

Over 100 Advocacy Organizations Urge WH And Congress Not To Endanger Americans With Importation Of Non-FDA Approved Drugs

April 9, 2019

Dear President Donald J. Trump,
members of the United States Senate, and members of the United States House of Representatives:

As organizations that represent thousands of law enforcement, healthcare professionals, patient advocates, taxpayer organizations, business groups, and consumer interest groups, we are writing to express our deep concerns with and opposition to proposals to import non-FDA-approved medications that would endanger the health and safety of our communities.

Importing non-FDA-approved medications outside the licensed and secure supply chain endangers patients

Historically, attempts to import drugs from “safe countries” like Canada result in Americans getting counterfeit, substandard or black market medication. These substandard products are often trans-shipped through Canadian free trade zones or shipped directly from countries like China or India, but they never enter the Canadian regulatory sphere.

There is no oversight, safety enforcement or United States FDA protection for medication obtained from foreign entities unlicensed in the United States. Health Canada does not inspect, regulate, or supervise the medication from other countries that Canadian companies sell to Americans because they aren’t bringing those medicines into the Canadian drug supply.

Four previous United States Food and Drug Administration commissioners have studied this problem and concluded that the added costs of attempting to secure medicine from black market sources would eliminate any savings possible through such a program. They are clear that American patient safety would be compromised.

Every day, United States law enforcement is working to prosecute these foreign counterfeiters, but they sometimes have a great deal of difficulty bringing them back to the United States for trial even when these counterfeiters have cost American lives. As has been noted in law enforcement efforts to stem the crisis of Chinese-made fentanyl, China and the United States do not have an extradition treaty. This requires that we get permission from the Chinese government to prosecute cases when their citizens harm Americans: permission we won’t always receive.

For many patients, a counterfeit medicine with substandard or no active ingredient is a death sentence, even if it does not contain dangerous additives. For individuals with HIV, these counterfeit medicines can impact viral suppression and create life-long treatment resistance. For those battling cancer, a counterfeit medication means that tumors grow unchecked and the patient’s fight against cancer is thwarted by a crime they may never detect.

Importing medications will worsen the opioid crisis and endanger law enforcement

According to the Centers for Disease Control, over 29,000 Americans overdosed on synthetic opioids such as fentanyl in 2017, most of which is imported from Chinese labs by global drug smugglers, including global drug cartels such as the Sinaloa cartel. As of the writing of this letter, fentanyl-based counterfeit medications have been found in 45 states and killed Americans in at least 26 states that the Partnership for Safe Medicines has documented.

Increasing the importation of black market medical products will make it harder to catch these dangerous products at the border, causing more American deaths. Additionally, since the explosion of synthetic opioid abuse in 2015, first responders have reported dangerous fentanyl exposure incidents in 17 states.

[August 2021 update: Since this letter was written in 2019, an increasing number of experts have agreed that it is not possible for a person to suffer fentanyl poisoning through passive exposure.]

Importing medications will directly disrupt the gold standard United States supply chain and create new liabilities for healthcare providers

As rare as counterfeits are in the closed, regulated drug supply chain, they have devastating results for patients involved. The Drug Quality and Security Act of 2013 set in motion a multi-year, extremely complex implementation of supply chain safety measures. Importation from unregulated foreign entities will break this “track and trace” system. Again, FDA Commissioners from both Republican and Democratic administrations have vocally opposed allowing importation. As fellow Americans, we do not discount the issue of financial barriers to access all forms of healthcare including medicine. However, there are a broad array of policy proposals that address concerns about medication. Legalized importation of non-FDA-approved medication should not be one of them.

We remain committed to working with you to better understand the concerns of our community. Our organizations may be contacted via the Partnership for Safe Medicines at 2019letter@safemedicines.org or through PSM’s Executive Director Shabbir Imber Safdar at the same email.

Sincerely,

Academy of Managed Care Pharmacy
Action CF
ADAP Advocacy Association
Advocates for Responsible Care (ARxC)
The AIDS Institute
Alabama Pharmacy Association
Alaska Pharmacists Association
Alliance for Safe Online Pharmacies
Alzheimer’s & Dementia Resource Center
American Autoimmune Related Diseases Association
American Pharmacists Association

Arizona Pharmacy Association
The BASE Chicago
BeMedWise
BioForward Wisconsin
BioNJ
Brain Injury Association of DE
Buckeye State Sheriffs’ Association
California Pharmacists Association
Caregiver Action Network
Caregiver Voices United
Center for Medicine in the Public Interest

Centro de Mi Salud, LLC
Children's Cause for Cancer Advocacy
Colorado BioScience Association
Colorado Gerontological Society
Colorado State Grange
Colorectal Cancer Alliance
Commerce and Industry Association of New Jersey
Community Access National Network (CANN)
Consumer Action for a Strong Economy
Council for Affordable Health Coverage
Council for Citizens Against Government Waste
Delaware BioScience Association
Delaware Ecumenical Council on Children and Families
Delaware HIV Consortium
Delaware Pharmacists Association
Dia de la Mujer Latina
Easterseals Central Texas
Florida Pharmacy Association
Georgia Pharmacy Association
Hawaii Pharmacists Association
Healthcare Distribution Alliance
HealthCare Institute of New Jersey (HINJ)
Healthcare Leadership Council
Hope Over Addiction
Illinois Pharmacists Association
Indiana Pharmacists Alliance
Indiana Sheriffs' Association
Institute for Safe Medication Practices
International AntiCounterfeiting Coalition
Iowa Pharmacy Association
Kansas Pharmacists Association
The Latino Coalition
Maine Pharmacy Association
Maryland Pharmacists Association
Massachusetts Independent Pharmacists Association
Men's Health Network
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Pharmacists Association
Missouri Pharmacy Association
National Alliance of State Pharmacy Associations
National Alliance on Mental Illness - Washington State
National Association of Boards of Pharmacy
National Association of Drug Diversion Investigators (NAD-DI)
National Association of Hispanic Nurses Houston
National Association of Manufacturers
National Association of Nutrition and Aging Services Pro-grams (NANASP)
National Black Justice Coalition
National Black Nurses Association
National Consumers League
National Cyber-Forensics and Training Alliance
National Grange of the Order of Patrons of Husbandry
National Hispanic Council on Aging
National Minority Quality Forum
The National Puerto Rican Chamber of Commerce
Nebraska Pharmacists Association
NeedyMeds, Inc.
The Nevada Sheriffs' and Chiefs' Association
New Hampshire Pharmacists Association
New Jersey Association of Mental Health and Addiction Agencies, Inc.
New Jersey Pharmacists Association
New Mexico Pharmacists Association
North Dakota Pharmacists Association
Northwest Parkinson's Foundation
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oncology Managers of Florida
Oregon State Pharmacy Association
The Partnership for Safe Medicines
Pennsylvania Pharmacists Association
Pharmaceutical Industry Labor-Management Association
Pharmaceutical Security Institute, Inc.
Pharmacists Society of the State of New York
Quality Connection
Re: Cancer
RetireSafe
Rx Partnership
Salud USA
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Taxpayers Protection Alliance
Tennessee Pharmacists Association
Texas Association of Manufacturers
Texas Pharmacy Association
Valley AIDS Council
Vermont Pharmacists Association
Virginia Bio
Virginia Pharmacists Association
VOICES FOR AWARENESS
Washington State Pharmacy Association
Young People in Recovery