AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

February 20, 2020

The Honorable Stephen Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(b) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry

Dear Commissioner Hahn:

On behalf of the physician and medical student members of the American Medical Association, I appreciate the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) recently released draft guidance regarding the importation of certain FDA-approved human prescription drug and biological products. We applaud the FDA's continued efforts to address competition and pricing in the prescription drug and biological product market under its existing authorities. We are pleased to see this work continue with the release of draft guidance potentially enabling certain prescription drug products to be offered to patients at lower list prices.

AMA policy has long called for actions by the Administration and Congress to lower the cost of prescription drugs. The AMA supports importation of prescription drug products as a method to potentially lower drug costs for American patients, provided that patient safety and product quality, authenticity, and integrity can be assured. To the extent this proposal can result in lower costs to American patients, the AMA urges the Administration to move towards finalization.

While we support moving forward, we are concerned that the current proposals on prescription drug importation may not ultimately impact amounts paid by patients for prescription drug products in a meaningful way. For example, while the draft guidance may allow manufacturers to offer certain products in the U.S. market at lower list prices than currently available, there is little evidence that shows that this savings will be passed on to patients. Furthermore, it is unclear how prescription drug products offered with a new National Drug Code (NDC) will be treated by health plans and offered to insured patients given that they may be outside the scope of current arrangements with payers and/or pharmacy benefit managers. Changes to the current system of contracting for prescription drug products, without proper policies in place, could cause disruption to the market that may ultimately result in increased costs to patients (e.g., higher premiums). There is also the possibility for increased administrative burdens for many parties in the health care system by management of what could be multiple NDC codes for the same drug product. While we understand payer policies for coverage and payment of prescription drug products are well outside FDA's scope and authority, we strongly encourage the FDA to consider all possible implications of these proposals and to move towards finalization only when the agency can be assured

that these changes in policy will result in direct savings for health care consumers and not create significant administrative burdens for stakeholders across the health care system.

Along with impacts on patient drug costs, patient safety is of the utmost importance when considering importation of foreign-manufactured drug products marked for sale in foreign markets. AMA policy requires assurances of the quality and safety of any prescription drug products imported into the United States. Any proposal to allow for the importation of prescription drug products into the U.S. must ensure that all drug products are subject to reliable electronic track and trace requirements and meet all other FDA regulatory requirements regarding the authenticity and integrity of the products in question. We therefore urge the FDA to include these requirements in any final guidance allowing for importation of multi-market approved products.

At a time when prescription drug prices are quickly reaching unsustainable levels, we must look for new and creative solutions to ensure that patients can afford and have access to critical drug products. In a marketplace that has consistently proven resistant to changes that benefit American consumers, we applaud FDA for taking steps to improve competition and lower prices for prescription drugs. Where drug importation can be achieved safely and can ensure lower costs for health care consumers, the AMA supports these actions. However, we encourage FDA to consider the possible unintended consequences of policy changes in this space before moving towards finalization of the draft guidance.

We look forward to continuing to work with you on these important issues. Please do not hesitate to contact Shannon Curtis, Assistant Director of Federal Affairs at shannon.curtis@ama-assn.org or 202-789-8510 with any questions concerning these comments.

Sincerely,

James L. Madara, MD