The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

IACC International AntiCounterfeiting Coalition

NADDI National Association of Drug Diversion Investigators

NASCSA National Association of State Controlled Substances Authorities

NCL National Consumers League

ASOP Global | Alliance for Safe Online Pharmacies

September 4, 2025

The Honorable Bill Cassidy
455 Dirksen Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Bernard Sanders
332 Dirksen Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Brett Guthrie
2161 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
2107 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

RE: FDA FY26 Legislative Proposals Enhance Patient Safety

Dear Chairman Cassidy, Ranking Member Sanders, Chairman Guthrie and Ranking Member Pallone:

As organizations committed to protecting patient safety and securing the integrity of the United States supply chain, we write to express our support for one of the U.S. Food and Drug Administration's (FDA) proposed legislative priorities for Fiscal Year 2026. This proposal could significantly strengthen the FDA's ability to detect, deter and respond to the growing threat of counterfeit and illicit pharmaceutical products entering the country.

FDA PROPOSAL: REQUIRE DESTRUCTION OF IMPORTED PRODUCTS THAT POSE A SIGNIFICANT PUBLIC HEALTH RISK

Streamlining the seizure and destruction processes for unapproved and adulterated medicines and medical devices by border inspectors from either CBP or FDA must be a priority in order to protect patients from malicious bad actors who aim to harm American patients and consumers. The current requirement to hold and adjudicate these obviously dangerous products sometimes results in their return to the rogue manufacturers, allowing these rogue manufacturers to port shop. After this return, the **rogue manufacturers simply reship them back to the United States**, again aiming to breach our pharmaceutical border security and harm American patients.

We applaud FDA's efforts to disincentivize rogue manufacturers from attempting to sneak their products by customs by making them subject to seizure.

FDA legislative proposal text: "Under section 801 of the Federal Food, Drug, and Cosmetics Act, importers have the option to export an entry refused by FDA within 90 days of the refusal regardless of the seriousness of the public health concern posed by the product. FDA proposes to amend section 801 to give the Agency authority to require an importer to destroy any FDA-regulated product(s) refused entry into the U.S. that presents a significant public health concern, thus removing their option to export such product(s). The Agency has observed importers exporting or attempting to re-import commercial-sized shipments that pose a significant public health concern including food contaminated with Salmonella, Listeria and carcinogenic unapproved animal drugs; human drugs such as hand sanitizer contaminated with methanol; and misbranded or adulterated devices such as contact lenses, COVID-19 test kits, and personal protective equipment. In May 2023, a high-volume importer/wholesaler pled guilty to attempting to re-import 2100 cartons of frozen eels from China that were refused by FDA because testing confirmed contamination with a carcinogenic unapproved animal drug. FDA believes this new authority would prevent reimportation of refused products and would deter importers from seeking to import products they know or have reason to believe would pose a significant public health risk and could be ordered destroyed. This authority would also increase efficiency by reducing the need to involve the Customs and Border Protection in the seizure of unsafe FDA-regulated products and allow the Agency to require importers to pay the destruction costs up front, thereby avoiding additional legal action to recoup such costs."

Bad actors continue to exploit gaps in our import enforcement system, using legal loopholes to reintroduce dangerous, rejected products into the U.S. market. The current process – **allowing these products to be returned to the sender rather than seized and destroyed** – creates a revolving door that puts American patients at risk. Granting FDA authority to mandate the destruction of high-risk, noncompliant imports is a critical step toward closing this loophole. It will help prevent repeat offenses, deter malicious manufacturers, and ensure that our pharmaceutical border security is not a point of vulnerability in the fight to keep unsafe, counterfeit or substandard medicines and medical devices out of our healthcare system.

We urge Congress to advance this commonsense, patient-focused reform to strengthen the FDA's ability to protect Americans from unsafe and counterfeit medicines and medical products. This proposal represents a critical opportunity to close dangerous loopholes, reinforce our pharmaceutical border security, and uphold the integrity of our supply chain.

We stand ready to support efforts that prioritize patient safety and ensure that only safe, effective and FDA-approved products reach American patients.

Sincerely,

Shabbir Safdar
Executive Director, The Partnership for Safe Medicines

Carrie Harney
Board Chair, Alliance for Safe Online Pharmacies (ASOP)

Travis D. Johnson
Vice President - Legislative Affairs, Senior Counsel, The International AntiCounterfeiting Coalition

Charlie Cichon
Executive Director, National Association of Drug Diversion Investigators

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Nancy Glick
Director, Food and Nutrition Policy
National Consumers League

cc: U.S. Senate Health, Education, Labor, and Pensions Committee Members
U.S. Senate Appropriations Committee Members
U.S. House of Representatives Energy and Commerce Committee Members
U.S. House of Representatives Appropriations Committee Members
Dr. Martin Makary, Commissioner, U.S. Food and Drug Administration