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**A REPORT TO THE CITIZENS' COMMISSION
TO PROTECT THE TRUTH**

MARCH 5, 2014

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Foreword by Samuel A. Ball, PhD, President and Chief Executive Officer

Fifty years ago, the Surgeon General released the landmark report which provided irrefutable evidence that smoking is detrimental to health. Since then, many policies and regulations have been proposed and enacted to reduce tobacco use in the United States. Through extensive anti-tobacco education, prevention and treatment initiatives and the dedicated work of many from diverse fields, the rates of smoking in the U.S. have dropped from 42 percent to 18 percent since the report was issued. This is a remarkable accomplishment. An estimated eight million deaths were prevented. However, more than two to three times as many have died from smoking during this time.

Much more work is needed. For several years, the U.S. has been stuck around the 20 percent rate of smokers. More than 40 million American adults and 3.5 million middle and high school students cannot stop a behavior that is the most preventable cause of cancer.

Important research continues to evaluate the characteristics or subgroups of people with higher rates of smoking initiation and lower rates of smoking cessation. Research also has identified factors that contribute to the initiation or continuation of smoking, particularly among these high-risk groups. This is one of the primary messages of this report. For these groups especially and for everyone, the decision to ban menthol is long overdue.

The 2009 *Family Smoking Prevention and Tobacco Control Act* placed new restrictions on cigarettes, including a ban on flavorings that increase the appeal of smoking, particularly to children, blacks and women. However, menthol was excluded from the list of banned flavorings. The *Act*

authorized the Food and Drug Administration (FDA) to determine if and how to regulate menthol. The FDA has repeatedly failed to act despite mounting evidence and countless calls from health experts to enact a ban.

In response to the FDA's reluctance to ban menthol, the Citizens' Commission to Protect the Truth requested that CASAColumbia® prepare this white paper, *Time to Ban Menthol*. The Citizens' Commission is a group of former U.S. Secretaries of Health, Education, and Welfare and of Health and Human Services, Surgeons General, and Directors of the Centers for Disease Control and Prevention. Their critically important work has been supported by Legacy® which funded this report summarizing the research on menthol and its effects. *Time to Ban Menthol* finds overwhelming evidence in support of the conclusion that menthol should be completely banned in cigarettes and other tobacco products.

Time to Ban Menthol summarizes the evidence for the role of menthol in increasing the risk of smoking initiation and addiction involving nicotine and decreasing smokers' chances of successfully quitting. It summarizes how menthol is disproportionately marketed to and favored by young people, blacks and women. For tobacco companies, it has been incredibly effective for sustaining profits by enticing new smokers and ensuring that they remain addicted to their products.

Although the 2009 *Family Smoking Prevention and Tobacco Control Act* banned all flavorings except menthol, it applied only to cigarettes, not alternative products such as cigars, smokeless tobacco and electronic cigarettes. Given the concerns raised about menthol and other flavorings and additives, a ban on menthol cigarettes, while overdue, may not go far enough. The presence of these flavorings and additives in alternative tobacco

products will continue to increase the risks of new users and of addiction.

The FDA is tasked with protecting public health. The evidence regarding the dangers of menthol in tobacco products is abundant and clear. The failure to act places many lives in jeopardy. As this report argues, the safest action the FDA can take is a complete ban on menthol additives in cigarettes and other tobacco products.

Many individuals made important contributions to this work. We extend special thanks to Legacy for their financial support of this project. For donating their time and expertise in reviewing a draft of this paper and providing insightful comments, we thank Stanton A. Glantz, PhD, Professor, University of California, San Francisco (UCSF) School of Medicine, and Director of the Center for Tobacco Control Research and Education; Jonathan Foulds, PhD, Professor of Public Health Sciences & Psychiatry, Penn State College of Medicine; and Suchitra Krishnan-Sarin, PhD, Associate Professor of Psychiatry and Vice-Chair, Human Investigations Committee, Yale University School of Medicine.

While many individuals and institutions contributed to this effort, the findings and opinions expressed herein are the sole responsibility of CASAColumbia.

Time to Ban Menthol

It has been almost five years since the enactment of the *Family Smoking Prevention and Tobacco Control Act* which banned all characterizing flavorings from cigarettes with the notable exception of menthol--the most prevalent of these flavorings¹--and which granted the Food and Drug Administration (FDA) the authority to extend that ban to menthol.²

It has been nearly three years since the Tobacco Products Scientific Advisory Committee (TPSAC)--a committee of experts convened to provide the Secretary of Health and Human Services recommendations on tobacco regulation--formally concluded in its report to the FDA that the removal of menthol cigarettes from the market would benefit the public health in the United States.³

Countless health experts have voiced support for banning menthol and data from a growing body of scientific research repeatedly underscores the cause for concern:

- Menthol is an insidious ingredient in most cigarettes and other tobacco products. It eases the harsh sensations associated with smoking,⁴ making tobacco products more palatable and appealing and thereby facilitating their initiation and perpetuating their use.⁵
- Menthol is used by the tobacco industry to target groups that historically were less apt to smoke--young people, blacks and women.⁶
- Menthol facilitates early initiation of tobacco products,⁷ increases the risk of addiction,⁸ and makes cessation more difficult, particularly among black smokers.⁹
- Research suggests that removing menthol from tobacco products could

reduce smoking initiation rates¹⁰ and survey data indicate that many menthol smokers would attempt to quit smoking rather than switch to non-menthol products.¹¹

It is time for the FDA to use this evidence to exercise the authority granted by Congress and completely ban menthol additives from all cigarettes and other tobacco products.

What Is Menthol and Why Is It Added to Tobacco Products?

Menthol is made from mint oils and, due to its anesthetic and counterirritant qualities, it is used to relieve throat irritation and increase the palatability of foods and other oral products.¹² Menthol has a distinct mint flavor and scent and causes a numbing sensation when applied to skin.¹³ At lower concentrations, menthol produces a cooling feeling when added to tobacco products, tempering the harshness of tobacco smoke and making cigarettes and other tobacco products easier to use.¹⁴

Menthol cigarettes have been available since the 1920s.¹⁵ Menthol is present to some degree in most cigarettes.¹⁶ When not promoted as a characterizing flavor, menthol often is included in non-menthol cigarettes and other tobacco products as an unadvertised additive* to make them more palatable.¹⁷

Menthol plays a central role in helping to make smoking more appealing than it otherwise would be, facilitating the initiation of smoking,¹⁸ perpetuating the use of tobacco products and thereby facilitating the maintenance and growth of tobacco industry profits.

Industry documents reveal how carefully menthol levels are manipulated to attract particular types of consumers.¹⁹ Menthol greatly affects the 'impact' of a cigarette,

which is the tobacco industry's term for the sensation that follows inhaling cigarette smoke and the stimulation of the sensory receptors associated with pain.²⁰ Tobacco companies carefully manipulate the balance between menthol and nicotine in order to achieve the desired sensation resulting from tobacco use.²¹ At lower concentrations, menthol produces a soothing, cooling sensation, lessening the impact of a cigarette, masking strong flavors and harsh sensations associated with tobacco, and making cigarettes more palatable and appealing to new smokers.²² This type of product includes Newport and Marlboro Milds, which contain 0.32 and 0.36 percent[†] menthol, respectively. At higher concentrations, such as can be found in Marlboro Menthol (0.55 percent menthol), the menthol taste is more intense, which tobacco companies capitalize on to appeal to established menthol smokers.²³

Menthol Facilitates Initiation of Tobacco Use

Tobacco companies require a constant stream of new smokers, as consumer attrition is significant due to higher mortality rates among smokers and decreased smoking rates resulting from the success of recent anti-smoking public health campaigns.²⁴ Tobacco industry documents[‡] provide considerable insight into the industry's practices in targeted marketing, particularly with regard to the need to recruit

[†] Percentage of tobacco weight.

[‡] A class action litigation by the State of Minnesota and Blue Cross Blue Shield Minnesota against the tobacco industry resulted in the release of previously confidential industry documents. The 1998 Master Settlement Agreement (MSA)--an agreement between the largest U.S. tobacco companies and the attorneys general of the majority of the states in the U.S. to settle lawsuits against the tobacco industry and recover states' tobacco-related health-care costs--required tobacco companies to continue to make these documents available to the public. A 2006 ruling finding tobacco companies in violation of the *Racketeer Influenced and Corrupt Organizations (RICO) Act* further extended this requirement until 2021.

* Also referred to as a trace element.

new smokers at young ages.²⁵ Tobacco industry research shows that more than two-thirds of male smokers start smoking by age 18 and less than five percent of smokers begin after age 24.²⁶ National data demonstrate that 82.6 percent of individuals ages 12 and older who meet diagnostic criteria for addiction involving nicotine began smoking before age 18, and nearly all (93.4 percent) initiated smoking before age 21.²⁷

The industry has a clear interest in marketing to young people to establish brand preference, customer loyalty and a long-term market base. Early industry documents show that tobacco companies recognized that one way to hook new smokers was via the addition of flavorings, including menthol, to make cigarettes more palatable.²⁸

Menthol Users More Likely To Become Addicted and Less Likely To Stop Using

Because of its addictive properties,²⁹ nicotine perpetuates the use of tobacco products leading to the many well-documented medical conditions resulting from their use.³⁰ Menthol perpetuates the use of tobacco products by enhancing their palatability.³¹ The easier these products are to use, the more people will use them and the greater their exposure will be to the addicting effects of nicotine and the hazards of cigarette smoking and other tobacco product use.

Research suggests that smoking menthol cigarettes is associated with an increased risk of symptoms associated with addiction involving nicotine³² and decreased success in smoking cessation efforts.³³

Although the exact cause of the link between menthol and addiction involving nicotine has not been well established, preliminary research suggests that menthol might contribute to addiction on a

neurological level. A recent small study found that smoking menthol cigarettes may reduce the rate at which nicotine is metabolized, which may increase the smoker's exposure to the drug.³⁴ Other recent research indicates that menthol may alter the nicotine receptors in the brain.³⁵ As nicotine binds to these brain receptors, it releases dopamine--the key rewarding brain chemical--which increases the risk of addiction.³⁶ Menthol also may reduce the aversive sensory effects of nicotine.³⁷

Research suggests a link between menthol smoking and symptoms of addiction in young people.³⁸ One study that examined measures of craving--a symptom of addiction--found that high school aged children who regularly smoke menthol cigarettes are 2.6 times as likely to smoke within one hour of waking and 1.6 times as likely to report experiencing cravings as non-menthol smokers.³⁹ Studies examining adults have found a significant association between smoking menthol cigarettes and waking at night to smoke, another symptom of addiction.⁴⁰

Adolescence is *the* critical period of vulnerability for beginning to use addictive substances such as nicotine and for developing the disease of addiction.⁴¹ The earlier a person begins to use tobacco products, the greater the likelihood of using and developing addiction involving nicotine and a range of other substances.⁴²

CASAColumbia's analysis of national data found that the average age of smoking initiation among high school students who have smoked is 13.7 years old.⁴³

Individuals ages 12 and older who report starting smoking before age 15 report symptoms of addiction involving nicotine at almost twice the rate of those who report starting smoking at age 21 or older (19.3 percent vs. 10.1 percent).⁴⁴

Several studies suggest that menthol may interfere with smoking cessation success.⁴⁵ One study of black smokers under age 50 found that non-menthol smokers were twice

as likely to successfully quit smoking after six weeks compared to menthol smokers.⁴⁶ Other research shows that the lower smoking cessation rate among menthol smokers is particularly notable among black and Hispanic menthol smokers,⁴⁷ with the odds of successful smoking cessation about half that of black and Hispanic non-menthol smokers.⁴⁸

Menthol Disproportionately Appeals to Young People, Blacks and Women

Tobacco companies historically have experimented with adding menthol to tobacco products in order to make cigarettes more palatable and appeal to certain target groups.⁴⁹ Industry documents show that the greatest growth potential in market base was seen among adolescents, blacks and women, leading tobacco companies to design products that appealed to these groups by manipulating menthol levels in a way that would encourage smoking, and to target these groups in their marketing efforts.⁵⁰ Prevalence rates of menthol cigarette use reflect this targeted marketing.

Young People. Industry research indicates that the early years of smoking are critical for establishing brand loyalty.⁵¹ Young people are viewed by the tobacco industry as the main source of replacement smokers for those lost through smoking cessation, illness or death.⁵²



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Industry documents highlight the importance of young people to the marketing of menthol brands; low menthol cigarettes are identified as the product most likely to appeal to young people.⁵³ Three major menthol brands--Newport, Salem and Kool--built their consumer base largely using a low-menthol approach to appeal to new, young smokers.⁵⁴



From the collection of Stanford University
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Exposure to cigarette advertising is associated with an increased likelihood of smoking.⁵⁵ In the 1998 Master Settlement Agreement (MSA), tobacco companies agreed to cease targeted advertisements to adolescents in compliance with the stipulation that “no participating manufacturer may take any action, directly or indirectly, to target youth within any settling state in the advertising, promotion or marketing of tobacco products, or take any action the primary purpose of which is to initiate, maintain or increase the incidence of youth smoking within any settling state.”⁵⁶ However, determining what exactly constitutes an “adolescent-targeted advertisement,” especially in magazines, was not sufficiently clear to completely stop the practice of targeted marketing. Since 2000, adolescents’ exposure to cigarette advertisements in magazines has declined, although one study found that exposure to menthol cigarette advertisements during this

time generally was slightly higher than exposure to non-menthol cigarette advertisements.⁵⁷

Blacks. Blacks also have been viewed by the tobacco industry as a group with significant growth potential and have been one of the main target groups of menthol cigarette advertising.⁵⁸ There is some evidence that black people are less inclined to smoke cigarettes than whites--they tend to start smoking later (average age of initiation is 16.9 years vs. 15.7 years) and they generally smoke at slightly lower rates (21.8 percent vs. 23.6 percent), particularly among adolescents (4.9 percent vs. 9.6 percent).⁵⁹



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In the early 1950s, menthol smoking rates were only slightly higher among blacks than whites; five percent of black smokers smoked menthol cigarettes compared to two percent of white smokers.⁶⁰ Building off this slight disparity in preference, the tobacco industry began targeting blacks heavily.⁶¹

Throughout the 1950s and 1960s, menthols were marketed as “fresh and modern,” which resonated with several movements that appealed to black young adults, including the Civil Rights Movement and the Jazz Age.⁶² Industry documents also indicate that advertisements were

Uptown

The development of the “Uptown” brand of menthol cigarettes in 1988 is a prime example of targeted marketing to blacks. The tobacco company R.J. Reynolds created this lightly mentholated brand with the intention of marketing it to blacks, choosing Philadelphia as its test market because of its large black population. This drew outrage from several organizations, including the National Association for the Advancement of Colored People (NAACP), American Cancer Society (ACS), Fox Chase Cancer Center, Graduate Hospital, the American Lung Association (ALA), the Black Clergy of Philadelphia and the Philadelphia Chapter of the National Black Leadership Initiative on Cancer (NBLIC). These organizations along with many black citizens and leaders came together to form the Coalition Against Uptown Cigarettes. The movement prompted Dr. Louis Sullivan, the Secretary of the U.S. Department of Health and Human Services at the time, to publicly condemn the Uptown cigarette brand. The attention caused R.J. Reynolds to completely abandon the brand in 1990.⁶⁵

strategically placed to reach black audiences.⁶³ Even in more recent years, magazines with a largely black readership have had more advertisements for menthol cigarettes than those with a predominantly white audience.⁶⁴



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Historically, as black people began to move to urban areas, tobacco companies began to concentrate advertisements and product placement for menthol cigarettes in these areas.⁶⁶ Recent research indicates that neighborhoods with large black populations have higher concentrations of menthol cigarette advertisements and lower prices for a pack of menthol cigarettes relative to predominantly white neighborhoods.⁶⁷ Black adolescents have higher exposure to and recognition of menthol brands compared to white adolescents.⁶⁸

Women. Among smokers ages 18 and older, women tend to report a later age of smoking initiation than men (average age of initiation is 16.5 years vs. 15.6 years) and they generally smoke at lower rates (21.1 percent vs. 26.4 percent).⁶⁹ Tobacco companies acknowledged the need to target women as a group and capitalized on their preference for a milder, better tasting cigarette.⁷⁰ Menthol cigarettes were viewed as a way to deliver the taste experience that women prefer (“mild,” “satisfying,” “enjoyment”).⁷¹



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Current Users of Menthol Cigarettes*

National data[†] indicate that 22 percent of the U.S. population ages 12 and older report being current smokers; 13.9 percent smoke non-menthol cigarettes and 8.2 percent smoke menthol cigarettes.⁷² Among these current smokers, more than one-third (37.1 percent) smoke menthol cigarettes.⁷³

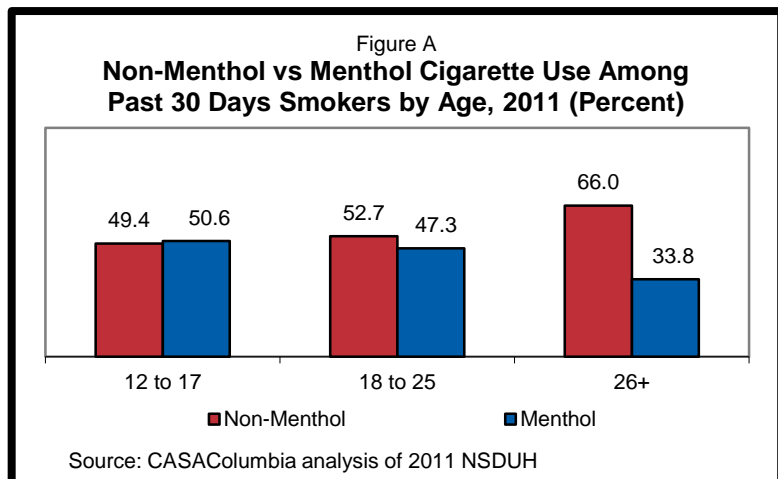
Cigarette smoking in general is more prevalent among young adults, whites and males; however, the use of menthol cigarettes is disproportionately more prevalent among younger people, blacks and women.⁷⁴ (See Appendix A for a more complete account of prevalence rates of past 30 day cigarette use in the total U.S. population, ages 12 and older, by key demographic groups.)

Younger Smokers Are More Likely Than Older Smokers To Report Current Use of Menthol Cigarettes

Menthol cigarettes are used by 50.6 percent of smokers ages 12 to 17 and by 47.3 percent of smokers ages 18 to 25 who report current smoking. In contrast, 33.8 percent of smokers age 26 and older smoke menthol cigarettes. (Figure A) This disproportionate use of menthol cigarettes among younger smokers compared with older smokers may reflect menthol's role in facilitating smoking initiation among young people⁷⁵ as well as the targeted marketing of menthol products to them.⁷⁶

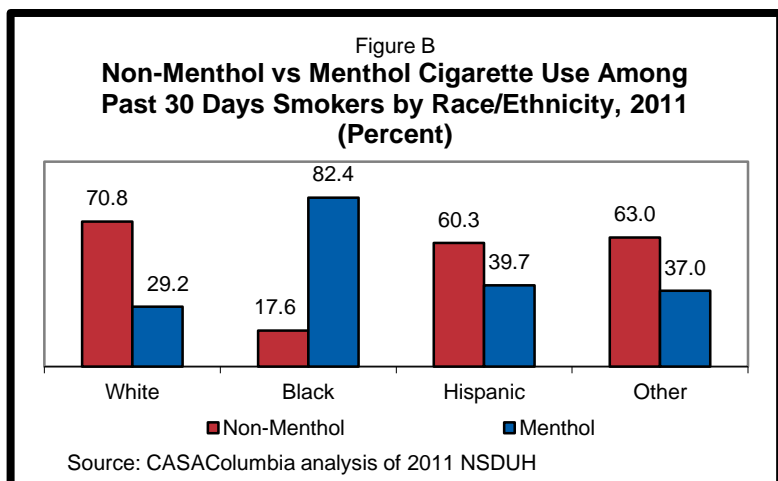
* Current users are those who report having smoked cigarettes in the past 30 days.

† National data that allow for comparisons of menthol versus non-menthol product use are available only for cigarettes.



The Majority of Black Smokers Report Current Use of Menthol Cigarettes

Black people show a strong preference for menthol cigarettes: they are more than twice as likely as other racial/ethnic groups to use them (17.9 percent vs. 6.9 percent of whites, 7.1 percent of Hispanics and 6.5 percent of other racial/ethnic groups in the U.S. population, ages 12 and older). More than four times as many black current smokers report smoking menthol cigarettes as non-menthol cigarettes (82.4 percent vs. 17.6 percent). This pattern is in direct contrast to preferences among smokers of other racial/ethnic groups where non-menthol cigarettes are smoked at considerably higher rates than menthol cigarettes.⁷⁷ (Figure B)



Female Smokers Are More Likely Than Male Smokers To Report Current Use of Menthol Cigarettes

Female smokers are more likely than male smokers to use menthol cigarettes.⁷⁸ While current use of non-menthol cigarettes is more prevalent than use of menthol cigarettes among both male and female smokers, female smokers are more likely than male smokers to report using menthol cigarettes (42.0 percent vs. 32.9 percent).⁷⁹

Use of Menthol Cigarettes Is Highest among Smokers Living in Large Metropolitan Areas, Those with Lower Incomes and the Unemployed

The rate of current menthol cigarette use is higher among those living in large metropolitan areas (40.8 percent) than among those living in small metropolitan (35.0 percent) and non-metropolitan (27.3 percent) areas. The rate of menthol cigarette use also is higher among those earning less than \$20,000 per year (43.2 percent) than among those earning between \$20,000 and \$75,000 per year (35.5 percent) and those earning more than \$75,000 per year (33.3 percent). The unemployed also use menthol cigarettes at a higher rate (47.2 percent) than those employed part time (37.9 percent) or full time (36.2 percent).⁸⁰

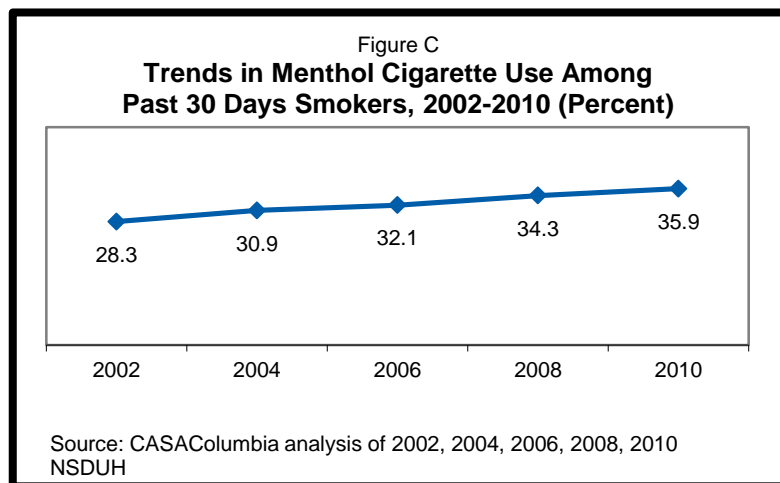
The Proportion Using Menthol Cigarettes Is on the Rise

While the rate of cigarette use has been declining, the proportion of smokers using menthol cigarettes has been on the rise, especially among young people, blacks and women.⁸¹

In 1965, a year after the Surgeon General released a report declaring that cigarettes were harmful to health, 42.4 percent of

adults smoked cigarettes.⁸² By 2011, this number was cut by more than half.*⁸³

Among current smokers, the rate of menthol cigarette use has increased over the past decade, from 28.3 percent in 2002 to 35.9 percent in 2010.⁸⁴ (Figure C)



A recent study found that while non-menthol cigarette smoking rates have declined significantly between 2004 and 2010, the rate of menthol cigarette use generally has remained constant or increased in all age groups.⁸⁵ This suggests that menthol cigarette use may contribute to the attenuation in the recent decline in overall smoking rates.⁸⁶

Between 2002 and 2010, rates of menthol cigarette use have increased among adults in all age groups, with the exception of those ages 35 to 49. Rates of menthol use have increased most dramatically among adolescents ages 12 to 17 (from 36.3 percent in 2002 to 50.0 percent in 2010) and young adults ages 18 to 25 (from 29.6 percent in 2002 to 46.3 percent in 2010).⁸⁷

While rates of non-menthol cigarette use have declined between 2002 and 2010,

* In contrast to other national data presented in this paper which are from the National Survey on Drug Use and Health (which includes individuals ages 12 and older), these data are from the National Health Interview Survey which surveys adults over age 18.

rates of menthol cigarette use have increased to some extent among all racial/ethnic groups. Notably, the increase among blacks has been the most dramatic (blacks: from 68.8 percent in 2002 to 85.2 percent in 2010; whites: from 22.2 percent in 2002 to 26.6 percent in 2010; Hispanics: from 24.8 percent in 2002 to 37.8 percent in 2010).⁸⁸

The increase in rates of menthol cigarette use during this time was found for both male and female smokers; however, the increase was somewhat higher among females than among males (females: from 31.3 percent in 2002 to 40.1 percent in 2010; males: from 25.3 percent in 2002 to 31.7 percent in 2010).⁸⁹

There has been an even greater increase over the past several years in the use of menthol cigarettes among individuals ages 12 and older who recently initiated smoking.⁹⁰ Among those who reported smoking a cigarette for the first time in the past year in surveys conducted between 2007 and 2010, 51.7 percent reported current use of menthol cigarettes, up from 41.7 percent in surveys conducted between 2004 and 2006.⁹¹

Industry Marketing Practices and Regulatory Responses

Since their advent in the 1920's,⁹² menthol cigarettes have been marketed as a milder and healthier smoking option.⁹³ In 1932, the "Kool" brand of menthol cigarettes was marketed this way; some advertisements touted it as a type of cold relief because of its soothing properties.⁹⁴ In 1942, the Federal Trade Commission (FTC) sent a cease and desist order to the tobacco company Brown and Williamson regarding the unfounded claims that menthol cigarettes could help treat a cold.⁹⁵ From 1945-1960, the FTC sent several additional cease and desist orders to tobacco companies and then finally prohibited them

from making any health claims in cigarette advertisements in 1964.⁹⁶



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Over the next 50 years, tobacco companies faced additional regulations--such as prohibiting tobacco advertising on television and radio and requiring the FTC to report on tobacco sales, advertising and marketing;⁹⁷ however, none of these regulations were targeted specifically at menthol cigarettes.⁹⁸ Legal challenges also were raised in response to increasing efforts by the tobacco industry to conduct targeted marketing of menthol cigarettes to specific populations--including young people, blacks and women--but these were unsuccessful.⁹⁹

The Family Smoking Prevention and Tobacco Control Act, the Findings of the Tobacco Products Scientific Advisory Committee (TPSAC) and the FDA Report on Menthol

In 2009, the *Family Smoking Prevention and Tobacco Control Act*, which gave the FDA the power to regulate the tobacco industry and place new or additional regulations on the manufacture, marketing and sale of tobacco products, banned all characterizing flavorings in cigarettes.¹⁰⁰ However, menthol was excluded from the list and stipulated as a flavoring that would continue to be allowed in cigarettes.¹⁰¹

Although menthol was excluded from the list of banned flavorings, the Act set up the Tobacco Products Scientific Advisory Committee (TPSAC), a committee of 12 members tasked with providing the Secretary of Health and Human Services recommendations on several issues related to tobacco¹⁰² including recommendations on "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."¹⁰³ In 2011, TPSAC released its report on menthol and concluded that menthol is not simply a flavor additive but rather that tobacco companies have intentionally manipulated menthol levels in tobacco products to make them more palatable, increasing the

likelihood of addiction involving nicotine, especially among young people and blacks.¹⁰⁴ The committee further noted that menthol has an adverse effect on public health, and that there are no public health benefits of menthol compared to non-menthol cigarettes.¹⁰⁵ The TPSAC concluded that the removal of menthol cigarettes from the market would benefit the public's health.¹⁰⁶ (See Appendix B for a summary of the TPSAC findings.)

At the time the TPSAC report was submitted to the FDA, members of the tobacco industry released their own report, stressing that menthol cigarettes are not more toxic than non-menthol cigarettes and do not increase the risk of disease over and above the risks posed by non-menthol cigarettes, thereby shifting the focus from population level to individual level health concerns.¹⁰⁷

These conclusions are based on the industry's analysis of data collected by Philip Morris. However, experts in tobacco research unaffiliated with the industry argued that the interpretation of those results was biased.¹⁰⁸ Subsequent analysis found that the inclusion of menthol in cigarettes and other tobacco products facilitates initiation and continued use of these products, increasing the risk of addiction involving nicotine.¹⁰⁹

Despite the TPSAC findings and conclusions regarding a ban on menthol in cigarettes, the federal government has yet to implement such a ban. In July 2013, the FDA issued an Advance Notice of Proposed Rulemaking asking for additional information on menthol in order to determine whether and how to regulate it.

Also in July 2013, the FDA released a report, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes*.¹¹⁰ It concluded that menthol is associated with an increased risk of smoking initiation among adolescents and young adults. It also found that menthol is associated with a

greater likelihood of addiction and less success with cessation efforts.¹¹¹

These factors combined with menthol's cooling properties led the FDA to conclude that menthol cigarettes present a public health risk greater than non-menthol cigarettes.¹¹² Toxicity and disease risk--issues that were a focus of the Industry report--are primarily issues of individual health, while patterns of initiation, use and cessation are more pertinent to public health. Because the FDA is tasked with acting in the interest of public health, these factors should weigh most heavily on their decision regarding menthol regulation. Yet the FDA report explicitly noted that its findings should not be construed as a decision to regulate menthol cigarettes.¹¹³

Efforts by Other Organizations

Several groups have voiced their support for a ban on menthol. In 2013, a citizens' petition was submitted to the FDA by the Tobacco Control Legal Consortium urging the agency to take the TPSAC recommendation and ban menthol as a characterizing flavor in cigarettes.¹¹⁴ This petition was co-signed by several public health organizations and health experts.*¹¹⁵ The Citizens' Commission to Protect the Truth--a group of former U.S. Secretaries of Health, Education, and Welfare and of Health and Human Services; former U.S.

* These include 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, the Association for the Treatment of Tobacco Use and Dependence, the Campaign for Tobacco-Free Kids, Corporate Accountability International, 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, and Valerie B. Yerger, ND.

Surgeons General; and former Directors of the Centers for Disease Control and Prevention--which aims to prevent youth from smoking, also released a press statement urging the Obama Administration to ban menthol flavoring in cigarettes.¹¹⁶ The Society for Research on Nicotine and Tobacco also released a list of recommendations, urging the FDA to adopt a new standard for menthol that would prohibit any detectable menthol from smoked tobacco products.¹¹⁷ In late 2013, with the strong support of Mayor Rahm Emmanuel, the Chicago Department of Public Health began a new public awareness campaign that highlights the dangers of menthol cigarettes and addresses their disproportionate use among youth and minorities.¹¹⁸ Also in 2013, the Delta Sigma Theta Sorority, Inc., a sisterhood of 240,000 predominantly black, college educated women, passed a resolution calling on the FDA to prohibit the use of menthol as a characterizing flavor in cigarettes.¹¹⁹

International Efforts To Ban Menthol

In March 2012, Brazil approved a ban on the sale of all flavored tobacco products, including menthol.¹²⁰ The industry was given 18 months to remove these additives from cigarettes and 24 months to remove them from other tobacco derivatives, including cigars and cigarillos.¹²¹ And in late 2012, the European Union released a draft directive that proposed banning cigarettes with characterizing flavoring, including menthol.¹²² It approved the ban in October 2013, despite objections by tobacco companies.¹²³ The ban is expected to take effect in 2022.¹²⁴ Exact details regarding how it will be implemented in member states still need to be worked out.

Expected Benefits of Banning Menthol

A ban on menthol would likely result in measurable reductions in the number of

people who will initiate use of tobacco products, continue to use these products, become addicted, develop tobacco-related illnesses or die from tobacco-related diseases.¹²⁵ Thirty-nine percent of menthol smokers report that they would quit smoking altogether if menthol cigarettes were banned.¹²⁶ The beneficial health and life-saving effects of a ban would be particularly pronounced for the main users of menthol cigarettes--young people, blacks and women who smoke.

The public generally supports a ban on menthol; one national survey of adults found that 56.1 percent of respondents favor a ban, with stronger support among never smokers, former smokers and non-menthol current smokers than among those who currently use menthol cigarettes.¹²⁷ There also is more support for a ban among blacks compared to whites (68.0 percent of blacks vs. 53.4 percent of whites).¹²⁸

One of the tobacco industry's main arguments against a ban on menthol is that there will be an emergence of illegal production and a black market in menthol tobacco products.¹²⁹ In November 2013, the attorneys general of 24 states and three territories submitted comments to the FDA arguing that should a black market for menthol cigarettes emerge, there are adequate law enforcement tools to handle it and stressing that the threat of contraband should not outweigh the public health benefits that would result from a ban.¹³⁰

Reduced Initiation and Prevalence of Use

Menthol appears to be a starter product for smoking¹³¹ and linked both to an increased risk of addiction involving nicotine and lower rates of smoking cessation success.¹³² The reduced rates of initiation and addiction and increased rates of successful cessation that likely would result from a ban on menthol would translate into an overall decline in use of these products.¹³³ The fact that young, newer smokers prefer menthol cigarettes

suggests that banning menthols may contribute to a reduction in smoking initiation among young people.¹³⁴

Looking at menthol as it relates to the continued use of tobacco products, a national survey of almost 3,000 adult menthol smokers found that 39 percent said that they would quit smoking if menthol cigarettes were no longer sold.¹³⁵ The proportion of menthol smokers who said they would quit under these circumstances was greater among black (46.8 percent) and female (41.8 percent) menthol smokers.¹³⁶

Further, economic models indicate that non-menthol cigarettes are not a good substitute for menthol cigarettes, particularly among young smokers and black smokers.¹³⁷

Reduced Morbidity, Mortality and Costs to Society

The negative health consequences of smoking have been well documented for more than 50 years.¹³⁸ Use of tobacco products is the leading cause of preventable death and a primary contributor to numerous health conditions, including multiple forms of cancer and cardiovascular and respiratory diseases.¹³⁹ Since the 1964 Surgeon General's report was released, more than 20 million persons in the United States have died because of smoking.¹⁴⁰ Between 1964 and 2009, smoking caused an estimated 5.8 million cancer deaths, 7.0 million cardiovascular disease deaths and 3.2 million respiratory disease deaths. Each year, smoking is estimated to cause about 480,000 deaths.¹⁴¹ Currently, about 5.6 million people ages 17 and younger are expected to die prematurely due to a smoking-related health condition.¹⁴² Smoking has been shown to cause diseases in virtually every organ in the body.¹⁴³

Menthol cigarettes contribute to this health burden to the extent that they are associated with increased risk of addiction involving nicotine and greater difficulty

quitting.¹⁴⁴ Eliminating menthol from the market is projected to lower smoking prevalence rates and ease these health burdens.¹⁴⁵

Simulation models are designed to examine smoking behavior, smoking-attributable deaths and the effects that various policies would have on the public.¹⁴⁶ A study using the simulation model *SimSmoke* examined a variety of scenarios resulting from a menthol ban, finding that if 10 percent of menthol smokers quit and 10 percent of those who would have started smoking menthol cigarettes do not initiate smoking because of a ban (a conservative estimate), more than 323,000 smoking-attributable deaths would be avoided by 2050; 91,744 (28.4 percent) of these would be among black smokers.¹⁴⁷ A 20 percent reduction is predicted to prevent 478,154 smoking-attributable deaths and a 30 percent reduction would prevent 633,252 smoking-attributable deaths by 2050.¹⁴⁸

Another simulation model, the *Mendez* model commissioned by TPSAC, examined the impact of the availability of menthol cigarettes on premature smoking-related deaths and on the increased likelihood of smoking initiation. It estimates that by 2050, 327,565 premature deaths would occur as a result of menthol in cigarettes and that 9.1 million people would initiate smoking by 2050 who otherwise would not have because of the availability of menthol cigarettes.¹⁴⁹ Among blacks, 66,524 premature deaths would occur by 2050, and about 1.7 million people would initiate smoking if menthol is not banned.¹⁵⁰

Smoking places a huge financial burden on the health care system. A 2014 report by the U.S. Surgeon General found that between 2009 and 2012, the smoking-attributable economic cost in the United States was between \$289 and \$333 billion. Approximately \$133 to \$173 billion were spent on direct medical care for adults, \$151 billion on lost productivity due to premature death and another \$6 billion on

lost productivity due to secondhand smoke.¹⁵¹ The government shoulders an exorbitant share of these smoking-attributable health costs; Medicaid spends an estimated \$40 billion and Medicare spends an estimated \$45 billion.¹⁵² Removing menthol from the market would ease this economic burden to the extent that menthol contributes to smoking initiation and perpetuation.

The Shift in the Market to Non-Cigarette Tobacco Products

As the rate of cigarette use in general has declined over the past decade, the use of alternative tobacco products has increased.¹⁵³ Although this trend is due in part to the fact that many people perceive non-cigarette tobacco products to be safer alternatives to cigarette smoking,¹⁵⁴ it also may be due to the less restrictive regulations that apply to the manufacture and marketing of these products, such as those that allow for the inclusion of a range of appealing flavoring additives including menthol.¹⁵⁵ Notably, the 2009 *Family Smoking Prevention and Tobacco Control Act* provision which banned the addition of flavoring additives (other than menthol and tobacco flavorings) applied only to cigarettes and not to cigars, cigarillos, smokeless tobacco products or electronic cigarettes.¹⁵⁶

These alternative tobacco products--electronic cigarettes being the most recent prominent example--are offered up as less harmful alternatives to conventional cigarettes,¹⁵⁷ which contributes to their popularity.¹⁵⁸

Most non-cigarette tobacco products come in a variety of flavors including menthol.* One study of moist snuf tobacco found that approximately 75 out of 100 brands are

flavored; about 45 use wintergreen (menthol) as a characterizing flavor.¹⁵⁹

A recent study of tobacco use among young people ages 18 to 34 who reported current use of a tobacco product found that a flavored brand was used by 17 percent of e-cigarette users, 20 percent of cigar users, 20 percent of chewing tobacco users, 47 percent of little cigar users, 50 percent of pipe tobacco users and 59 percent of hookah users.¹⁶⁰ Another recent survey found that among adolescents in grades 6-12 who are current users of cigarettes or little cigars, 42.4 percent reported using a flavored version, with menthol being the most popular of these flavors.¹⁶¹

Menthol also is used as an additive in electronic cigarettes. Use of e-cigarettes has increased among both adults and adolescents in recent years. Among adults, reports of ever having used e-cigarettes more than doubled, from 2.3 percent in 2010 to 5.8 percent in 2011.¹⁶² The reported rate of ever using e-cigarettes has more than doubled among adolescents in the United States, from 4.7 percent in 2011 to 10.0 percent in 2012. Additionally, 80.5 percent of adolescent current e-cigarette users also report smoking cigarettes.¹⁶³ This dual use is worrisome because e-cigarettes may only be perpetuating nicotine use and addiction, allowing users to maintain nicotine levels when they are unable to smoke a cigarette.

* There is limited research on the proportion of non-cigarette tobacco products that contains menthol.



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The ready availability of e-cigarettes in menthol and other alluring flavors further enhances their appeal and ease of use, particularly among those groups that traditionally have preferred menthol cigarettes.¹⁶⁴ While they appear to be less toxic than conventional cigarettes, the available evidence to date regarding their role as a reduced harm product is not sufficient to assure their safety or their efficacy in smoking cessation.¹⁶⁵ There also is some evidence to suggest that they may carry their own negative health consequences.¹⁶⁶ Because e-cigarettes deliver nicotine, an addictive drug,¹⁶⁷ they may be used as a bridge to the use of other addictive substances including conventional cigarettes.



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Conclusions and Recommendations

The addition of menthol to tobacco products serves one purpose only: to promote and perpetuate use of these dangerous substances by making them more palatable and easing users down the path to addiction. Its inclusion either as a characterizing flavor or as an unadvertised additive in cigarettes and other tobacco products serves only to boost the profits of the tobacco industry to the detriment of the public health.

CASAColumbia joins numerous health experts and leading health organizations in calling on the FDA to:

- ***Completely ban menthol in cigarettes, both as a characterizing flavor and as an unadvertised additive, and***
- ***Issue deeming regulations to assert jurisdiction over all tobacco products and then completely ban all flavorings including menthol in all other tobacco products, both as a characterizing flavor and as an unadvertised additive.***

The vast range of negative health effects associated with the use of tobacco products makes them the number one cause of preventable illness and death in the United States.¹⁶⁸ A ban on menthol, and a concomitant decrease in nicotine use, would reduce the prevalence of a range of smoking-related illnesses along with the rate of addiction involving nicotine.¹⁶⁹

While cigarettes have been the target of the majority of recent tobacco control regulations, it is important to extend these regulations--particularly the ban on characterizing flavorings that would include menthol--to all tobacco products that appeal to new users. This extension is critical. The use of any product containing nicotine increases the risk of addiction involving nicotine, particularly among young people. Since menthol promotes and perpetuates use, all tobacco products should be regulated in a manner that would protect people from their potential harms.

The most effective action the FDA can take to protect the public health and to build on the tremendous gains that have been made over the past 50 years in reducing smoking rates is to ban menthol in cigarettes and to extend the ban on all flavors to all tobacco products.

Appendix A

Prevalence of Past 30 Day Cigarette Use in the U.S. Population, 2011

Cigarette Use in the Past 30 Days by Key Demographics in the U.S. Population Ages 12 and Older, 2011 (Percent)

	Total Cigarette Use	Non-Menthol Cigarette Use	Menthol Cigarette Use
Total	22.0	13.9	8.2
Gender			
Male	24.4	16.4	8.0
Female	19.8	11.5	8.3
Age			
12-17	7.9	3.9	4.0
18-25	33.2	17.5	15.7
26-34	32.0	19.9	12.1
35-49	25.4	17.4	8.0
50-64	20.4	13.1	7.3
65+	9.6	7.2	2.3
Race			
White	23.6	16.7	6.9
Black	21.8	3.8	17.9
Hispanic	17.8	10.8	7.1
Other	17.5	11.0	6.5
Geographic Area			
Metro >1mil	20.3	12.0	8.3
Metro <1mil	23.4	15.2	8.2
Non-metro	27.6	20.0	7.5
Income			
<\$20K	31.2	17.7	13.5
\$20K to \$49.9K	25.6	16.5	9.1
\$50K to \$74.9K	19.1	12.3	6.8
\$75K +	14.4	9.6	4.8
Employment			
Full time	23.3	14.9	8.4
Part time	22.1	13.7	8.4
Unemployed*	38.7	20.4	18.3

* Unemployed is defined as anyone over the age of 14 who did not have a job last week and was not looking for a job. Does not include those who are not in the workforce (e.g., those who are retired, homemakers, students, disabled).

Note: Unweighted N = 58,397; Weighted N = 257,598,945

Source: CASAColumbia analysis of 2011 NSDUH data.

Appendix B

The TPSAC Report Findings¹⁷⁰

TPSAC QUESTIONS AND ANSWERS (Copied Verbatim From the TPSAC Report)

1. Does the availability of menthol cigarettes increase the likelihood of experimentation?
2. Does the availability of menthol cigarettes increase the likelihood of becoming a regular smoker?
 - *The evidence is sufficient to conclude that a relationship is more likely than not that the availability of menthol cigarettes increases experimentation and regular smoking.*
3. Does the inclusion of menthol in cigarettes increase the likelihood of becoming addicted?
4. Does the inclusion of menthol in cigarettes increase the degree of addiction of the smoker?
 - *The evidence is sufficient to conclude that a relationship is more likely than not that the availability of menthol cigarettes increases the likelihood of addiction and the degree of addiction in youth smokers. There is insufficient evidence to conclude that menthol cigarettes increase the likelihood of addiction and the severity of addiction in adults.*
5. Are smokers of menthol cigarettes less likely to quit successfully than smokers of non-menthol cigarettes?
 - *The evidence is sufficient to conclude that a relationship is more likely than not that the availability of menthol cigarettes results in lower likelihood of smoking cessation success in African Americans, compared to smoking non-menthol cigarettes. The evidence is sufficient to conclude that a relationship is as likely as not that the availability of menthol cigarettes results in lower likelihood of smoking cessation success in other racial/ethnic groups.*
6. Do biomarker studies indicate that smokers of menthol cigarettes receive greater doses of harmful agents per cigarette smoked compared with smokers of non-menthol cigarettes?
 - *The evidence is insufficient to conclude that it is more likely than not that menthol smokers inhale more smoke per cigarette or that they are exposed to higher levels of nicotine and other tobacco toxins.*
7. Do smokers of menthol cigarettes have increased risk for diseases caused by smoking compared with smokers on non-menthol cigarettes?
 - *The evidence is insufficient to conclude that it is more likely than not that smokers of menthol cigarettes have increased risk for diseases caused by smoking compared with smokers of non-menthol cigarettes.*
8. Does the availability of menthol cigarettes increase the prevalence of smoking in the population, beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?
 - *The evidence is sufficient to conclude that it is more likely than not that the availability of menthol cigarettes increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such cigarettes were not available, in the general population and particularly in African Americans. The evidence is sufficient to conclude that it is more likely than not there is a causal relationship between the availability of menthol cigarettes and regular smoking among youth.*
9. Does the tobacco company marketing of menthol cigarettes increase the prevalence of smoking beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?
 - *The evidence is sufficient to conclude that it is more likely than not that menthol cigarette marketing increases prevalence of smoking beyond anticipated prevalence if such cigarettes were not available for the whole population, and for youth and African Americans. The evidence is sufficient to conclude that it is as likely as not that menthol cigarette marketing increases prevalence of smoking beyond anticipated prevalence if such cigarettes were not available for Hispanics.*
 - *The evidence is insufficient to conclude that it is more likely than not that menthol cigarette marketing increases prevalence of smoking beyond anticipated prevalence if such cigarettes were not available for Asian Americans, Hawaiians/Pacific Islanders and women.*

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