



March 19, 2024

The Honorable Joe Biden
 President of the United States
 The White House
 1600 Pennsylvania Ave NW
 Washington, DC 20500

Dear Mr. President:

In December 2023, the 22 undersigned organizations, whose collective missions have been to work for decades to save lives from cancer, submitted a letter to implore you to finalize the Food and Drug Administration’s (FDA’s) proposed rules on eliminating menthol as a characterizing flavor in cigarettes and all characterizing flavors in cigars, both as written, by the end of the calendar year. As that date has passed without finalization of the rules and the Unified Agenda deadline of March 2024 is rapidly approaching, we write to you again to ask that you finalize these rules now.

We remain deeply troubled by the delay in the release of these rules and are concerned this year could end without finalization. Our organizations are committed to working with you to achieve your Cancer Moonshot goal to “end cancer as we know it.” Lives cannot be saved from cancer without reducing tobacco use and we cannot reduce tobacco use without eliminating menthol as a characterizing flavor in cigarettes and eliminating all characterizing flavors in cigars.

Everyone in America has been impacted by cancer in some way. There are more than 18 million people — our friends, family members, and neighbors — who have a history of cancer, most who were diagnosed years ago no longer with evidence of disease.¹ Unfortunately, the number of people with cancer continues to grow. In 2024, a little over 2 million Americans will be diagnosed with cancer and approximately 611,720 Americans will die from the disease.

¹ American Cancer Society. Cancer Facts & Figures 2023. Atlanta: American Cancer Society; 2023.

Tobacco² use is the leading cause of preventable death in the U.S., with more than 480,000 deaths each year caused by cigarette smoking,³ including 30% of all cancer deaths.⁴ Smoking increases the risk for cancers of the lung, mouth, larynx (voice box), pharynx (throat), esophagus, kidney, cervix, liver, bladder, pancreas, stomach, and colon/rectum. It also raises the risk of acute myeloid leukemia.⁵

Tobacco use is one of the primary causes of cancer-related health disparities — disproportionately impacting people by race, ethnicity, sexual orientation, gender identity, disability status, mental health, income and education levels, and geographic location.^{6,7,8} For example, as much as 40% of cancer deaths in parts of the South and Appalachia are still caused by smoking.⁹ Eliminating cancer disparities depends heavily on eliminating tobacco use.

Research shows that while overall cancer mortality rates in the U.S. are dropping, populations that have been marginalized are bearing a disproportionate burden of cancer.¹⁰ This is especially true of tobacco-related cancers with the disproportionate burden among communities of color, limited-income communities, and other populations that have been marginalized and targeted by the tobacco industry for use of their addictive products. Commercial tobacco use is responsible for 80% of lung cancer deaths, with death rates higher for men than women, non-Hispanic Black and American Indian and Alaska Native individuals than for white individuals, and highest in the South and parts of Appalachia in the U.S. This is not surprising, given these are also the populations with some of the highest tobacco use rates due in large part to tobacco industry targeting.

Saving lives from cancer will take thoughtful public policy and programmatic efforts that leave no one behind. Our community combating cancer works to provide patient services, advance research, and

² Our organizations recognize the important role of ceremonial tobacco for many Indigenous communities. This letter is intended to address commercial tobacco, not the provision, possession, or use of tobacco products as part of an Indigenous practice or other recognized religious or spiritual ceremony or practice. All references to tobacco and tobacco products in this letter refer to commercial tobacco.

³ US Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Washington, DC: US Department of Health and Human Services, CDC; 2014. Available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

⁴ Islami F, Goding Sauer A, Miller KD, Siegel RL, Fedewa SA, Jacobs EJ, McCullough ML, Patel AV, Ma J, Soerjomataram I, Flanders WD, Brawley OW, Gapstur SM, Jemal A (2018) Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin* 68: 31-54

⁵ American Cancer Society. *Cancer Facts & Figures 2023*. Atlanta: American Cancer Society; 2023.

⁶ Irvin Vidrine J, Reitzel LR, Wetter DW. The role of tobacco in cancer health disparities. *Curr Oncol Rep*. 2009 Nov;11(6):475-81. doi: 10.1007/s11912-009-0064-9. PMID: 19840525; PMCID: PMC5031414.

⁷ Webb Hooper M. Editorial: Preventing Tobacco-Related Cancer Disparities: A Focus on Racial/Ethnic Minority Populations. *Ethn Dis*. 2018 Jul 12;28(3):129-132. doi: 10.18865/ed.28.3.129. PMID: 30038472; PMCID: PMC6051506.

⁸ Tong EK, Fagan P, Cooper L, Canto M, Carroll W, Foster-Bey J, Hébert JR, Lopez-Class M, Ma GX, Nez Henderson P, Pérez-Stable EJ, Santos L, Smith JH, Tan Y, Tsoh J, Chu K. Working to Eliminate Cancer Health Disparities from Tobacco: A Review of the National Cancer Institute's Community Networks Program. *Nicotine Tob Res*. 2015 Aug;17(8):908-23. doi: 10.1093/ntr/ntv069. PMID: 26180215; PMCID: PMC4542844.

⁹ Islami F, Bandi P, Sahar L, Ma J, Drope J, Jemal A. Cancer deaths attributable to cigarette smoking in 152 U.S. metropolitan or micropolitan statistical areas, 2013-2017. *Cancer Causes Control*. 2021;32: 311-316.

¹⁰ American Cancer Society. *Cancer Facts & Figures 2022*. Atlanta: American Cancer Society; 2022.

advocate for evidence-based public policies designed to reduce pain and suffering due to cancer and reduce health care disparities. The elimination of menthol as a characterizing flavor in cigarettes is one of the most important public policy actions this administration can take to save lives from cancer and is fully supported by scientific evidence.

The FDA's Tobacco Product Scientific Advisory Committee (TPSAC) Report *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* concluded that "Removal of menthol cigarettes from the marketplace would benefit public health in the United States."¹¹ The FDA's *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* and *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021*¹² concluded that: "These findings, combined with the evidence indicating that menthol's cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."

The FDA's most recent scientific review¹³ concluded menthol is associated with:

- "...positive smoking experiences that contribute to cigarette smoking...
- ...progression to regular cigarette smoking among youth and young adults...
- ...greater dependence in youth.
- ...reduced cessation success among African American smokers...and...likely associated with reduced cessation success among the general population."

The consequences of menthol cigarettes and the tobacco industry's targeted marketing have been great, and not fully quantified. One study that looked at how menthol increased the number of people who smoked and died found that from 1980 to 2018, menthol cigarettes were responsible for 10.1 million extra people who smoke, 3 million life years lost and 378,000 premature deaths.¹⁴ Specifically, among Black Americans, menthol cigarettes were responsible for 1.5 million new people who smoke, 1.5 million life-years lost, and 157,000 smoking-related premature deaths.¹⁵ To understand this disparity these figures represent, respectively, 15%, 41%, and 50% of the total harm caused by menthol cigarettes while Black Americans comprise 12% of the total U.S. population.

¹¹ Tobacco Product Scientific Advisory Committee, FDA. *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*. 2011.

¹² FDA. *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021* April 2022. <https://www.fda.gov/media/86497/download>

¹³ FDA. *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021* April 2022. <https://www.fda.gov/media/157642/download>

¹⁴ Le TT, Mendez D. An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018. *Tob Control*. 2021 Feb 25;tobaccocontrol-2020-056256. doi: 10.1136/tobaccocontrol-2020-056256. Epub ahead of print. PMID: 33632809; PMCID: PMC8384947.

¹⁵ Mendez D, Le TTT. Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018. *Tob Control*. 2021 Sep 16;tobaccocontrol-2021-056748. doi: 10.1136/tobaccocontrol-2021-056748. Epub ahead of print. PMID: 34535507; PMCID: PMC8924008.

Finalizing the proposed rule to eliminate menthol as a characterizing flavor in cigarettes and all characterizing flavors in cigars can end this devastation and save lives from cancer, along with many other health conditions. Published studies estimate that the elimination of menthol as a characterizing flavor in cigarettes could save between 324,000 to 654,000 lives over the next 40 years.¹⁶ The rules will particularly benefit those populations that have been most impacted by tobacco industry targeting of menthol cigarettes and flavored cigars, including youth, young adults, and Black people. Notably, in July 2023, 32 members of the Congressional Black Caucus wrote to FDA Commissioner Robert M. Califf, M.D., “in strong support of the proposed rule the Food and Drug Administration (FDA) announced in April 2022 to remove menthol as a characterizing flavor in cigarettes.”¹⁷

Your administration has already taken decisive action in many areas of cancer research, prevention, treatment, and survivorship to save lives from cancer. We ask that you finalize FDA’s proposed rules to eliminate menthol as a characterizing flavor in cigarettes and all characterizing flavors in cigars, both as written, now to save lives from cancer and reach your Cancer Moonshot goals. Any further delay in the promulgation of these rules will lead to more needless illness and suffering. We stand ready to work with you to support the implementation of these rules.

Thank you,

American Cancer Society Cancer Action Network

American Association for Cancer Research

American Lung Association

Association for Clinical Oncology (ASCO)

Association of American Cancer Institutes

Bladder Cancer Advocacy Network

Dana-Farber Cancer Institute

Free ME from Lung Cancer

GO2 for Lung Cancer

Hope for Stomach Cancer

LiveLung

Lung Cancer Research Foundation

LUNGevery Foundation

Moffitt Cancer Center

National Comprehensive Cancer Network

National LGBT Cancer Network

Oncology Nursing Society

Pennsylvania Prostate Cancer Coalition (PPCC)

¹⁶ Food and Drug Administration. Proposed Rule: Tobacco Product Standard for Menthol in Cigarettes. 21 CFR Part 1162 [Docket No. FDA-2021-N-1349] RIN 0910-AI60.

¹⁷ Letter from Rep. Robin Kelly et al. July 31, 2023. <https://robinkelly.house.gov/sites/evo-subsites/robinkelly.house.gov/files/evo-media-document/menthol-letter-8.1.2023.pdf>

Prevent Cancer Foundation
Roswell Park Comprehensive Cancer Center
Streak For A Cure, Inc.
Upstage Lung Cancer

CC:

Stephen K. Benjamin
Assistant to the President, Senior Advisor to the President and Director of the White House Office of
Public Engagement

Danielle Carnival
Deputy Assistant to the President for the Cancer Moonshot and Deputy Director for Health Outcomes
in the White House Office of Science and Technology Policy

Tom Perez
Senior Advisor and Assistant to the President and Director of the Office of Intergovernmental Affairs

Richard Revesz
Administrator, Office of Information and Regulatory Affairs

Neera Tanden
Domestic Policy Advisor

The Honorable Shalanda Young
Director, Office of Management and Budget

Jeff Zients
White House Chief of Staff