March 6, 2020

Dr. Stephen M. Hahn
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Bethesda, MD 20993

RE: Importation of Prescription drugs - FDA-2019-N-5711

Submitted electronically via www.regulations.gov

Dear Dr. Hahn:

I am writing on behalf of the National Association of Health Underwriters (NAHU), a professional association representing more than 100,000 licensed health insurance agents, brokers, general agents, consultants and employee benefits specialists. We are pleased to have the opportunity to provide comments in response to the proposed rule published in the *Federal Register* on December 23, 2019, titled "Importation of Prescription Drugs."

The members of NAHU help individual Americans and businesses of all sizes purchase private health insurance and assist consumers with their benefit questions, claims issues, and administrative needs throughout the duration of their coverage. Cost is one of the biggest obstacles our members face when helping everyone from large corporations to single people find health plan options that meet their needs and budgets. The cost of medical care is what drives the price of private health insurance premiums and cost-sharing requirements. Americans deal with astronomical prescription drug prices more often than any direct medical care cost. According to the Kaiser Family Foundation, one in four people taking prescription drugs reports difficulty affording their medications. Our members have daily first-hand experience with how Americans are struggling with pharmaceutical prices. As such, we have a great interest in the proposed rule and its stated aim: to lower prescription drug prices and reduce out-of-pocket costs for American patients.

For most American healthcare consumers, one of the most frustrating aspects of high prescription drug prices is how little they can do to personally control and reduce their drug costs. Even when people shop responsibly for lower-cost options, stick to formularies, look for generic alternatives and seek to optimize any prescription drug coverage benefits they have, people are frequently overwhelmed by the cost of their prescriptions. It's particularly an issue for the millions of people with chronic or serious medical conditions.

Health insurance issuers and sponsors of group health and welfare benefit plans are equally frustrated by prescription drug prices and the limited options available to control the pharmaceutical spend rate of health plan participants. The astronomical price of many prescription drugs in the United States has a significant impact on benefit designs, contributing to higher out-of-pocket costs for enrollees with both fully insured and self-funded health insurance coverage.

The significant cost of prescription pharmaceuticals is a problem that is largely unique to the United States. In other industrialized countries, the government is much more involved in either negotiating the cost of drugs or actually setting limits on the maximum cost. As a result, in other countries, the retail cost of specific prescription medications is often a fraction of the price for the same medication sold through an American pharmacy.

In recognition of the substantial price differences between prescription drug costs here in the United States and the same medications when sold in neighboring countries, the proposed rule would allow for the importation of certain prescription drugs from Canada. It would do so by creating limited importation programs authorized by Section 804 of the Federal Food, Drug and Cosmetic Act of 2003. Each Section 804 Importation Program (SIP) would need to be specifically reviewed and authorized by the FDA. As proposed, SIPs would be managed by states or certain other non-federal governmental entities. SIPs could be co-sponsored by a pharmacist, a wholesaler, or another state or non-federal governmental entity.

NAHU values and supports the intent of the proposed regulation. However, we view it as one small piece in the puzzle of ensuring that all Americans have access to affordable medications. Importing drugs from other countries does not address the crucial issue of why prescription medications are so expensive when purchased within the United States. Instead, factors like patent protections, advertising costs, market factors and a longer-than-average drug-approval process cause prescription drug prices to be significantly higher in the United States than in comparable nations. Accordingly, NAHU believes that additional, much more extensive public policy action needs to occur to reduce the cost of prescription pharmaceuticals in the United States. This activity will need to be coupled with significant market-based changes in order to truly have an impact on both individual and group medical care consumers.

With regard to this specific proposal, NAHU members appreciate its focus on safety, which needs to be paramount. Some of the many measures in the proposal designed to ensure that SIPs distribute quality medications include a mandated direct supply chain, screening drugs for damage or counterfeiting, relabeling provisions, requiring FDA approval for each shipment, laboratory testing of samples from each shipment, and the development of a system so that physicians and consumers can report adverse drug interactions. While we believe these protections are extremely important, as you work to finalize this proposal, we ask that you review the details of each of these elements to ensure that they are necessary, well-structured and cost-efficient. For example, while the provision to relabel medications might make sense if medications came from a country where English was not the primary language, Canadian drug packaging and instructions are written in English already. Our membership wants to ensure that any Americans who might have access to SIPs pharmaceuticals are kept safe, but through sensible provisions that do not add unnecessary layers of cost and administrative hurdles to the process.

NAHU members also note that while SIPs have the potential to provide substantial cost savings to participants, the program populations are inherently limited. Based on the criteria for SIP management outlined in the proposal, only a state government, tribal or territorial governmental entity would be eligible. Furthermore, eligible entities will need to be able to take on the significant requirements required for program approval and maintenance. Therefore, even if there is widespread adoption and approval of SIPs, which is in no way guaranteed, only a very small portion of the American public would potentially benefit.

The scope of drugs that could be available through a SIP is also restricted. Controlled substances, biological drug products (including insulin), intravenous drugs, drugs that are subject to FDA-approved Risk Evaluation and Mitigation Strategies (REMS) programs, and drugs injected in the spine or eye would all be excluded at that this time. Further, we note that the Administration is considering limiting other classes of pharmaceuticals, and is seeking comments on which other types of drugs, if any, should be stricken from the scope of a SIP. NAHU members support restrictions on certain types of medications for safety reasons, including drugs with extraordinary delivery, transportation and storage concerns. We understand the reason for these types of limitations but also note that some of these are the costliest prescriptions. So, even SIP participants will not be fully shielded from extremely high prices for the drugs they need, particularly for specialty drugs.

We do have concerns that the reach of SIPs could be limited by both the American judicial system and the Canadian government. According to the proposed rule, if one or more of the safety provisions outlined by the proposed rule is invalidated by judiciary action, then the rule, as a whole, would no longer adequately protect public health and would be invalidated by the Trump Administration. Therefore, if there is a legal challenge to the proposed rule, all SIPs could be in jeopardy. Furthermore, the Canadian government may be a mitigating factor in the success of any SIP. According to the proposed rule's supply-chain provisions, a "foreign seller" must be a Canadian wholesaler licensed by Health Canada and approved by the FDA. However, the Canadian government has made it clear that it wishes to protect its national supply chain for the benefit of its own citizens. Therefore, it is unclear if Health Canada will provide foreign sellers with the certification they need to participate in a SIP or if, over time, they may limit Canadian wholesaler participation.

The proposal does contain a specific request for comments about an alternative proposal that would allow drug wholesalers or pharmacists to serve as SIP sponsors. It also asks for comments on whether "non-governmental entities other than pharmacists and wholesalers, such as group purchasing organizations, pharmacy benefit managers [PBMs], or union health and welfare benefit plans, should be permitted to co-sponsor SIPs." Given the overall limitations of SIPs and the potential threat to the Canadian supply chain if SIPs are deemed by the Canadian government to be limiting for its citizens, NAHU members do not support expansion of the SIP concept to other entities at this time. Instead, we recommend that the FDA continue with the policy practices that are already providing millions of American consumers with safe access to legitimate pharmaceuticals from other countries.

As you know, Section 801 (d) (1) of the Food, Drug and Cosmetic Act bans all importation of prescription drugs manufactured in the U.S. except by the manufacturer in order to prohibit wholesale distribution of U.S. prescription drugs bought in other countries by other commercial entities. However, given the realities of our global economy and personal and business travel, since 1954 the FDA has maintained a personal-use enforcement exemption that allows individuals to reimport up to a 90-day supply of non-scheduled prescription drugs purchased through legitimate pharmacies in other countries for personal use, provided that such drugs are "considered not to represent an unreasonable risk."

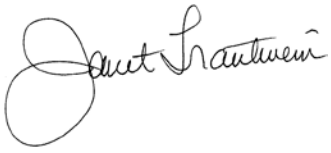
Millions of individual consumers, including many Medicare beneficiaries, routinely reimport personal-use drugs during the course of business and personal travel or through specific trips to bordering countries like Canada. According to a 2016 Kaiser Family Foundation health tracking poll, eight percent of Americans indicate that they purchase prescription drugs outside of the United States. This figure represents approximately 19 million people, according to current

population estimates. Additionally, the United States International Trade Commission indicates that between 150,000 and 320,000 directly name health travel as their specific reason for travelling outside of the United States. Furthermore, American employer group plan sponsors have embraced the concepts of medical tourism and personal-use importation as means of helping to mitigate prescription drug costs. The state of Utah currently operates a well-publicized program for state employees, whereby it reimburses employees with certain high-cost-drug expenses and pays for travel and a $500 bonus if these employees obtain certain specialty prescriptions from specific Canadian and Mexican pharmacies.

NAHU members have a vast number of clients who utilize the current personal-use exemption. Given the limited nature of the proposed rule, and the huge number of Americans who obtain benefit from the FDA's existing personal-use importation exemption, NAHU hopes that when finalizing this measure, you take steps to ensure and clarify that nothing in it precludes the continuation of your existing policies. Furthermore, in order to finalize and implement this measure and comply with Section 804 of the Food, Drug and Cosmetic Act, the Administration must certify to Congress that drug importation will "pose no additional risk to the public's health and safety." NAHU asks that in providing this certification you act in a broad manner so as to not negatively affect the personal-use importation process that is currently helping millions of Americans better afford their prescription drugs.

NAHU sincerely appreciates the opportunity to provide comments on the proposed rule. If you have any questions or need additional information about our thoughts on this critical matter, please do not hesitate to contact me at either (202) 595-0639 or jtrautwein@nahu.org.

Sincerely,



Janet Stokes Trautwein
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