



March 3, 2021

Dr. Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Need for action on menthol cigarettes and other flavored tobacco products (FDA-2013-P-0435-0001)

Dear Dr. Woodcock:

The undersigned public health, medical, education and community organizations write to urge prompt action by the Food and Drug Administration to prohibit menthol cigarettes and other non-tobacco flavored tobacco products, including e-cigarettes and cigars.

The public health and medical community has long been united in calling on FDA to use its authority under the Family Smoking Prevention and Tobacco Control Act (TCA) to issue product standards ending the manufacture and sale of flavored tobacco products. There is no question that flavored products are particularly attractive to young people, leading to increased tobacco initiation. As FDA already has found, “the availability of tobacco products with flavors at these development stages attracts youth to initiate use of tobacco products and may result in lifelong use.”¹ The FDA/NIH Population Assessment of Tobacco and Health study found that

¹ FDA, Advance Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294-95 (March 21, 2018).

almost 81% of 12-17 year olds who had ever used a tobacco product initiated use with a flavored product.²

Among other efforts to call on FDA to take action against flavored products, in 2013 various organizations filed a Citizen Petition urging FDA to remove cigarettes that have menthol as a characterizing flavor. As a result of litigation against FDA brought by the African American Tobacco Control Leadership Council, Action on Smoking and Health, the American Medical Association and the National Medical Association alleging “unreasonable delay” by the agency in addressing the specific issue of mentholated cigarettes, FDA has represented to a federal court in California that it will issue a final response to the Citizen Petition by April 29, 2021.³ The undersigned groups are united in urging FDA to grant the Citizen Petition and announce that it will issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes without delay. This is the only decision consistent with the public health standard set out in the TCA, as well as the relevant science, as FDA itself repeatedly has recognized.

Menthol in cigarettes leads to greater initiation of smoking among youth, makes it harder to quit smoking and has a disproportionate adverse impact on the health of Black Americans. As directed by Congress in the TCA, the Tobacco Products Scientific Advisory Committee (TPSAC) issued a report in 2011 (TPSAC Report), with two primary conclusions: (1) “Menthol cigarettes have an adverse impact on public health in the United States,” and (2) “There are no public health benefits of menthol compared to non-menthol cigarettes.”⁴ Indeed, the TPSAC Report projected the adverse impact of menthol in cigarettes from 2011 to the present day, finding that “by 2020, about 17,000 premature deaths will occur and about 2.3 million people will have started smoking, beyond what would have occurred absent availability of menthol cigarettes.”⁵ Based on these findings, TPSAC made the following “overall recommendation” to FDA: “Removal of menthol cigarettes from the marketplace would benefit the public health in the United States.”⁶

Two years after issuance of the TPSAC Report, FDA completed its own independent, peer-review evaluation of the available science concerning menthol cigarettes. FDA’s *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus*

² Bridget K. Ambrose, et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 J. Am. Med. Ass’n 17, 1871-3 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6467270/>.

³ Stipulation to Extend Deadlines, *African American Tobacco Control Leadership Council et al. v. United States Department of Health and Human Services et al.*, Case No. 3:20-cv-04012 (N.D.Cal. January 21, 2021), ECF No. 43.

⁴ TPSAC, FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, 2011, <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (TPSAC Menthol Report).

⁵ *Id.* at 221.

⁶ *Id.* at 225.

Nonmenthol Cigarettes reached the overall conclusion, consistent with TPSAC's, that it is "likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."⁷

FDA has never wavered in its conclusion that menthol cigarettes have an adverse impact on public health. Indeed, in November of 2018, then-Commissioner Scott Gottlieb announced the agency's intention to "advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars. . . ." after expressing his "deep concern" about "the availability of menthol-flavored cigarettes," which "represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes" and "exacerbate troubling disparities in health related to race and socioeconomic status."⁸

These conclusions have been bolstered by recent comments filed in the FDA's Citizen Petition Docket (FDA-2013-P-0435-0001) by a coalition of 68 public health, medical and community organizations; an extensive supplement to the Citizen Petition filed by the petitioners and other public health organizations; separate comments filed by the National Medical Association; comments filed by 46 scientific experts, led by Jonathan Samet, M.D., M.S. the first chair of TPSAC and its chair at the time of the TPSAC report; and comments filed by 23 state attorneys general.⁹ As the chief law enforcement officers of their respective states, the attorneys general addressed the tobacco industry's longstanding assertion that a menthol ban would lead to a burgeoning illicit market. They concluded that "[t]here is little reason to suggest that prohibiting menthol cigarettes will cause the emergence of an illicit market that will threaten the public health gains from prohibiting menthol cigarettes or that state and federal authorities will be unable to prevent the emergence of such illicit activity. The FDA should not be swayed by the tobacco industry's doomsday predictions of an increase in illicit trade."

If FDA is to adhere to its longstanding commitment to entirely science-based decision-making, it must grant the Citizen Petition and inaugurate a regulatory process to prohibit menthol as a characterizing flavor in cigarettes. Moreover, to prevent the industry from selling menthol cigarettes masquerading as cigars, FDA's menthol rule should apply to menthol in cigars as well. Finally, FDA's grant of the Citizen Petition on or before April 29 should be the first step toward a broader set of product standards prohibiting all non-tobacco flavors in all tobacco products.

Respectfully submitted,

⁷ FDA, *Preliminary Scientific Evaluation of the Possible Public Health effects of Menthol versus Nonmenthol Cigarettes*, 2013, <https://www.fda.gov/media/86497/download> (FDA Report).

⁸ FDA Statement, *FDA Commissioner Scott Gottlieb, M.D. on proposed new steps to protect youth by prevention access to flavored tobacco products and banning menthol in cigarettes*, Nov. 15, 2018, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>.

⁹ See comments filed in Tobacco Control Legal Consortium, et al – Citizen Petition, April 12, 2013, Docket ID: FDA-2013-P-0435, Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke, <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

1. Action on Smoking & Health (ASH)
2. African American Tobacco Control Leadership Council (AATCLC)
3. Allergy & Asthma Network
4. American Academy of Oral and Maxillofacial Pathology
5. American Academy of Oral and Maxillofacial Radiology
6. American Academy of Oral Medicine
7. American Academy of Otolaryngology—Head and Neck Surgery
8. American Academy of Pediatrics
9. American Association for Cancer Research
10. American Association for Dental Research
11. American Association for Respiratory Care
12. American Cancer Society Cancer Action Network
13. American College Health Association
14. American College of Cardiology
15. American College of Chest Physicians (CHEST)
16. American College of Obstetricians and Gynecologists
17. American College of Physicians
18. American Dental Association
19. American Dental Education Association
20. American Heart Association
21. American Lung Association
22. American Medical Student Association
23. American Public Health Association
24. American Society of Addiction Medicine
25. American Thoracic Society
26. Americans for Nonsmokers' Rights
27. Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL)
28. Association of Black Cardiologists
29. Association of Schools and Programs of Public Health
30. Association of State and Territorial Health Officials
31. Asthma and Allergy Foundation of America
32. Big Cities Health Coalition
33. Black Ladies in Public Health
34. Black Women's Health Imperative
35. Campaign for Tobacco-Free Kids
36. Cancer Prevention and Treatment Fund
37. CATCH Global Foundation
38. Catholic Health Association of the United States
39. ClearWay Minnesota
40. Common Sense
41. Community Anti-Drug Coalitions of America (CADCA)
42. COPD Foundation

43. Counter Tools
44. District of Columbia Tobacco Free Coalition
45. Eta Sigma Gamma - National Health Education Honorary
46. First Focus Campaign for Children
47. GO2 Foundation for Lung Cancer
48. League of United Latin American Citizens (LULAC)
49. March of Dimes
50. Mesothelioma Applied Research Foundation
51. NAACP
52. National Association of County and City Health Officials
53. National Association of Pediatric Nurse Practitioners
54. National Association of School Nurses
55. National Association of Social Workers
56. National Caucus and Center on Black Aging, Inc. (NCBA)
57. National Consumers League
58. National Dental Association
59. National Education Association
60. National LGBT Cancer Network
61. National Medical Association
62. National Network of Public Health Institutes
63. North American Quitline Consortium
64. Oncology Nursing Society
65. Parents Against Vaping e-cigarettes (PAVe)
66. Prevent Cancer Foundation
67. Public Health Law Center
68. Public Health Solutions
69. Save a Girl, Save a World (SAGSAW)
70. Society for Cardiovascular Angiography and Interventions
71. Society for Public Health Education
72. Students Against Destructive Decisions (SADD)
73. The Center for Black Equity
74. The Links, Inc.
75. The Society of State Leaders of Health and Physical Education
76. The Society of Thoracic Surgeons
77. Trinity Health
78. Truth Initiative
79. US PIRG

cc: Mitch Zeller, Director, Center for Tobacco Products