

March 4, 2020

Stephen M. Hahn, MD
Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Re: Docket No. FDA-2019-N-5711 for "Importation of Prescription Drugs"

Dear Commissioner Hahn:

The National Association of Boards of Pharmacy[®] (NABP[®]) is a 501(c)(3) nonprofit association that, for over 116 years, has protected public health by assisting its member boards of pharmacy and offering programs that promote safe pharmacy practices for the benefit of consumers. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, and 10 Canadian provinces. NABP's mission is to protect public health.

NABP has tracked the issue of drug importation since at least 2003. While NABP appreciates policymakers' important efforts to increase patient access to affordable medications, we must also ensure that those medications are safe. For that reason, NABP has consistently held the position that, when considering the importation of prescription drugs from other countries, the safety of the US supply chain and the delivery of care should not be compromised.

While we are encouraged by some of the safeguards that have been included in FDA's Proposal for the Importation of Prescription Drugs (Proposal), we believe that the Proposal lacks *sufficient* protections to meet the statutory mandate that it pose "no additional risk to the public's health and safety." For this reason, NABP believes that the Proposal should be redrafted to ensure that it protects patients by maintaining the integrity of the US drug supply chain.

- I. **While NABP applauds the FDA's decision not to implement the personal importation provisions of Section 804(j), we believe the Proposal does not sufficiently address the likelihood of increased illegal activities by rogue actors who seek to prey on American patients.**

NABP believes that FDA has correctly decided not to implement the personal importation provisions under Section 804(j) of the Food, Drug, and Cosmetic Act. As background, the Proposal notes that "[w]hile there are pharmacy websites that operate legally and offer convenience, privacy, and safeguards for purchasing medicines, **there are many rogue online pharmacies that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States.**" (Emphasis added). As further described in the Proposal, patients purchase what they *believe* to be

life-saving medication from sophisticated criminal enterprises masquerading as Canadian pharmacies. Not only do these patients receive unapproved, falsified, and/or substandard drugs, they are denied access to the care a licensed pharmacy is required to provide under the law.

If any portion of Section 804 is implemented, NABP anticipates that publicity regarding legalized Canadian importation will embolden these criminals, who will increase their efforts to prey on vulnerable American patients. This concern is not without precedent. For years, we have seen illegal actors intentionally misrepresent FDA's Personal Importation Policy to suggest that their illicit websites are fully compliant. We suspect we will see similar misrepresentations of FDA's Proposal, as American patients are exposed to headlines like: "FDA Approves the Importation of Drugs from Canada" and "HHS Secretary Tells Congress Canadian Drugs Pose No Risk to Americans." As written, the Proposal does not provide safeguards to protect Americans from an increase in rogue online network activity that targets US consumers.

NABP also anticipates that these rogue actors will attempt to participate in Section 804 Importation Plans (SIPs). Indeed, the Proposal references the case of Canada Drugs Ltd. (Canada Drugs), a Canadian company that shipped misbranded and unapproved drugs directly to US consumers as well as through wholesale channels. Canada Drugs' wholesale unit shipped counterfeit versions of Avastin (a chemotherapy treatment) that contained no active pharmaceutical ingredient and caused harm to vulnerable cancer patients. It is important to remember that, at the time of the crime, this company was licensed as a wholesaler by both Health Canada and the provincial authority in Manitoba, just like a Foreign Seller authorized to operate under the Proposal. As part of their criminal network, Canada Drugs purchased a small wholesaling operation in the US called Montana Healthcare Solutions, which distributed counterfeit cancer drugs within the US; the role of Montana Healthcare Solutions is similar to the role of an Importer under the Proposal. Once these drugs entered the US supply chain, they were distributed under several aliases and organizations, including Quality Specialty Products (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, Infusion Options, UK Pharmacy Services, and Clinical Care. Once the horse was out of the barn, it was incredibly difficult for FDA to re-secure the supply chain for Avastin. Indeed, the agency was required to issue nearly 1,000 warning letters in 48 states and 2 US territories.

For these reasons, NABP believes that:

- a. All SIPs should include a State, tribal, or territorial government;
- b. Extensive background checks should be performed on Foreign Sellers and their affiliated businesses, agents, and principals including at least 5 years of records for all Foreign Sellers;
- c. If a Foreign Seller has been licensed for less than 5 years, they should be ineligible to participate in a SIP;
- d. Foreign Sellers should be licensed by Health Canada and their respective provincial authority;
- e. Extensive background checks should be performed on all Importers and their affiliated businesses, agents, and principals, including at least 7 years of records for all Importers;
- f. If an Importer has been licensed for less than 7 years, they should be ineligible to participate in a SIP;

- g. Importers should be either (1) wholesalers appropriately licensed by all relevant state authorities and registered with the FDA; or (2) pharmacists licensed by all appropriate Boards of Pharmacy where they are providing services;
- h. All background checks should include a review by and recommendation from FDA's Office of Criminal Investigations (OCI). Although OCI's recommendation should be an important factor in evaluating a SIP Proposal, the recommendation should be kept confidential and remain within FDA;
- i. A conviction or final disciplinary action should not be required to deny a SIP Proposal;
- j. All SIP Proposals should be published and open to a reasonable public comment period;
- k. SIP Proposals should include and account for all enforcement costs;
- l. SIP Proposals should have a detailed methodology for detecting drug products that are suspected of transshipment; and
- m. Foreign Sellers should have an authorized agent registered and domiciled in the jurisdiction of the government Sponsor that can be held both civilly and criminally liable.

II. The Proposal should require meaningful engagement by state boards of pharmacy in the development, implementation, and operation of the SIP.

To ensure patient safety, NABP believes that a federal or state government entity should be a required Sponsor of a SIP; however, not all government agencies have equal experience in protecting patients. With respect to government involvement, NABP has two primary concerns: (1) as written, the Proposal does not require meaningful engagement by boards of pharmacy in the development, implementation, or operations of a SIP; and (2) even if the Proposal is amended to require active participation by boards of pharmacy, the boards may lack appropriate resources to effectively enforce the provisions of a SIP.

Regarding our first concern: There are very few government agencies – at either the federal or state level – that have expertise in regulating the drug supply chain. As the primary drug regulator in the US, FDA clearly has the most experience with drug importation, recalls, quality testing, and overall drug safety. In most states, the board of pharmacy regulates the practice of pharmacy, sale of drugs between intermediaries, and the general provision of pharmaceutical care to state residents.

FDA appears to anticipate that states will actively utilize their boards of pharmacy to provide primary oversight of the SIP. In requiring state involvement, the Proposal notes:

States provide the primary oversight of wholesale distributors' storage, handling, and distribution practices to ensure the quality of drugs is maintained. States also ensure that pharmacies and pharmacists comply with statutes and regulations governing the practice of pharmacy, which includes dispensing of drugs to patients. States have the authority to inspect pharmaceutical supply chain participants and to take disciplinary action against them if warranted. States also have tools that they can use to respond rapidly should activities under their SIP adversely affect the public health.

The activities described above are principally overseen by boards of pharmacy. However, it is NABP's understanding that current state plans: (1) have not been drafted with significant input from

boards of pharmacy; and (2) once implemented, do not require meaningful involvement from boards of pharmacy in the oversight of the SIP. Failure to require meaningful board of pharmacy involvement could lead to negative outcomes ranging from poor safety records of SIPs to significant underestimates of costs, specifically with regard to operations and enforcement.

Regarding our second concern: This Proposal comes at a time when boards of pharmacy around the country are feeling pressure to do more with less. It is vital that the very expertise the Proposal contemplates utilizing within the state government is sufficiently resourced to handle the incredibly important safety obligations this Proposal would place on Sponsors.

III. The Proposal fails to address issues that arise after unapproved foreign drugs enter the US supply chain.

Once a SIP drug product enters the US supply chain, there are no SIP-specific restrictions on its use or sale. Because this Proposal could create fifty new importation schemes with various regulatory requirements and cost savings, NABP is concerned that this will create a “race to the bottom” – that is, the state with the least stringent requirements and enforcement will corner the market on drug importation. Relaxed standards could include infrequent testing, minimal background checks, or lower penalties for non-compliance. If this happens, there is very little that other states could do to prevent these less-regulated products from being dispensed to their residents.

The Proposal is also silent regarding how SIP drug products will be handled under drug product substitution laws. Will an imported drug product be listed in the Orange Book or will it use the proxy of an existing drug approval? If SIP drug products are not listed in the Orange Book, will laws and regulations regarding substitution need to be altered in order to realize the anticipated costs savings? If substitution is permitted, widespread importation of a brand name drug could suppress generic drug development, preventing long-term cost savings. If imported products are substitutable, will prescribers know when patients are taking drug products that have not been evaluated by FDA? A prescriber could easily mistake a super- or sub-therapeutic response as a patient-specific reaction, overlooking the confounding variable of a SIP drug product. In these instances, the drug product will likely not be reported through an adverse drug reporting system. Similarly, patients may not be informed that they are taking a SIP drug product, as the labeling changes appear to modify only the manufacturer labeling, which often is not dispensed at the patient-level. It is unclear how FDA will track drug quality deviations.

At a minimum, FDA should clarify its intent with regard to substitution and continuously monitor the post-importation impact that SIP drugs will have on the supply chain.

IV. The Proposal has not adequately addressed other issues that plagued previous attempts to implement safe and cost-effective drug importation.

As noted in the Proposal, past efforts to allow Canadian importation have been unsuccessful because: (1) FDA could not ensure the safety and effectiveness of drugs imported via such a program; (2) by opening the “closed” US drug distribution system, proposed importation programs increased the opportunity for counterfeit drugs to enter the supply chain; and (3) proposed importation programs did not result in a significant reduction in costs to American consumers, as

required by law.

The Proposal claims to have addressed these issues; however, NABP remains concerned about the following:

- a. The Proposal fails to demonstrate how implementation of Section 804 will provide a significant reduction in costs to American consumers. In drafting Section 804, Congress specifically excluded biologics, infused drugs, and intravenously injected drugs. After accounting for these congressional exclusions and reviewing Health Canada-approved drugs, it appears that, at most, only 14 of the 50 most expensive drugs found in the 2018 Medicare Part D Drug Spending Data are considered “eligible products” under the Proposal. Without the inclusion of these high-priced drugs, substantial cost savings are difficult to achieve. Instead of proving that the Proposal will result in a significant reduction in costs to American consumers, the FDA has deferred the cost savings analysis until after congressional certification, with the assumption that states will prove cost savings at a later date. Simultaneously, the Proposal requests comment on how cost savings should be calculated.

With respect to the Proposal’s questions regarding cost calculations, NABP believes that any cost saving should include all enactment, enforcement, and operational costs and demonstrate definitive savings for American consumers by demonstration of actual out-of-pocket savings via co-pays, cash payments, premium reductions, or expansion of coverage. The cost of dispensed prescription drugs is notoriously difficult to calculate due to the methods used for reimbursement; for these reasons, we do not believe a retail cash price measurement will be logical for most SIPs. We believe any definition of “significant reduction of costs” should mirror the expectations of patients.

While considering cost analysis, FDA should also consider the reactions of market participants. For example, manufacturers may cut off supply to Foreign Sellers, delaying drug approval in either the US or Canada, or create different dosage strengths for US and Canadian products. Pharmacy benefit managers may not pass on savings to consumers. They may also refuse to include SIP drug products in their formularies due to the administrative burden associated with these products.

- b. The Proposal relies on the maturation and growth of supply chain security due at least in part to the enactment of the Drug Supply Chain Security Act (DSCSA); however, as noted in the Proposal, DSCSA is not yet fully implemented. Since 2015, FDA has been working with industry to build an interoperable platform to exchange transaction information. At this time, FDA anticipates that this platform will be completed in 2023. Unless the requirements set forth in DSCSA are fully operational, we believe it cannot provide the security that is necessary for the successful operation of this Proposal.
- c. The Proposal intends to rely on manufacturers’ anti-counterfeit technologies to help prevent counterfeit drugs from entering the supply chain. However, these technologies are designed by manufacturers to prevent lost revenue. If these technologies are used to help facilitate importation – and, in so doing, *reduce* manufacturer revenue – manufacturers may simply stop implementing these anti-counterfeit technologies. This will not only short-circuit an

important safeguard relied on by the Proposal, but may also increase the number of substandard drugs in the US, exposing patients to additional risk.

In conclusion, NABP believes that there remains significant safety concerns regarding the implementation of Section 804. Unless and until these concerns are addressed, this Proposal will pose additional risk to the public's health and safety. If the Proposal moves forward as-is, we fear an increase in unsafe personal importation and participation of illicit actors in the SIPs. Because the Proposal attempts to bypass fundamental safety measures of the US drug supply system, NABP believes that it will introduce additional risks to patients.

We thank you for the opportunity to provide comments and respectfully request the FDA redraft this Proposal.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

A handwritten signature in cursive script, appearing to read 'C. Catizone'.

Carmen Catizone MS, RPh, DPh
Executive Director/Secretary