

Congress of the United States
Washington, DC 20515

October 1, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Kyle Diamantas
Acting Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Markwayne Mullin
Secretary
Department of Homeland Security
2707 Martin Luther King Jr. Ave SE
Washington, DC 20032

The Honorable Rodney Scott
Commissioner
Customs and Border Protection
1300 Pennsylvania Ave NW
Washington, DC 20004

Dear Secretary Kennedy, Secretary Mullin, Acting Commissioner Diamantas, and Commissioner Scott:

We write to express concern that new U.S. Customs and Border Protection (CBP) procedures for international mail shipments, taking effect October 22, could disrupt Americans' longstanding ability to obtain lower-cost prescription medicines from Canada and other countries for their personal use. We urge the U.S. Department of Health and Human Service (HHS), the Food and Drug Administration (FDA), and CBP to ensure that implementation of these procedures does not prevent Americans from obtaining genuine, non-controlled prescription medicines from licensed pharmacies when those medicines do not appear to present an unreasonable risk.

An estimated 2.3 million Americans with prescriptions purchase medicines internationally each year.¹ For years, our constituents who have struggled with high prescription drug prices have obtained their medicines from pharmacies outside the United States, especially from Canada. This option – in which medication is dispensed pursuant to a valid prescription by licensed pharmacies in countries with established pharmaceutical regulatory systems – provides Americans with a safe and affordable source of needed medicines. While personal importation is subject to federal restrictions, FDA has long exercised enforcement discretion over certain personal-use shipments.

These new CBP procedures could significantly change how our constituents' shipments are processed. International mail shipments subject to FDA requirements will require electronic filing through CBP's Automated Commercial Environment, providing the government with substantially more information about incoming packages.

We support CBP's goal of using better data to identify and intercept high-risk shipments. However, we are concerned that the new process could be implemented in a manner that prevents personal-use prescription medicines from being shipped to the United States or results in their routine refusal, including medicines Americans have long obtained from licensed pharmacies abroad. Greater visibility should instead improve the government's ability to distinguish dangerous products from lower-risk prescription medicines and preserve appropriate enforcement discretion.

Congress has already provided specific agency direction on this issue. Section 804(j)(1) of the Federal Food, Drug, and Cosmetic Act states that, in enforcing restrictions on personal prescription drug importation, the Secretary "should focus enforcement on cases in which the importation by an individual poses a significant threat to public health" and should exercise enforcement discretion for imports that are "clearly for personal use" and "do not appear to present an unreasonable risk to the individual." This risk-based approach is particularly appropriate as CBP implements a system providing the government with better information about incoming shipments.

FDA's own enforcement experience underscores the importance of distinguishing personal prescription medicines from dangerous drugs. Of the approximately 53,000 drug packages FDA examined at international mail facilities in fiscal year 2022, none contained fentanyl and 33 contained opioids. Many instead contained medicines used to treat conditions including asthma, diabetes, cancer, HIV, thyroid disease, and high cholesterol.

We strongly support enforcement against counterfeit drugs, illicit fentanyl and other controlled substances, and products that present genuine threats to public health. **At the same time, we urge HHS, FDA, DHS, and CBP to delay any implementation of new procedures with respect to prescription medicines unless you can provide clear assurances that your agencies will not prevent genuine prescription medicines clearly intended for personal use and not appearing to present an unreasonable risk from entering the United States.**

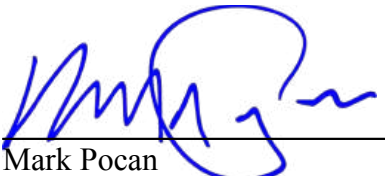
¹ Hong Y, Hincapie-Castillo JM, Xie Z, Segal R, Mainous AG. Socioeconomic and Demographic Characteristics of US Adults Who Purchase Prescription Drugs from Other Countries. JAMA Open. 2020;3(6):e208968. doi:10.1001/jamanetworkopen.2020.8968

No later than October 8, 2026, we request a response to the following questions:

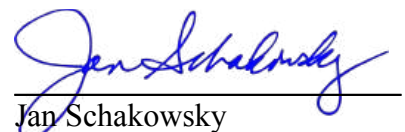
1. Will FDA or CBP adopt any policy, procedure, or automated screening criterion that categorically prevents prescription medicines clearly intended for personal use from entering the United States, regardless of whether the shipment does not appear to present an unreasonable risk?
2. For a prescription medicine imported clearly for personal use pursuant to a valid prescription, what information will FDA and CBP review, what criteria will they apply in determining whether the shipment presents an unreasonable risk, and what process will be available to the recipient if the shipment is detained or refused?
3. What data will FDA and CBP collect regarding international mail shipments of prescription medicines, including the number of shipments screened, detained, refused, or referred for further review, and the reasons for those actions? Will the agencies make this information publicly available?
4. Does FDA distinguish between prescription medicines obtained from licensed pharmacies in Canada or other countries with established pharmaceutical regulatory systems and medicines obtained from unknown or unverified foreign sellers?
 - a. If so, how will the new procedures operationalize that distinction?
5. How will FDA and CBP prevent implementation of the new procedures from interrupting treatment for Americans who currently rely on prescription medicines obtained through international mail, including domestically high-cost medicines or those for chronic conditions?

Americans should not lose access to affordable medicines simply because the government has better information about packages entering the country. We urge your agencies to use that information to focus enforcement on where the risks are greatest while preserving appropriate access to safe and affordable medicines for personal use.

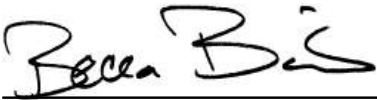
Sincerely,



Mark Pocan
Member of Congress



Jan Schakowsky
Member of Congress



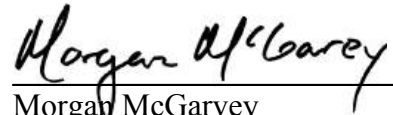
Becca Balint
Member of Congress



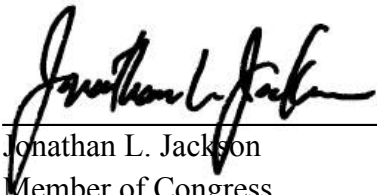
Joseph D. Morelle
Member of Congress



Chris Pappas
Member of Congress



Morgan McGarvey
Member of Congress



Jonathan L. Jackson
Member of Congress



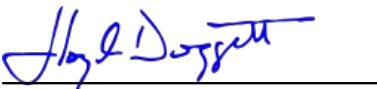
Chellie Pingree
Member of Congress



Madeleine Dean
Member of Congress



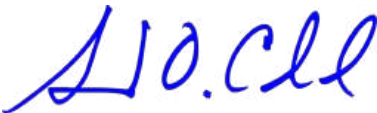
Eleanor Holmes Norton
Member of Congress



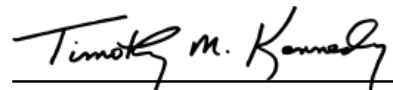
Lloyd Doggett
Member of Congress



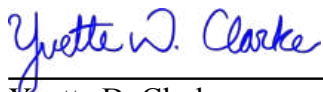
Sharice L. Davids
Member of Congress



Salud Carbajal
Member of Congress



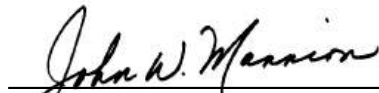
Timothy M. Kennedy
Member of Congress



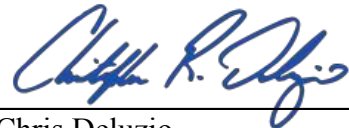
Yvette D. Clarke
Member of Congress



Rashida Tlaib
Member of Congress



John W. Mannion
Member of Congress



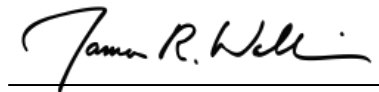
Chris Deluzio
Member of Congress



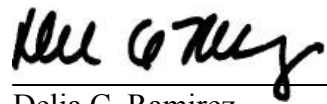
Adam Smith
Member of Congress



Rick Larsen
Member of Congress



James R. Walkinshaw
Member of Congress



Delia C. Ramirez
Member of Congress



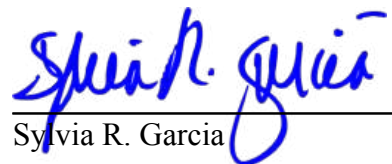
Seth Moulton
Member of Congress



Greg Casar
Member of Congress



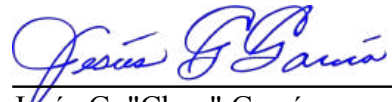
Debbie Wasserman Schultz
Member of Congress



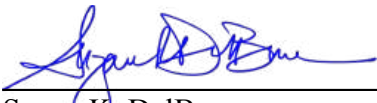
Sylvia R. Garcia
Member of Congress



Teresa Leger Fernández
Member of Congress



Jesús G. "Chuy" García
Member of Congress



Suzan K. DelBene
Member of Congress



Adenita S. Grijalva
Member of Congress



Janelle S. Bynum
Member of Congress



Maxwell Alejandro Frost
Member of Congress



James P. McGovern
Member of Congress



George Latimer
Member of Congress



Pramila Jayapal
Member of Congress



Raja Krishnamoorthi
Member of Congress



Yassamin Ansari
Member of Congress



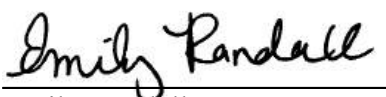
Robin L. Kelly
Member of Congress



Robert Garcia
Member of Congress



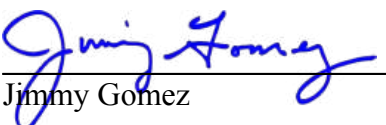
Frederica S. Wilson
Member of Congress



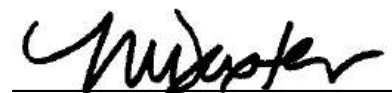
Emily Randall
Member of Congress



Lois Frankel
Member of Congress



Jimmy Gomez
Member of Congress



Maxine Dexter, M.D.
Member of Congress



Mark Takano
Member of Congress



Bradley Scott Schneider
Member of Congress



Marilyn Strickland
Member of Congress



Alexandria Ocasio-Cortez
Member of Congress



Ro Khanna
Member of Congress



JIM Tokuda
Member of Congress



Val Hoyle
Member of Congress



Veronica Escobar
Member of Congress



Paul D. Tonko
Member of Congress



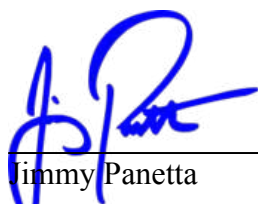
André Carson
Member of Congress



Dwight Evans
Member of Congress



Doris Matsui
Member of Congress



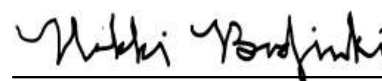
Jimmy Panetta
Member of Congress



Nanette Diaz Barragán
Member of Congress



Greg Landsman
Member of Congress



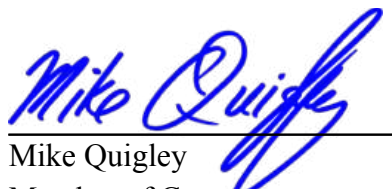
Nikki Budzinski
Member of Congress



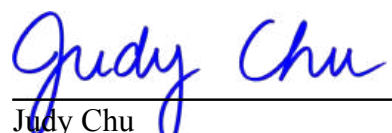
Brendan F. Boyle
Member of Congress



Steve Cohen
Member of Congress



Mike Quigley
Member of Congress



Judy Chu
Member of Congress



Andrea Salinas
Member of Congress



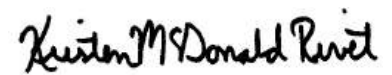
Diana DeGette
Member of Congress



Mark DeSaulnier
Member of Congress



Thomas R. Suozzi
Member of Congress



Kristen McDonald Rivet
Member of Congress



Sam T. Liccardo
Member of Congress



Stephen F. Lynch
Member of Congress