

May 17, 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:

The Pew Charitable Trusts is an independent, nonpartisan research and policy organization with a longstanding focus on the quality and safety of drugs and medical devices. We applaud your strong bipartisan discussion draft on comprehensive over-the-counter (OTC) drug monograph reform, and we appreciate the opportunity to provide our comments. A more detailed markup of the draft legislation is enclosed for your consideration.

Your proposed legislation would enhance efficiency and improve patient safety by establishing a more streamlined system for the Food and Drug Administration's review of OTC drug ingredients and conditions of use. By including OTC monograph reform in the user fee system, this proposal will ensure FDA has the resources necessary to keep up with evolving science and ensure that nonprescription drugs are safe and effective. Further, FDA will have the flexibility it needs to take expedited action when a drug, class of drugs, or combination of drugs poses an imminent hazard, or when a labeling change is expected to mitigate a serious harm, enhancing the agency's ability to address safety issues.

By authorizing the Secretary to issue administrative orders to permit new uses, dosage forms and other developments that are generally recognized as safe and effective (GRAS/E), this bill greatly improves efficiency, and will encourage innovation in the OTC market. New OTC options will enhance consumer choice and may augment safety. The legislation also enables the agency to specify the kinds and format of information needed for it to make decisions about ingredients and uses, which will enhance FDA's performance and productivity.

Our enclosed comments identify opportunities to further enhance this legislation by evaluating the efficiencies of procedures and the appropriateness of the product differentiation period, and by clarifying FDA's authority to specify packaging. While we offer these recommendations for your consideration, we reiterate our support for this bipartisan draft legislation, which would significantly enhance efficiency and safety compared to the existing monograph system.

We look forward to working with your offices to ensure the Food and Drug Administration Reauthorization Act of 2017 includes meaningful OTC drug monograph reform. Thank you for the opportunity to comment. 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 or (202) 540-6601.

Sincerely,

Elizabeth Jungman
Director, Public Health Programs
The Pew Charitable Trusts

Kirsten Moore,
Director, Health Care Products
The Pew Charitable Trusts