Citizen Petition

Asking the U.S. Food and Drug Administration to Prohibit Menthol as a Characterizing Flavor in Cigarettes




April 12, 2013

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Tobacco Control Legal Consortium
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Dear Colleague,

As you know, tobacco companies add flavors to their products to mask the harsh taste of tobacco, making it easier for young people to start smoking. That's why Congress banned the sale of flavored cigarettes in 2009. But Congress made one exception to the flavor ban, deferring action on the most popular of all flavors — menthol — and directing the U.S. Food and Drug Administration to decide whether continued sale of menthol cigarettes is "appropriate for public health."

On April 12, 2013, the Tobacco Control Legal Consortium joined many leading national organizations in filing the enclosed Citizen Petition, urging the FDA to remove menthol cigarettes from the market. Participating in the petition were:

- The African American Tobacco Control Leadership Council,
- The American Academy of Pediatrics,
- The American Association for Cancer Research,
- The American Cancer Society — Cancer Action Network,
- The American Heart Association,
- The American Legacy Foundation,
- The American Lung Association,
- The American Public Health Association,
- Americans for Nonsmokers' Rights,
- Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL),
- The Association for the Treatment of Tobacco Use and Dependence,
- The Campaign for Tobacco-Free Kids,
- Corporate Accountability International,
- NAATPN, Inc. (parent organization of the National African American Tobacco Prevention Network),
- The National Association of County and City Health Officials,
- The National Latino Alliance for Health Equity,
- The Society for Research on Nicotine and Tobacco,
- Summit Health Institute for Research and Education, Inc., and
- Valerie B. Yerger, N.D.

Prohibiting the sale of menthol cigarettes is one of the most powerful steps the FDA can take to improve America's health. In light of the scientific evidence, there is no justification for continuing to give special treatment to the most deadly of all cigarette flavors. Menthol cigarettes are the source of addiction for nearly half of all teen smokers. Menthol increases the palatability of smoking, especially among youth and members of racial and ethnic populations, and menthol increases the difficulty of quitting.

We hope you will add your voice to the chorus urging the FDA to act now. The FDA will be requesting comments from the public on this proposal, and the process for commenting is not complicated. For information about how to share your views, or for technical assistance in preparing comments, you can contact our FDA Tobacco Project at publichealthlawcenter.org/topics/tobacco-control/fda-tobacco-action-center or call us at 651-290-7506. We encourage you to weigh in, and to include additional evidence — whether scientific data or information based on your practical experience — about the approach you believe the agency should take to best protect our nation's health.

Sincerely,

D. Douglas Blanke
Executive Director
Tobacco Control Legal Consortium

PETITIONERS

African American Tobacco Control Leadership Council

A national organization that educates the African American community about tobacco use and cessation and partners with community stakeholders and public health agencies to inform and affect the direction of tobacco policy, practices, and priorities as it affects the lives of African Americans.

American Academy of Pediatrics

A professional membership organization of 60,000 primary care pediatricians, pediatric medical sub-specialists and pediatric surgical specialists dedicated to the health, safety, and well being of infants, children, adolescents and young adults.

American Association for Cancer Research

The oldest and largest scientific organization in the world focused on every aspect of high-quality, innovative cancer research.

American Cancer Society — Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society (ACS), with the shared mission of eliminating cancer as a major health problem. ACS helped establish the original scientific link between tobacco use and cancer. Therefore, ACS CAN works to promote effective tobacco control policies at the federal, state, and local levels. With nearly one million advocates, ACS CAN is the leading voice to fight cancer nationwide.

American Heart Association

The nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke — America's No. 1 and No. 4 killers. The organization teams with millions of volunteers to fund innovative research, fight for stronger public health policies, and provide lifesaving tools and information to prevent and treat these diseases.

American Legacy Foundation

The largest non-profit public health charity in the nation devoted specifically to preventing teen smoking and encouraging smokers to quit.

American Lung Association

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research.

American Public Health Association

The oldest and most diverse organization of public health professionals in the world, which aims to protect all Americans, their families and their communities from preventable, serious health threats and strives to assure community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States.

Americans for Nonsmokers' Rights

A national advocacy organization with more than 8,000 members, which promotes the protection of everyone's right to breathe smoke-free air, educates the public and policy-makers regarding the dangers of secondhand smoke, works to prevent youth tobacco addiction, and tracks and reports on the adversarial effects of the tobacco industry.

Asian Pacific Partners for Empowerment, Advocacy and Leadership

A national health justice organization working to achieve health equity for Asian Americans, Native Hawaiians, Pacific Islanders and other underserved communities.

Association for the Treatment of Tobacco Use and Dependence

A national membership-based group of professionals devoted to supporting and promoting evidence-based treatment for tobacco users.

Campaign for Tobacco-Free Kids

A non-profit organization that works to reduce tobacco use and its deadly toll in the United States and around the world. Tobacco-Free Kids advocates for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

Corporate Accountability International

A non-profit organization, founded in 1977, that wages campaigns to protect public health, the environment, and democracy from abuse by transnational corporations.

NAATPN, Inc.

NAATPN, Inc. works to address the health impact of tobacco products on African Americans through education and advocacy. It is the parent organization of the National African American Tobacco Prevention Network, a Centers for Disease Control and Prevention-funded network that focuses on assessing the impact of tobacco within disparate populations, identifying gaps in data, interventions, and research involving African Americans and tobacco use.

National Association of County and City Health Officials

A national organization that represents the nation's 2,800 local public health departments and supports efforts that protect and improve the health of all people and all communities by promoting national policy, developing resources and programs, seeking health equity and supporting effective local public health practice and systems.

National Latino Alliance for Health Equity

A national organization of Latino health leaders working together to move the nation to achieve Latino health equity by advocating for policies and regulations that will impact environmental health, access to health care, improved product regulation and other policies related to tobacco control and other topics.

Society for Research on Nicotine and Tobacco

A national nonprofit, member-focused association whose mission is to stimulate the generation of new knowledge concerning nicotine in all its manifestations - from molecular to societal.

Summit Health Institute for Research and Education, Inc.

A nonprofit 501(c)(3) organization, established in 1997, dedicated to the promotion of health and wellness for all people, that works to eradicate health disparities and aid vulnerable populations in attaining optimal health.

Tobacco Control Legal Consortium

A national network of legal centers providing technical assistance to public officials, health professionals and advocates in addressing legal issues related to tobacco and health, and supporting public policies that will reduce the harm caused by tobacco use in the United States.

Valerie B. Yerger, N.D.

Dr. Yerger is a licensed naturopathic doctor and associate professor of health policy in the Department of Social and Behavioral Sciences at the University of California, San Francisco. Dr. Yerger's research focuses on the tobacco industry's targeting of African American communities, the use of menthol in tobacco products, and smoke-free policies in multi-unit housing.

CITIZEN PETITION HIGHLIGHTS

With the Family Smoking Prevention and Tobacco Control Act of 2009, Congress took an important step to prevent youth smoking by banning flavored cigarettes. Because tobacco manufacturers use flavors, herbs and spices to mask the harshness of tobacco and attract new generations of underage smokers, Congress prohibited fruity and candy-like additives as characterizing flavors in cigarettes and cigarette smoke.

There was one exception, however. Despite menthol's minty flavoring and youth appeal, as well as its popularity among adult smokers, including a large proportion of smokers from minority populations, menthol was exempted from Congress' flavor prohibition. The Tobacco Control Act did, however, provide the U.S. Food and Drug Administration with the authority to prohibit menthol if "appropriate for public health" and made the issue of menthol in cigarettes a priority for FDA consideration.

To ensure that the FDA was advised about menthol and other scientific issues, the Tobacco Control Act established the Tobacco Products Scientific Advisory Committee, made up of leading scientific experts. After a lengthy and careful review of the evidence, the Committee concluded: "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." More than eighteen months after receiving the Committee's report, the FDA has yet to act.

On April 12, 2013, twenty leading national organizations filed a formal Citizen Petition, urging the FDA to exercise its regulatory power, and to protect America's health by prohibiting menthol as a characterizing flavoring in cigarettes. These organizations include —

- Organizations focused on health disparities and communities of color — African American Tobacco Control Leadership Council; Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL); NAATPN, Inc. (the parent organization of the National African American Tobacco Prevention Network); and National Latino Alliance for Health Equity;
- Preeminent health advocacy organizations — American Cancer Society — Cancer Action Network, American Heart Association, and American Lung Association;
- Leading tobacco control advocacy organizations — Campaign for Tobacco-Free Kids, Americans for Nonsmokers' Rights, and American Legacy Foundation;
- Leading voices for public health and children's health — American Public Health Association and American Academy of Pediatrics;
- The voice of America's local health departments — National Association of County and City Health Officials;
- A leading corporate watchdog — Corporate Accountability International;
- Leading scientific organizations and societies — American Association for Cancer Research; Association for the Treatment of Tobacco Use and Dependence; Society for Research on Nicotine and Tobacco; Summit Health Institute for Research, Education, Inc.; and Dr. Valerie Yerger; and
- The national legal network for tobacco control policy — Tobacco Control Legal Consortium.

The pressing need for the FDA to act on the health hazards posed by menthol in cigarettes is supported by a vast body of evidence, including statistics clearly indicating that —

Smoking remains a critical public health issue

- Tobacco use remains the leading cause of preventable death and disease in the United States. As of 2011, 19% of U.S. adults — 43.8 million people — smoked cigarettes.
- Cigarette smoking kills more than 440,000 Americans each year and leaves millions more to suffer from tobacco-related chronic disease.
- Smoking costs the U.S. $193 billion annually, including $97 billion per year in lost productivity and $96 billion per year in healthcare costs.
- Each day 3,800 adolescents try smoking for the first time, 1,000 of whom will become addicted.

Menthol cigarettes hurt kids

- Kids smoke menthol cigarettes. According to national surveys, 47.7% of adolescent (age 12-17) smokers report menthol cigarette use compared to 40.8% of young adult smokers (age 18-25) and 31.5% of older adult smokers (age 26 or older).
- Among kids, the youngest smokers are the most likely to smoke menthols, with a greater proportion of middle school age smokers reporting menthol use than high school age smokers.
- Menthol in cigarettes results in more youth initiation. Among youth and young adult smokers, menthol cigarette use is also more prevalent among those who started smoking in the past year than among those who started smoking more than one year ago.

Menthol cigarettes harm minority smokers

- Many menthol smokers support the elimination of menthol cigarettes. Studies have found that among menthol smokers, nearly half (49.5%) of respondents either supported prohibiting menthol in cigarettes or did not have a strong opinion for or against such a regulation. Another study showed 56.1% of all respondents and 75.8% of African American survey respondents saying that they supported prohibiting menthol cigarettes "like other flavored cigarettes."
- A national study found that many menthol smokers would quit smoking if menthol cigarettes were prohibited, especially African American (44.5%) and female (44.0%) menthol smokers.
- According to a leading economic model, fully one-third of the lives saved by eliminating menthol cigarettes and causing menthol smokers to quit will be African American.
- Menthol cigarettes are used disproportionately in communities of color. According to the combined 2004-2008 National Survey on Drug Use and Health (NSDUH) data, menthol cigarettes are used at disproportionately higher rates by racial and ethnic minority smokers, including African Americans (82.6%), Native Hawaiian or Pacific Islanders (53.2%), Hispanics or Latinos (32.3%) and Asian Americans (31.2%), relative to White smokers (23.8%).
- Racial and ethnic differences in menthol use appear at young ages. The same NSDUH data shows that among 12-17 year old smokers, 72% of African Americans, 51% of Asians, and 47% of Hispanics, in comparison to 41% of Whites, used menthol cigarettes. The pattern continues into young adulthood (18-25 year olds), with 85% of African Americans, 38.2% of Hispanics, and 35.8% of Asians using menthol cigarettes in comparison to 28.8% of Whites.

Prohibiting menthol cigarettes would benefit health

- One model estimates that if menthol were prohibited as a characterizing flavor in cigarettes, between 2010 and 2020 over 2.2 million would not start smoking. By 2050, the number of people who would not smoke would be 9 million.
- A leading model of smoking in the United States predicts that a 10% quit rate among menthol smokers would save thousands of lives, preventing over 4,000 smoking-attributable deaths in the first ten years, and that 300,000 lives would be saved over forty years. Approximately 100,000 of those whose lives would be saved would be African American.

Smoking is the leading preventable cause of death and disease. It costs the United States almost $200 billion in health costs and lost productivity each year. Moreover, preventing young people from becoming addicted smokers and increasing the likelihood of successful smoking cessation are key health goals that, in fact, are the focus of the Tobacco Control Act's public health standard and should be the goal of FDA regulation.

The results of study after study are clear: prohibiting menthol in cigarettes is perhaps the single most powerful measure readily available to the FDA to improve America's health. When menthol cigarettes are the source of addiction for nearly half of all adolescent smokers; when menthol increases the palatability and attractiveness of smoking to both youth and racial and ethnic populations; and when menthol clearly increases the difficulty of quitting smoking, there can be no justification for further delay in eliminating the special treatment of the most harmful of all cigarette flavor additives.

April 12, 2013

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

The undersigned submit this petition pursuant to Title 21, Chapter 9, Subchapter V, Part A of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 10.30 to request that the Commissioner of the U.S. Food and Drug Administration (FDA) prohibit menthol as a characterizing flavoring of cigarettes. The authority to adopt tobacco product standards that would restrict the addition of menthol as a characterizing flavor is found in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).[1]

I. PRELIMINARY STATEMENT

Cigarette smoking continues to be a public health problem of staggering dimensions, killing more than 440,000 Americans each year and leaving millions more to suffer from chronic disease.[2] Strikingly, this death and disease, along with the associated economic costs, is preventable — leading the Centers for Disease Control and Prevention to characterize the reduction of tobacco use as a public health priority, or "Winnable Battle,"[3] meriting continued investment and innovative strategy by national, state, and local governments. Preventing youth from starting to smoke is a particularly important element of any approach to reduce tobacco use and tobacco-related disease and death, given that the vast majority of smokers start as youth and that the lifetime risk of many tobacco-related diseases is linked to the duration of smoking.[4]

With the Tobacco Control Act, Congress took an important step toward the goal of preventing youth smoking by prohibiting candy-like additives as characterizing flavorings of cigarettes and cigarette smoke, recognizing that such flavorings are a tool for tobacco companies to attract and hook younger generations of smokers.[5] Congress also recognized the urgent importance of addressing the impact of menthol cigarettes on youth and other specific populations by requiring FDA's Tobacco Product Scientific Advisory Committee (TPSAC), as its first order of business following its creation, to study "the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities."[6] The statute further directed TPSAC to submit its report and recommendations on menthol within the first year of TPSAC's operation.[7]

TPSAC members spent months reviewing scientific data and hearing testimony from researchers and advocates in an effort to amass a comprehensive body of evidence documenting the impact of menthol cigarettes on the public health. TPSAC's review gave full consideration to the arguments and evidence of the tobacco industry, whose representatives held three non-voting seats on TPSAC and submitted their own extensive comments to the committee.

The TPSAC Report was submitted to FDA in final form on July 21, 2011, almost eighteen months ago. Based on a comprehensive review of the scientific evidence available as of that time, TPSAC reached two primary conclusions: (1) that menthol cigarettes have an *adverse impact on public health* in the United States; and (2) that menthol cigarettes offer *no public health benefits*, compared to non-menthol cigarettes.[8] Specifically, TPSAC concluded that the availability of menthol cigarettes *increases the likelihood of addiction and the degree of addiction in youth smokers*.[9] TPSAC quantified the impact on public health, estimating 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 the availability of menthol cigarettes.[10] It made the following "overall recommendation" to FDA in clear and certain terms: *"Removal of menthol cigarettes from the marketplace would benefit public health in the United States."*[11]

The Act explicitly grants the FDA the authority to regulate menthol in cigarettes by adopting a product standard that is "appropriate for the protection of public health."[12] Yet during the many months that have passed since receiving the TPSAC Report, the FDA has responded only by initiating a "thorough review" of the TPSAC Report.[13] Despite having received an unequivocal recommendation from the committee of experts charged by Congress to examine whether removal of menthol cigarettes would meet the public health standard, the FDA has taken no action to initiate a rulemaking to remove menthol cigarettes from the marketplace through

an appropriate product standard. FDA action on the public health harm caused by menthol is now long overdue; the agency must conclude its independent review of the evidence and take action to regulate menthol in tobacco products.

As the evidence analyzed in the TPSAC Report and numerous other authorities have established, the science on this issue justifies immediate action to reduce the human toll resulting from mentholated tobacco products. Although the manufacturers of menthol cigarettes have raised the specter of countervailing effects from a prohibition of menthol cigarettes, their arguments are unpersuasive and any such effects are trivial in comparison to the highly significant public health benefits that such a prohibition would produce.

The action requested here addresses only part of the larger public health threat posed by adding menthol to tobacco products. As cigarette manufacturers have acknowledged in internal documents, cigarettes with menthol at levels too low to impart a characterizing flavor can reduce the harshness and sting associated with cigarette smoke[14] — effects that likely increase initiation and deter cessation.[15] These products, with menthol added at "subliminal levels," constitute the majority of the cigarette market.[16] Therefore, petitioners believe it is incumbent on the FDA to exercise its duty and authority to take appropriate steps to determine what regulatory action is necessary to address the health effects of lower levels of menthol and other additives that increase and prolong addiction to all tobacco products.

With this petition, the undersigned respectfully request that the FDA extend the prohibition on characterizing flavorings in cigarettes and cigarette smoke to include menthol. In light of the convincing evidence that menthol impacts key smoking behaviors in the entire population, there is no public health justification for refusing to act.

II. ACTION REQUESTED

Petitioners urge the FDA to take immediate action to prohibit menthol as a characterizing flavoring in cigarettes.[17] Given the Tobacco Control Act's express purpose of reducing youth tobacco use and the substantial body of evidence indicating that menthol facilitates experimentation and progression to regular smoking, the FDA must take action to regulate menthol in tobacco products. Failing to include menthol in the prohibition against characterizing flavors ignores the fact that menthol has the same gateway properties[18] as other flavorings, misleads consumers, and undermines the credibility of FDA tobacco regulation.

Moreover, there is no justification for failing to institute a product standard that, as established by the evidence cited by TPSAC as well as more recent studies, would benefit the overall public health by decreasing the likelihood of youth smoking initiation and increasing the likelihood of adult cessation. The magnitude of the anticipated public health impact of a prohibition on menthol cigarettes, combined with the growing proportion of youth smokers who use menthol cigarettes, warrants immediate FDA action the on this issue.

Specifically, Petitioners request that the FDA take the following actions. Support for this action is found in the evidence cited in the TPSAC Report as well as more recent studies, all of which are further described in the body of this Petition.

Add menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarettes and cigarette smoke, directed by § 907(a)(1)(A) of the Tobacco Control

Act. FDA should promulgate a rule that prohibits menthol as a characterizing flavoring in cigarettes, explicitly including both synthetic (racemic) and natural (l-menthol) menthol.

Work with appropriate entities to provide support to smokers of menthol cigarettes who will quit as a result of the requested prohibition on menthol cigarettes. FDA should collaborate with providers of cessation programs, including those that provide comprehensive cessation services that are accessible by all populations and conduct related public education efforts designed to serve current and former menthol smokers, to mitigate any potential countervailing effects resulting from adding menthol to the prohibition on characterizing flavors in cigarettes and cigarette smoke.

III. STATEMENT OF GROUNDS

1. Legislative context and intent regarding FDA regulation of menthol cigarettes

Tobacco use remains the leading cause of preventable death and disease in the United States.[19] As of 2011, 19.0% of U.S. adults, 43.8 million people, smoked cigarettes.[20] Each year, over 440,000 deaths in the U.S. are attributable to smoking.[21] Through multiple biochemical mechanisms, tobacco smoke damages every organ in the body and causes a wide array of devastating illnesses, including cardiovascular disease, multiple forms of cancer, and reproductive issues.[22] Additionally, the economic impact of smoking is staggering, costing the U.S. $193 billion annually, including $97 billion per year in lost productivity and $96 billion per year in healthcare costs.[23]

One particular concern is the continuing problem of underage and young adult smoking. Each day 3,800 adolescents try smoking for the first time. Of these, 1,000 adolescents will become addicted.[24] While adolescent smoking rates declined from 1997–2003, the decline has subsequently slowed, stalling among certain subpopulations.[25]

Also alarming is the phenomenon of disproportionate tobacco-related health effects among minority subpopulations. Racial and ethnic minorities, particularly African Americans, bear a disproportionate burden of tobacco-related disease, with higher rates of smoking-attributable lung cancer occurring among African American men than any other group.[26] In addition, multiple studies have found that lesbian, gay, bisexual and transgender (LGBT) individuals are significantly (1.5 to 2.5 times) more likely to smoke than their heterosexual counterparts.[27] Such statistics are especially disturbing given that racial and sexual minorities are less likely to access tobacco cessation treatments and health care services, in general.[28]

Recognizing the ongoing health and economic burden imposed by tobacco use[29] and the failure of previous tobacco control efforts to adequately curb tobacco use among young people,[30] Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) in 2009, granting the FDA the jurisdiction to regulate the manufacture, distribution, and marketing of tobacco products.

This jurisdiction includes the authority to adopt tobacco product standards "appropriate for the protection of the public health."[31] In finding that a product standard is appropriate for the public health, the FDA is required to take a broad, population-level view that takes into consideration "the increased or decreased likelihood that those who do not use tobacco products will start using such products;" "the

increased or decreased likelihood that existing users of tobacco products will stop using such products;" and, ultimately, "the risks and benefits to the population as a whole, including users and nonusers of tobacco products." [32]

The Tobacco Control Act mandates a public health standard of review that is entirely different from the "safe and effective" standard that the FDA has traditionally used to evaluate drugs and medical devices, since tobacco products are inherently not "safe" or "safe and effective."[33] Congress intended this new "public health standard" to be a "flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products."[34]

Opponents of a prohibition on menthol in cigarettes have argued that the FDA cannot implement such a prohibition unless it can prove via a showing of strict causation that smoking menthol cigarettes harms individual smokers more than smoking non-menthol cigarettes.[35] This argument ignores the nature of the public health standard as well as the standard of proof envisioned by Congress in the Tobacco Control Act. In order to implement a tobacco product standard, Congress directs the FDA to determine that this tobacco product standard is "appropriate for the protection of public health" and frames this requirement in terms of "risks and benefits to the population as a whole" and "increased or decreased likelihood" of tobacco product cessation or initiation.[36] The tobacco industry misrepresents the weight of the evidence needed for FDA to act. It also ignores the fact that an assessment of what is "appropriate for the public health," as defined by the Tobacco Control Act, necessarily involves broader and different considerations,[37] requiring: 1) consideration of the *likely* impact of a product standard on smoking initiation and cessation, analyzed in the context of the serious health effects of tobacco use, and 2) a weighing of the anticipated risks and benefits to the entire population, including nonusers of tobacco.[38]

Not only is menthol subject to the FDA's authority to adopt tobacco product standards appropriate for the protection of public health, but Congress also explicitly made menthol a priority, directing the FDA to determine the effects of menthol on public health on an expedited basis. Specifically, the Act provides that "[i]mmediately upon the establishment" of TPSAC, "the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities."[39] The Act further directs TPSAC to submit its menthol report and recommendations within the first year of TPSAC's operations.[40] Finally, the Act reiterates FDA's authority ultimately to establish a product standard on menthol by providing that "[n]othing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol."[41] Similar language making clear the FDA's authority to issue a product standard on menthol appears in the provision of the Act under which Congress banned the use of characterizing flavors (other than menthol) in cigarettes.[42] Moreover, Congress plainly recognizes that the FDA's decision to regulate menthol should be informed not only by the broad public health considerations required under the Tobacco Control Act, but also more specific concerns regarding the impact of menthol use on the health of children, African Americans, Hispanics, and other racial and ethnic minorities.[43]

This petition urges the FDA to remove cigarettes with menthol as a characterizing flavor from the marketplace because this action is necessary and appropriate for the health of the American population as a whole.[44] The evidence clearly estab-

lishes that removing mentholated cigarettes from the marketplace would generate significant health benefits for the entire population, including current users and nonusers of cigarettes. This overall health benefit is further supported by the evidence discussed below concerning the increased popularity of menthol cigarettes among youth and young adults as well as the evidence that menthol cigarettes are used at high rates by populations that have been identified by the Centers for Disease Control and Prevention as experiencing significant tobacco-related disparities, including African American, Hispanic/Latino, Asian American, Native Hawaiian, and Pacific Islander.[45]

2. Adding menthol to the additives and constituents to the prohibition on characterizing flavors in cigarettes and cigarette smoke is appropriate for the protection of the public health as required by the Tobacco Control Act.

As directed by Congress, TPSAC conducted an exhaustive review of the scientific evidence on the public health impact of menthol in cigarettes. It reviewed and considered multiple sources of evidence, including peer-reviewed literature, additional data and information commissioned by the FDA at the request of TPSAC, tobacco company submissions, and public comments from a wide range of stakeholders. It conducted the most thorough study of the impact of menthol in cigarettes ever undertaken. Based on its exhaustive work, TPSAC came to two primary conclusions:

1. "Menthol cigarettes have an adverse impact on public health in the United States."

2. "There are no public health benefits of menthol compared to non-menthol cigarettes."[46]

Based on these conclusions, TPSAC made the following "overall recommendation" to FDA: "Removal of menthol cigarettes from the marketplace would benefit the public health in the United States."[47]

In making this recommendation, TPSAC joined a strong international consensus supporting the need to prohibit the use of menthol in cigarettes. The World Health Organization Framework Convention on Tobacco Control (FCTC) is the international treaty addressing the public health crisis of tobacco use. It has been adopted by 176 countries representing ninety percent of the world's population.[48] The official guidelines for the implementation of the relevant provisions of the FCTC, adopted unanimously by the participating nations, call on parties to "regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products."[49] The guidelines specifically list menthol as one of the ingredients that should be restricted or prohibited because they are used to increase palatability.[50]

As set forth below, the strength of the evidence reviewed in the TPSAC report, and now supplemented by subsequently published evidence, supports the elimination of menthol in cigarettes. Menthol is an additive that increases the number of youth who use tobacco products. It is not only a flavoring, but a chemical with complex, drug-like properties that can impact smoking initiation, addiction, and cessation. A review of this evidence under the public health standard established by the Tobacco Control Act, along with an analysis of the purported risks and benefits, support a prohibition on menthol.

A. Existing evidence indicates that mentholated cigarettes increase initiation of smoking and decrease cessation

Although researchers have not shown that smoking menthol cigarettes — when compared to other types of cigarettes — increases an individual smoker's risk of disease or death,[51] the tobacco industry's reliance on these data to argue

that there is "no greater harm" from menthol cigarettes tells an incomplete story that misleads consumers and fails to address the population level considerations explicitly required by the Tobacco Control Act. Moreover, by focusing only on the individual smoker, the tobacco industry ignores the Tobacco Control Act's directive to the FDA to take all action "appropriate for the protection of the public health."[52]

Among the many findings made by TPSAC, after an exhaustive review of the scientific evidence, are (1) that "the availability of menthol cigarettes increases the likelihood of addiction and the degree of addiction in youth smokers," and (2) that "the availability of menthol cigarettes increases the prevalence of smoking in the general population and particularly in African Americans, beyond the anticipated prevalence if such cigarettes were not available."[53] The net effect of menthol in cigarettes is an increase in the number of people who smoke, and thus are exposed to the disease-causing toxins in cigarette smoke.[54] This effect is made all the more harmful by the high prevalence of menthol cigarette use in groups more vulnerable to or disproportionately burdened by the health effects of smoking, including youth and racial and ethnic minorities.[55] Youth and racial/ethnic minorities, in particular, have historically been targets of menthol cigarette marketing and design,[56] and were identified as populations of concern in regards to mentholated cigarettes by the Tobacco Control Act.[57]

After considering the effects of removing menthol on the likelihood that those (particularly youth) who do not currently smoke will start smoking, on the likelihood that existing menthol smokers will stop smoking, and on the health of the entire population, as required by the Tobacco Control Act's public health standard, the FDA should determine that prohibiting menthol in cigarettes is both necessary and appropriate for the protection of public health.

i. Removing mentholated tobacco products from the marketplace would benefit the health of youth and the overall population by decreasing smoking initiation.

As TPSAC noted, "[r]egular cigarette smoking begins with experimentation, typically during adolescence."[58] To understand "the role of menthol cigarettes in the continuum that ends with regular smoking," TPSAC closely examined data on the prevalence and patterns of menthol cigarette smoking in youths ages 12–17 and studies about the sensory impacts of menthol cigarette smoke, as well as reviewed evidence from internal tobacco company documents and consumer research on the influences of menthol cigarette advertising and marketing on smoking of menthol cigarettes. Based on its review, TPSAC concluded that menthol plays a role in increasing experimentation and progression to regular smoking.[59] This conclusion is part of a growing recognition that menthol cigarettes are just as much of a "starter" or "gateway" product as the characterizing flavorings prohibited by the Tobacco Control Act.[60] A large body of evidence demonstrates that menthol has youth-attractive properties that extend beyond its role as a flavoring. In light of the large and growing impact of menthol cigarettes on youth smoking, as well as the well-documented health implications of youth smoking,[61] removing mentholated tobacco products from the marketplace would substantially benefit the health of youth and the population as a whole.

a. Menthol has youth appeal that extends beyond its role as a flavoring.

Nearly half of adolescent smokers begin as menthol smokers, and the youngest smokers are the most likely to smoke menthols.[62] And menthol use is increasing. In concluding that the availability of menthol cigarettes increases the likelihood of experimentation and of becoming

a regular smoker, TPSAC analyzed smoking patterns among various age groups. It found a "higher proportion of menthol cigarette smokers among youth smokers than adult smokers."[63] It further found that "younger adolescent smokers have a higher proportion of menthol cigarette smokers than older adolescent smokers."[64]

National survey data indicate that menthol cigarette use is inversely proportional to age, with 47.7% of adolescent (age 12–17) smokers reporting menthol cigarette use compared to 40.8% of young adult smokers (age 18–25) and 31.5% of older adult smokers (age 26 or older).[65] Even within the youth population, the preference for menthol cigarettes skews younger, with a greater proportion of middle school age smokers reporting menthol use than high school age smokers.[66] Within the population of youth and young adult smokers, menthol cigarette use is also more prevalent among those who started smoking in the past year than among those who started smoking more than one year ago.[67]

There is also evidence that menthol has properties that facilitate experimentation and progression to regular smoking among younger, newer smokers. TPSAC found that:

> Menthol's cooling and anesthetic properties reduce the harshness of cigarette smoke for new smokers. Menthol cigarettes produce sensory cues, such as a minty taste and odor, a cooling sensation and throat irrigation or impact — all of which may provide strong cigarette-associated cues that reinforce smoking behavior.[68]

While menthol's familiar, minty flavoring alone increases youth appeal,[69] the sensory appeal of menthol to young and inexperienced smokers extends beyond its flavor. Menthol acts on sensory nerves of the mouth, nose, and airway that detect temperature and chemical irritation, producing cooling and anti-irritation effects when added to cigarettes at low to moderate levels.[70] Specifically, menthol reduces tobacco smoke-related airway irritation by acting on the same receptors that mediate the pain and irritation responses to nicotine and other tobacco-associated chemicals.[71] Additionally, menthol has local anesthetic or analgesic effects, potentially by providing a "counter-irritation" to the pain signals from noxious chemicals in cigarettes smoke, or by interacting with receptors involved in sending pain signals to the brain.[72]

Even as the tobacco industry insists that menthol is only a flavoring,[73] there is evidence that tobacco companies were aware of menthol's ability to make cigarette smoke more palatable to young, novice smokers, and took advantage of that ability to attract a larger share of the youth and young adult markets. A review of tobacco industry documents determined that tobacco companies "knew, not only from their own internal studies but also from monitoring studies in the open literature, that menthol has cooling and anaesthetic properties that moderate the harshness and irritation of tobacco and affect how cigarettes are smoked."[74] Tobacco company studies also reveal that even very low or "subliminal" concentrations of menthol that are otherwise undetectable reduce the harshness and sting associated with cigarette smoke.[75,76]

Moreover, industry documents show that tobacco companies connected the moderating properties of low concentrations of menthol with youth appeal, observing that milder, low-menthol cigarettes tend to appeal to younger smokers while higher menthol-content cigarettes appeal to long-term menthol smokers.[77] A Brown & Williamson memo noted that "a successful 'starter' cigarette would need to provide a low tobacco taste, low impact and irritation, low tobacco aftertaste, and low menthol content."[78] Similarly, R.J. Reynolds explicitly recognized that "First-time smoker reaction is generally negative…Initial negatives can be alleviated with a low level of menthol."[79] By the 1990s, the attraction of low levels of menthol to younger

smokers was sufficiently obvious that the major tobacco companies, including Brown & Williamson, Philip Morris, and R.J. Reynolds, took a cue from the youth success of Newport and developed cigarettes with lower levels of menthol to increase their brands' appeal to younger smokers.[80] Menthol brands, notably Newport, also specifically targeted adolescents and young adults with their marketing messages by using youthful imagery that emphasized fun, child-like silliness, and good times.[81] The TPSAC Report found "substantial evidence" that menthol marketing has been targeted to youth, "with youthful imagery, messages promoting an appealing sensory experience, and peer group acceptance."[82]

This evidence clearly shows that menthol's appeal to youth extends beyond its role as a flavoring, smoothing the sensation to make the poison go down easier. The tobacco companies have exploited this fact, targeting young smokers by using menthol to make cigarettes more palatable to young people.

b. The youth-attractive properties of menthol cigarettes have profound implications for the health of youth and the overall public health.

The importance of preventing youth from starting smoking and becoming regular smokers cannot be overstated. Smoking by younger people extends the potential duration of life-time exposure to cigarette smoke, which is critical since the risk of many chronic, smoking-caused diseases grows with increasing duration of exposure.[83] Additionally, smoking during adolescent periods of growth and maturation may enhance the health-damaging effects of smoking.[84] For example, there is evidence that adolescent smoking contributes to impaired lung growth, chronic respiratory symptoms, and cardiovascular damage in adolescents and young adults.[85] Youth smoking also substantially drives the overall smoking rate, as virtually all smokers initiate cigarette use as adolescents or young adults; nearly 90% of adult smokers start smoking before the age of 18 and nearly 99% start before the age of 25.[86] Thus, even modest effects on rates of youth initiation that could be achieved by removing menthol cigarettes and their youth-attractive properties from the market would translate to significant benefits for the health of youth and the entire population.

The potential benefits of removing mentholated cigarettes from the marketplace are even greater in light of the large and growing share of the youth cigarette market represented by menthol cigarette users. As noted above, 47.7% of all 12–17 year old smokers use menthol cigarettes and menthol cigarette use is even higher among African American (72%) and Asian (51.5%) youth smokers.[87] TPSAC found that the proportion of menthol cigarette use among youth smokers is growing while non-menthol cigarette use is trending downward or is flat.[88] From 2004–2010 the overall prevalence of menthol cigarette use among 12–17 year olds remained relatively stable, increasing from 7.0% in 2004 to 7.4% in 2012, despite a decrease in non-menthol cigarette use among all 12–17 year olds over the same time period from 6.4% to 3.7%.[89] Similarly, the overall prevalence of menthol cigarette use among 18–25 year olds increased from 13.4% in 2004 to 15.9% in 2010, while non-menthol cigarette use among 18–25 year olds declined from 25.9% to 18.1%.[90] Such trends suggest that menthol cigarettes are retaining — or even gaining — market share, underscoring the need to regulate menthol cigarettes in a timely manner. In order to take effective action to reduce youth smoking, FDA should focus on the products that are increasingly prevalent with young smokers.

By prohibiting menthol as a characterizing flavor in cigarettes and cigarette smoke, the FDA would prevent tobacco companies from continuing to attract young smokers with an additive that has a complex, known youth appeal

— reducing the likelihood that youth will start smoking and become regular smokers. Given the increasing prevalence of menthol cigarette use among young smokers and the health implications of youth smoking, such an action is both justified and appropriate under the public health standard established by the Tobacco Control Act.[91] Moreover, a failure by the FDA to remove menthol from cigarettes would be misleading — implying that menthol does not have the same "gateway" properties as the other flavorings prohibited by the Tobacco Control Act when in fact menthol has youth-attractive properties that extend beyond its familiar taste.

ii. Removing mentholated tobacco products from the marketplace would increase the likelihood that current smokers will quit.

The Tobacco Control Act requires that the FDA also consider the impact of a product standard on the likelihood that smokers will quit smoking, an issue that has significant implications for the health of current smokers. Nicotine addiction can be fairly characterized as a chronic disease, since "the majority of users persist in tobacco use for many years and typically cycle through multiple periods of remission and relapse."[92] The powerful nature of this addiction is illustrated by the difficulty smokers face in quitting; a 2010 national survey found that only 6.2% of smokers succeeded in quitting over the past year, despite the fact that 68.8% of smokers reported a desire to completely quit and 52.4% of smokers had made a past-year quit attempt.[93]

The difficulty smokers face in trying to overcome nicotine addiction has broad health implications. Smoking harms nearly every organ of the body, causing multiple deadly diseases and reducing the health of smokers in general.[94] On average, adult smokers die fourteen years earlier than nonsmokers.[95] Quitting, however, provides significant health benefits in both the short- and long-term, including decreased respiratory symptoms, slowed decline in lung function, reduced risk of infertility, and reduced risk of cancers, chronic obstructive pulmonary disease (COPD), and coronary heart disease — ultimately improving both the quantity and quality of life.[96]

The available epidemiological evidence indicates that the addition of menthol to cigarettes enhances addiction among youth smokers and decreases successful quitting among adults.[97] Moreover, the physiological properties of menthol suggest that mentholated tobacco products have addiction-enhancing and cessation-discouraging properties to which the broad population of menthol smokers is vulnerable.[98] Considering the powerful nature of nicotine addiction and the health benefits associated with quitting, removal of menthol from the market would close a regulatory gap that decreases the likelihood that current smokers will be able to improve their health by successfully quitting.

a. Menthol is associated with a greater likelihood and degree of addiction among adolescents and a decreased likelihood of successful quitting among adults.

TPSAC found "clear evidence" of a relationship between menthol cigarettes and nicotine addiction in youth. Among its key findings were that "[y]outh who initiated with menthol cigarettes were more likely to become daily, regular, or established smokers than youth who initiated with non-menthol cigarettes" and that "[a]dolescent menthol cigarette smokers have a higher prevalence of nicotine dependence and more severe nicotine addiction than those who smoke non-menthol cigarettes."[99] Published studies have observed a significant association between menthol cigarette smoking and higher measures of nicotine dependence in adolescents, even when controlling for sociodemographic factors.[100] One recently published study also found that youth who initiate smoking with menthol cigarettes are more likely to become regular, addicted smokers and are more likely to

show higher measures of dependence than youth who initiate with non-menthol cigarettes.[101] While there is little to no data comparing cessation rates between adolescent menthol and non-menthol smokers,[102] more severe addiction as a result of mentholated cigarette use would pose a greater barrier to successful quitting.

There is also strong evidence that menthol in cigarettes decreases the likelihood of successful quitting among some adult populations. According to TPSAC, "empirical and qualitative research — including consumer research conducted by tobacco companies — showed consumers, particularly African Americans, hold beliefs about the implicit health benefits of menthol cigarettes, which could undermine quitting intentions and attempts."[103] TPSAC found the evidence sufficient to conclude that, more likely than not, menthol in cigarettes decreases smoking cessation success, at least among African Americans and other racial/ethnic groups.[104] However, the available evidence is sufficient to support an even stronger conclusion. A 2010 evaluation of the body of quality studies measuring cessation outcomes among menthol and non-menthol smokers concluded that "[t]he weight of the scientific evidence shows that adult menthol smokers are less likely than adult non-menthol smokers to successfully quit smoking despite increased quit intentions and quit attempts."[105] Six studies of adult smokers in national, representative surveys have assessed cessation outcomes rather than only quit attempts or intent to quit.[106] The four of these six studies that consistently controlled for confounding variables (e.g. race, gender, smoking variables) and assessed long-term quit success, found decreased quit success among adult menthol smokers relative to adult non-menthol smokers, either across all racial groups or among African American and Hispanic smokers.[107] Such results were further corroborated by multiple high-quality cohort and randomized controlled studies that have reported decreased cessation among menthol smokers in comparison to non-menthol smokers.[108]

Data published after the TPSAC and the 2010 American Legacy Foundation reviews were completed further corroborate the adverse effect of menthol on smoking cessation among adults. A recently published clinical study of bupropion-assisted smoking cessation among African American light smokers found that, compared to continuing smokers, study participants who remained abstinent seven and twenty-six weeks into the study were significantly more likely to have been non-menthol smokers than menthol smokers.[109] Another recently published study found that white smokers attempting to quit who had used menthol cigarettes at baseline were less likely to maintain continuous, short-term abstinence from smoking than were white non-menthol smokers.[110] A cross-sectional study of Boston women enrolled in a cessation trial also found an effect of menthol on smoking dependence and cessation, observing that female menthol smokers had higher measures of tobacco dependence than female non-menthol smokers.[111]

Although there is some inconsistency of findings across all studies, the available evidence, in the aggregate, "establish[es] that the existence of a relationship between menthol smoking and reduced cessation are more likely than not" and "persuasively suggest that the removal of menthol from cigarettes would more likely than not improve smoking cessation outcomes."[112] Thus, removal of menthol from cigarettes would specifically address the second prong of the Tobacco Control Act's public health standard,[113] increasing the likelihood that existing users of cigarettes will successfully quit smoking.

b. The physiological properties of menthol have the potential to enhance addiction and undermine cessation.

The likelihood that prohibiting menthol in cigarettes will improve smoking cessation outcomes is further supported by the physiological effects of menthol, which provide multiple

plausible mechanisms for an effect of menthol on addiction and cessation. Moreover, there is evidence that the tobacco companies knowingly took advantage of the complex pharmacology of menthol to facilitate continued smoking and addiction among young smokers, to increase sensory rewards for established menthol smokers, and to position menthol cigarettes as an alternative to cessation.

First, menthol reduces the harshness and irritation associated with nicotine and other cigarette smoke components.[114] By decreasing a new smoker's initial negative reactions to nicotine, menthol facilitates continued smoking, which, in turn, facilitates addiction.[115] Menthol also produces distinct sensory experiences that can reinforce smoking behavior and addiction.[116] Menthol produces a pleasant minty taste that is closely tied to the cooling sensation produced by menthol's interaction with cold receptors expressed on sensory nerves of the mouth, nose and airway.[117] However, the level of mentholation must be calibrated to avoid too high a level of the flavoring because tobacco company studies also demonstrate that, at high levels, menthol produces irritation that mirrors the irritating effects of nicotine on the airway.[118] Menthol and nicotine both stimulate the trigeminal nerve in the mouth and throat,[119] contributing to the sensation of throat "grab" or "impact" that is "crucial in providing much of the immediate satisfaction gained by smoking."[120] Thus, producing a cigarette containing an optimal level of menthol has been an ongoing priority for tobacco product manufacturers. Newport, America's second most popular cigarette brand,[121] is the menthol product that has been most successful, both in the youth market and in the market in general,[122] largely because it avoids the harshness that characterizes cigarettes with higher levels of mentholation.[123]

Although nicotine is the primary factor in cigarette addiction, non-nicotine sensory cues — such as the taste, smell, and impact associated with menthol — are potentially important contributors to cigarette addiction.[124] One study has shown that menthol's sensory cues are part of the overall perception of "reward" menthol smokers obtain from smoking cigarettes.[125] Given the reinforcing effects of sensory cues for cigarette addiction, TPSAC expressed concern that the presence of menthol and menthol-like minty taste and odor in commonly consumed products, such as toothpaste and foods, has the potential to evoke cravings and relapse in smokers attempting to quit.[126]

Additionally, there is evidence that tobacco companies knew and took advantage of the reinforcing sensory properties of menthol to facilitate continued smoking among younger smokers and maintain their base of older, established smokers. A review of tobacco industry documents indicated that industry marketing research broadly divided menthol smokers into two categories: those who are averse to the harshness and irritation of cigarette smoke and thus prefer lower menthol concentrations, and those who actively seek out the taste, cooling, and other sensations associated with higher concentrations of menthol.[127] In response to this phenomenon, tobacco companies not only engineered low menthol cigarette varieties to appeal to the first group, which tends to "skew younger," but also maintained varieties with higher menthol content to appeal to the second group.[128] For example, Philip Morris increased the menthol content of its Marlboro Menthol variety to satisfy franchise menthol smokers after introducing low-menthol Marlboro Milds to the market.[129]

Menthol's masking effects and interactions with nicotine can also circumvent health concerns that might otherwise encourage smokers to quit. A review of industry documents found in-house studies that concluded that menthol has nicotine-like sensory properties, with the relative levels of nicotine, tar, and menthol in a cigarette determining overall smoker impact and

satisfaction.[130] Tobacco companies recognized that menthol could act as a partial replacement for nicotine — permitting design of low tar/low nicotine cigarettes without sacrificing the impact or strength smokers expect.[131] Thus, menthol may have been part of a tobacco industry scheme to reduce cessation by falsely marketing low-nicotine or low-tar cigarettes as less harmful alternatives to full-flavor cigarettes.[132]

Moreover, the physiological effects of menthol circumvent the body's defenses and warnings, providing health reassurance that can discourage cessation. Menthol changes perception of airway flow, helping smokers feel as if they are breathing more easily.[133] Menthol also reduces airway pain and irritation[134] and can suppress coughing.[135] As a result, continuous menthol smoking can mask the early warning symptoms of smoking-induced respiratory problems,[136] blocking health cues that might otherwise provide an impetus to quit smoking. As a review of menthol's respiratory effects notes, mentholated cough and cold remedies frequently carry a warning label indicating that they are not for long-term use and can mask the warning signs of a more serious condition.[137] Ironically, no such warning is required for mentholated cigarettes, which deliver toxins that impair lung function and cause deadly respiratory diseases. The health reassurances provided by the sensory properties of menthol are further reinforced by health messages implied by tobacco industry marketing of menthol cigarettes.[138]

The evidence reviewed by TPSAC and published in more recent studies demonstrates that the presence of menthol cigarettes on the market decreases the likelihood that current smokers will be able to improve their health by successfully quitting. In light of this evidence, there is no public health justification for refusing to remove mentholated cigarettes from the marketplace.

iii. Removing mentholated tobacco products from the marketplace will decrease the prevalence of tobacco use in the overall population.

As noted above, the Tobacco Control act specifies that the benefits of a proposed product standard must be assessed for the population as a whole.[139] The impact of menthol on tobacco initiation, addiction, and cessation, in combination with menthol smokers' behavioral intentions toward a menthol prohibition, collectively indicate that prohibiting mentholated tobacco products will provide a broad public health benefit — decreasing the overall prevalence of tobacco use.

The evidence that menthol increases the likelihood that youth will start smoking and become regular, addicted smokers has profound implications for the overall prevalence of tobacco use, particularly since youth smoking rates substantially drive the overall smoking rate and since the prevalence of menthol cigarette use is increasing among youth even as overall youth smoking rates decline.[140] Additionally, studies have indicated that a portion of smokers who initiate with menthol cigarettes ultimately switch to non-menthol cigarettes — suggesting that the effects of menthol on youth initiation and addiction impact not only the overall prevalence of menthol cigarette smoking, but also the prevalence of non-menthol cigarette smoking.[141]

A model of U.S. smoking estimates that, from 2010 to 2020, over 2.2 million people will start smoking in excess of that which would be expected if menthol cigarettes were not available.[142] By 2050, the number of "excess initiators" attributable to menthol cigarettes will increase to 9 million.[143] Even if prohibiting mentholated tobacco products would only prevent a fraction of these estimated excess initiators from taking up smoking, this would translate to significant benefits for the health of potential youth smokers and

the overall population in light of the undisputed health risks associated with smoking.

Prohibiting menthol in tobacco products would further reduce smoking prevalence through effects on cessation. Recently published, peer-reviewed data from a national cross-sectional survey suggest that a substantial proportion of menthol smokers (38.9%) would quit in response to prohibition of menthol cigarettes, while another 25% of menthol smokers would both switch to non-menthol cigarettes and try to quit.[144] The intent to quit was even higher among African American (44.5%) and female (44.0%) menthol smokers.[145] Notably, 16–18% of menthol smokers who said they would quit in response to removal of menthol cigarettes from the market were not otherwise interested in quitting smoking.[146]

These data are strikingly similar to the results of the two other studies that have addressed the issue of menthol smokers' behavioral intentions in the event of a prohibition on menthol in cigarettes. A second peer-reviewed study released in 2012 found that over 35% of surveyed menthol smokers said that they would try to quit smoking in response to prohibition of menthol, while another 27% said that they would smoke less,[147] which can be characterized as a step on the continuum to quitting.[148] Unpublished national survey data presented to the TPSAC similarly showed that 39% of current menthol smokers, including 47% of African American menthol smokers and 42% of female menthol smokers, indicated that they would quit smoking and not use any other tobacco product (instead of switching to non-menthol cigarettes or to another tobacco product, or choosing an option not listed) if menthol cigarettes were no longer sold.[149]

While intent to quit does not guarantee quit success, removing easy access to menthol cigarettes has the real potential to reduce the risk of relapse among smokers whose addiction is fueled by the sensory rewards and reinforcement provided by menthol, as discussed above. Additionally, there are a variety of pharmacological and non-pharmacological treatments available that greatly improve smokers' chances of quit success.[150] Ultimately, the estimated willingness of at least 35% of menthol smokers to quit or reduce tobacco consumption represents an opportunity for the FDA and other national health agencies to maximize the public health benefits of a menthol prohibition.[151] Targeted expansion of access to quit resources in underserved communities and public education directing menthol smokers to these resources would help to ensure that a menthol prohibition would actually achieve significant benefits for the health of current smokers.

More conservative estimates of the quit rate as a result of prohibiting menthol cigarettes would still convey large benefits to public health. A model of smoking in the United States predicts that a 10% quit rate among menthol smokers would save thousands of lives, preventing over 4,000 smoking-attributable deaths in the first ten years and 300,000 in forty years.[152] Approximately 100,000 of those whose lives would be saved would be African American.[153] The total savings in human suffering from a regulation prohibiting menthol in tobacco products would ultimately be even higher, since this model does not take into account the potential effects of such a regulation on the incidence of non-fatal, smoking-attributable disease. The implications of a menthol prohibition for disease incidence must be taken into account, since for every person who dies from a smoking-related disease, twenty others suffer from at least one serious smoking-related illness.[154] Moreover removal of mentholated tobacco products from the market will not only make it less likely that nonsmokers will become smokers, but will also reduce the likelihood of exposure to secondhand smoke by way of anticipated reductions in overall smoking prevalence.

iv. Removal of menthol from cigarettes would have a particularly important public health benefit for African-Americans and other minority populations

In directing TPSAC to study the public health impact of the use of menthol in cigarettes, the Tobacco Control Act expressly included the impact of menthol on tobacco use, not only by children, but also by African Americans, Hispanics and other racial and ethnic minorities.[155] Among other findings, TPSAC determined that menthol smoking is higher among African American smokers,[156] that non-white, and particularly African American, menthol smokers are less likely to quit successfully than non-menthol smokers,[157] that menthol marketing has been especially targeted to African Americans and Hispanics, and that this marketing increases the prevalence of smoking.[158] Of greatest importance, according to TPSAC's best estimates, by 2020 the African American population will have suffered over 4,700 excess deaths due to menthol in cigarettes and over 460,000 more African Americans will have started smoking due to the impact of menthol.[159]

Underlying TPSAC's conclusions are data indicating that menthol cigarettes are disproportionately used by and targeted to racial and ethnic priority populations. Findings based on the combined 2004–2008 National Survey on Drug Use and Health (NSDUH) data indicate that menthol cigarettes are used at disproportionately higher rates by racial and ethnic minority smokers, including African Americans (82.6%), Native Hawaiian or Pacific Islanders (53.2%), Hispanics or Latinos (32.3%) and Asian Americans (31.2%), relative to White smokers (23.8%).[160] These findings are echoed by data from the 2003 and 2006/07 Tobacco Use Supplements to the Current Population Survey (TUS-CPS), which also indicated that menthol cigarette use by current smokers is higher among African Americans (73.6%), Hispanics (27.9%), and Asian/Pacific Islanders (26.2%) than among whites (21.1%).[161] Combined data from the 2004–2008 NSDUH also indicates that racial/ethnic differences in menthol cigarette use manifest at young ages. Among 12–17 year old smokers, 72% of African Americans, 51% of Asians, and 47% of Hispanics, in comparison to 41% of Whites, used menthol cigarettes.[162] The pattern continues into young adulthood (18–25 year olds), with 85% of African Americans, 38.2% of Hispanics, and 35.8% of Asians using menthol cigarettes in comparison to 28.8% of Whites.[163] Notably, menthol cigarette use among young adult Hispanic smokers increased over this four year period, from 33.9% in 2004 to 42.4% in 2008.[164]

In some regions and communities, such disproportionate use of menthol cigarettes is even more pronounced than indicated by the national, aggregate data sets. For example, analysis of the TUS-CPS data showed that the prevalence of mentholated cigarette smoking among different racial/ethnic groups varied by region, with rates highest in the Northeast U.S. for white, Hispanic, and American Indian/Alaska Native smokers, in the Midwest for African American smokers, and in the West for Asian/Pacific Islander smokers.[165] Similarly, a 2006 study commissioned by the Maryland Department of Mental Health and Hygiene observed greater differences in menthol cigarette use, particularly among Hispanic smokers relative to white smokers, than did the national studies.[166] The Maryland study found that 82.4% of African American, 50.6% of Hispanic, 39.3% of American Indian, 51.3% of Asian, and 69.2% of "other" race/ethnicity smokers, relative to 30.7% of white smokers, reported use of menthol cigarettes.[167]

Additionally, there is evidence that menthol cigarette marketing was targeted to racial and ethnic minorities. For example, two studies that compared menthol cigarette advertising between the English- and Spanish-language versions of the

same magazines both observed significantly more menthol ads in the Spanish language version than in the English.[168] There is a particularly large body of evidence demonstrating targeted marketing of menthol cigarettes to African American smokers, who use menthol cigarettes at the highest rates "across all sociodemographic and smoking-related categories."[169] Industry documents reveal specific, aggressive marketing of menthol cigarettes in urban, low-income, African American neighborhoods using tactics such as greater display space for menthol cigarettes, greater menthol interior and exterior signage, and more desirable promotions for menthol cigarettes (e.g. buy one, get one free vs. buy two or three, get one free).[170] More broadly, the tobacco companies sought to embed menthol within the culture of the community, through targeted music and media campaigns,[171] bombardment with menthol marketing messages related to racial identity and urban nightlife,[172] and strategic philanthropy to African American community organizations.[173] The campaign to target African Americans was pervasive: "the blanketing of menthol messages to this community has covered literally every aspect of life, from Black-owned publications and jazz concerts through civil rights groups, to massive billboards throughout the black community."[174] As another study of industry documents concluded, "menthol is the linchpin in a tightly integrated series of campaigns aimed at the urban poor, particularly African Americans."[175]

Over the last couple decades, tobacco companies have come under fire for even more blatant targeting of the African American community through specialized menthol brands or advertising campaigns. For example, public outcry forced R.J. Reynolds to shelve its proposed Uptown brand of menthol cigarettes, which was scheduled to be introduced to the Philadelphia market to coincide with celebration of Black History month.[176] In 2004, Brown & Williamson abandoned its Kool Mixx campaign promoting its menthol cigarettes in response to criticism from community-based coalitions and lawsuits from state attorneys general that the campaign's use of hip hop culture and music was an attempt to specifically attract African American youth to Kool cigarettes, violating multiple terms of the Master Settlement Agreement in the process.[177]

There is strong evidence of disproportionate use within and targeting of menthol cigarettes to the African American community, as well as evidence of a higher incidence of smoking-related cancer morbidity and mortality as compared to other populations.[178] A number of factors can and likely do contribute to this disparity, but to dismiss the contribution of menthol cigarettes is scientifically unsound. The impact of menthol on key smoking behaviors, in combination with predatory tobacco industry marketing practices and the high prevalence of menthol cigarette use among African American smokers, pose a significant concern for the health of the African American community. As noted by former federal health secretaries, failure to restrict or prohibit menthol is to perpetuate "a loophole big enough for a herd of wild animals to romp through and trample the health of African Americans."[179]

Menthol cigarettes are not only used at high rates among children and racial and ethnic minorities, but they also are likely disproportionately marketed to LGBT populations. A series of 1997 Phillip Morris inter-office memoranda concerned with community event sponsorship efforts targeted to the gay and lesbian communities noted not only that the gay and lesbian market has a higher incidence of smoking than the general public,[180] but also that "many General Market and African American Gay and Lesbian adult smokers indicated on their survey forms in 1997 that they smoke menthol-flavored cigarettes."[181] The memo authors concluded that "since many Gay and Lesbian adult smokers have a preference for menthol brands they are a good prospect for future growth of the Benson & Hedges brand," ultimately recommending that "Benson & Hedges continue its presence in the Gay and Lesbian marketplace" — a "presence"

that included blatant sponsorship or marketing at gay and lesbian community events.[182] Such evidence suggests that the tobacco industry has long been aware of the appeal of menthol cigarettes to sexual minorities, and has used this appeal as a basis for expanding their brands. Appallingly, this document and other studies of tobacco industry marketing to the LGBT community indicate that the tobacco industry eagerly sought to exploit the social and legal discrimination faced by sexual minorities, paralleling the targeted marketing of menthol cigarettes to racial minorities.[183]

After a comprehensive review of the scientific evidence of the public health impact of menthol in cigarettes, TPSAC concluded that removal of menthol cigarettes from the marketplace will protect the public health. Studies published since the TPSAC completed its report support the same conclusion. The FDA has the authority and the evidence, and must take action by adding menthol to the additives and constituents prohibited as characterizing flavors in cigarettes and cigarette smoke.

B. The health benefits of a menthol prohibition would outweigh any perceived challenges.

The Tobacco Control Act requires an assessment of the countervailing effects of menthol on the health of cigarette users and nonusers, including the creation of a "significant demand" for contraband.[184] While there are legitimate concerns surrounding the removal of a product that represents 28–34% of the entire cigarette market,[185] opponents have grossly overstated these concerns relative to the anticipated health benefits of a menthol prohibition, as discussed below. First, the health risks associated with increased rates of smoking cessation in response to a menthol prohibition are minimal and are manageable on both the individual and population levels. Second, opponents' claims that a menthol prohibition will produce massive expansion of the illegal cigarette market neglect to consider a number of mitigating factors, resulting in predictions that have little basis in reality.

i. Any health risks associated with cessation are manageable and are minimal relative to the risks of continued tobacco use.

The health benefits associated with quitting tobacco use outweigh any potential risks that quitting could pose to current users. It is undisputed that nicotine-dependent smokers who choose to quit in response to a prohibition will experience symptoms of withdrawal, including depression, anxiety, irritability, difficulty concentrating, insomnia, restlessness, weight gain, and cravings for nicotine.[186] Such symptoms, while significant and distressing, are far outweighed by the immediate and long-term health benefits conferred on those who quit. Quitting smoking has both immediate and long-term health benefits, decreasing disease risk and improving overall health.[187] While quitting has benefits at all ages, there is evidence that quitting smoking before middle age can improve a smoker's life expectancy to that of individuals who have never smoked.[188] Moreover, the symptoms of nicotine withdrawal and risk of relapse can be managed through pharmacological and non-pharmacological interventions,[189] which themselves pose only minor risks relative to the benefits of quitting.[190]

To the extent that a surge in demand for cessation services is anticipated, it could be addressed by a notice period or phase-in of the removal of menthol tobacco products from the marketplace, which would allow the government, health care organizations, and other providers of cessation resources time to prepare for greater demand and would spread out the demand for cessation resources over a longer period of time. This type of phase-in implementation of the prohibition would also allow time for public education about the prohibition and available cessation services. For example, Brazil's recently approved prohibition on

menthol cigarettes, presently on hold due to tobacco industry litigation, would provide 18 months for cigarette manufacturers to remove menthol cigarettes from the market and 24 months for removal of other flavored cigarettes.[191]

A related concern is that certain subpopulations, including racial, ethnic, and sexual minorities, are less likely to participate in cessation services or receive cessation advice from health care providers.[192] The 1998 Surgeon General's Report on tobacco use among racial and ethnic minorities noted that barriers to cessation services include a lack of cultural competence among health care providers and cessation programs, underdeveloped tobacco control infrastructures, and lack of financial resources, both at the level of the individual smoker and at the level of the community.[193] LGBT individuals face similar barriers, including lack of cultural competence among providers and disparities in health insurance coverage.[194] To maximize the anticipated health benefits of a regulation prohibiting menthol tobacco products, it is clear that implementation of the regulation will need to be accompanied by national efforts to increase access to comprehensive, quality, culturally relevant cessation resources, particularly in underserved communities. While this will require investment of FDA and other national health agency resources, such investment needs to be made regardless of whether the FDA adopts a regulation prohibiting menthol cigarettes, given the enormous human and economic cost of smoking and the continuing need to reduce smoking rates.

ii. The risks of expansion of the contraband cigarette market have been overstated relative to the health benefits of a menthol prohibition.

The tobacco industry asserts that prohibiting menthol in cigarettes will ultimately neutralize anticipated health benefits by dramatically increasing the size of this contraband market, resulting in increased crime and increased consumption of unregulated cigarettes.[195] While the contraband market is a legitimate concern, the tobacco industry overstates the willingness of tobacco users to purchase illegal products and underestimates both the impact of a prohibition on public health, as well as the potential for recent legislation and strategic implementation of a menthol prohibition to mitigate expansion of the contraband market.

Moreover, development of a black market in menthol cigarettes would not be easy. Black markets function best when illicit products can be passed off as legal products.[196] By definition, a prohibition on mentholated cigarettes would render them illegal. It would be very difficult to build a significant market for menthol cigarettes without advertising, marketing, and packaging them as such. However, to do so would only advertise the illicit nature of the product. Thus, the potential for the development of a significant black market for menthol cigarettes is limited.[197]

There is ultimately little evidence to back the tobacco industry's claims that prohibiting the sale of menthol cigarettes will lead to massive expansion of the illegal market, with contraband menthol sales equaling as much as 87% of the current menthol market.[198,199] A recently published study indicates that 25% of current adult and adolescent menthol smokers intend to "find a way to buy a menthol brand" if the sale of menthol cigarettes were prohibited, implying a willingness to turn to the contraband market in cigarettes.[200] While this study suggests that there is a segment of menthol smokers who are willing to engage in illegal purchase of menthol cigarettes, it also suggests that the vast majority of menthol smokers intend to pursue the legal options remaining to them (i.e. over 35% would try to quit, 15% would switch to non-menthol cigarettes) or are unsure as to what they would do (28%).[201] Such intentions represent an opportunity for the FDA and other health agencies to utilize public education and cost-effective investment in increased access to comprehensive

cessation resources to maximize public health gain from a menthol prohibition and minimize migration to the contraband market.[202]

Effective publicity and education is all the more likely to maximize public health gain and minimize expansion of the illegal market in light of peer-reviewed data suggesting that a substantial portion of the public supports, or at least does not oppose, prohibiting menthol in cigarettes. In a national cross-sectional survey of 2,649 never, former, and current smokers, 20% of respondents approved of a prohibition on menthol cigarettes while 51.9% did not have a strong opinion for or against a menthol prohibition.[203] Support was highest among Hispanics (36.4%) and African Americans (29.0%)[204] — populations that disproportionately use menthol cigarettes.[205] Even among menthol smokers, nearly half (49.5%) of respondents either supported prohibiting menthol in cigarettes or did not have a strong opinion for or against such a regulation (12.8% of menthol smokers approved of a prohibition of menthol in cigarettes, 29.9% neither agreed nor disagreed, and 6.8% didn't know).[206] Still greater support for prohibiting menthol was observed in a 2011 peer-reviewed study, with 56.1% of all respondents and 75.8% of African American survey respondents saying that they supported prohibiting menthol cigarettes "like other flavored cigarettes."[207] By all indications, public sentiment is not resolved against a prohibition on menthol in cigarettes, suggesting that the FDA has a window of opportunity in which to obtain public cooperation for a rule prohibiting of mentholated tobacco products.

Additionally, recent legislation poses challenges to expansion of an illegal market in cigarettes. The Prevent All Cigarette Trafficking Act (PACT), which went into effect June 2010, limits illegal Internet and mail-order sales by requiring advance payment of state and local excise taxes and by making cigarettes "nonmailable matter."[208] According to a GAO report issued one year after PACT went into effect, experts observed that PACT had already been effective in reducing illegal internet sales of tobacco products. Even with a contraband market already established, widespread expansion of this market to serve the millions of menthol smokers distributed across the country will be made difficult by PACT's limitations on the ability to utilize the Internet and major carriers for sales and distribution. Additionally, PACT instituted stricter criminal penalties and additional enforcement mechanisms that further decrease the incentive to engage in illicit cigarette trade.[209] The ability of the contraband market to expand can be further limited by stricter penalties for smugglers of illegal cigarettes and stricter enforcement, altering the "high reward, low risk" equation that facilitates illicit trade in tobacco.[210]

Claims that a prohibition on menthol would result in massive expansion of a contraband cigarette market are further undermined by evidence that the rise of contraband markets in other countries was not merely a result of market forces, but was facilitated, directly or indirectly, by tobacco companies. For example, one review of industry documents found evidence that British American Tobacco actively sought to direct illicit cigarette trade in Asia, in part to undermine the perceived viability of import bans and to facilitate entry of closed markets.[211] There is also evidence that the key to the rise of contraband tobacco in Canada was the participation of Canadian manufacturers, who exported cigarettes to the U.S. for smuggling back to Canada.[212] The history of tobacco company facilitation of illegal cigarette trade suggests that the tobacco companies themselves will play a role in determining just how much the contraband market expands in response to a menthol prohibition.[213] On one hand, this renders the industry's market predictions concerning smuggling less credible. On the other hand, this suggests that supply chain controls, such as the track and trace regulations that the FDA is directed to promulgate under the To-

bacco Control Act,[214] as well as other pending federal efforts to address smuggling, may be effective in further reducing illicit tobacco trade in response to a menthol prohibition.[215]

Indeed, FDA should move expeditiously to design and propose the track and trace system called for by Section 920(b) of the Tobacco Control Act, affording the ability to track goods from the point of manufacture through each stage in the supply chain to the ultimate point of retail sale, and the capacity to trace back those goods to identify points along the chain where the goods changed hands. An effective system would combine the required use of unique identifying codes applied to each tobacco product with comprehensive recordkeeping at every level of distribution. As to a potential illegal market in mentholated cigarettes, such a system would allow the easy identification of contraband products not bearing the required code, while facilitating enforcement against non-compliant products that do bear the code by allowing identification of all sellers in the supply chain of those products.

Furthermore, even tobacco industry estimates that take into account predicted illegal market expansion, anticipate that a menthol prohibition would have a substantial public health benefit. In a study commissioned by Lorillard, Compass Lexecon determined that a 10% increase in effective price of illegal cigarettes would result in illegal market sales 87% of the current menthol cigarette market and would lead to an initial overall decline in smoking of 1%.[216] While the factors discussed above make it highly unlikely that illegal sales equaling 87% percent of the current menthol market, or over 16 million people (assuming 19 million menthol smokers[217]), will result from a menthol prohibition, even under this unlikely scenario at least 450,000 smokers are predicted to quit (assuming 45.3 million total smokers[218]). Given the morbidity and mortality associated with cigarette smoking, this reduction in smoking represents a substantial public health benefit. More likely, this prediction substantially underestimates the health benefits that would flow from a menthol prohibition since, as TPSAC notes, this analysis does not take into account the effect of a menthol prohibition on youth smoking initiation, or the cumulative effect of a prohibition over the course of several years.[219] Additionally, this analysis does not take into account the greater price sensitivity of youth and young adults, who represent a sizeable fraction of menthol smokers.[220]

Taken together, the available evidence indicates that illegal market predictions regarding a menthol prohibition, and the negative health consequences that would flow from an increase in illegal, unregulated cigarette trade, have been overstated relative to the potential health benefits of a prohibition. Several factors, including, menthol smokers' behavioral intentions, public sentiment, and greater restrictions on cigarette sales and distribution pose barriers to massive expansion of the contraband market. The demand for contraband could be further reduced by efforts to increase and publicize the availability of cessation resources to underserved communities, particularly those that contain a high proportion of menthol smokers — efforts that should be undertaken regardless of a menthol prohibition. Thus, in total, the risks of a contraband menthol cigarette market are minor relative to the public health benefits of a menthol prohibition.

IV. CONCLUSION

Smoking remains the leading cause of preventable death in the United States, costing the United States billions in health costs and lost productivity each year. In this context, preventing young people from becoming regular, addicted smokers and increasing the likelihood of successful smoking cessation are key health goals that, in fact, are the focus of the Tobacco Control Act's public health standard and should be the goal of FDA regulation. Prohibiting menthol in cigarettes is not only expressly within the regulatory authority granted to the FDA by the Tobacco Control Act, but also would make meaningful progress toward serving these critical goals by preventing the marketing and sale of a product that facilitates experimentation and progression to continued smoking and that poses greater barriers to successful smoking cessation. The importance of a prohibition on menthol is further highlighted by the high, growing prevalence of menthol cigarette use among youth and other populations, affecting the health of the population as a whole. In total, the benefits of a menthol prohibition would outweigh the purported challenges, justifying extension of the cigarette flavoring prohibition to menthol under the broad, public health considerations required by the Tobacco Control Act.

V. ENVIRONMENTAL IMPACT

The action requested in this Petition will not have any significant effect on the quality of the human environment.

VI. ECONOMIC IMPACT

No statement of economic impact of the requested action is presented as none has been requested by the Commissioner.[221]

VII. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition that are unfavorable to the petition.[222]

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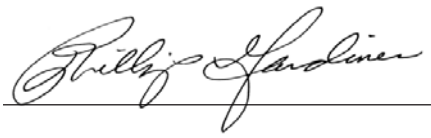

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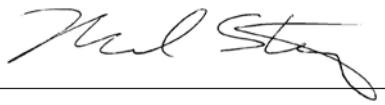

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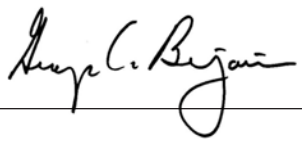

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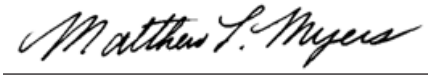

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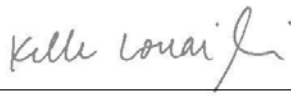

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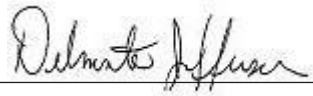

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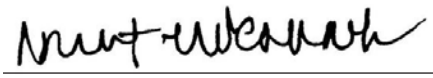

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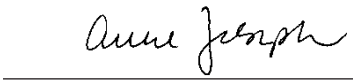

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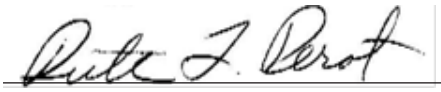

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Endnotes

1 Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, tit. I, sec. 101, § 907(a)(1)(A), (3)(A)-(B), 123 Stat. 1776, 1799-1800 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A), (3)(A)-(B)) [hereinafter Tobacco Control Act].

2 U.S. Dep't of Health & Human Servs., The Health Consequences of Smoking: A Report of the Surgeon General, ch. 7 p. 858 (2004), *available at* http://www.surgeongeneral.gov/library/reports/smokingconsequences/index.html [hereinafter SGR 2004].

3 Ctrs. for Disease Control & Prevention, *Winnable Battles, Tobacco Use*, http://www.cdc.gov/WinnableBattles/Tobacco/index.html (last visited Feb. 22, 2013).

4 U.S. Dep't of Health & Human Servs., Preventing Youth Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General ch. 3 p. 134 (2012), *available at* http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html [hereinafter SGR 2012]; *id.* at ch.7 pp. 850-51, tbl. 7.1 (presenting data from the 2010 National Survey on Drug Use and Health, which indicated that 88.2% of 30- to 39-year-olds who had ever smoked daily first tried a cigarette before age 18 and 65% began smoking daily before age 18; 98.8% had first tried a cigarette and 98.6% began smoking daily before the age of 25).

5 Tobacco Control Act, §907(a)(1)(A), 123 Stat. at 1799-1800 (codified at 21 U.S.C. § 387g(a)(1)(A)).

6 Tobacco Control Act, §907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)).

7 Tobacco Control Act, §907(a)(1)(A), 123 Stat. at 1799-1800 (codified at 21 U.S.C. § 387g(a)(1)(A)).

8 Tobacco Products Scientific Advisory Comm., U.S. Food & Drug Admin., Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations 220 (2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf (final as reviewed and approved by the TPSAC on July 21, 2011) [hereinafter TPSAC Report].

9 *Id.* at 216. TPSAC also concluded that "the availability of menthol cigarettes results in a lower likelihood of smoking cessation success in African-Americans, compared to smoking non-menthol cigarettes." *Id.* at ch. 8 p. 217.

10 *Id.* at 221.

11 *Id.* at 225.

12 Tobacco Control Act, § 907(a)(1)(A), (a)(3)(A)-(B), 123 Stat. at 1799-1800 (codified at 21 U.S.C. 387g(a)(1)(A), (a)(3)(A)-(B)).

13 U.S. Food & Drug Admin., Frequently Asked Questions: Tobacco Products Scientific Advisory Committee's Report and Recommendation on the Impact of the Use of Menthol in Cigarettes 2, *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247652.pdf.

14 *See infra* note 75.

15 *See infra* notes 70-82 (explaining how the smoothing and harshness-reducing properties of menthol likely contribute to experimentation and initiation among younger, newer smokers); *see infra* notes 114-123 (explaining how the harshness-reducing properties of menthol have the potential to enhance addiction/undermine cessation).

16 Cigarettes marketed as menthol cigarettes accounted for 22-27% of the cigarette market in 2009/2010. TPSAC Report, *supra* note 8, at 53; Federal Trade Comm'n, Cigarette Report for 2009 and 2010 at 8 (2012), *available at* http://www.ftc.gov/os/2012/09/120921cigarettereport.pdf. However, 90% of all tobacco products contain menthol at some level, including cigarettes that do not contain menthol as a characterizing flavor. TPSAC Report, *supra* note 8, at 16. Typically, non-menthol cigarettes contain 0.01-0.03% menthol, TPSAC Report, *supra* note 8, at 18, while the average "menthol" cigarette contains 0.389% menthol (3.89 mg menthol per gram tobacco). *See* Celebucki et al., *infra* note 76, at 527-29 tbl. 2.

17 All references to menthol or mentholated cigarettes in this petition refer to cigarettes that have menthol as a characterizing flavor.

18 By the term "gateway properties" we refer to the qualities of a product that make it more accessible to experimentation by non-smokers (the vast majority of whom are youth) because the harsh taste of nicotine is masked by taste and other sensations stimulated by the flavoring.

19 Ctrs. for Disease Control & Prevention, *Current Cigarette Smoking Among Adults, United States, 2011*, 61(44) MMWR 889, 891 (2012), *available at* http://www.cdc.gov/mmwr/pdf/wk/mm6144.pdf .

20 *Id.* at 891.

21 Ctrs. for Disease Control & Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses — United States*, 2000–2004, 57(45) MMWR 1226, 1226 (2008), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf.

22 U.S. Dep't of Health & Human Servs., How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease, A Report of the Surgeon General ch. 1 pp. 10-12 (2010), *available at* http://www.surgeongeneral.gov/library/reports/tobaccosmoke/index.html [hereinafter SGR 2010] (summarizing the mechanisms by which smoking damages the major organ systems and causes cancer, which are described in detail in chapters 5 - 8).

23 Ctrs. for Disease Control & Prevention, *supra* note 21, at 1226.

24 Ctrs. for Disease Control & Prevention, *Youth and Tobacco Use Fact Sheet*, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (last accessed on Feb. 22, 2013) (citing data from Substance Abuse & Mental Health Servs. Admin., NSDUH Series H-41, HHS Publ'n No. (SMA) 11-4658, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings 55 (2011)).

25 Ctrs. for Disease Control & Prevention, *Cigarette Use Among High School Students — United States 1991-2009*, 59(26) MMWR 797, 798, 800 (2010), *available at* http://www.cdc.gov/mmwr/pdf/wk/mm5926.pdf (noting that after declines from the late 1990s to 2003, current cigarette use remained stable from 2003-2009 among male students overall, white students overall, white male students, Hispanic female students, Hispanic male students, and 11th and 12th grade students).

26 U.S. Dep't of Health & Human Servs., Tobacco Use Among U.S. Racial/Ethnic Minority Groups: A Report of the Surgeon General 138 (1998), *available at* http://www.cdc.gov/tobacco/data_statistics/sgr/1998/index.htm [hereinafter SGR 1998]. There is, however, evidence that the disparity in tobacco-related cancer death rates between African-American and Whites may be decreasing. J.O.L. DeLancey, et al., *Recent Trends in Black-White Disparities in Cancer Mortality*, 17(11) Cancer Epidemiol. Biomarkers Prev. 2908, 2910-11 (2008).

27 A review of 46 studies of tobacco use among sexual minorities generally found "a positive association between sexual minority status and cigarette use with [odds ratios] between 1.5 and 2.5." J.G.L. Lee, G.K. Griffin & C.L. Melvin, *Tobacco Use Among Sexual Minorities in the USA, 1987 to May 2007: a Systematic Review*, 18 Tobacco Control 275, 277 (2009). Similarly, a more recent study found that the prevalence of cigarette use was significantly higher among LGBT adults than heterosexual-straight adults (32.8% vs. 19.5%). Brian A. King, Shanta R. Dube, Michael A. Tynan, *Current Tobacco Use Among Adults in the United States: Findings from the National Adult Tobacco Survey*, 102(11) Am. J. of Pub. Health e93, e95, e96 tbl. 1 (2012). The rates of smoking also are higher among young sexual minorities, with adolescent/young adult sexual minority males smoking at a rate about 60% greater than their heterosexual male peers and adolescent/young adult sexual minority females smoking at a rate nearly twice that of their heterosexual female peers. Heather L. Corliss et al., *Sexual-Orientation Disparities in Cigarette Smoking in a Longitudinal Cohort Study of Adolescents*, Nicotine & Tobacco Research doi: 10.1093/ntr/nts114, at 4, 5 tbl. 1 (2012) (published electronically ahead of print).

28 *See infra* notes 192-194 and accompanying text.

29 Tobacco Control Act, Pub. L. 111-31, sec. 2(1), (2), (13)&(14), 123 Stat. 1776, 1777 (2009).

30 Tobacco Control Act, sec. 2(6)-(7), 123 Stat. at 1777.

31 Tobacco Control Act, tit. I, sec. 101, § 907(a)(3)(A), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(A)).

32 Tobacco Control Act, §907(a)(3)(B)(i)(I)-(III), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)-(III)).

33 H.R. Rep. 111-58(i), at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488.

34 *Id.*

35 Non-Voting Industry Representatives on TPSAC and Other Tobacco Industry Stakeholders, Menthol Cigarettes: No Disproportionate Impact on Public Health: The Industry Menthol Report 54, 68, 80, 247 (2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf [hereinafter Industry Menthol Report].

36 Tobacco Control Act, §907(a)(3)(B)(i)(I)-(III), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)-(III)).

37 The 2004 Surgeon General Report separated causal conclusions from public health recommendations, "a decoupling [that] is necessary, as decision-making in the face of uncertainty involves different issues than those that pertain to the uncertainty itself…." SGR 2004, *supra* note 2, at ch. 1 p. 24. The Report notes that public health recommendations are necessarily informed by broader considerations than "conclusions regarding causality": "The proportion of cases in the population as a result of exposure (the population attributable risk), along with the total prevalence and seriousness of a disease, are more relevant for deciding on actions than the relative risk estimates typically used for etiologic determinations." *Id.* at ch. 1, p. 18.

38 Tobacco Control Act, § 907(a)(3), 123 Stat. at 1799 (codified at 21 U.S.C. 387g(a)(3)).

39 Tobacco Control Act, § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(1)).

40 Tobacco Control Act, § 907(e)(2), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(2)).

41 Tobacco Control Act, § 907(e)(3), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(3)).

42 *See* Tobacco Control Act, §907(a)(1)(A), 123 Stat. at 1799 (codified at 21 U.S.C. § 387g(a)(1)(A)) ("[n]othing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.").

43 *See* Tobacco Control Act, § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(1)) (requiring that the Secretary refer to the Tobacco Products Scientific Advisory Committee "the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities.").

44 Tobacco Control Act, § 907(a)(3)(B)(i)(I), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)).

45 Nat'l Networks for Tobacco Control & Prevention, *Priority Populations*, http://www.tobaccopreventionnetworks.org/site/c.ksJPKXPFJpH/b.2582389/k.737A/Priority_Population_Info.htm (last visited Feb. 22, 2013).

46 TPSAC Report, *supra* note 8, at 220.

47 TPSAC Report, *supra* note 8, at 225.

48 World Health Org., *About the WHO Framework Convention on Tobacco Control*, http://www.who.int/fctc/about/en/index.html (last visited Feb. 22, 2013).

49 World Health Org., Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC Part 3.1.2.2 (2010), *available at* http://www.who.int/fctc/protocol/guidelines/adopted/article_9and10/en/index.html.

50 Tobacco Control Act, Pub. L. 111-31, tit. I, sec. 101, § 907(a)(1)(A), 123 Stat. 1776, 1799 (2009) (codified at 21 U.S.C. 387g(a)(1)(A)); § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C.A. § 387g(e)(1)).

51 TPSAC Report, *supra* note 8, at 218.

52 Tobacco Control Act, § 907(a)(3)(A), 123 Stat. at 1800 (codified at 21 U.S.C.A. 387g(a)(3)(A)).

53 TPSAC Report, *supra* note 8, at 219.

54 TPSAC Report, *supra* note 8, at 218-19, 220-21.

55 *See infra* notes 63-67, 156-167 and accompanying text.

56 *See infra*, notes 73-82, 168-177 and accompanying text.

57 Tobacco Control Act, § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C.A. § 387g(e)(1)).

58 TPSAC Report, *supra* note 8, at 215.

59 TPSAC Report, *supra* note 8, at 216.

60 *E.g.*, James Hersey et al., *Are Menthol Cigarettes a Starter Product for Youth?* 8(3) Nicotine & Tobacco Research 403, 407, 410 (2006); Phillip Gardiner & Pamela I. Clark, *Menthol Cigarettes: Moving Toward a Broader Definition of Harm*, 12(suppl. 2) Nicotine & Tobacco Research S85, S87 (2010); U.S. Food & Drug Admin., *Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law*, FDA News Release (Sept. 22, 2009) http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm (last visited Feb. 23, 2013) (quoting FDA Commissioner, Margaret A. Hamburg, who characterizes the flavored cigarettes banned by the Tobacco Control Act as "a gateway for many children and young adults to become regular smokers").

61 *See* SGR 2012, *supra* note 4, at ch. 2 pp. 16-19 (summarizing the conclusions from previous Surgeon General's reports on the adverse effects of tobacco use and exposure to secondhand smoke in children and young adults); *id.* at ch. 2 pp. 79-96 (detailing the effects of tobacco on pulmonary function and chronic respiratory symptoms in children and young adults); *id.* at ch. 2 pp. 97-109 (detailing the effects of tobacco on cardiovascular disease); *id.* at ch. 2 pp. 110 ("active smoking across adolescence and young adulthood increases the development of atherosclerosis and limits lung growth while also accelerating the onset of decline in lung function").

62 TPSAC Report, *supra* note 8, at 41.

63 TPSAC Report, *supra* note 8, at 215.

64 *Id.*

65 Office of Applied Studies, Substance Abuse & Mental Health Servs. Admin., NSDUH 09-1119, The NSDUH Report: Use of Menthol Cigarettes 2 fig. 1 (2009), *available at* http://store.samhsa.gov/product/Use-of-Menthol-Cigarettes/NSDUH09-1119 [hereinafter SAMHSA 2009].

66 James Hersey et al., *Menthol Cigarettes Contribute to the Appeal and Addiction Potential of Smoking for Youth*, 12(suppl. 2) Nicotine & Tobacco Research S136, S141 tbl. 3 (2010).

67 SAMHSA 2009, *supra* note 65, at 4 fig. 5; *see also* TPSAC Report, *supra* note 8, at 215 ("[t]here is some evidence that new smokers — those who have been smoking for less than a year — have a greater prevalence of menthol cigarette use than established smokers.").

68 TPSAC Report, *supra* note 8, at 215.

69 World Health Org., *supra* note 49.

70 Karen Ahijevych & Bridgette E. Garrett, *Menthol Pharmacology and its Potential Impact on Cigarette Smoking Behavior*, 6(suppl. 1) Nicotine & Tobacco Research S17, S19 (2004); TPSAC Report, *supra* note 8, at 19-20.

71 TPSAC Report, *supra* note 8, at 19-20; *see also* Paul M. Wise, George Preti, Jason Eades, & Charles J. Wysocki, *The Effect of Menthol Vapor on Nasal Sensitivity to Chemical Irritation*, 13(10) Nicotine &Tobacco Research 989, 992 & fig. 2, 993 & fig. 3 (2011) (finding that pretreatment with menthol vapor reduced nasal sensitivity to the irritant acetic acid, but enhanced sensitivity to the irritant allyl isothiocyanate — suggesting that menthol may have a complex modulatory effect on sensations in the upper airway induced by cigarette-associated chemicals).

72 *See* Geoffrey Ferris Wayne & Gregory N. Connolly, *Application, Function, and Effects of Menthol in Cigarettes: A Survey of Tobacco Industry Documents*, 6(suppl. 1) Nicotine & Tobacco Research S43, S48 (2004) (citing a 1972 Brown & Williamson memo: "[t]his perceived reduction [in the perceived intensity of tobacco pain-sensitive sensations] may be due to a drug effect that reversibly impedes impulse transmission in peripheral nerves and nerve endings, or 'the addition of smoke sensations (*e.g.* "cooling") [that] reduces only the *apparent* intensity of tobacco pain-suggestive sensations.' In the latter case menthol is a counterirritant causing the loss of ability to recognize or identify local pain sensation."); *see also* TPSAC Report, *supra* note 8, at 20 (citing evidence that menthol may produce analgesic effects through interaction with nociceptive c receptors, which mediate the transmission of pain signals).

73 *See* Industry Menthol Report, *supra* note 35, at 202 ("speculative explanations of how menthol may mask nicotine or other components of tobacco smoke based on existing mechanistic data do not appear to be as likely or important reasons for brand selection as are simple subjective taste preferences.").

74 Valerie B. Yerger & Phyra McCandless, *Menthol Sensory Qualities and Smoking Topography: A Review of Tobacco Industry Documents*, 20(suppl. 2) Tobacco Control ii37, ii38 (2010).

75 *Id.*; Valerie B. Yerger, *Menthol's Potential Effects on Nicotine Dependence: a tobacco industry perspective*, 20(suppl. 2) Tobacco Control ii29, ii30 (2011); *see also* Wayne & Connolly, *supra* note 72, at S47 (citing a Brown & Williamson study, which reportedly showed that "even 'below the [recognition] threshold level, menthol tends to "smooth" the smoke'").

76 While individuals differ in their ability to detect menthol by taste/cooling sensation, Lorillard presented evidence to TPSAC indicating that menthol is generally detectable at a level of 0.12% menthol in the tobacco blend. TPSAC Report, *supra* note 8, at 18 (citing to William R. True, Lorillard Tobacco Co., *Characterization of Menthol* 13 (2010), (presentation to the TPSAC July 15-16, 2010 meeting), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM220039.pdf). An independent study of menthol content in U.S. cigarettes branded as metholated found that all 48 menthol sub-brands surveyed contained well above this level, averaging 3.89 mg menthol/g tobacco (0.389%) with a range of 2.35 mg menthol/g tobacco (0.235%; for Newport 85mm regular) to 7.76 mg menthol/g tobacco (0.776%; for Marlboro 85 mm Ultra). Carolyn C. Celebucki et al., *Characterization of Measured Menthol in 48 U.S. Cigarette Sub-Brands*, 7(4) Nicotine & Tobacco Research 523, 527-29 tbl. 2 (2004). Menthol is also present in 90% of all tobacco products, including cigarettes *not* marketed as menthol cigarettes, TPSAC Report, *supra* note 8, at 16. Menthol is typically in non-menthol cigarettes at concentrations of 0.01%-0.03%. TPSAC Report, *supra* note 8, at 18 (citing Wayne & Connolly, *supra* note 72, at S45).

77 Jennifer M. Kreslake et al., *Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults*, 98(9) Am. J. of Pub. Health 1685, 1686 (2008); Kim Klausner, *Menthol Cigarettes and Smoking Initiation: a tobacco industry perspective*, 20(suppl. 2) Tobacco Control ii12, ii14 (2011).

78 Jennifer M. Kreslake et al., *The Menthol Smoker: Tobacco Industry Research on Consumer Sensory Perception of Menthol Cigarettes and its Role in Smoking Behavior*, 10(4) Nicotine & Tobacco Research 705, 710 (2008).

79 Kreslake et al., *supra* note 77, at 1686.

80 *Id.* at 1686-87 (reviewing evidence that R.J. Reynolds reformulated all of its Salem brand varieties to have lower menthol levels; that Brown & Williamson sought to create a product with low menthol loading and repositioned its Kool Milds variety to attract young adults; and that Marlboro pursued a 2-pronged approach to capture a greater share of the menthol market, targeting young adults with its lower-menthol Marlboro Milds brand and increasing the levels of menthol in its Marlboro Menthol brand intended for older smokers); Klausner *supra* note 77, at ii13.

81 Charyn Sutton & Robert G. Robinson, *The marketing of menthol cigarettes in the United States: Populations, messages, and channels*, 6(suppl. 1) Nicotine & Tobacco Research S83, S87 (2004); Klausner *supra* note 77, at ii15-17.

82 TPSAC Report, *supra* note 8, at 219.

83 SGR 2012, *supra* note 4, at ch. 2 p. 22.

84 *Id.*

85 *See supra* note 61 and accompanying text (summarizing the 2012 Surgeon General Report's conclusions about the health effects of smoking on youth).

86 *See supra* note 4.

87 Valerie Rock et al., *Menthol Cigarette Use Among Racial and Ethnic Groups in the United States*, 2004-2008, 12(suppl. 2) Nicotine & Tobacco Research S117, S120 tbl. 2 (2010) (analyzing data from the 2004-2008 National Survey on Drug Use and Health).

88 TPSAC Report, *supra* note 8, at 215.

89 Office of Applied Studies, Substance Abuse & Mental Health Servs. Admin., NSDUH 11-1118, The NSDUH Report: Recent Trends in Menthol Cigarette Use 2-3 (2011), *available at* http://store.samhsa.gov/product/Recent-Trends-in-Menthol-Cigarette-Use/NSDUH11-1118. These statistics indicate the percent of menthol smokers among *all* 12-17 year olds surveyed, including smokers and non-smokers.

90 *Id.* These statistics indicate the percent of menthol smokers among all 18-25 year olds surveyed, including smokers and non-smokers.

91 *See* Tobacco Control Act, Pub. L. 111-31, tit. I, sec. 101, §907(a)(3)(B)(III), 123 Stat. 1776, 1800 (2009) (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(III)) (requiring consideration of the effect of a proposed standard on the "likelihood" that non-users will start using tobacco products).

92 Pub. Health Serv. , U.S. Dep't of Health & Human Servs., Clinical Practice Guideline, Treating Tobacco Use and Dependence: 2008 Update 15 (2008) *available at* http://www.ahrq.gov/clinic/tobacco/treating_tobacco_use08.pdf.

93 Ctrs. for Disease Control & Prevention, *Quitting Smoking Among Adults — United States, 2001–2010*, 60(44) MMWR 1513, 1515 tbl. 1 (2011) (analyzing data from the 2010 National Health Interview Survey).

94 *See supra* note 22.

95 Ctrs. for Disease Control & Prevention, *supra* note 21, at 1228.

96 U.S. Dep't of Health & Human Servs., The Health Benefits of Smoking Cessation: A Report of the Surgeon General ch. 1 pp. 7, 9-12 (1990), *available at* http://profiles.nlm.nih.gov/NN/B/B/C/T/ [hereinafter SGR 1990]. See generally *id.* at ch. 3-9 for detailed review of scientific and clinical evidence regarding the impact of smoking cessation on risk of cancers, cardiovascular disease, respiratory disease, reproductive function, and overall morbidity and mortality.

97 *See infra* Part III.2.A.ii.a.

98 *See infra* Part III.2.A.ii.b.

99 TPSAC Report, *supra* note 8, at 216.

100 Hersey 2006 *supra* note 60 at 408, 411 tbl. 5; Hersey 2010 *supra* note 66 at S141-42 tbl. 5; TPSAC Report, *supra* note 8, at 130-32.

101 James Nonnemaker et al., *Initiation with Menthol Cigarettes and Youth Smoking Uptake*, 108 Addiction 171, 175, 177 tbl. 3 & 4 (2013) (finding a positive, significant association between initiation with menthol cigarettes and both progression to regular smoking as well as measures of nicotine addiction).

102 TPSAC Report, *supra* note 8, at 147.

103 TPSAC Report, *supra* note 8, at 217.

104 TPSAC Report, *supra* note 8, at 216-17; *see* generally *id.* at 133-150 for summaries of the studies *available at* the time the TPSAC Report was written.

105 Am. Legacy Found., The Impact of the Use of Menthol in Cigarettes on the Public Health, 8, (2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM246050.pdf (public submission to the FDA Tobacco Product Scientific Advisory Committee, for the Jan. 10-11, 2011 meeting) [hereinafter Legacy].

106 Legacy, *supra* note 105, at 8-9 (referring to Dennis R. Trinidad et al., *Menthol Cigarettes and Smoking Cessation Among Racial/Ethnic Groups in the U.S.*, 105(suppl. 1) Addiction 84 (2010); David T. Levy et al., *Quit Attempts and Quit Rates Among Menthol and Non-Menthol Smokers in the United States*, 101(7) Am. J. of Pub. Health 1241 (2011); Pebbles Fagan et al., *Nicotine Dependence and Quitting Behaviors Among Menthol and Non-Menthol Smokers with Similar Consumptive Patterns*, 105(suppl. 1) Addiction 55 (2010); Mandy Stahre et al., *Racial/Ethnic Differences in Menthol Cigarette Smoking, Population Quit Ratios, and Utilization of Evidence-Based Tobacco Cessation Treatments*, 105(suppl. 1) Addiction 75 (2010); Catherine Cubbin et al., *The Intersection of Gender and Race/Ethnicity in Smoking Behaviors Among Menthol and Non-menthol Smokers in the U.S.* 105(suppl. 1) Addiction 32 (2010); Daniel A. Gunderson, *Exploring the Relationship Between Race/Ethnicity, Menthol Smoking, and Cessation in a Nationally Representative Sample of Adults*, 49(6) Preventative Med. 553 (2009)).

107 Legacy, *supra* note 105, at 8-9 (referring to Levy et al., 2011, Stahre et al., 2010, Trinidad et al., 2010, & Gunderson et al., 2009, *supra* note 106).

108 Legacy, *supra* note 105, at 10-11.

109 Babalola Faseru et al., *Predictors of Cessation in African American Light Smokers Enrolled in a Bupropion Clinical Trial*, 38 Addictive Behaviors 1796, 1799 & tbl. 1 (2013).

110 Laura R. Reitzel et al., *Race Moderates the Effect of Menthol Cigarette Use on Short-Term Smoking Abstinence*, Nicotine & Tobacco Research, doi: 10.1093/ntr/nts335 at 1, 3-4 (2013) (published online ahead of print) (analyzing data from a longitudinal study of cessation of smokers from Houston, Texas, looking at abstinence up to 3 weeks postquit).

111 Judith Rosenbloom et al., *A Cross-sectional Study on Tobacco Use and Dependence Among Women: Does Menthol Matter?*, 10(19) Tobacco Induced Diseases at 3, 4 tbl. 1 (2012), *available at* http://www.tobaccoinduceddiseases.com/content/10/1/19.

112 Legacy, *supra* note 105, at 11-12.

113 Tobacco Control Act, Pub. L. 111-31, tit. I, sec. 101, §907(a)(3)(B)(II), 123 Stat. 1776, 1800 (2009) (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(II)).

114 *See supra* notes 70-75 and accompanying text.

115 TPSAC Report, *supra* note 8, at 24.

116 Yerger & McCandless, *supra* note 74, at ii38; Wayne & Connolly, *supra* note 72, at S47; TPSAC Report, *supra* note 8, at 27.

117 *See* Yerger & McCandless, *supra* note 74, at ii38 (citing a Phillip Morris document: "'Four key menthol taste effects that appeal to smokers are cooling, clean/antiseptic, numbing/anaesthetic, refreshing'; noting in particular, 'menthol is a "sensation" in which menthol taste and cooling are indistinguishable'").

118 Wayne & Connolly, *supra* note 72, at S47; *see also* Valerie B. Yerger, *Menthol's potential effects on nicotine dependence: a tobacco industry perspective*, 20(suppl. 2) Tobacco Control ii29, ii33 (2011) (reviewing tobacco industry studies by Phillip Morris and R.J. Reynolds that indicated that menthol produces nicotine-like sensory characteristics by stimulating trigeminal fibers).

119 Wayne & Connolly, *supra* note 72, at S47.

120 Yerger, *supra* note 118, at ii30.

121 Ctrs. for Disease Control & Prevention, *Tobacco Brand Preferences, Smoking & Tobacco Use*, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/brand_preference/index.htm (last visited Feb. 23, 2013).

122 Kreslake et al., *supra* note 77, at 1688.

123 *Id.* at 1686, 1688, 1689. The presence of lower levels of menthol in Newport cigarettes has been confirmed by a survey of menthol content in major U.S. cigarette sub-brands, which found that Lorillard's Newport sub-brands contained, on average, a lower amount of menthol per cigarette and menthol per gram of tobacco (2.15 mg menthol/cigarette, 3.04 mg menthol/g tobacco) than any other brand tested, including R.J. Reynolds, Philip Morris, and Brown & Williamson menthols. Celebucki, *supra* note 76, at 527-29 tbl. 2. The lowest levels of menthol in any menthol sub-brand tested were found in Newport's 85mm regular sub-brand. *Id.* at 527 tbl. 2.

124 Jed E. Rose, *Nicotine and Nonnicotine Factors in Cigarette Addiction*, 184 Psychopharmacology 274, 278 (2006) (reviewing studies related to contribution of nonnicotine sensory factors to addiction: "The findings summarized above, which implicate nonnicotine factors as potentially important contributors to cigarette addiction do not negate the primary reinforcing role of nicotine. Thus, sensory cues have likely become reinforcing due to the Pavlovian association with nicotine or via sensitization of their incentive value by nicotine-mediate dopamine release").

125 Jed E. Rose & Frederique M. Behm, *Extinguishing the Rewarding Value of Smoke Cues: Pharmacological and Behavioral Treatments*, 6(3) Nicotine & Tobacco Research 523, 531 (2004).

126 TPSAC Report, *supra* note 8, at 27.

127 Kreslake et al., *supra* note 78, at 711.

128 *See* Kreslake et al., *supra* note 77, at 1686-87 (describing marketing strategies of R.J. Reynolds, Brown & Williamson, and Phillip Morris to attract younger smokers through development of varieties with low-menthol formulations, such as Salem Black Label, Marlboro Milds, and Kool Milds, while aiming to keep their older consumers' satisfied through the offering of higher menthol varieties, such as Salem Green Label or Marlboro Menthol); *id.* at 1686 ("R.J. Reynolds attributed the appeal of Newport among younger smokers to its lower menthol content, observing in 1987 that 'the want for less menthol does indeed skew younger adult.'"); *see also* Klausner *supra* note 77, at ii14 (observing that the evolving preference for more menthol as smokers age "creates a dilemma for brand managers"; this dilemma was recognized by the tobacco companies, including R.J. Reynolds, who noted that "'A [menthol] brand which has a strategy of maximizing franchise acceptance will invariably increase its menthol level. Thus, once a brand becomes successful, its product will evolve in a manner that is not optimal for younger adult non-menthol smokers/switchers.'").

129 Kreslake et al., *supra* note 77, at 1687 tbl. 1.

130 Yerger, *supra* note 118, at ii31-32.

131 *Id.* at ii32.

132 *See United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 560-61 (D.D.C. 2006) for a summary of tobacco company knowledge and marketing activities regarding low tar or low nicotine cigarettes:

> It is clear, based on [the defendant tobacco companies'] internal research documents, reports, memoranda, and letters, that the Defendants have known for decades that there is no clear health benefit from smoking low tar/low nicotine cigarettes as opposed to conventional full-flavor cigarettes. […] Defendants also knew that many smokers who were concerned and anxious about the health risks from smoking would rely on the health claims made for low tar cigarettes as a reason, or excuse, for not quitting smoking. […] By engaging in this deception, Defendants dramatically increased their sales of low tar/light cigarettes, assuaged the fears of smokers about the health risks of smoking, and sustained corporate revenues in the face of mounting evidence about the health dangers of smoking.

133 Ahijevych & Garrett, *supra* note 70, at S20; Connolly & Wayne, *supra* note 72, at S49; Jennifer M. Kreslake & Valerie B. Yerger, *Tobacco Industry Knowledge of the Role of Menthol in Chemosensory Perception of Tobacco Smoke*, 12(suppl. 2) Nicotine & Tobacco Research S98, S99 (2010).

134 *See supra* notes 68-75 and accompanying text.

135 Paul M. Wise, Paul A.S. Breslin, & Pamela Dalton, *Sweet Taste and Menthol Increase Cough Reflex Thresholds*, 25 Pulmonary Pharmacology & Therapeutics 236, 238-239 (2012) (finding that inhaled menthol vapor, as well as orally-administered sucrose, increased the concentration of the irritant capsaicin needed to trigger the cough reflex in humans); A.H. Morice et al., *Effect of Menthol on Citric Acid Induced Cough in Normal Subjects*, 49 Thorax 1024, 1025 fig. 2, 1026 (1994) (finding that inhaled menthol significantly reduced chemically-induced coughing in human subjects).

136 *See* Samuel Garten & R. Victor Faulkner, *Continual Smoking of Mentholated Cigarettes May Mask the Early Warning Symptoms of Respiratory Disease*, 37(4) Preventative Med., 291, 294-295 (2003) (synthesis of the available scientific literature suggests that continuous inhalation of menthol via routine smoking of menthol cigarettes reduces many of the early warning symptoms of respiratory disease).

137 *Id.* at 294-95.

138 *See* Sutton & Robinson, *supra* note 81, at S86 (noting that manufacturers of the earliest menthol cigarettes, such as Spud, Penguin, and Kool promoted their brands as healthier and that the health association remains, "Even when the health benefits of menthol smoking were not stated explicitly in the advertising the health association remained" as "'People judge that menthol has some beneficial properties related to pulmonary conditions because they encounter it only in cough and cold remedies'"); Stacey J. Anderson, *Marketing of Menthol Cigarettes and Consumer Perceptions: a Review of Tobacco Industry Documents*, 20(suppl. 2) Tobacco Control ii20, ii23-24 (2011) (finding evidence in tobacco industry documents that the industry was aware that a "pseudo-health image," "health overtones" or "therapeutic implications" had attached to menthol cigarettes in the minds of consumers).

139 Tobacco Control Act, Pub. L. 111-31, tit. I, sec. 101, § 907(a)(3)(B)(i)(I)-(III), 123 Stat. 1776, 1800 (2009) (codified at 21 U.S.C. § 387g(a)(3) (B)(i)(I)-(III)).

140 *See supra* notes 86-90 and accompanying text.

141 TPSAC Report, *supra* note 8, at 113-115, 218. The TPSAC Report cited an unpublished 2010 submission from Gary A. Giovino in its discussion of switching patterns. *Id.* at 115. This data, which showed that 15.0% of 16-24 year old participants who had been menthol smokers at baseline had switched to non-menthol cigarettes at 24 month follow-up, compared to 6.9% switching from non-menthol to menthol cigarettes, is now published: Andrea C. Villanti et al., *Menthol Brand Switching Among Adolescents and Young Adults in the National Youth Smoking Cessation Survey*, 102(7) Am. J. of Pub. Health 1310, 1311 tbl. 1, 1312 (2012).

142 *Id.* at 221-22 tbl. 1 (referring to predictions based on TPSAC best estimates).

143 *Id.*

144 Jennifer L. Pearson et al., *A Ban on Menthol Cigarettes: Impact on Public Opinion and Smokers' Intention to Quit*, 102(11) Am. J. of Pub. Health e107, e112 tbl. 3 (2012).

145 *Id.*

146 *Id.* at e111.

147 Richard J. O'Connor et al., *What Would Menthol Smokers do if Menthol in Cigarettes Were Banned? Behavioral Intentions and Simulated Demand*, 107 Addiction 1330, 1332 & 1336 (2012).

148 James Hersey, *Commentary on O'Connor et al. (2012): Planning to Effectively Ban Menthol Cigarettes*, 107 Addiction 1339, 1339 (2012).

149 Anne Hartman, What Menthol Smokers Report They Would Do If Menthol Cigarettes Were No Longer Sold 3,6 (2011) *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM243628.pdf (public submission to the FDA Tobacco Product Scientific Advisory Committee, for the Feb. 10, 2011 meeting).

150 Pub. Health Serv., *supra* note 92. These Clinical Practice Guidelines were developed by a panel of scientists and clinicians reviewing the available scientific and clinical data relating to tobacco dependence treatments. The panel ultimately concluded that multiple forms of pharmacological and non-pharmacological tobacco dependence treatments are both clinically effective and highly cost effective. *Id.* at 6-8. The panel's clinical recommendations recognize that there are numerous effective medications, ranging from over-the-counter nicotine replacement therapies to buproprion, available for treatment of tobacco dependence, *id.* at 7, and that physicians should recommend their use to all smokers *see*king to quit, except when medically contraindicated. *Id.* at 7. The panel also noted that individual, group, and telephone counseling has been demonstrated to be effective in treating tobacco dependence. *Id.* at 8. A combination of medication and counseling was deemed even more effective than either method alone. *Id.* For additional evidence that NRT and other pharmacotherapies greatly increase the rate of quit success *see* L.F. Stead et al., *Nicotine replacement therapy for smoking cessation (Review)*, Issue 11, Cochrane Review, 2 (2012) (observing a 50-70% increase in quit success with NRT vs. placebo, regardless of setting, in meta-analysis of over 100 trials and 50,000 patients); Mark J. Eisenberg et. al, *Pharmacotherapies for smoking cessation: a meta-analysis of randomized controlled trials*, 179(2) CMAJ 135, 142 (2008) (observing that NRT, bupropion and varenicline are more effective than placebo at 6 and 12 months out in a metaanalysis of 69 trials, over 30,000 patients).

151 Hersey, *supra* note 148, at 1339.

152 David T. Levy et al., *Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States*, 101(7) Addiction 1236, 1239 tbl. 1 (2011); *id.* at 1237 (assuming that 10% of those who would have initiated with menthol cigarettes do not initiate as a result of a ban).

153 *Id.* at 1239 tbl. 1.

154 Ctrs. for Disease Control & Prevention, *Cigarette smoking-attributable morbidity — United States, 2000*, 52(35) Morbidity and Mortality Weekly Report 842, 842 (based on 440,000 smoking-attributable deaths each year and 8.6 million sufferers of 12.7 million serious, tobacco-attributable diseases), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5235.pdf.

155 Tobacco Control Act, Pub. L. No. 111-31, tit. I, sec. 101, § 907(e)(1), 123 Stat. 1776, 1804 (2009) (codified at 21 U.S.C. § 387g(e)(1)).

156 TPSAC Report, *supra* note 8, at 219.

157 *Id.* at 217.

158 *Id.* at 219.

159 *Id.* at 223.

160 SAMHSA 2009, *supra* note 65, at 4 fig. 4.

161 Deirdre Lawrence et al., *National Patterns and Correlates of Mentholated Cigarette Use in the United States*, 105(suppl. 1) Addiction 13, 18 tbl. 2 (2010). This study also determined that, after controlling for sociodemographic factors and "smoking behavior variables," the most significant factor correlated with menthol cigarette use was race/ethnicity, with African American smokers estimated to be nearly 11 times more likely to use mentholated cigarettes than white smokers (an adjusted odds ratio of 10.92) and Hispanic and Asian/Pacific Islander smokers, to be approximately twice as likely (adjusted odds ratios of 1.92 and 2.07, respectively). *Id.* at 19, 22 tbl. 4.

162 Rock et al., *supra* note 87, at S119, S120 tbl. 2. It has been suggested that these data may considerably underestimate the actual rates of use, at least among African American youth. Anthony P. Polednak, Letter: Underestimation of Menthol Cigarette Use Among Young U.S. Black Smokers: Comment on the Article by Rock et al., 14(2) Nicotine & Tobacco Research 248 (2012).

163 Rock et al., *supra* note 87, at S119, S120 tbl. 2.

164 *Id.* at S120.

165 Lawrence et al., *supra* note 161, at 19, 20 tbl. 3.

166 Maryland Dept. of Health & Mental Hygiene, Report on Disparities in Tobacco Use Behaviors by Adult Minority Populations in Maryland, 2006 at 43 (2008), *available at* http://www.sph.umd.edu/epib/cultural_competency/TobaccoDisparities.html.

167 *Id.*

168 Senaida Fernandez et al., *Cigarette Advertising in Magazines for Latinas, White Women, and Men, 1998-2002: A Preliminary Investigation*, 30(2) J. of Cmty. Health 141, 145 tbl. 1 (2005) (finding a significantly higher prevalence of menthol cigarette ads in the Spanish-language versions of *Cosmopolitan* and *Glamour* than in the English-language versions: 51.1% vs. 28.3% of cigarette ads); Hope Landrine et al., *Cigarette Advertising in Black, Latino, and White Magazines, 1998-2002: An Exploratory Investigation*, 15 Ethnicity & Disease 63, 64-65 tbl. 2 (2005) (finding significantly higher prevalence of menthol cigarette ads in magazines targeted to Latino or African American audiences, *People in Spanish* or *Ebony*, than in a magazine targeted to a White audience, *People*).

169 Lawrence et al., *supra* note 161, at 17, 19.

170 Tess Boley Cruz et al., *The Menthol Marketing Mix: Targeted Promotions For Focus Communities*, 12(suppl. 2) Nicotine & Tobacco Research S147, S150 (2010); *see also* Rachel Widome et al., *The Relationship of Neighborhood Demographic Characteristics to Point-of-Sale Tobacco Advertising and Marketing*, Ethnicity & Health 1, 8 tbl. 3 (2012) (published electronically ahead of print) (finding that tobacco retailers in areas of the St. Paul, Minnesota metro area with higher proportions of African American or Asian residents had more ads for menthol cigarette brands, relative to areas with a lower percent of racial/ethinic minority residents).

171 Gardiner & Clark *supra* note 60, at S88.

172 TPSAC Report, *supra* note 8, at 66-67.

173 Phillip S. Gardiner, *The African Americanization of Menthol Cigarette Use in the United States*, 6(suppl. 1) Nicotine & Tobacco Research S55, S62 (2004).

174 Gardiner & Clark, *supra* note 60, at S88.

175 Cruz et al., *supra* note 170, at S151.

176 Cheryl G. Healton et al., *Why We Should Make Menthol Cigarettes History*, 12(suppl. 2) Nicotine & Tobacco Research S94, S95 (2010).

177 Id; Navid Hafez & Pamela L. Ling, *Finding the Kool Mix: How Brown & Williamson Used Music Marketing to Sell Cigarettes*, 15 Tobacco Control 359, 362-63 (2006).

178 *See supra* note 26 and accompanying text.

179 Joseph A. Califano, Jr. et al., *Text of Letter to Senators on Menthol Exemption for Cigarettes*, N.Y. Times, June 5, 2008, *available at* http://www.nytimes.com/2008/06/05/business/05TobaccoLetter.html?_r=0.

180 Y. Robinson, Philip Morris USA, *CEM's Lesbian and Gay Marketing Efforts*, Oct. 9, 2007, Bates no. 2071145109/5110, http://legacy.library.ucsf.edu/tid/xht49h00/pdf .

181 *Id.*; Y. Robinson, Philip Morris USA, *CEM's Lesbian and Gay Marketing Efforts*, Oct. 16, 2007, Bates no. 2071145111/5112, http://legacy.library.ucsf.edu/tid/wht49h00/pdf .

182 Y. Robinson, Philip Morris USA, *CEM's Lesbian and Gay Marketing Efforts*, Nov. 11, 2007, Bates no. 2072431966/1969, http://legacy.library.ucsf.edu/tid/xnh80h00/pdf (noting that "In 1997 Community Event Marketing commenced its marketing efforts toward Gay and Lesbian adult smokers. Ten events, identified by Spare Parts Marketing and Communication, were effective in exposing the Benson & Hedges brand to over [redacted] Gay and Lesbian adult smokers and secured [redacted] names for the database. [...] These events allowed Benson & Hedges to 'get a head start' on the competition in the Gay and Lesbian market.").

183 *See id.* (supporting the statement that gay and lesbian smokers are a "good prospect for future growth" with the finding that "the Gay and Lesbian lifestyle exposes them to many adverse situations that give them a better understanding and appreciation for the right of adults to choose"); *see also* Harriet A. Washington, *Burning Love: Big Tobacco Takes Aim at LGBT Youths*, 92(7) Am. J. of Pub. Health 1086, 1089-90, 1093-94 (2002) (noting parallels between the evolution of targeted marketing of African Americans to the ways in which tobacco companies are currently pursuing the LGBT market, particularly in the tobacco industry's portrayal of itself as "corporate friend" to the LGBT community by financially supporting LGBT organizations and publications, forging political ties with the LBGT community, and hiring more sexual minorities); Perry Stevens, Lisa M. Carlson & Johanna M. Hinman, *An Analysis of Tobacco Industry Marketing to Lesbian, Gay, Bisexual, and Transgender (LGBT) Populations: Strategies for Mainstream Tobacco Control and Prevention*, 5(3)(suppl.) Health Promotion Practice 129S, 131S-33S (2004) (noting that the tobacco industry has worked to build and maintain loyalty from gays and lesbians by publicizing its support of the gay and lesbian communities in LGBT publications — touting corporate contributions to the fight against HIV/AIDS, expressing a commitment to nondiscriminatory hiring policies, and articulating messages of solidarity with the LGBT community).

184 Tobacco Control Act, Pub. L. 111-31, tit. I, sec. 101, § 907(b)(2), 123 Stat. 1776, 1801 (2009) (codified at 21 U.S.C. § 387g(b)(2)).

185 TPSAC Report, *supra* note 8, at 41.

186 U.S. Dep't of Health & Human Servs., Reducing Tobacco Use: A Report of the Surgeon General, ch. 4 pp. 130-31 (2000), *available at* http://www.surgeongeneral.gov/library/reports/tobacco_use/index.html; SGR 2010, *supra* note 22, at ch. 4 p. 118.

187 SGR 2004, *supra* note 2, Executive Summary at 8.

188 Richard Doll et al., *Mortality in Relation to Smoking: 50 Years' Observation on Male British Doctors*, BMJ, doi:10.1136/bmj.38142.554479.AE at 6-7 (2004) (observing that British doctors who stopped smoking before age 35 had similar patterns of survival as British doctors who had never smoked, gaining 10 years of life expectancy; however, even smokers who quit between the ages of 55 and 64 gained, on average, three years life expectancy).

189 *See supra* note 150.

190 *See* Pub. Health Serv., *supra* note 92, at 7 (advising that "clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this guideline" — implicitly recognizing that the risks of cessation therapies are far outweighed by the benefits of quitting). See also *id.* at chapters 3, 4, and 6 generally for more detail regarding the effectiveness of counseling, behavioral therapies, and cessation medications.

191 Framework Convention Alliance, *Brazil Bans Flavoured Tobacco* (Mar. 23, 2012), http://www.fctc.org (search "Brazil bans flavoured tobacco") (last accessed Feb. 22, 2013).

192 SGR 1998, *supra* note 26, at ch. 1 p. 14, ch. 5 p. 259, 284; Daniel S. Blumenthal, *Barriers to the Provision of Smoking Cessation Services Reported by Clinicians in Underserved Communities*, 20 J. of the Am. Bd. of Family Med. 272, 278 (2007).

193 SGR 1998, *supra* note 26, ch. 1 p. 14. See generally *id.* at ch. 5 for a review of studies of tobacco cessation services/strategies among racial/ethnic minority groups.

194 Comm. on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities, Inst. of Med., The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for a Better Understanding 61-67 (2011), *available at* http://www.iom.edu/reports/2011/the-health-of-lesbian-gay-bisexual-and-trangender-people.aspx; *see also* Thomas Buchmueller & Christopher S. Carpenter, *Disparities in Health Insurance Coverage, Access, and Outcomes for Individuals in Same-Sex Versus Different-Sex Relationships, 2000-2007*, 100(3) Am. J. of Pub. Health 489, 493-94 (2010) (finding that men and women in same-sex relationships were significantly less likely to report having health insurance than men and women in different-sex relationships, with the differential driven largely by the high rates of coverage among *married* different-sex couples; men and women in same-ex relationships were also significantly more likely to report unmet medical needs).

195 Industry Menthol Report, *supra* note 35, at 213.

196 *See*, *e.g.*, Jess Alderman, Tobacco Control Legal Consortium, *Strategies to Combat Illicit Tobacco Trade* at 2-4 (2012), http://publichealthlawcenter.org/sites/default/files/resources/tclc-syn-smuggling-2012.pdf.

197 *Id.*

198 Compass Lexecon, Estimating Consequences of a Ban on the Legal Sale of Menthol Cigarettes 40 (2011) (public submission to the FDA Tobacco Products Science Advisory Committee, for the Jan. 10-11, 2011 meeting), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM246047.pdf (predicting black market sales of menthol cigarettes in response to a ban, assuming a 10% increase in effective price).

199 The Tobacco Control Act is the subject of a dispute in which Indonesia filed a complaint with the World Trade Organization (WTO) arguing that prohibiting cloves as a characterizing flavor while exempting menthol violates international trade agreements. The WTO agreed with Indonesia, finding, among other things, that prohibiting menthol cigarettes would not increase illicit trade: "[I]t is not clear that the risks that the United States claims to minimize by allowing menthol cigarettes to remain in the market would materialize if menthol cigarettes were to be banned, insofar as regular cigarettes [which, like menthol cigarettes, contain nicotine] would remain in the market." Appellate Body Report, *United States–Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 225, WT/DS406/AB/R (Apr. 4, 2012). The U.S. has until July 24, 2013 to comply with the ruling. If the U.S. fails to do so, Indonesia could *see*k compensation or permission from the WTO's Dispute Settlement Board to impose sanctions on U.S. exports to Indonesia. Adding menthol to the list of prohibited characterizing flavors in cigarettes and cigarette smoke would bring the U.S. into compliance with the WTO ruling.

200 O'Connor, *supra* note 147, at 1332-33 tbl. 1.

201 *Id.*

202 Hersey, *supra* note 148, at 1339 (commenting on O'Connor *supra* note 120). Dr. Hersey states that:

> The opportunity indicated by the study is that more than a third of menthol smokers indicated that they would try to quit smoking altogether if menthol were banned, and 27% of menthol smokers said that they would smoke less than they do now — a reduction in smoking is an early step along the continuum towards cessation — and 28% of menthol smokers indicated that they were not sure what they would do, which may indicate an opening to cessation efforts.

Id. Dr. Hersey also notes that the results presented by O'Connor et al. indicate the need to accompany a ban with specific steps to promote cessation and increase access to cessation services in order to maximize the anticipated health benefits of a ban. *Id.*

203 Pearson et al., *supra* note 144, at e108.

204 *Id.* at e110 tbl. 2.

205 *See supra* notes 160-165 and accompanying text for data indicating that menthol cigarettes are used at disproportionately high rates by minority menthol smokers.

206 Pearson et al., *supra* note 144, at e108.

207 Jonathan P. Winickoff et al., *US Attitudes About Banning Menthol in Cigarettes: Results From a Nationally Representative Survey*, 101(7) Am. J. of Pub. Health 1234, 1234 (2011).

208 Prevent All Cigarette Trafficking Act of 2009, Pub. L. No. 111-154, sec. 2(c), § 2A(d), 124 Stat. 1087, 1093 (2010) (codified at 15 U.S.C. § 376a(d))(prohibiting delivery of cigarettes or smokeless tobacco absent advance payment of state or local excise taxes); sec. 3(a), § 1716E(a), 124 Stat. at 1103 (codified at 18 U.S.C. § 1716E(a)) (classifying cigarettes and smokeless tobacco as "nonmailable matter").

209 PACT increases the relevant criminal penalties from 6 months imprisonment to 3 years imprisonment. Pub. L. 111-154, 2(d), § 3(a), 124 Stat. at 1100 (codified at 15 U.S.C. § 377(a)). In addition, PACT imposes civil penalties on both sellers (a minimum of $5,000 for a first violation, $10,000 for all other violations) and common carriers ($2,500 for a first violation, $5,000 for a violation within 1 year of a previous violation) who violate the Act's restrictions on delivery sales of cigarettes or smokeless tobacco. Pub. L. 111-154, sec. 2(d), § 3(b), 124 Stat. at 1100 (codified at 15 U.S.C. § 377(b)). PACT also authorizes state Attorneys General and local/tribal governments to bring actions in federal court to "prevent or restrain" violations of PACT or to obtain "appropriate relief," including civil penalties, money damages, or injunctions. Pub. L. 111-154, sec. 2(e), § 4(c), 124 Stat. at 1101 (codified at 15 U.S.C. § 378(c)).

210 U.S. Gov't Accountability Office, GAO-11-313, Illicit Tobacco: Various Schemes are Used to Evade Taxes and Fees: Report to Congressional Committees 14 (2011), *available at* http://www.gao.gov/products/GAO-11-313 ("according to a Department of Justice Office of the Inspector General report on the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), tobacco diversion is attractive to criminals because it can provide large profits and the criminal penalties are less than the penalties for smuggling drugs.").

211 J. Collin et al., *Complicity in Contraband: British American Tobacco and Cigarette Smuggling in Asia*, 13(suppl. II) Tobacco Control ii104, ii106, ii109 (2004).

212 In the 1990s, Canadian tobacco companies evaded domestic taxes on cigarettes by exporting cigarettes to duty-free warehouses in the United States, knowing that the cigarettes would be purchased by groups intent on smuggling them back into Canada for sale on the illicit market. Robert Schwartz & Teela Johnson, *Problems, Policies, and Politics: A Comparative Case Study of Contraband Tobacco From the 1990s to the Present in the Canadian Context*, 31 J. of Pub. Health Policy 342, 344-45 (2010). In July 2008, two of Canada's largest tobacco companies, Imperial Tobacco and Rothmans, Benson, & Hedges, plead guilty to evasion of domestic excise taxes by way of this scheme. Bruce Campion-Smith, *Big Tobacco Pays the Price*, Toronto Star at A.1 (Aug. 1, 2008).

213 *See* Legacy, *supra* note 105, at 14 ("the very cigarette companies that raise the specter of a large black market will play a significant role in determining whether or not such a black market rises").

214 Tobacco Control Act, Pub. L. No. 111-31, div. A, tit. III, sec. 301, § 920(a), (b), 123 Stat. 1776, 1850-51 (2009) (codified at 21 U.S.C. § 387t(a), (b)).

215 *See* L. Joossens & M. Raw, *Progress in Combating Cigarette Smuggling: Controlling the Supply Chain*, 17 Tobacco Control 399, 403 (2008) (observing, based on the success of anti-smuggling measures utilized by the UK, Spain, and Italy, that "enforceable measures to control the supply chain should be at the heart of the FCTC protocol on the illicit tobacco trade. […] They should introduce measures including licensing all participants in the tobacco business; tracking and tracing systems from the points of manufacture to all points of sale […].").

216 Compass Lexecon, *supra* note 198, at 40.

217 TPSAC Report, *supra* note 8, at 41 (citing to data from the National Survey on Drug Use and Health).

218 Ctrs. for Disease Control & Prevention, *Vital Signs: Current Cigarette Smoking Among Adults Aged > 18 Years — United States, 2005-2010*, 60(35) MMWR 1207, 1208 (2011), *available at* http://www.cdc.gov/mmwr/pdf/wk/mm6035.pdf.

219 TPSAC Report, *supra* note 8, at 227.

220 *Id.*

221 C.F.R. § 10.30(b).

222 *Id.*

223 The Consortium's affiliated legal centers include ChangeLab Solutions in Oakland, California; the Legal Resource Center for Tobacco Regulation, Litigation & Advocacy at the University of Maryland School of Law in Baltimore, Maryland; the Tobacco Control Resource Center, a project of the Public Health Advocacy Institute at Northeastern University School of Law in Boston, Massachusetts; the Smoke-Free Environments Law Project at the Center for Social Gerontology in Ann Arbor, Michigan; the Public Health Law Center at the William Mitchell College of Law in Saint Paul, Minnesota; the Tobacco Control Policy and Legal Resource Center at New Jersey GASP in Summit, New Jersey; and the Center for Public Health and Tobacco Policy at New England Law in Boston, Massachusetts, which provides technical assistance to communities in the state of New York. All of the Consortium's affiliated legal centers join this petition.

About the Tobacco Control Legal Consortium

The Tobacco Control Legal Consortium is a network of legal programs supporting tobacco control policy change throughout the United States. Drawing on the expertise of its collaborating legal centers, the Consortium works to assist communities with urgent legal needs and to increase the legal resources available to the tobacco control movement. The Consortium's coordinating office, located at William Mitchell College of Law in St. Paul, Minnesota, fields requests for legal technical assistance and coordinates the delivery of services by the collaborating legal resource centers. Our legal technical assistance includes help with legislative drafting; legal research, analysis and strategy; training and presentations; preparation of friend-of-the-court legal briefs; and litigation support.