

June 14, 2017

The Honorable Johnny Isakson
U.S. Senate
Washington, DC 20510

The Honorable Bob Casey
U.S. Senate
Washington, DC 20510

Dear Senators Isakson and Casey:

We, the undersigned organizations, write to offer our strong support and gratitude for your bipartisan effort to reform the over-the-counter (OTC) drug monograph system. We applaud your leadership on this important issue, and thank you for taking the steps necessary to improve the current regulatory system. We appreciate this revised draft incorporates stakeholder feedback and comments; additional final comments may come under separate cover. However, the undersigned are in agreement that OTC monograph reform can and should be included within the Food and Drug Administration Reauthorization Act (FDARA) of 2017.

The Food and Drug Administration, industry, and public health stakeholders are in clear consensus that OTC drug regulation reform is long overdue and should be a top priority for this Congress. Your proposed legislation would authorize the FDA to handle safety concerns appropriately and swiftly, and streamline OTC drug regulation, thus making significant and much needed improvements to the OTC regulatory process.

Currently, making a simple amendment to an existing monograph, even those which enhance safety, initiates a burdensome rulemaking process. This creates undue delay for the public good and is an inefficient use of public resources. Your proposed bill would modernize the OTC regulatory framework to become more science-based and responsive to public health concerns, encourage sponsor submission of innovative OTC advances, and provide resources to enhance FDA's capacity to review OTC ingredient applications in a timely and consistent manner.

We thank you again for your hard work on this legislation, and for your commitment to safeguarding the public's health and ensuring efficient use of FDA resources. We look forward to working with you to ensure FDARA includes your proposed legislation to modernize the OTC regulatory process. 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 Pediatrics
American Public Health Association
Consumer Healthcare Products Association
March of Dimes
National Association of County and City Health Officials
The Pew Charitable Trusts
Society for Maternal-Fetal Medicine

CC: Senator Lamar Alexander, Senator Patty Murray