April 24, 2019

Norman E. Sharpless, M.D.
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Sharpless:

We, the undersigned organizations, write to congratulate you on your recent appointment to be Acting Commissioner of the Food and Drug Administration (FDA). Though the agency faces challenges presented by a number of pressing public health issues, we ask that you continue to prioritize efforts to reform the monograph system for over-the-counter (OTC) drugs. Dr. Janet Woodcock and former Commissioner Gottlieb worked successfully with both chambers of Congress to develop policy to modernize this system and to address this urgent public health need through the bipartisan, bicameral Over the Counter Drug Safety, Innovation and Reform Act. With a consensus having emerged across FDA, industry, and public health stakeholders, it is our hope that FDA will continue to work with Congressional leaders toward final passage and implementation of this legislation.

Though millions of Americans depend on nonprescription OTC products, oversight of the market has been burdened by an outdated framework and a lack of agency resources. Reform of the monograph system is long overdue, and this legislation would streamline regulation for these drugs, transitioning away from the current rulemaking process and authorizing the use of administrative orders. This would provide the agency with the flexibility necessary to promptly respond to emerging public health threats. This flexibility would also allow for greater product innovation

Additionally, through a modest user fee, the Agency would have resources to oversee this market and to clear the substantial backlog of unfinished monographs, providing patients and consumers with greater confidence in the safety of OTC products and more choice among products that might best meet their health needs.

As public health stakeholders, we believe this bill reflects the key principles essential to the enhanced oversight of the 34 billion-dollar market for nonprescription drugs[i] that will improve consumer safety and product innovation. We thank you for your commitment to public health and the efficient use of FDA resources and look forward to working with you to ensure passage and implementation of these reforms. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Sarah Despres at the Pew Charitable Trusts at sdespres@pewtrusts.org or (202) 540-6601.

Sincerely,

American Academy of Allergy, Asthma & Immunology
American Academy of Pediatrics
American Public Health Association
Consumer Healthcare Products Association (CHPA)
March of Dimes
National Association of County and City Health Officials (NACCHO)
The Pew Charitable Trusts
Society for Maternal-Fetal Medicine

CC: Chairman Lamar Alexander, Ranking Member Patty Murray, Chairman Frank Pallone, Jr., Ranking Member Greg Walden

[i] https://www.chpa.org/PR_OTCRetailSales.aspx