesscouncil/2021/10/13/how-alternative-funding-programs-can-ease-the-cost-burden-of-specialty-drugs/?sh=1733ab15595b.

operate an approved Section 804 program an entity must (1) be an approved entity; (2) have passed a state law authorizing importation from Canada; and (3) received approval from HHS to operate a Section 804 program. A program must meet all three requirements to comply with Section 804.

First, Section 804 programs exclusively permit states, Indian Tribes, and specific pharmacists or wholesale distributors to import prescription drugs under *approved* programs. The third-party companies managing alternative funding programs, are not states, Indian Tribes, and specific pharmacists or wholesale distributors, and, therefore, do not fall within the scope of approved Section 804 entities.

Second, only nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Vermont, Wisconsin, and Texas) have enacted laws permitting a state drug importation program. The use of alternative funding programs is not limited to these states.[34]

Third, among these states, **only** Florida has received a Section 804 approval from the FDA.[35] Moreover, Florida's Section 804 program was only recently approved on January 5, 2024. This approval is restricted to the importation of specific prescriptions aimed at assisting individuals with chronic health conditions, such as HIV/AIDS, mental illness, prostate cancer, and urea cycle disorder, and under specific care providers, including the Agency for Persons with Disabilities, Department of Children and Families, Department of Corrections, and Department of Health.[36] Given that this program was recently approved, it is not yet in operation. Consequently, alternative funding programs cannot rely on Section 804 to justify their international importation of prescription drugs, even within the State of Florida.

In conclusion, alternative funding programs cannot justify the importation of prescription drugs under either the personal importation policy or Section 804 programs.

D. Unregulated Importation of Prescription Drugs Potentially Exposes Consumers to Unapproved and Misbranded Drugs

Despite the option for individuals to *personally* import their medications from Canada, it is crucial to recognize that this choice is intended to be voluntary. The decision to import medications from abroad should be a personal and voluntary one, as it entails increased risks of receiving unregulated treatments. These concerns have been acknowledged by FDA in its *Imported Drugs Raise Safety Concerns* resource, where it stated the potential risks with medication importation, including quality assurance deficiencies, counterfeit possibilities,

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[34] *See e.g. Lebanon County Missouri ShaRx Contract,* https://www.lebanonmissouri.org/DocumentCenter/View/36193/Council-Bill-No-6299--Agreements-Pharmacy-Services-and-Business-Associate-SHARx.

[35] Christina Jewett and Sheryl Gay Stolberg, *F.D.A. Issues First Approval for Mass Drug Imports to States From Canada*, N.Y. TIMES (Jan. 5, 2023), https://www.nytimes.com/2024/01/05/health/drug-imports-canada-florida.html.

[36] Ron DeSantis, *Florida Becomes First in the Nation to Have Canadian Drug Importation Program Approved by FDA* (Jan. 5, 2024), https://www.flgov.com/2024/01/05/florida-becomes-first-in-the-nation-to-have-canadian-drug-importation-program-approved-by-fda/.

untested substances, unsupervised use, labeling and language issues, and lack of information from importation sources.[37]

The original intent of this program was not to become a compulsory channel dictated by a health plans for accessing drugs. However, under these programs, consumers are ***compelled*** to enroll in an alternative funding program to import their medication from outside the United States. For consumers, the only alternative is to face a substantial 100 percent co-insurance, that does not contribute towards their deductibles or annual cost-sharing limits. Consequently, under these programs, consumers are unable to object to the importation of their medication from outside the United States, deviating from the personal choice framework that the FDA intended.

E. Despite FDA's Clear Warning Letter, AFPs Continue to Import Prescription Drugs on Behalf of Consumers

As a result of a lack of explicit guidance and action by the FDA regarding the importation of prescription drugs by alternative funding programs, these programs perpetuate without accountability or oversight. Concerningly, these programs are also increasing consumer confusion as to the legality of these programs, by publicly claiming their programs are compliant with FDA regulations.

For example, in March 2023, the FDA issued a warning letter to a third-party company for the unlawful introduction of unapproved new drugs and misbranded drugs into interstate commerce in violation of sections 301(a), 301(d), and 505(a) of the FD&C Act.[38] The company engaged in activities akin to those of alternative funding programs, acting as an intermediary between foreign pharmacies and the employee-sponsored health insurance plans to provide enrolled employees with prescription drugs imported from foreign pharmacies.[39] The FDA's letter asked the company to "promptly cease causing the distribution of unapproved new drugs and misbranded drugs to U.S. consumers and correct any other violations of the FD&C Act."[40]

In response to the FDA's letter, the company assured its clients that its importation practices "comply[] with the exemptions surrounding personal importation."[41] Notably, the company's public statement included a link to a video featuring Governor Ron DeSantis discussing Florida's program to import prescription drugs from Canada.[42] However, at the time of Governor DeSantis' recording, Florida's SIP had not yet been approved. The company further explained, "We understand that you want to provide and sustain meaningful and affordable

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[37] U.S. Food & Drug Admin., *Imported Drugs Raise Safety Concerns* (Mar. 1, 2018), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/imported-drugs-raise-safety-concerns.
[38] U.S. Food & Drug Admin., *Warning Letter, ElectRx and Health Solutions, LLC, MARCS-CMS 614251* (Mar. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023.
[39] *Id.*
[40] *Id.*
[41] ElectRx, *FDA Response* (Mar. 2, 2023), https://electrx.com/index.php/fda-response/
[42] *Id.*

benefits to your employees. That's why we work with your health plan to offer *Personal Importation* (PI). PI provides lower plan cost and lower employee cost."[43]

Similarly, several other alternative funding programs have made similar claims regarding their importation practices. Below is a list of statements issued by these programs justifying their international importation practices:

- "[The company] and your employer remain in full compliance with the FDA and U.S. Customs and Border Protection," later explaining, "Individuals are allowed to import FDA approved prescription medications for their own personal use."[44]
- "We take advantage of all opportunities for the plan to save money through Personal Importation."[45]
- "We help facilitate medications dispensed both domestically and from [C]anada."[46]
- "[The company] may be able to arrange for home delivery of your medication shipped directly from an International Pharmacy in countries such as Canada, England, New Zealand, or Australia – again, at no cost to you."[47]
- "[The company] identifies opportunities for cost savings, contacts members, assists them through the registration process and authorizes each shipment when [ ] [i]nternational pharmacy partners are utilized."[48]

These public statements and explicit claims of legality highlight the immediate need for clarity on the scope of FDA's personal importation policy and importation under Section 804 programs. These examples demonstrate the state of confusion among alternative funding programs, resulting in consumers receiving misinformation regarding the safety, risk, and legality associated with these imported products.

Addressing this misunderstanding is crucial to prevent the widespread importation of unapproved and misbranded prescription drugs and to ensure that consumers are accurately informed about the legal parameters and safety considerations associated with prescription drug importation.

Furthermore, with the recent FDA approval of Florida's SIP, it is critical to ensure that the legal importation of drugs under this program does not inadvertently contribute to misconceptions surrounding international importation practices. To mitigate this risk and consumer confusion, it is imperative to comprehensively clarify the distinctions between FDA-

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[43] ElectRx, *How Does ElectRx Save Me Money?,* https://electrx.com/index.php/how-electrx-works/ (emphasis added).
[44] PassRx, *FAQ*, https://gopassrx.com/faq/.
[45] Drug Channels, *The Shady Business of Specialty Carve-Outs, a.k.a., Alternative Funding Programs* (Aug. 2, 2022), https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html.
[46] RxFree4me, https://www.rxfree4me.com/#homeIMPO.
[47] US-Rx, *Helpful Tips and Steps to Take When Something is Preventing Your Pharmacy from Dispensing Medication,* https://cherokeecountyga.gov/Human-Resources/_resources/documents/US-Rx%20Care_Prescription%20Drug%20Navigation%20Guide%20-%20SS%20w%20International%202023_v.1.pdf.
[48] Capital BlueCross, *Proposed Program Costs, at Appendix B,* https://www.yorkcity.org/wp-content/uploads/2022/11/Health_Insurance_Contracts-11.15.2022.pdf.

approved state programs, personal importation policies, and all other unapproved importation practices. By clearly outlining the legal boundaries and regulatory frameworks that govern drug importation, consumers would have a clearer understanding on how they may object to an international importation program. Simultaneously, employers and third-party companies would also gain clarity on the types of international sourcing that are permissible under federal law.

Ultimately, publishing comprehensive guidance to clarify which importation practices are impermissible will foster a more accountable environment. This will serve as a deterrent for future actors looking to exploit perceived ambiguities within FDA regulations. A clearer understanding of the legal landscape surrounding drug importation will empower employers to confidently navigate these options, ensuring the well-being of their employees while adhering to established regulations. Moreover, as consumers become aware of the illegality and safety risks associated with imported drugs, they will be better equipped to make informed decisions about their healthcare, brokers, and health plan contracts. Finally, understanding existing reporting channels for individuals and organizations to notify the FDA of unauthorized practices will establish an additional layer of accountability. This will help safeguard consumers from potential dangers associated with receiving unapproved, misbranded, and illegally imported prescription drugs.

III. Conclusion

For the reasons discussed above, the Petitioner respectfully asks the FDA to issue a guidance document addressing the following questions:

1. Whether third-party companies that partner with employer-sponsored health plans can legally require employees to import their prescription drugs from outside the United States;
2. Whether third-party companies that partner with employer-sponsored health plans can import prescription drugs on behalf of consumers enrolled in an alternative funding program; and
3. An explanation of existing reporting pathways for individuals and organizations to notify the FDA of instances where entities engage in such unauthorized practices.

IV. Environmental Impact

The Petitioner claims a categorical exclusion from the requirements of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.30.

V. Economic Impact

The Commissioner has not requested that the Petitioner submit an economic impact statement.[49]

[49] 21 C.F.R. § 10.30(b)(3).

VI. Certification

I, the undersigned Petitioner, certify that, to the best of my knowledge and belief, this petition includes all information and views upon which this petition relies, and that it includes representative data and information known to me that is unfavorable to the petition.

Thank you for your attention to this important public health matter. We look forward to your prompt responsive actions and written reply.

Sincerely,

Ashira Vantrees

Ashira Vantrees
Counsel
Aimed Alliance