AIMED ALLIANCE

October 7, 2025

Dr. Martin A. Makary
Commissioner
Food and Drug Administration
Department of Health and Human Services
FDAImportsInquiry@fda.hhs.gov

Dan Solis
Assistant Commissioner for Import Operations
Food and Drug Administration
Department of Health and Human Services
Dan.Solis@fda.hhs.gov

Via Electronic Communication

RE: Follow-Up Request Regarding Employer-Mandated Drug Importation Programs (Docket FDA-2024-P-1058)

Dear Commissioner Makary and Mr. Solis:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to follow up on our Citizen Petition submitted to the U.S. Food and Drug Administration (FDA) in March 2024 regarding third-party companies that partner with employer-sponsored health plans to mandate employees import prescription drugs from outside the United States, also known as alternative funding programs.[1]

In that petition, we requested:

1. An interpretation and clear position statement regarding whether third-party companies that partner with employer-sponsored health plans can legally mandate employees import their prescription drugs from outside the United States;
2. An interpretation and clear position statement regarding whether employers can mandate their employees work with a third-party company to import prescription drugs on behalf of consumers; and
3. An explanation of existing reporting pathways for individuals and organizations to notify the FDA of instances when entities engage in the unsafe and unauthorized importation of prescription drugs in a manner inconsistent with federal law.

We appreciate receiving an interim response from the FDA in August 2024, in which the Agency acknowledged the complexity of the issues raised and stated it was "unable to reach a decision [at the time] because [the petition raised] complex issues requiring extensive review and analysis by Agency officials."[2] We acknowledge the FDA's deliberate approach in evaluating these nuanced legal and policy concerns. Moreover, we recognize and applaud the Trump

[1] Aimed Alliance, Citizen Petition, https://aimedalliance.org/wp-content/uploads/2024/04/Aimed-Alliance-Citizen-Petition-3.1.24.pdf. A detailed explanation of AFP international importation practices is described in Aimed Alliance's 2024 citizen petition. Additional information about alternative funding programs is available at Aimed Alliance, *Alternative Funding Programs,* https://aimedalliance.org/alternative-funding-programs/.
[2] U.S. Food and Drug Admin., *Interim Response to Aimed Alliance*, Docket No. FDA-2024-P-1058, https://aimedalliance.org/wp-content/uploads/2024/08/FDA-Interim-Response-to-Aimed-Alliance-Citizen-Petition-2024-P-1058.pdf.

Administration's commitment to lowering prescription drug costs for Americans and commend the Administration's ongoing efforts to address price disparities between the U.S. and other countries. In advancing that goal, we believe it is essential to ensure that consumers retain access to safe and effective prescription drugs.

As such, we are particularly concerned by the conduct of third-party programs that partner with employer-sponsored health plans to mandate the importation of prescription drugs through non-FDA-approved pathways. These programs can create patient confusion, obscure the origin of imported products, and, in some cases, pressure patients into accepting foreign-sourced medications without full understanding or informed consent.

To that end, and in light of the FDA's ongoing efforts to improve prescription drug affordability, we respectfully request that the Agency establish clear requirements for any programs that facilitate, mandate, or promote international prescription drug importation, specifically:

1. **Third-party programs must inform employers and employees of the legal basis used to justify their international prescription drug importation program;**

Third-party programs often allege that their programs are consistent with federal law and FDA policy. However, these programs are not part of the FDA-approved Section 804 program, import prescription drugs from countries outside of Canada, and are not used voluntarily by consumers. As such, employers who agree to work with these third-party programs should be aware of their risks and liabilities when partnering with these programs and not be misled by false statements that insinuate that these programs are "FDA-approved" or "consistent with federal law."

2. **Third-party programs and employers must inform consumers of the risks associated with international importation;**

Patients must be clearly advised that medications imported from other countries, not through FDA-approved Section 804 programs, may not have been reviewed or approved by the FDA. As such, these products may not meet the same safety, efficacy, or labeling standards required in the United States. Without this information, patients may unknowingly use medications that are substandard, counterfeit, or incompatible with their treatment needs, ultimately putting their health at risk.[3]

3. **Third-party programs and employers must disclose to the beneficiary or employee the pharmacy from which the prescription drug originates; and provide all information on the drug's chain of custody up until it reaches the consumer;**

Transparency is essential to ensuring drug integrity and traceability. Any importation program must require disclosure of the manufacturer, distributor, and shipping intermediaries.

[3] Holly Campbell, *4 facts on why drug importation is bad for patients*, PHRMA, https://phrma.org/blog/4-facts-on-why-drug-importation-is-bad-for-patients.

This includes foreign and domestic wholesalers, shipping companies, and re-packagers. A clear chain of custody will help protect against or respond to counterfeit, adulterated, contaminated, or spoiled products.

4. Ensure that labeling and packaging are in English;

To promote safe and effective medication use, all drug labeling, usage instructions, and packaging must be provided in English. This includes information on dosage, contraindications, warnings, storage, and expiration. Without proper labeling, patients are unable to identify if they have received the correct medication and may misunderstand how to use their medications, which could lead to harmful or even life-threatening consequences.[4]

5. Affirm that patients may refuse international importation without penalty.

Patients should retain full autonomy over their treatment options. No individual should be coerced into accepting imported medications by being threatened with a loss of coverage, denials or delays in treatment, or increased out-of-pocket costs. Importantly, FDA's personal importation policy relies on the premise that a consumer is *individually* sourcing their prescription drug from outside the United States, and assuming the risk for this decision. Thus, any program that encourages, mandates, or facilitates importation must include explicit protections ensuring that patients may decline to participate without experiencing adverse consequences to their health insurance benefits.

In conclusion, these guardrails are necessary to ensure that cost-saving strategies do not come at the expense of patient safety, transparency, or choice. We would greatly appreciate your consideration of this follow-up request, and would like to schedule a meeting with your office to further discuss in greater detail the issue and its impact on patients, providers, and caregivers.

Please contact us obackhaus@aimedalliance.org to schedule a time that works best to meet with you and your staff.

Sincerely,

Olivia Backhaus
Staff Attorney

[4] Terry Davis et al., *Improving Patient Understanding of Prescription Drug Label Instructions*, 1 Journal of General Internal MEDICINE, 57-62 (2008), https://pmc.ncbi.nlm.nih.gov/articles/PMC2607498/.