Robyn Boerstling

Vice President

Infrastructure, Innovation and Human Resources Policy

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Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, S.W., Room 600E
Washington, D.C. 20201

Office of the Administrator
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

Submitted via: http://regulations.gov

On behalf of the 14,000 members of the National Association of Manufacturers, the largest manufacturing association in the United States, the NAM submits these comments to the Department of Health and Human Services and its Food and Drug Administration. We request a full reconsideration of the Notice of Proposed Rulemaking on the Importation of Prescription Drugs through a State Importation Plan (Pathway 1) and urge the FDA to withdraw this proposal. Pathway 1 would introduce a new drug supply through an unproven process that risks eroding the high public health standards that U.S. prescription drugs are held to and could needlessly expose Americans to lower quality or even counterfeit drugs. Further, importing price-controlled drugs from Canada conflicts with our market-based system and innovation.

The NAM represents small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes $2.3 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for more than three-quarters of all private-sector research and development in the nation. Pharmaceutical manufacturers contribute to 28 percent of total manufacturing R&D. The NAM is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The publicly managed Canadian health system differs significantly from the American market-based system that provides consumer choice and honors innovation. Drug purchasing in Canada is managed at the provincial level and Health Canada does not make product safety guarantees to the United States. Further, the Pathway 1 importation proposal would be an intentional deviation from the uniquely American track and trace system authorized in 2013, that is now being implemented nationally to more comprehensively protect patients from counterfeit products. Unfortunately, Canada does not have a compatible or comparable program to track and trace. Waiving track and trace requirements would create new opportunities for counterfeit or unsafe drugs to enter the U.S. drug supply.

Additionally, Pathway 1 does not implement or follow the letter of a 2003 law that allows importation under a set of stringent criteria requiring the Secretary of HHS to certify the safety and cost savings of imported medicines. To date, no HHS Secretary has made this certification,

and the NPRM does not make a compelling case that explains the precise cost savings for patients as there are unknowns associated with State Importation Plans. The NPRM acknowledges that the government lacks information to estimate savings for patients, making cost savings an assumed outcome. Additionally, the NPRM does not rebut past bipartisan HHS opposition to drug importation. It is likely that significant compliance measures for importation could erode savings for patients, but that dynamic is neither tested nor fully understood, further contributing to the questions associated with this unproven proposal.

We believe that the four pillars that have made America exceptional—free enterprise, competitiveness, individual liberty and equal opportunity—must guide the search for solutions. Importing price controls to our innovative, free-market economy would be highly problematic, undercutting innovation and neglecting to address many of the most important cost drivers in our own health care system. There is no question that skyrocketing health care costs are disrupting families and businesses around the country. However, allowing imported drugs from Canada is not a real solution. Manufacturers stress that the drug importation proposal runs counter to many of the core economic principles and values that drive the American economy. Progress can and should be made by reforming existing programs and avoiding new government-driven proposals that are contrary to basic free market principles.

The NAM has long opposed the importation of prescription drugs as it is not a matter of free or fair trade. Drug importation is simply an importation of a medicine directly purchased by a foreign government and lacks the strong safeguards Americans have come to know and trust from our drug safety system. There cannot be any doubt or uncertainty when it comes to patient safety and their well-being. Manufacturers support a successful, competitive and affordable health care system that is second to none and appreciate the opportunity to request that the administration withdraw its importation of prescription drugs proposal.

Comments Submitted by:

Robyn M. Boerstling
Vice President, Infrastructure, Innovation and Human Resources Policy
National Association of Manufacturers
733 10th Street NW, Suite 700
Washington, DC 20001