

October 30, 2019

The Honorable Lamar Alexander
United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
United States Senate
154 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

We, the undersigned organizations, thank you for your support of public health and for your work on the bipartisan Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019. As organizations representing public health advocates, health care providers, and manufacturers of nonprescription drugs and sunscreens, we applaud your efforts to modernize the Food and Drug Administration's (FDA) over-the-counter (OTC) monograph system and are glad to see that the bill is proceeding to a Committee mark up. As FDA itself acknowledges, the current regulatory system was designed decades ago, and reform is long overdue. Congress must now act to make these reforms a reality.

As demonstrated by the recent finalization of the antiseptic hand wash monograph, 45 years after initial notice of proposed rulemaking, the current framework does not allow FDA to keep pace with the science in a timely way. This bill would streamline agency oversight, transitioning from the current formal rulemaking process to a more nimble administrative order procedure. Through this change, FDA will be better positioned 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 the bill will provide FDA with needed resources, increasing the agency's capacity to review OTC ingredient applications, clear the backlog of unfinished monographs, and respond expeditiously if safety concerns emerge. Speeding FDA's ability to make changes to OTC monographs will encourage product innovation, which will enhance choice and allow patients and consumers to better meet their specific health needs.

Without action on this legislation, FDA will miss out on new resources necessary for timely review and the agency will be forced to continue working under an inefficient regulatory framework that simply cannot keep up with today's science. A more efficient regulatory structure will enable the agency to better ensure safety and allow manufacturers to bring innovative options to market. Should you have any questions or require additional information, 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
March of Dimes

National Association of County and City Health Officials
Protecting Access to Pain Relief Coalition
Public Access to SunScreens Coalition
The Pew Charitable Trusts
Society for Maternal-Fetal Medicine

CC: Senator Johnny Isakson, Senator Bob Casey