

ASOP Global Statement on the Publication of FDA's Final Rule on Drug Importation

WASHINGTON – September 25, 2020 – In response to yesterday's publication of the U.S. Food and Drug Administration's (FDA) Final Rule on Drug Importation, the Alliance for Safe Online Pharmacies (ASOP Global) issued the following statement:

Less than six weeks out from the 2020 presidential election, the Trump Administration's release of its final rule regarding prescription drug importation from Canada serves as a political tool rather than providing U.S. consumers with safe and affordable prescription drugs. In fact, the Administration's action runs contrary to twenty years of FDA and Department of Health and Human Services leadership and policy grounded in science and prioritization of public health – as ASOP Global outlined exhaustively in its [public comment](#) on the proposed rule earlier this year.

Economists and the nonpartisan [Congressional Budget Office](#) overwhelmingly agree that importation programs would do little, if anything, to solve America's drug pricing problem. Just ask officials in Illinois, Maine, Minnesota and Vermont, where drug importation programs all failed miserably.

What drug importation is virtually guaranteed to do is put patient safety at risk by effectively altering the closed, secure supply chain that the U.S. healthcare industry relies upon daily to provide care for hundreds of millions of Americans.

For decades, [patient advocacy organizations](#) and numerous government health officials on both sides of the aisle – including President Trump's former FDA Commissioner Scott Gottlieb – have all voiced serious concern over the safety and operability of these programs.

Fearing drug shortages and higher prices of their own in Canada, [government officials](#), [patient advocacy groups and healthcare professionals](#) have expressed their steadfast opposition to importation plans that pose a significant risk to the limited Canadian national drug supply.

In fact, the timing on the final rule couldn't be worse. Illegal, unsafe websites have long dominated the Internet and now online criminals are [exploiting the pandemic](#) for further profit, with more than 100,000 COVID-related domains registered at the outset of the pandemic. Of those, thousands have been confirmed as malicious sites responsible for misinformation campaigns, malware, phishing and related scams. Meanwhile, U.S. consumer purchasing habits during the pandemic demonstrate that Americans are comfortable buying everything – including medicine – online now. News of this action is likely to drive American and Canadian patients to unknowingly access counterfeit, substandard or unapproved medicines online, put a further strain on the pharmaceutical supply chain and place consumers at risk for considerable harm. As published, the rule is reckless and does nothing to protect patients from the thousands of illegal online drug sellers masquerading as "Canadian pharmacies," close these illicit internet markets or hold domain name registrars and registries accountable.

As long-time patient advocates, ASOP Global supports efforts to make safe, approved medicines more accessible and affordable to patients. But the fact remains, drug importation is not the answer. The Final Rule raises significant problems within a complex, global supply chain and does little to resolve the issues at hand. There are simply too many points of vulnerability, too much opportunity for

criminality and meddling associated with sourcing drugs from outside the highly regulated U.S. supply chain, which could result in Americans receiving dangerous – even deadly – fake drugs.

Now, it's up to states and smart consumers to reject the false promises of drug importation and instead demand policies that put patients, not politics, first.

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ABOUT ASOP GLOBAL

The Alliance for Safe Online Pharmacies (ASOP Global), a 501(c)(4) nonprofit organization headquartered in Washington, D.C. with activities in U.S., Canada, Europe, Latin America and Asia, is dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers.