September 10, 2018

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Charles Schumer
Minority Leader
United States Senate
Washington, D.C. 20510

The Honorable Paul Ryan
Speaker
United States House of Representatives
Washington, D.C. 20515

The Honorable Nancy Pelosi
Minority Leader
United States House of Representatives
Washington, D.C. 20515

Dear Leader McConnell, Leader Schumer, Speaker Ryan, and Leader Pelosi:

We, the undersigned organizations representing a diverse group of professional medical, public health, industry and consumer interest organizations, write to offer our support for the bipartisan effort to reform the over-the-counter (OTC) monograph system and urge its final passage. As the Food and Drug Administration (FDA) itself acknowledges, the current regulatory system overseeing most OTC medicines is inefficient and burdensome, preventing the agency from quickly updating OTC monographs when needed, such as in response to safety concerns or other issues. Reform is long overdue, and both chambers have advanced legislation with overwhelming support. More than 60 percent of all medicines on the market today are OTC. So, while we understand that there are many important issues before the Congress, it is vital that both the House and Senate prioritize OTC monograph reform and finalize legislation before the work period ends. By coming to accord on the few remaining differences between the two bills, Congress can ensure that the FDA has the tools necessary to safeguard public health and advance the interests of both patients and industry.

Americans rely on a wide variety of OTC drugs for their everyday health needs. This marketplace includes over 300,000 unique OTC drug products[1] with annual sales of $34 billion.[2] Yet, the framework for evaluating these medications, established in 1972,[3] has not kept pace with scientific discovery or consumer use. As an example, in September 2016, FDA published a final rule for OTC consumer antiseptic washes, 42 years after the process to update the monograph began.

We appreciate that both chambers have done considerable work to establish a streamlined system for the FDA's review of OTC drugs. The House and Senate bills transition from the current formal rulemaking process to a more nimble administrative order procedure. This better positions FDA to take appropriate action in the event of a safety concern and to respond to the latest science with updates in dosage and labeling. Additionally, the user fees authorized by both bills provide the FDA with needed resources, increasing the agency's capacity to review OTC ingredient applications, clear the backlog of

[1] Food and Drug Administration, "Drug Applications for Over-the-Counter (OTC) Drugs," accessed Dec. 19, 2016, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm.
[2] OTC Retail Sales 1964-2017," Consumer Healthcare Products Association, accessed September 6, 2018, https://chpa.org/OTCRetailSales.aspx.
[3] U.S. Department of Health and Human Services, Food and Drug Administration, "Procedures for Classification of Over-the-Counter Drugs," 37 Fed. Reg. 9464 (May 11, 1972).

unfinished monographs, and respond expeditiously if safety concerns emerge. Enacting these changes will move FDA's OTC monograph system into the 21st century, reflecting goals supported by FDA, the OTC drug industry, and public health stakeholders alike.

More efficient regulation will empower FDA and allow drug makers to bring innovative options to market—both of which serve the public health. We thank you for your leadership on this issue and encourage both chambers to expeditiously finalize reform of FDA's OTC monograph system.

Sincerely,

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, Senator Johnny Isakson, Senator Bob Casey, Chairman Michael Burgess, Ranking Member Gene Green, Representative Brett Guthrie, Representative Bob Latta, Representative Diana DeGette, and Representative Debbie Dingell