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:

We, the undersigned organizations representing a diverse group of professional medical, public health, and consumer interest organizations, write to offer our support for your bipartisan effort to reform over-the-counter (OTC) drug regulations. We appreciate that the discussion draft released last week seeks to enhance the Food and Drug Administration's (FDA) efficiency and improve patient safety – goals which are supported by FDA, the over-the-counter drug industry, and public health stakeholders alike. It is vital that the FDA have the tools to keep up with evolving science and ensure that nonprescription drugs are safe and effective.

Americans routinely purchase and consume a wide variety of OTC drugs. This marketplace includes over 300,000[i] unique OTC drug products and has annual sales of $32 billion.[ii] But the framework for evaluating these medications, established in 1972,[iii] has not kept pace with scientific discovery or consumer use, putting consumers at risk and slowing innovation of OTC drugs. Both industry and the FDA support the proposed legislation that will eliminate the burdensome formal rulemaking process, and modernize FDA's OTC monograph system.

The undersigned organizations have endorsed six core principles which we believe should be incorporated in any effort to streamline and modernize FDA's OTC monograph system. Based on our analysis of the discussion draft, we have identified below where we believe the proposal addresses our principles. While some organizations may submit issue specific comments under separate cover, we are encouraged by the proposal and hope the committee will move forward with including meaningful OTC monograph reform in the *Food and Drug Administration Reauthorization Act* of 2017.

Specifically, the draft language will:

Eliminate the rule-making process for creating and updating the OTC monograph system so FDA has a more efficient mechanism for making changes.

Section 505G(c) authorizes the Secretary to issue administrative orders determining the conditions under which drugs, classes of drugs, or combination of drugs are deemed generally recognized as safe and effective. This will replace the current rulemaking process which includes reviews by outside agencies and requires FDA to receive and respond to public comment throughout the revision process. The additional review steps for monographs add considerable time and there is no deadline by which monographs must be finalized. We support language that will streamline the review process.

Allow FDA to take swift action to address emerging safety issues regarding the use and misuse or abuse of OTC drugs.

Currently FDA is unable to respond quickly to new information – even when safety and efficacy concerns arise. Updating OTC monographs—whether to make a basic change or to reflect a safety concern—can take many years.

Section 505G(c)(5) provides the Secretary with an expedited procedure for administrative orders when a drug, class of drugs, or combination of drugs poses an "imminent hazard to the public health," and when changes in labeling are "reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event[.]" Refinements to this language to clarify FDA's authority would further enhance it's ability to fulfill its mission of safeguarding the public health in a timely manner, but overall we support the need for an expedited process so that FDA can act quickly on emerging safety issues.

Allow FDA to accommodate innovation in OTC drug products, permitting new uses, dosage forms, and other developments that have been demonstrated to be safe and effective.

Innovations in OTC products create new options for consumer use and in some instances may offer additional safety advantages. Section 505G(b)(6) permits entities engaged in marketing, manufacturing, processing, or developing nonprescription drugs to initiate an administrative order. These entities seeking FDA determination that a new drug or condition of use can be incorporated into an OTC drug product can file a request with the Secretary. Coupled with additional resources, these provisions will make it easier for innovative new OTC products and uses to reach the market.

Include an efficient mechanism for FDA to receive and compile data to make determinations of safety and effectiveness, including a means to obtain the data from industry within a reasonable time frame and a standardized procedure to facilitate data submission, collection, and analysis.

Stakeholder submissions to inform FDA's decisions about drug products are not submitted in a standardized format. Thus, reviewers often must evaluate large volumes of unorganized, sometimes out-of-date, material and collate that information into a form that permits meaningful review. Furthermore, because FDA has no authority to require specific data from manufacturers and there is no obligation to submit negative evidence, the agency must conduct its own rigorous analysis to ensure the record is complete.

Several places in the discussion draft provide FDA authority to specify the format for submissions to the agency: section 505(c)(3)(B)(i)(II) for administrative orders initiated by the Secretary; section 505(c)(6)(B)(i) for orders initiated by a requestor; section 505(l) for all submissions under section 505G. Furthermore, section 505G(c)(3)(B)(iii) requires that those submitting data in support of a determination that a drug or use is generally recognized as safe and effective certify that they have submitted *all* evidence created, obtained, or received. This will help ensure that FDA receives all relevant data and information.

Establish FDA as the final arbiter of scientific evidence on the safety and effectiveness of ingredients and changes to monographs, as is true for prescription drugs and medical devices.

Decisions regarding the safety and effectiveness of drug products are scientific decisions that FDA has the appropriate expertise to make. Currently decisions about ingredients and conditions of use are made by FDA for prescription drug products, but most OTC drugs must go through a more complicated regulatory process. By converting the regulatory process into an administrative order process, the proposed legislation would align decision-making authority for OTC products with the authority for prescription drugs, such that in both circumstances decisions about ingredients and conditions views are made by the agency scientists with relevant expertise.

Ensure that FDA has adequate resources devoted to OTC oversight.

FDA's ability to implement these regulatory reforms is limited without sufficient resources. Without reform, competing demands will limit the resources available for OTC review and monitoring; indeed, statutory requirements that fix the ratio of appropriated funds to user-fee funds for other product categories mean that areas such as OTC review may be especially under-resourced. Enhanced funding is critical to ensuring the agency's ability to clear a backlog of unfinished monograph reforms, allow for greater innovation, and address safety issues in a timely way. The user fees in Section 3 of the discussion draft will help provide additional resources dedicated to the OTC program.

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Legislation that addresses these principles will make the system for oversight of OTC drugs and their conditions of use more flexible and evidence-based, and will permit the agency to respond more rapidly to evolving science and new information on the safety and effectiveness of both new and existing nonprescription drugs.

We thank you for your work to make the OTC drug system safer and more efficient, and for the opportunity to provide input on the development of legislation to advance this important public health and policy issue. We look forward to continued collaboration with your offices to ensure the Food and Drug Administration Reauthorization Act of 2017 includes comprehensive OTC drug monograph reform.

Sincerely,

American Academy of Pediatrics
American Public Association
March of Dimes
National Association of County and City Health Officials
The Pew Charitable Trusts
Society for Maternal-Fetal Medicine

[i] Food and Drug Administration, "Drug Applications for Over-the-Counter (OTC) Drugs," accessed Dec. 19, 2016, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm.

[ii] "OTC Retail Sales 1964-2015," Consumer Healthcare Products Association, accessed Nov. 18, 2016, http://www.chpa.org/PR_OTCRetailSales.aspx.

[iii] U.S. Department of Health and Human Services, Food and Drug Administration, "Procedures for Classification of Over-the-Counter Drugs," 37 Fed. Reg. 9464 (May 11, 1972).