Alliance of Specialty Medicine

20TH ANNIVERSARY

Sound Policy. Quality Care.

March 9, 2020

Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

RE: FDA-2019-N-5711, "Importation of Prescription Drugs"

Dear Commissioner Hahn:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians, and is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. The undersigned members of the Alliance write to provide feedback on the Food and Drug Administration's proposed rule entitled "Importation of Prescription Drugs."

The proposed regulation seeks to implement Section 804 Importation Programs (SIPs) through the Food Drug and Cosmetic Act. A SIP would be approved by FDA and managed by States or certain other non-federal governmental entities, and could be co-sponsored by a pharmacist, a wholesaler, or another State or non-federal governmental entity. A SIP would last for 2 years with the possibility of extensions for 2-year periods. To be eligible for importation, prescription drugs must be sold legally on either the Canadian market or the American market with appropriate labeling and currently be marketed in the United States.

As practicing specialists, we are keenly aware of the burden high out-of-pocket costs can create for patients, with detrimental effects on adherence and disease management. We commend the Administration for its continued focus on these issues, but, as outlined below, ensuring the integrity and safety of products moving through our drug supply chain must be paramount.

The Agency asks whether there are other entities, such as pharmacy benefit managers (PBMs), who should be allowed to participate as co-sponsors in a SIP. ***We strongly oppose empowering PBMs to participate in SIPs***. In our view, PBMs have become a harmful part of our national drug supply chain and any proposal to further broaden their role is extremely concerning. PBMs have failed to control coinsurance and copay costs for patients because they do not pass through the price concessions they negotiate from manufacturers. Additionally, they harm patient care by delaying or denying patients' access to needed medications. Currently, the Administration and Congress are attempting to create some transparency and accountability in this industry through various policy proposals; we urge the agency not to undermine these needed initiatives by providing additional power to the PBM industry in its current form.

We strongly support the categorical exclusion of certain products, such as biologics, due to safety reasons. We have always urged caution for any policies related to biologics, as these are complex, sometimes fragile products that may require specialized storage and handling requirements. For that reason, they do not lend themselves to safe importation by entities and individuals who may not be trained or equipped to properly handle these types of products. Similarly, controlled substances are not good candidates for a SIP and we support their exclusion. Our country's opioid crisis is far from resolved and opening up another distribution channel for these products would be ill-advised.

While not statutorily exempted, other categories of drugs will be ineligible for importation due to the Agency's judgment that these products cannot, at this time, be safely imported. For example, FDA will exclude drugs that are subject to risk evaluation and mitigation strategies (REMS) and both intrathecally and intraocularly injected parenteral drugs. Since intraocular injections pose significant risks and raise concerns of potential impact on adjacent tissue, we strongly support this exclusion. Additionally, REMS may include restricted distribution channels, which would be difficult to protect if our national supply chain is no longer closed. As such, ***we strongly support the agency's cautious approach with regard to these products.***

There are additional categories of products that were considered for exclusion, but FDA proposes instead to consider them for importation on a product-by-product basis. The concept of case-by-case determination raises significant questions: who would conduct these reviews within the agency? What requirements would have to be met? Will these reviews divert scarce resources from other drug-related agency priorities? This process seems burdensome for the agency. A more safety-conscious and resource-saving approach would be to simply exclude products for which there is any potential safety concern warranting additional review.

Thank you for your consideration of our comments. Please do not hesitate to reach out to any of the undersigned organizations, should you have questions or require additional information.

Sincerely,

American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations