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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.

March 9, 2020

The Honorable Stephen M. Hahn, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: NPRM "Importation of Prescription Drugs," Dkt. No. FDA-2019-N-5711, 84 Fed. Reg. 70796 (December 23, 2019)

The American College of Cardiology (ACC) would like to thank you for the opportunity to comment on the notice of proposed rulemaking by the Food and Drug Administration (FDA), "Importation of Prescription Drugs". The American College of Cardiology (ACC) envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines.

The twenty-first century has ushered in a new era of innovation, leading to novel therapies and cures for diseases and conditions that were not thought possible previously. However, it has also brought on unsustainable spending on drugs. Far too many seniors and individuals living at or close to the poverty line are forced to choose between critical medications and other necessities.

The ACC has long advocated that access to healthcare is not merely about availability; but cost plays a significant role in access and must be treated as such. The cost of many prescription drugs poses a significant obstacle for patients seeking treatment in today's health care environment. The ACC is committed to addressing this public health challenge and protecting patient access to high-quality care and is supportive of initiatives that address these issues. The ACC supports affordable access for all patients, regardless of coverage or lack thereof, to all approved prescription drugs with scientific evidence of net clinical benefit or as articulated in clinical practice guidelines. Excessive out-of-pocket expense represents an insurmountable hurdle for many patients. The ACC believes it's essential to diminish any healthcare related financial barriers including co-pays, co-insurance and deductibles.

An attempt to implement section 804 of the Food, Drug and Cosmetic Act to allow importation of some prescription drugs from Canada could be helpful for some medications and seems worth pursuing if it can be done safely and effectively. Currently, much of the U.S. drug supply is manufactured overseas. The FDA estimates that nearly 40 percent of finished drugs and 80 percent of active pharmaceutical ingredients (API) are manufactured in registered establishments in more than 150 countries (GAO, 2016). As this notice of proposed rulemaking pertains to drugs being imported specifically from Canada, the College is in favor of this provision as the GAO has reported that Canada is one of 10 countries most frequently inspected by the FDA.

To further aid with informed accessibility, the College believes accurate information on drug prices, plan benefits, formulary changes and discounts should be readily available for clinicians and patients for discussions regarding excepted cost-sharing and treatment plans. The College believes that pricing decisions should emphasize value assessed through analysis of comparative and cost-effectiveness.

The ACC appreciates the opportunity to provide these comments and welcome the opportunity to provide further feedback if requested. If you have any questions or concerns, please contact Sarah Cartagena at scartagena@acc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Kovacs". The signature is fluid and cursive, with the first name "Richard" and last name "Kovacs" clearly distinguishable.

Richard J. Kovacs, MD, FACC
President, American College of Cardiology

GAO. (2016, December). Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices. Retrieved from <https://www.gao.gov/assets/690/681689.pdf>