



September 04, 2025

The Honorable Brett Guthrie  
Chairman  
House Energy and Commerce  
Subcommittee on Health  
2434 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone Jr.  
Ranking Member  
House Energy and Commerce  
Committee  
2107 Rayburn House Office Building  
Washington, DC 20515

The Honorable Bill Cassidy, M.D.  
Chairman  
Senate Health, Education, Labor, and  
Pensions Committee  
455 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Bernie Sanders  
Ranking Member  
Senate Health, Education, Labor, and  
Pensions Committee  
332 Dirksen Senate Office Building  
Washington, DC 20510

Dear Chairmen Guthrie and Cassidy and Ranking Members Pallone and Sanders:

As members of the Patient, Consumer, and Public Health Coalition (PCPH), we are working with the Food and Drug Administration and other stakeholders to ensure that the user fee program for over-the-counter (OTC) products fulfills its goals to ensure that submissions are reviewed in a timely manner with adequate evidence for their safe and effective use in the United States. The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations that represent millions of Americans.

The Over-the-Counter Monograph Drug User Fee Amendments (OMUFA) were established as part of the 2020 Coronavirus Aid, Relief, and Economic Security Act (CARES Act; PL 116-136) and will expire on September 30, 2025. We understand the impending negotiations between the House and Senate for the final version of OMUFA II and are writing to share concerns about the evidentiary requirements for OTC products that include ingredients in sunscreens for use by American consumers.

We appreciate your consideration of these recommendations related to the proposed amendment by Senators Banks and Kim<sup>1</sup> and the final legislation on nonprescription or OTC sunscreen active ingredients.

## **Concerns regarding Senators Banks and Kim Amendment – Least Burdensome Approach**

### 1. Lowering FDA Burdens Means Raising the Burden and Risks for Consumers and Patients

The "least burdensome approach" in the proposed Banks–Kim amendment is similar to that in MDUFA (P.L.112-144 Section 602)<sup>2</sup>. The FDA defines the Least Burdensome Approach as "...the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time."<sup>3</sup> In practice, this means that during the premarket review of medical devices, staff at the FDA may ask for additional information from a sponsor about their product, and sponsors can determine whether the agency's request is relevant or necessary to fulfill the statutory criteria for clearance or approval. This may seem reasonable, but when the "least burdensome approach" was adopted by MDUFA, it resulted in lowering standards of evidence in ways that harmed patients. When FDA required less information from companies, information about the risks and benefits of that product was less accurate or dependable. This shifts the burden from companies to patients, consumers, and healthcare providers since they need to make medical and healthcare decisions without essential information. Although the FDA states that "The least burdensome provisions do not change the standards for premarket approval or substantial equivalence,"<sup>4</sup> in reality, it has contributed to the clearance and approval of medical products that are not beneficial and where little evidence is publicly available about risks or benefits. Although OTC products are less expensive than most medical products, millions of consumers buy them and they deserve to be able to trust their quality and safety.

### 2. Additional Meetings between FDA and Industry are not in the OMUFA II Commitment Letter and Would Divert Critical Resources

The Banks-Kim amendment also encourages additional meetings between the FDA and industry beyond those outlined in the OMUFA II Proposed Commitment Letter that was negotiated between the FDA and the industry. These meetings are very time-consuming for FDA staff, and reduces their availability for other critical functions, such as reviewing publicly available contamination or safety data or responding to Citizen Petitions about ineffective or unsafe OTC drugs. If industry wanted additional meetings with FDA staff, that would require higher user fees that should have been negotiated to cover these additional costs and specified in the Commitment Letter. Given the dramatic staff cuts at the FDA this year, requiring more meetings would be especially harmful without additional fees to pay for additional staff.

## **Postmarket Safety Activities for OTC [monograph] drugs**

We applaud the Senate for requiring the FDA to report on postmarket safety activities [Sec 5 (a)(vi)] by collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports; and by developing and using improved analytical tools, and adverse event data-collection systems. To protect consumers and patients, we urge lawmakers to maintain the Senate wording on postmarket surveillance in the final text for the reauthorization of OmuFA.

The Senate bill (S 2292) outlines the sunscreen final administrative order [Sec 6 (b)(3)] to incorporate the evidence and testing standards for sunscreen active ingredients detailed in section 505G(r) of the FDCA. We strongly support the inclusion of this provision in the final bill because otherwise the FDCA Section 505G allows for the marketing of sunscreen when there is insufficient data or not enough information to categorize them as "GRASE" [Generally recognized as safe] or "not GRASE [not generally recognized as safe]."<sup>5</sup>

In conclusion, we thank you for your work to protect the health and well-being of American consumers through the reauthorization of OmuFA. We urge you to continue to strengthen FDA's public health mission to make America healthy again by protecting consumers and prioritizing the safety and effectiveness of OTC monograph drugs, as recommended above.

Sincerely,

Doctors for America

Jacobs Institute of Women's Health

Medical Device Problems

National Center for Health Research

Our Bodies Ourselves

Patient Safety Action Network (PSAN)

TMJ Association

USA Patient Network

Washington Advocates for Patient Safety

Woodymatters

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<sup>1</sup> Senators Banks and Kim amendment <https://www.help.senate.gov/imo/media/doc/2cb7d0cb-0612-89b1-b50c-ec1d7aef26d3/Kim%20S.%202292%20Amendment%20%231.pdf>

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<sup>2</sup> PUBLIC LAW 112–144—JULY 9, 2012. 126 STAT. 993. <https://www.congress.gov/112/statute/STATUTE-126/STATUTE-126-Pg993.pdf>

<sup>3</sup> FDA. GUIDANCE DOCUMENT. The Least Burdensome Provisions: Concept and Principles. *Guidance for Industry and FDA Staff*. FEBRUARY 2019. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles#:~:text=We%20define%20%22least%20burdensome%22%20to,manner%20at%20the%20right%20time.>

<sup>4</sup> Sections 513(a)(3)(D)(iv), 513(i)(1)(D)(iii), and 515(c)(5)(D) of the FD&C Act

<sup>5</sup> FFDCa 505G(a)(3) [21 U.S.C. 355h(a)(3)]. The FFDCa 505G “allows for certain OTC monograph drugs not yet subject to a final GRASE determination to continue to be marketed, specifically if the drug is classified in Category III in a TFM [tentative final monograph] or Category I under an ANPR [advanced notice of proposed rulemaking] and meets the applicable requirements for OTC drugs (these drugs are expected to eventually be subject to FDA-initiated administrative orders);”