March 9, 2020

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-5711 for "Importation of Prescription Drugs."

Dear Sir or Madam:

On behalf of the 25 to 30 million Americans with one of the over 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the Food and Drug Administration (FDA or Agency) for the opportunity to provide comments on the Agency's proposed rule titled *"Importation of Prescription Drugs"* (Importation Proposed Rule).

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

The Importation Proposed Rule would implement section 804(b) through (h) of the FFDCA[1] when finalized. Per the statute, it would apply to importation of drugs from Canada. States or other non-federal governmental entities, like local governments, would submit an importation proposal, referred to as a SIP (section 804 importation program proposals), to FDA for review and authorization. SIPs would be time limited to 2-years. Extensions could be granted by FDA in 2-year increments. SIPs would be authorized by FDA, and managed by states or a non-federal governmental entity. An importation program could be cosponsored by a state, a non-federal governmental entity, a pharmacist, or a wholesaler. The SIP sponsor would have to demonstrate that there are no additional public health risks and that importation of a drug would lower its cost. The SIP would have to comply with supply chain requirements and the supply chain for each drug under a SIP would be limited to three entities – one manufacturer, one foreign seller, and one importer. The foreign seller would have to be licensed by Health Canada and registered with FDA as a foreign seller. The importer would have to be a wholesaler or pharmacist licensed to operate in the U.S. The products would have to have unique identifiers for each package. There would have to be a pre-import request and file in the Automated Commercial Environment (ACE) system. FDA would authorize the port of entry. The importer would need to arrange for lab testing and ensure that the label complies with U.S. law and regulations. FDA would review and accept testing results. There would be some post-importation reporting requirements, including on costs savings, adverse events, etc. FDA would have recall authority and could also terminate the SIP at any time.

[1] 21 USC §384(b) through (h)

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Although the intent of this Proposed Rule is to provide access to lower cost drugs, NORD is concerned that allowing importation will not achieve this intent and may cause harm to rare disease patients and others who rely on safe and effective drugs to treat or manage their serious health conditions. For reasons explained below, we urge FDA not to spend any further resources trying to finalize this misguided Importation Proposed Rule.

It is estimated that there are over 7,000 rare diseases, which are defined in the United States as diseases affecting 200,000 or fewer people. People living with rare diseases must be able to afford the therapies that come to the market. The high cost of prescription drugs has a direct impact on the ability of patients to access lifesaving care. The small patient populations and medical complexity associated with rare diseases can lead to costly therapies, but it is vital that these therapies remain affordable and, therefore, accessible to rare disease patients. Furthermore, these therapies must remain affordable so that the sustainability of the healthcare system as a whole is preserved.

As all levels of government and a variety of stakeholders look for legislative and regulatory tools to find ways to ensure that medicines are affordable, NORD has compiled the following principles to help guide NORD's engagement with these issues in a deliberate and transparent manner.

1. The policy must maintain FDA's standards of safe and effective therapies.
2. The policy must not raise out-of-pocket costs for rare disease patients.
3. The policy must not decrease patients' coverage of necessary therapies prescribed by their provider.
4. The policy must not place an undue burden on innovation of new therapies.
5. The policy must be supported by reliable data.

Importation of drugs poses a direct threat to NORD's first drug pricing principle – namely, the policy must maintain FDA's standards of safe and effective therapies. Rare disease patients in the United States rely on the quality and safety of FDA-approved medicines. Any policy to lower the cost of therapies must not lower the safety and effectiveness of the medicines rare disease patients need. However, importation has historically been a problem because FDA cannot ensure the safety and quality of imported drugs.

Unfortunately, there are many stories about substandard or counterfeit imported medicines, mainly purchased over the internet, resulting in serious health consequences for the consumer. According to the Partnership for SAFEMEDICINES®, "In 2012, the FDA discovered imported cancer treatments that contained no active ingredient in the American drug supply" and "people in 29 states have died because they accidentally took counterfeit prescription painkillers or fake Xanax." [2]

Although the Proposed Rule proposes that imported drugs comply with supply chain and quality regulations, no additional resources will be provided to FDA to oversee this program and ensure

[2] https://www.safemedicines.org/policymakers-media

the safety and quality of imports. In fact, the recently released President's Budget proposal for FY 2021 does not provide any funding for a drug importation program at FDA. So while hypothetically a drug manufacturer would have to comply with all these important safety and quality requirements, in all likelihood there would be very little oversight by FDA to verify compliance. This limited ability by FDA to protect the safety and quality of our nation's drug supply could jeopardize patients' safety. It could also lead to distrust in FDA and drugs in general.

Even if FDA had sufficient resources to properly oversee this program, NORD would still have several other concerns about importation. Given the requirements proposed in the Proposed Rule, it is difficult to see how a state could implement a SIP without significant cooperation with drug manufacturers, particularly on the supply chain, testing, and labeling requirements. But it is also difficult to understand why a manufacturer would elect to import a drug to the U.S. when they already have FDA approval to market directly in the U.S. We believe manufacturers are not going to participate in this program because the cost and challenges to comply with this initiative and the concerns that a breach in safety and quality would destroy a brand's reputation are too great. Beyond the additional hurdles a manufacturer would have to jump to ensure the imported drug is safe and of high quality and then relabeled, it is unclear if they would get reimbursement in the U.S. insurance market for their drug.

It is also difficult to see how complying with these requirements would result in cost savings and lower drug prices for patients. Moreover, the statute and the proposed rule exclude several categories of drugs, biologics (which would include insulin by the time this rule would be finalized), intravenously injected drugs, and infused drugs.[3] Instead, patients risk getting a substandard or counterfeit drug and then being stuck to pay the full cost of the drug out of pocket.

States are not drug manufacturers or the FDA, and therefore do not have the expertise needed to implement and oversee SIPs. Previous efforts to import drugs raise serious safety concerns. For example, in 2013, Maine attempted to allow importation of medications from Canada and other countries. At the time, the Maine Pharmacy Association ordered and tested three medications that supposedly came from Canada. All three were found to be substandard and contaminated. Less than two years after enactment, a federal judge struck down Maine's law.[4]

There are much better ways to lower drug costs that will not jeopardize patients' safety, for example incentivizing generics and biosimilars. FDA is a key player in these efforts, and it would be unfortunate if resources were diverted from these proven cost effective options to a dangerous, unproven importation program.

Another important factor that has not been taken into consideration is the needed cooperation of other countries, most notably Canada, for an importation program to work. One main constraint is that markets in Canada are not as large as the U.S., and importation could result in depletion of

[3] 21 USC §384(a)(3); 70804 Federal Register Vol. 84, No. 246, Dec. 23, 2019.
[4] https://www.safemedicines.org/maine-importation-2019

their drugs in a matter of months.[5] Canada's acting Ambassador to the United States, Kirsten Hillman, has already said redirecting Canada's drug supply to the U.S. would be unacceptable to Canadians.[6] Canada is unwilling and cannot be expected to be a gatekeeper for drugs imported to the U.S.

FDA has a long history of opposing drug importation proposals because of concerns that these proposals could endanger the U.S. drug supply and because the Agency does not have the resources to implement such a program.[7] As recently as 2017, four former FDA commissioners, of both Republican and Democrat administrations, penned a letter to Congress expressing concerns about importation proposals.[8] Since there are no additional resources provided to FDA to oversee this complex importation program, its proposal is an inexplicable, complete negation of longstanding Agency concerns.

This Importation Proposed Rule is bad for patients and for rare disease patients specifically who use orphan and other drugs. If an imported drug ends up being substandard or counterfeit, the implications could be huge for a rare disease patient where each and every dose of a drug is critically important to maintaining health. The consequences could be deadly even if the drug itself is not.

For the health and safety of rare disease patients, NORD urges FDA not spend any further resources trying to finalize this misguided Importation Proposed Rule. For questions regarding NORD or the above comments, please contact me at madams@rarediseases.org, or 202-588-5700.

Sincerely,

/s/
Michelle Adams
Director of Federal Policy

[5] https://www.canadianhealthpolicy.com/products/new-pathways-for-u-s--importation-threaten-canadian-prescription-drug-supply-.html
[6] https://connect2canada.com/2019/12/statement-from-canadas-acting-ambassador-to-the-united-states-on-u-s-importation-of-pharmaceutical-drugs-from-canada/
[7] https://thehill.com/homenews/senate/71307-fda-opposes-senate-drug-importation-amendmen
[8] https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf