

May 9, 2018

The Honorable Greg Walden
U.S. House of Representatives
Washington, DC 20510

The Honorable Frank Pallone, Jr.
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Walden and Ranking Member Pallone:

We, the undersigned organizations, write in support of H.R. 5333, the bipartisan “Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018” which will reform the over-the-counter (OTC) drug monograph system. We are grateful for the committee’s efforts to improve the current inefficient regulatory system and appreciate the inclusion of stakeholder feedback and comments in this draft. Our organizations previously developed principles that we agreed were critical for any reforms to the current OTC drug monograph system. In our view, the legislation addresses our key principles and, as such, we encourage the prompt passage of this bill.

As the subcommittee is aware, the current inefficient and burdensome rulemaking process prevents FDA from quickly updating monographs to respond to safety concerns. 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. In spite of FDA’s determination that 19 chemicals, including triclosan, were unsafe, it took until December 2017 for FDA to issue a similar rule for health care antiseptic products. And additional antiseptic monographs await FDA’s final rule.

The proposed bill would modernize the monograph system and would improve agency efficiency and patient safety by giving FDA the authority to finalize monographs in accordance with its review of the evidence and streamline that review process as new evidence is submitted. Moreover, the modest user fee program will enhance FDA’s ability to respond swiftly and effectively to such safety concerns, to review OTC ingredient applications in a timely manner, and to encourage sponsors to submit OTC innovations. These changes would provide FDA with the tools it needs to protect the public health.

We thank you again for considering legislation that would modernize FDA’s current authority to ensure that OTC products are safe. 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
March of Dimes

National Association of County and City Health Officials (NACCHO)

The Pew Charitable Trusts

Society for Maternal-Fetal Medicine

CC: Chairman Michael Burgess, Ranking Member Gene Green, Representative Brett Guthrie, Representative Bob Latta, Representative Diana DeGette, and Representative Debbie Dingell