June 6, 2023

Office of Management and Budget
Office of Information and Regulatory Affairs
725 17th St., NW
Washington D.C. 20503

Re: Request for Comments on Guidance Implementing Section 2(e) of the Executive Order of April 6, 2023, Docket OMB-2022-0011, 88 Fed. Reg. 20916 (April 7, 2023)

The undersigned organizations submit these comments on the Draft Guidance Implementing Section 2(e) of the Executive Order of April 6, 2023 (Modernizing Regulatory Review) ("Draft Guidance").[1] That section concerns the process for the public to request meetings with the Office of Information and Regulatory Affairs ("OIRA") officials regarding the substance of regulatory actions under OIRA review pursuant to Executive Order 12866, hereinafter referred to as "12866 meetings." Many of the undersigned organizations have participated in numerous 12866 meetings concerning proposed regulations and guidances issued by the U.S. Food and Drug Administration ("FDA") to implement the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA").

The Draft Guidance indicates that "OIRA is considering a variety of strategies to facilitate participation [in 12866 meetings] by those who have not historically requested E.O. 12866 meetings, including those from underserved communities." Draft Guidance, at 4. We write in strong support of this objective and of the specific strategies under consideration to advance that goal:

- design new OIRA tools to help members of the public request and participate in 12866 meetings;
- periodic public training on effective participation in 12866 meetings to reach communities that have not historically participated in those meetings;
- improving notice of 12866 meeting opportunities;
- consulting with the public to better understand current barriers to communicating information about and participating in 12866 meetings and identifying potential strategies for overcoming those barriers;
- reviewing and improving data collection related to 12866 meetings and identifying gaps in participation; and
- making the 12866 meeting request form more prominent in relevant areas of reginfo.gov.

See Draft Guidance at 4-5.

Efforts to improve participation in 12866 meetings by underserved communities are particularly important for regulatory actions involving tobacco products because those products take a

[1] https://www.whitehouse.gov/wp-content/uploads/2023/04/ModernizingEOSection2e DraftGuidance.pdf.

disproportionate toll of disease and death in certain of those communities, worsening long-standing health disparities. For example, due to decades of targeted marketing by cigarette companies directed at the Black community, menthol cigarettes are smoked by 85% of Black people who smoke, compared to 30% of white people who smoke.[2] To this day, Black Americans have the highest death rates and shortest survival for most tobacco-related cancers of any racial or ethnic group.[3] Menthol cigarettes are also disproportionately smoked by other underserved populations, many of which have been targeted by the industry, including Hispanic people, lesbian and bisexual people, those with severe psychological distress and those who live in poverty. A proposed rule prohibiting menthol as a characterizing flavor in cigarettes is currently pending at FDA;[4] once the proposed rule undergoes OIRA review, it will be critical for OIRA to hear from the communities most affected by those products.

The Executive Order on Modernizing Regulatory Review of April 6, 2023 provides that "[o]pportunities for public participation shall be designed to promote equitable and meaningful participation by a range of interested or affected parties, including underserved communities."[5] However, it must be admitted that, for the public generally, and particularly for underserved communities, the OIRA regulatory review process is largely opaque and inaccessible. The result, as the Draft Guidance observes, is "the risk or the appearance of disparate and undue influence on regulatory development." Draft Guidance at 4.

We urge OIRA to move forward to finalize the Draft Guidance and begin to implement, as quickly as possible, the reforms it proposes to proactively engage interested or affected parties, including those that have not historically requested 12866 meetings and those from underserved communities.

Respectfully submitted,

Action on Smoking & Health
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

---

[2] *See generally* Comments of public health, medical, education, civil rights and community organizations on Tobacco Product Standard for Menthol in Cigarettes, Docket No. FDA-2021-N-1349, at 20-21 (Aug. 2, 2022), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/Support_Prohibiting_Menthol_Cigarettes_8_2_2022.pdf.

[3] *Id.* at 20.

[4] 87 Fed. Reg. 26,454 (May 4, 2022).

[5] https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/06/executive-order-on-modernizing-regulatory-review/.