BEFORE THE

United States Department of Health and Human Services
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

In the Matter of:	)	
Notice of Proposed Rulemaking	)	**Docket ID: FDA-2019-N-5711-0001**
	)	**Federal Register Number: 2019-27474**
Importation of Certain Prescription Drugs Shipped from Canada	)	

COMMENT OF CENTER FOR INDIVIDUAL FREEDOM

IN OPPOSITION TO
PROPOSED RULEMAKING TO AMEND FOOD AND DRUG ADMINISTRATION REGULATIONS TO IMPLEMENT SECTION 804(b) THROUGH (h) OF THE FD&C ACT (21 U.S.C. 384(b) THROUGH (h)) TO ALLOW IMPORTATION OF CERTAIN PRESCRIPTION DRUGS SHIPPED FROM CANADA

March 9, 2020

I. Introduction

The Center for Individual Freedom (hereinafter "CFIF") is a non-profit, non-partisan 501(c)(4) organization with over 300,000 grassroots supporters and activists across the United States. CFIF was

established in 1998 for the purpose of safeguarding and advancing Constitutional rights, technological innovation, free market principles and fidelity toward the rule of law.

As a central part of that mission, CFIF advocates for public policies that preserve the United States of America's standing as the world's most innovative nation for pharmaceutical advances, and that ensure the American public maintains access to the safest, most effective and most comprehensive array of life-saving and life-improving pharmaceuticals possible. The Proposed Rulemaking under consideration by the Food and Drug Administration (hereinafter "FDA"), to implement Section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)) would undermine those important interests, and it is on that basis that CFIF respectfully submits this Comment in opposition to the Proposed Rulemaking.

II. Discussion

Allowing importation of prescription drugs from Canada would inflict immediate, profound and wholly unnecessary harm upon American consumers, as well as upon American pharmaceutical innovators, which remain unparalleled in the world.

As evidence, look no further than the comparative unavailability of new life-saving and life-improving drugs available in Canada vis-à-vis the American healthcare market.

For example, of all new cancer drugs developed between 2011 and 2018, American consumers are able to access 96% of them. In Canada, by contrast, only 56% of those new drugs became available to consumers.[1] Furthermore, Canada is no anomaly, as nations like Denmark (66%), Belgium (56%), Japan (50%) and Greece (11%) experience the same unavailability relative to the United States.[2]

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[1] *The United States vs. Other Countries: Availability of Cancer Medicines Varies*, Pharmaceutical Research and Manufacturers of America (PhRMA), January 2019, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/IPI-Model---Comparison-of-Cancer-Medicine-Availability---012819.pdf.

[2] *Id.*

The reason for that discrepancy is straightforward: Compared with Canada and other nations with similar healthcare systems, the United States protects patent and other intellectual property rights to a far greater degree, and practices more market-based solutions. By introducing importation of drugs from Canada or other similar systems less protective of those rights, we would thereby introduce the pricing mechanisms inherent to those systems, ultimately with similar negative consequences for Americans.

The Trump Administration has itself warned of that threat, citing conclusions reached by none other than the United Nations World Health Organization (WHO):

> *Every time one country demands a lower price, it leads to a lower price reference used by other countries. Such price controls, combined with the threat of market lockout or intellectual property infringement, prevent drug companies from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing those policies.*[3]

That is simply a risk that we simply cannot invite, and on that basis alone the Proposed Rulemaking merits rejection.

Consumer safety presents a second critical reason to reject the Proposed Rulemaking.

Currently, American consumers have the distinct benefit of the safest market for medicines in the entire world, overseen by the FDA.[4] According to the FDA, however, the noncompliance rate of inspected drug packages received through U.S. International Mail Facilities (IMFs) is nearly 9 in 10:

> *The IMFs receive international mail from more than 180 countries, which often lack advance information regarding the content of the packages that would aid in targeting*

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[3] *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, May 2018, https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[4] *Promoting Safe & Effective Drugs for 100 Years*, U.S. Food and Drug Administration, January-February 2006, https://www.fda.gov/about-fda/histories-product-regulation/promoting-safe-effective-drugs-100-years.

shipments that are likely to contain illegal, unapproved, counterfeit and potentially dangerous drugs. How large is the scope of the problem? There's no way for the FDA or any federal agency to know. But 87% of the packages that the FDA has reviewed contain illegal, counterfeit and potentially dangerous drugs.[5]

According to a 2018 WHO analysis, moreover, nearly 10% of all medical products shipped worldwide are counterfeit:

*No countries remain untouched by this issue – **from North America** and Europe through to sub-Saharan Africa, South East Asia, and Latin America. What was once considered a problem limited to developing and low-income countries has now become an issue for all. With the exponential increase in internet connectivity those engaged in the manufacture, distribution and supply of substandard and falsified medical products have gained access to a global market place. This extends both to consumers and business forums. A culture of self-diagnosis and self-prescribing has led to the emergence of thousands of unregulated websites providing unsupervised access to substandard and falsified medical products.*[6] *(emphasis added)*

Accordingly, to allow importation of drugs into the currently safe U.S. consumer market, including from our North American neighbor Canada, would open the floodgates to that potentially catastrophic peril of dangerous drugs.

On that basis, Department of Health and Human Services (HHS) Secretary Alex Azar himself stressed that, "The last thing we need is open borders for unsafe drugs," specifically citing the idea of

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[5] *U.S. Food and Drug Administration and the International Mail Facilities*, U.S. Food and Drug Administration, April 2019, https://www.fda.gov/media/111980/download.

[6] *Substandard and Falsified Medical Products, World Health Organization*, January 31, 2018, https://www.who.int/en/news-room/fact-sheets/detail/substandard-and-falsified-medical-products.

importing pharmaceuticals from Canada as a "gimmick."[7] Former Trump Administration FDA Commissioner Dr. Scott Gottlieb struck a similar chord, lambasting the idea of drug importation and itemizing some of the threats that it would introduce.[8]

Additionally, FDA Commissioners from 2002 through 2016 went on record in a 2017 open letter to Congress, warning that drug importation, "could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard or counterfeit drugs."[9]

Beyond safety concerns, the Proposed Rulemaking is additionally flawed because it wouldn't achieve its stated result of reducing U.S. drug prices.

To wit, the Congressional Budget Office (CBO) concluded after researching the issue that drug importation would have little to no impact in actually lowering prices. "Permitting importation only from Canada," the CBO found, "would produce a negligible reduction in drug spending."[10] And on this matter former FDA Commissioner Gottlieb agreed that the idea of drug importation, "would have added much cost to the imported drugs; they wouldn't be much cheaper than drugs sold inside our closed American system."[11]

A primary reason for that reality is that Canada's population is approximately one-tenth the U.S. population, so its drug market and pharmaceutical supply simply isn't large enough to satisfy sudden and enormous new demand from its much larger southern neighbor. To illustrate, a University of Texas

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[7] *Remarks on Drug Pricing Blueprint*, Alex Azar II, May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[8] Remarks by Dr. Scott Gottlieb, May 10, 2019, https://www.c-span.org/video/?c4797136/user-clip-fda-commissioner-importation.

[9] *Letter to Congress from former Commissioners of the U.S. Food and Drug Administration Donald Fortin, M.D., Mark McClellan, M.D., Margaret Hamburg, M.D., Andrew Von Eschenbach, M.D.*, March 16, 2017, https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf.

[10] *Would Prescription Drug Importation Reduce U.S. Drug Spending?*, Congressional Budget Office, April 29, 2004, https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf.

[11] *What Trump Should Have Said on Drug Prices*, Forbes, March 4, 2016, https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#39a60b9e2e74.

study concluded that if American consumers began sourcing even 20% of their pharmaceuticals from Canada, "the total Canadian brand name drug supply would be exhausted in 281 days."[12]

Echoing that logic, Canadian pharmaceutical experts agree that importation of drugs from Canada would cripple its much smaller consumer market:

> *The Canadian Pharmacists Association (CPhA) believes the Canadian medicine supply is not equipped to support both Canadian and U.S. consumers, and will make existing drug shortages in Canada even worse, disrupting patients' access to their medications. Drug shortages have "greatly increased" in the last 3-5 years according to a newly released survey of Canadian pharmacists. CPhA is calling on the federal government to clearly express its opposition to U.S. drug importation, and immediately develop an action plan to respond to these proposals including restricting exportation of drugs from Canada to the U.S.*[13]

In turn, that would open the door to unsafe counterfeits and imports from other black markets, exacerbating the safety issues discussed above. Even Canadian Prime Minister Justin Trudeau has made it a point to emphasize that, "Canada does not support actions that could adversely affect the supply of prescription drugs in Canada."[14]

Accordingly, in addition to undermining America's world-leading pharmaceutical innovation sector, threatening the lives and safety of American consumers and failing to achieve its intended goal

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[12] *U.S Importation Is a Catastrophic Threat to the Canadian Drug Supply: Two New Studies Advise Urgent Action from Canada's Federal Government*, Canadian Health Policy Institute, September 24, 2019, https://www.globenewswire.com/news-release/2019/09/24/1919835/0/en/US-importation-is-a-catastrophic-threat-to-the-Canadian-drug-supply-two-new-studies-advise-urgent-action-from-Canada-s-federal-government.html.

[13] *Canadian Pharmacists Association Renews Call for Federal Government to Protect Drug Supply in Light of U.S. Drug Importation Developments*, Canadian Pharmacists Association, July 31, 2019, https://www.pharmacists.ca/news-events/news/canadian-pharmacists-association-renews-call-for-federal-government-to-protect-drug-supply-in-light-of-u-s-drug-importation-developments/.

[14] Shortages Feared as U.S. Looks to Canada for Cheaper Prescription Drugs, Canadian Broadcasting Corporation, July 31, 2019, https://www.cbc.ca/news/politics/us-drug-plan-canadian-shortage-1.5232360.

of substantive price reductions in the U.S. market, the Proposed Rulemaking to allow prescription drug importation from Canada threatens Canada's own consumer pharmaceutical marketplace.

III. Conclusion

For the reasons set forth herein, CFIF opposes the Proposed Rulemaking under consideration.

Respectfully submitted,

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