

April 28, 2017

The Honorable Lamar Alexander
Chair
Senate Health, Education, Labor and Pensions
Committee
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor and Pensions
Committee
U.S. Senate
Washington, DC 20510

The Honorable Greg Walden
Chair
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Alexander, Ranking Member Murray, Chairman Walden, and Ranking Member Pallone:

We write to offer comment on the Senate and House health committees' discussion draft of the Food and Drug Administration's Reauthorization Act (FDARA) of 2017. We recognize the importance of renewing the user fee agreements in a timely fashion, which would help to provide the Food and Drug Administration (FDA) with increased resources and tools to review drug and device applications, and ultimately fulfill its mission of protecting the public's health, in a timely manner. Yet the current discussion draft omits a product category where FDA, industry, and public health stakeholders agree that reform is necessary to protect the public health and encourage innovation: over-the-counter drugs.

As Congress works to reauthorize the user fees, we urge you to adopt comprehensive OTC monograph reform accompanied by user fees to properly resource FDA's engagement with this product category. Congress has tasked the Food and Drug Administration (FDA) with upholding safety standards for medical products while simultaneously incentivizing scientific discovery. The over-the-counter (OTC) monograph system, by which the FDA reviews the safety and effectiveness of active ingredients in OTC drugs, was established in 1974 and has not been updated since.

Under the current regulatory process, publishing a new or amended OTC monograph requires the FDA to go through a formal rulemaking process, which may take years, or even decades, to formally resolve. Until the FDA finalizes pending changes on a monograph, OTC products with unsafe or ineffective ingredients can legally remain on the market.

We urge you to enact policy that will streamline and modernize FDA's OTC monograph system. By doing so, the monograph system becomes more flexible, evidence-based, and responsive to emerging public health concerns. Reform will also encourage sponsors to submit future applications for innovative OTC products knowing the applications will not be delayed by administrative burden.

We recognize that resource constraints limit FDA's ability to implement these reforms, and that reform is necessary, but not sufficient, to ensure the FDA's capacity to monitor and address emerging safety and effectiveness issues. Approximately 20 FDA staff are responsible for reviewing and monitoring the OTC market - which represents almost \$32 billion in annual sales. For this reason, we also recommend you provide FDA with the adequate staff and resources needed to successfully protect the public's health.

Without reform, other user fee and non-user fee areas under FDA's purview will continue to drain resources away from OTC review and monitoring. The proposed scope of OTC user fees is relatively

small compared with other user fee agreements. However, the fees are critical to ensuring the agency's ability to clear a backlog of unfinished monograph issues to allow for greater innovation.

We thank you for your work on this important public health and policy issue. We look forward to working with you to ensure FDARA of 2017 includes comprehensive OTC monograph reform and the appropriate resources required for its implementation. Should you have any questions, please do not hesitate to contact Sarah Despres at the Pew Charitable Trusts at sdespres@pewtrusts.org or (202) 540-6601 or Marc Schloss at the Consumer Healthcare Products Association at mschloss@chpa.org or (202) 429-3533.

Sincerely,

American Academy of Allergy Asthma & Immunology
American Academy of Pediatrics
American Public Health Association
Consumer Health Care Products Association
March of Dimes
National Association of County and City Health Officials
Pew Charitable Trusts