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March 9, 2020

The Honorable Stephen Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: FDA-2019-M-5711; Importation of Prescription Drugs Proposed Rule

Dear Commissioner Hahn:

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates the opportunity to provide comments on the Importation of Prescription Drugs proposed rule. As you are aware, the ever-increasing costs of prescription drugs continue to place significant financial strain on our patients and the health care system. We are pleased to see the Food and Drug Administration's (FDA) continued focus on this important issue.

Access to affordable medications is an issue of utmost importance to AMA members and their patients. Over the last several years, we have seen prices for new therapies reach numbers previously unimaginable. Prices for some older branded and generic medications have also skyrocketed, seemingly without reasonable justification for the increases. This disturbing trend has required our patients to make decisions they should not have to make—in some cases rationing or skipping doses to make expensive prescriptions last longer or potentially forgoing treatment altogether. The time has come for meaningful action to ease the financial burdens on our patients so they can access the prescription drugs they need and take their medications as prescribed. The AMA continues to encourage federal agencies and stakeholders to work towards new, innovative and sustainable solutions to this ever-growing problem.

The AMA supports efforts to import lower-cost prescription medications, so long as certain safeguards are in place to ensure product safety, quality, integrity, and authenticity. As such, the AMA welcomes initiatives by the FDA to explore allowing the importation of prescription drug products by wholesalers, pharmacies and other entities. However, the current proposal to create state-based programs to import prescription drugs from Canada raises questions and serious concerns that we urge the FDA, as well as the Department of Health and Human Services (*HHS*), to consider prior to moving towards finalization.

Ensuring the Safety, Quality, Integrity, and Authenticity of Imported Drug Products

As mentioned above, the AMA supports efforts to import lower-cost prescription drug products in the U.S., so long as safeguards are in place to ensure the safety of these drug products for our patients. The AMA supports the legalized importation of prescription drug products by wholesalers and pharmacies only if all drug products are FDA-approved and meet all other FDA regulatory requirements; if the drug

distribution chain is closed; and all drug products are subject to reliable track and trace technology. The AMA is concerned with the precedent set by allowing prescription drug products imported under Section 804 Importation Programs (SIPs) to be exempt from certain requirements of the Drug Supply Chain Security Act (DSCSA), and how that will impact full implementation of the Act by 2023. While we are pleased to see the proposed rule lay out additional safeguards to protect the supply chain as outlined in the proposed rule pursuant to the proposed exemptions, the AMA questions whether they will be sufficient to assure prescription drug product quality, authenticity, and integrity.

Traditionally, drug distribution within the U.S. has been a “closed” system, with the FDA serving as the centralized authority for monitoring drug manufacturing safety and quality and ensuring proper post-market surveillance and monitoring of drug-related adverse events. Moving to a state-based program of acquisition and distribution of drugs from foreign markets starts to somewhat de-centralize this authority, allowing for certain elements of oversight of imported drugs to potentially differ from state to state. Having a range of state-based programs also creates the potential for gaps or other information fragmentation in reporting and communication regarding adverse events and recalls for imported drug products. At the same time, the proposed rule stated that resource constraints can limit the FDA’s authority to provide effective safety oversight in this space. As such, we strongly urge the FDA to consider how best to ensure consistent application of FDA requirements across SIPs and to ensure seamless coordination among SIPs in the event of adverse events associated with imported drug products.

Availability of Prescription Drug Products from Canadian Suppliers

In order to ensure prescription drug importation results in lower drug prices for U.S. patients, those drug products must be easily available for import from foreign markets. Following the release of the FDA’s Safe Importation Action Plan in 2019, questions were raised regarding the ability of the Canadian market to meet the potential demand for products for import into the U. S. Should Canadian suppliers be unable or unwilling to provide drugs for import into the U.S., moving towards finalization of this proposal would be essentially meaningless and could potentially create confusion for U.S. patients. We urge the FDA and HHS to fully assess the ability of Canadian suppliers to participate in these programs before finalization of this rule.

Assuring Savings for U.S. Patients and Reducing Administrative Burdens

While the AMA supports proposals aimed at importing prescription drug products as a method of lowering drug costs in the U.S., with appropriate safeguards in place, it follows that U.S. patients should be assured they will see the savings resulting from these programs. When considering programs such as the SIPs proposed here, we have some concerns about the possibility that savings resulting from the importation of less-costly drugs from foreign markets may not ultimately be passed down to patients, but instead be absorbed by others within the distribution system. It seems foreseeable that savings captured by drug distributors, payors, or others could indeed stay with those parties, while patients do not see any corresponding reductions to insurance premiums, co-insurance amounts, or retail prices at the pharmacy counter. The FDA acknowledges within this proposal only that U.S. patients “may” experience savings and that drug distributors may pass “some” of these savings to consumers and other parties within the supply chain. Given the significant financial burdens placed on our patients by high drug costs, the AMA firmly believes that any programs created to realize savings from lower drug costs must benefit patients directly, not create a taxpayer-funded program that finds savings only for corporate members of the drug supply chain.

In addition to ensuring savings generated from this proposal are passed directly to patients, we urge the FDA to provide clarity on how physicians and pharmacists should consider the interchangeability of these products. Product selection confusion, as well as product interchangeability questions, could present issues and hassles for prescribing physicians, as well as at the pharmacy level, raising additional questions whether patients would be able to even access prescription drug products imported under SIPs.

The current proposal also raises additional questions about availability and access to these lower-priced, imported drugs. The AMA foresees that there could be issues with payment and coverage of imported products and how they will be designated throughout administrative/payment systems and at pharmacies in order to ensure patients benefit from the savings these drugs may provide. Accordingly, the AMA underscores the need for the FDA to work with HHS, the Centers for Medicare & Medicaid Services, private payers, and others to address how imported drug products will fit in to the current system for prescription drug coverage and payment, especially considering more than one SIP could potentially be operational within a geographic area. In addition, we could foresee situations in which patient access to lower cost, imported drug products could vary widely, even among plans and/or pharmacies within the same state. We urge the federal health agencies to work collaboratively to identify pathways by which patients will directly benefit from the savings generated through proposed importation programs prior to finalization.

Prescription Drugs Approved for Importation

Should the FDA determine that programs to import prescription drugs from Canada are viable and can ensure that savings from these programs directly benefit U.S. patients, we urge the FDA to consider reevaluating the drugs it approves for participation in SIPs. A number of high-priced prescription drug products that cause significant financial strain for our patients are excluded from participation in the SIPs under the current proposal. The AMA understands that importation of some medications may pose increased safety risks due to factors such as increased transit time when shipped from Canada. For drug products at higher risk of sterility, stability, or other safety and quality issues, we agree that these should not be considered for participation in importation programs. However, where importation would not pose additional risks to the quality and integrity of the product, but could offer significant savings for our patients, we urge FDA to consider allowing importation of those drug products. SIPs are unlikely to generate savings if drugs that create the most financial strain for patients are excluded from the programs. The high price of prescription drugs continues to be an issue of utmost importance to our members and their patients, as well as one of the most pressing problems facing our health care system. We applaud the FDA for its continued focus in this important area and its efforts to ensure robust competition in the market and continued availability of affordable treatment options. The AMA supports the FDA's consideration of importation as a method to ensure availability of lower-priced medications in the U.S. However, we have continuing questions about the overall viability of the proposal, how best to ensure consistent application of standards to ensure safety across state-based programs, how to ensure patients directly benefit from savings generated by the program, and how to best determine which drugs are included in the program. We urge the FDA to work collaboratively with other federal health departments and agencies, as well as stakeholders, to address these questions and concerns prior to finalization of this proposal.

We thank you for the opportunity to provide input on this important proposal. We look forward to continuing to work with you on this and other important actions to ensure the affordability of prescription

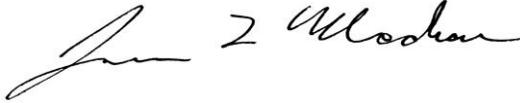
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drugs for our patients. Should you have any questions or wish to discuss further, please do not hesitate to contact Shannon Curtis, Assistant Director, Federal Affairs, at Shannon.Curtis@ama-assn.org or 202-789-8510.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim L Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD