

April 23, 2018

The Honorable Johnny Isakson  
United States Senate  
131 Russell Senate Office Building  
Washington, DC 20510

The Honorable Bob Casey  
United States Senate  
393 Russell Senate Office Building  
Washington, DC 20510

Dear Senators Isakson and Casey:

We, the undersigned organizations, write in support of the manager's amendment to S. 2315, the bipartisan Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018. As organizations representing public health advocates, health care providers, and manufacturers of nonprescription drugs, we applaud your efforts to modernize the Food and Drug Administration's (FDA) OTC monograph system. As FDA itself acknowledges, the current regulatory system was designed decades ago, and reform is overdue. For this reason, we sincerely appreciate your prioritization of monograph reform and urge Congress to pass this legislation promptly.

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.

More efficient regulation of OTC products is good for industry and good for consumers. It will give FDA more flexible tools to ensure safety and allow drug makers to bring innovative options to market. We thank you for your leadership on this issue and look forward to the bill's passage. Should you have any questions or desire additional information, please do not hesitate to contact Sarah Despres at the Pew Charitable Trusts at [sdespres@pewtrusts.org](mailto: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  
National Association of County and City Health Officials  
The Pew Charitable Trusts  
Society for Maternal-Fetal Medicine

CC: Chairman Lamar Alexander, Ranking Member Patty Murray