AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

President
Nick Mamalis, MD

Executive Director
Steve Speares

February 28, 2020

Stephen M. Hahn, MD
Commissioner
The Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

Dear Commissioner Hahn:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing nearly 7,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care.

We appreciate this opportunity to provide comments on the proposed rule entitled "Importation of Prescription Drugs."

In our comments on this proposed rule, we:

- **Strongly support the proposal to exclude intraocular and biologic products from importation to ensure patient safety and quality assurance of these drugs.**
- **In addition, we support FDA's proposal that all other sterile and ophthalmic drugs be considered on a product-by-product basis for importation.**
- **We also encourage the FDA to use caution when determining who can participate as co-sponsor of an authorized Section 804 Importation Program (SIP) and strongly oppose pharmacy benefit managers (PBMs) from participating as SIPs.**

<u>Importation of Ophthalmic Drugs</u>

ASCRS supports the exclusion of intraocular injections and biologic drugs from importation for patient safety reasons. Contaminated intraocular injections pose risks to the eye and could significantly impact the delicate adjacent tissue. We also agree with the agency's rationale that this route of administration poses extreme risks as it will bypass some of the body's natural defenses, and contaminated drugs could quickly cause lasting damage to a patient's vision. Given the potential threat to patients' eyesight from contaminated drugs and the high risks associated with this route of administration, we support the exclusion.

In addition to intraocular injections, ASCRS supports FDA's proposal to exclude biologic products from importation. Biologics, especially those that are injected intraocularly, are complex and may require specialized storage, including temperature, packaging, and handling requirements. While the proposed rule addresses these factors, we are concerned that the importation pathway would pose significant risks to patients if biologic injections—particularly for intraocular use—were included. For these reasons, biologic drugs do not lend themselves to safe importation.

For drugs that are not injected intraocularly and where the risk of contamination is significantly less, we support the proposal to have all other ophthalmic and sterile drugs reviewed on a product-by-product basis. However, we have concerns that developing yet another complicated review system could create an unnecessary burden on the agency's limited resources. We have questions regarding implementation of the review process for each product that will be determined. Who will be reviewing these products? What requirements would have to be met to be approved for importation? We encourage the FDA to provide more information in regard to the review process for prescription drugs that will determined on a product-by-product basis for importation and then allow for further stakeholder comments.

PBMs

ASCRS strongly opposes allowing PBMs to participate in SIPs, due to lack of transparency and cost savings passed on to the patient. ASCRS applauds the FDA for taking steps to lower prescription drug prices and reduce out of pocket costs for patients, while still ensuring the safety and effectiveness of drugs imported through its proposal to allow importation of certain prescription drugs shipped from Canada. In the proposed rule, the FDA would authorize states or certain other non-federal governmental entities to be SIPs. A SIP could be co-sponsored by a pharmacist, a wholesaler, or another state or non-federal governmental entity. The agency requested feedback on whether PBMs should be allowed to participate as co-sponsors in a SIP.

PBMs act as the middleman in negotiating cost with drug manufactures and pharmacies; yet, they often fail to pass down rebate and discount savings to patients. Furthermore, PBMs limit their formularies, ultimately denying patients access to the medications they need. **While we recognize that the administration has recently proposed polices to address these issues with PBMs**, **none of them have been finalized to date.** Furthermore, expanding their reach into SIPs would not be consistent with the administration's overall goals to reduce the cost of prescription drugs for patients. **For these reasons, we strongly urge the FDA to exclude PBMs from participating in SIPs.**

We support the agency's efforts to address drug costs and access to prescription drugs for patients. We would be pleased to provide further input or clarification of our comments, as needed. Please contact Allison Madson, manager of regulatory affairs, at 703-591-2220 if you have any questions or would like to arrange a meeting.

Sincerely,

Nick Mamalis, MD
President, ASCRS