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March 9, 2020

Stephen M. Hahn
Administrator
Food and Drug Administration
Docket No. FDA-2019-N-5711
5360 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: FDA-2019-N-5711: Importation of Prescription Drugs**
84 Fed. Reg. 70796 (December 23, 2019)

Dear Administrator Hahn:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Importation of Prescription Drugs proposed rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influences evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

More than 1.7 million new cancer cases are expected to be diagnosed in the United States this year.[1] Drug therapies play an integral role in cancer treatment. Advances in research have improved our understanding of cancer at the molecular level – leading to the development of more precise detection and diagnostic tools and corresponding therapies that are able to more specifically attack cancer. Both cancer patients and survivors rely on drug therapies to treat their disease and prevent recurrence. As more innovative therapies become available, we need to make sure that patients who are likely to benefit from these advances can also afford them so that we can achieve the national goal of eliminating death and suffering from cancer.

We commend the Administration for examining ways to tackle the problem of prescription drug affordability. However, we are concerned that the proposal as outlined raises a number of serious questions about the administrative feasibility, safety and actual savings for consumers. We have these concerns despite the fact that according to the proposal, the U.S. Food and Drug Administration (FDA) would not include all drugs in the new program but would limit the scope to only certain drugs imported from Canada.

For example, the preamble notes that the "Federal Government would incur one-time fixed as well as ongoing costs to implement the rule … and to review [Section 804 Importation Program] (SIP) Proposals

[1] American Cancer Society, *Cancer Facts and Figures* 2020, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf.

and reports."[2] But while the costs of the proposed program are certain, the savings are uncertain – the proposed rule states that the FDA is "unable to estimate the savings from the proposal because it lacks information about the likely size and scope of the SIP programs and about the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the United States, and which SIP-eligible products are produced by U.S. drug manufacturers."[3] We are seriously concerned that without added resources, the costs and human capital needed to implement and monitor this program risks diverting resources needed to carry out critically important existing drug review and oversight mechanisms at FDA. The safety and efficacy of our nation's prescription drug supply cannot be compromised for the promise of savings that may or may not materialize.

## V. DESCRIPTION OF THE PROPOSED RULE

### B. Definitions

FDA proposes to define prescription drugs that would be subject to possible importation as those drugs that could be sold legally on either the Canadian market or the American market with appropriate labeling. The FDA proposes to exclude several categories of drugs including controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs subject to risk evaluation and mitigation strategies (REMS). The FDA considered, but decided against, excluding drugs requiring special storage conditions, modified-release drugs, and sterile drugs.

ACS CAN supports FDA's proposal to exclude several categories of drugs from importation. We agree that due to the unique issues associated with the categories of drugs identified by the FDA (e.g., controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs subject to REMS) that these drugs should not be subject to an importation program.

### C. Section 804 Importation Program Proposals and Section 804 Pre-Import Requests

#### *1. The Section 804 Importation Program Proposal*

Under the proposed rule, before a SIP could import prescription drugs from Canada it would need to submit a proposal to the FDA, including an overview of the SIP sponsor's, SIP proposal, and SIP sponsor's importation plan. Among the items included in the SIP plan would be an identification of the repackager or re-labeler in the United States that would relabel the imported drugs with the required U.S. labeling, including the carton and container labels, prescribing information, and any patient labeling, such as medication guides, instruction for use documents, and patient package inserts. FDA seeks comment on whether a SIP Proposal should also be required to describe the SIP Sponsor's plan for ensuring that the FDA-approved patient labeling is dispensed to patients with the imported drug.[4] The SIP Proposal would also need to explain how the SIP Sponsor expects that the SIP would result in a significant reduction in the cost to the American consumer of the prescription drug imported under the SIP Plan.

*Patient labeling*: As proposed the SIP Sponsor would only need to identify the entity that would relabel the imported drugs. ACS CAN urges the FDA to go a step further and require the SIP Sponsors' plans to

[2] 84 Fed. Reg. at 70825.
[3] Id.
[4] 84 Fed Reg at 70807.

provide details on how they would ensure that the appropriate FDA-approved labeling is dispensed to the patient. The FDA-approved label for patients provides helpful information on what the prescription drug is supposed to do and how to effectively use the medication.

*Expectation of consumer savings*: While we appreciate that the FDA is proposing to require the SIP to explain how its proposal would result in savings to consumers, it is unclear how a SIP could demonstrate ultimate savings to the end user (e.g., a specific patient) because the SIP Sponsor, in most cases, is not a health plan administrator and thus would not be in a position to ensure savings are accruing to the patient. In addition, we note that drug prices may vary over the course of a year, and thus we would strongly encourage the FDA to require that as part of their SIP Proposal, SIP Sponsors detail how they will ensure that consumers realize savings over the course of the SIP Plan, and not just in certain months.

**I. Listing and Labeling of Eligible Prescription Drugs**

We agree with the requirement for conspicuous labels indicating drugs that have been imported through this Section 804 process so that pharmacists and consumers will know when they have received an imported drug. We further agree with the use of a unique national drug code (NDC) that will enable tracking of any adverse events tied to imported drugs. While we understand the rationale for not breaching closure systems in order to repackage some drugs, we do have some concerns that Canadian packaging (e.g., printing on foil blister pack backing) may have informational elements incorporated in that packaging that may be hard to obscure and could result in confusion if it is not concordant with U.S. labeling information.

**CONCLUSION**

Thank you for the opportunity to comment on the Importation of Prescription Drugs proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network