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April 3, 2018

The Honorable Bob Latta  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Diana DeGette  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Michael Burgess  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Gene Green  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Brett Guthrie  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Debbie Dingell  
U.S. House of Representatives  
Washington, DC 20515

Dear Representatives Latta, DeGette, Burgess, Green, Guthrie and Dingell:

We write in support of the bipartisan H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018. Millions of Americans use OTC health products every day, and as organizations dedicated to promoting public health, we appreciate your efforts to modernize the Food and Drug Administration's (FDA) monograph system for nonprescription drugs. For too long, oversight of OTC products has been burdened by an outdated regulatory framework and a lack of resources. This bill would change that, and we urge its prompt passage.

This legislation would provide for the timely response to potential safety concerns by transitioning from the current rulemaking process to administrative orders. Through this change alone, the bill greatly improves the efficiency of OTC oversight, providing FDA with the flexibility necessary for the timely response to emerging public health threats while also encouraging innovation in the OTC market.

Furthermore, by establishing a modest user fee system, the bill would provide FDA with the resources necessary to fully implement the reforms in this bill and provide effective OTC review and monitoring. With greater resources, the agency will be better able to clear the backlog of unfinished monographs, providing patients and consumers with greater confidence and choice in the OTC products they use to address their health needs.

This bill reflects the key principles we believe to be essential in any comprehensive monograph reform and we believe its implementation will greatly enhance oversight of the OTC market. We thank you again for your work on this issue and appreciate the opportunity to provide our

comments. 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

March of Dimes

National Association of County and City Health Officials (NACCHO)

The Pew Charitable Trusts

Society for Maternal-Fetal Medicine

CC: Chairman Greg Walden, Ranking Member Frank Pallone, Jr.