Impact of Menthol Cigarettes on Tobacco Use

FDA Review of the Scientific Evidence

According to the Federal Register notice, "over the past several years, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes."[3] The first of these reviews was mandated by Congress in the Family Smoking Prevention and Tobacco Control Act. Congress was so concerned by the "unique issues surrounding menthol cigarettes," the high prevalence of use by Black smokers, the targeting of Black Americans by the tobacco industry, and the potential for "unique health risks to those who smoke [menthol cigarettes]," that Congress ordered the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) to immediately begin its review as the Committee's first order of business.[4] The TPSAC report, which was released in 2011, concluded that "removal of menthol cigarettes from the marketplace would benefit the public health in the United States."[5] At the time, menthol cigarettes represented one quarter of all cigarette sales in the U.S. and were smoked by nearly 7 in 10 Black smokers. Unfortunately, menthol cigarette sales and prevalence have only increased since that time.

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[1] U.S. Department of Health & Human Services. Smoking Cessation: A Report of the Surgeon General. 2020.

[2] Roy A, et al. Tobacco and Development. The

[3] 87 FR at 26458.

[4] Family Smoking Prevention

In 2020, menthol cigarettes made up 37% of domestic cigarette sales in the U.S.[6] and 85% of Black smokers now smoke menthol cigarettes.[7]

In 2013, the TPSAC report was followed by a separate internal review conducted by FDA scientists. Like the TPSAC report, the FDA found that menthol increases initiation and progression to regular smoking and enhances the addictiveness and dependence of tobacco.[8,9] Similar to TPSAC, the FDA report concluded that menthol cigarettes likely pose a greater public health risk than non-menthol versions.[10]

More recently, the FDA conducted two additional reviews of menthol cigarettes. The first, "Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021," examined peer-reviewed literature on menthol cigarettes' impact on regular use, dependence, and cessation. The second, "Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes," looked at the impact a menthol ban may have on a variety of outcomes such as tobacco use behavior, tobacco sales, illicit sales, user modification of products, and more. Both reports were released in conjunction with this proposed rule and add to the substantial evidence base.

In addition, the FDA received voluminous public feedback in response to two advanced notices of proposed rulemaking on the potential regulation of menthol (2013) and the potential regulation of all fl

Studies show that menthol makes cigarettes easier to smoke. Menthol provides a cooling effect in the back of the throat, reduces the harshness of cigarette smoke, and suppresses coughing.[11] Youth and young adults "who initiate smoking with menthol cigarettes are more likely to report having a pleasant first smoking experience"[12] and fewer experience nausea.[13] This makes menthol cigarettes a "starter product" for youth or other inexperienced users to initiate tobacco use.

Menthol also masks the taste of tobacco, making cigarettes taste better. According to discussion groups conducted by Creative Research Group (CRG) for British American Tobacco in 1982, "There is no question that menthol has a significant masking effect on both the taste of the tobacco and the harshness of the smoking experience. Some menthol smokers seek as much masking effect as possible, attempting to eradicate the tobacco taste altogether."[14] Participants in those focus groups shared feedback such as: "As far as I am concerned, I want the menthol to completely cover up the taste of the tobacco. I don't like the taste of tobacco" or "If the menthol was gone, I wouldn't be able to stand the cigarette!"[15] indicating that some smokers do not find non-mentholated cigarettes appealing.

Menthol cigarettes increased in popularity after the FDA implemented the flavored cigarette ban. In 2019, approximately half of youth (46.7%) and young adult (51%) cigarette smokers smoked menthol cigarettes; that number declines for older smokers to 39%.[16] According to the FDA's 2013 scientific evaluation of menthol, younger populations have the highest rate of smoking menthol cigarettes. In fact, the FDA found that menthol is substantially more popular among newer smokers than the general population.[17] Youth and young adults are also more likely to try a menthol cigarette as their first cigarette.[18]

Menthol's popularity among youth and young adults is clear – and the result of intentional targeting by the tobacco industry. As the 2012 Surgeon General's Report on Preventing Tobacco Use Among Youth and Young Adults concluded, the tobacco industry designed their products to appeal to youth, including the use of menthol and other youth-appealing flavors,

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[11] FDA Preliminary Scientific Evaluation.
[12] 87 FR at 26464. Cohn, A. and J. D'Silva. Menthol Smoking and Subjective Response to the First Cigarette Smoked. Tobacco Regulatory Science, 5(6):554–566, 2019.
[13] 87 FR at 26470. D'Silva, J. et al. Differences in Subjective Experiences to First Use of

to remain profitable over the long-term.[19] For example, one industry document calls menthol a good starter product "because new smokers appear to know that menthol covers up some of the tobacco taste and they already know what menthol tastes like, vis-à-vis candy," while another document notes that "the base of our business is the high school student."[20] The industry has also exploited positive misperceptions about menthol cigarettes. According to a Truth Initiative survey, 41% incorrectly believe that there are health benefits associated with menthol compared with non-menthol cigarettes; and 61% believe that menthol makes it easier to quit smoking.[21] These perceptions, combined with the appealing flavor and advertising that uses youthful imagery,[22] help tobacco companies recruit young "replacement smokers" to replace older smokers who die of a tobacco-related disease. Unfortunately, these efforts appear to be working, as a recent study found that menthol cigarettes alone were responsible for 10.1 million extra smokers (or approximately 265,000 new smokers each year) between 1980 and 2018.[23] During this same time period, menthol cigarettes also resulted in 378,000 premature deaths and 3 million life years lost.[24]

Menthol Increases Progression to Regular Smoking

Menthol increases the likelihood that new users who experiment with cigarettes will progress to regular use and nicotine dependence.

Studies show that menthol facilitates repeated use. As the FDA found in its most recent scientific review, "[t]he sensory effects of menthol make cigarettes more palatable by masking the harsh taste of tobacco and reducing aversive responses associated with initial smoking experiences (e.g., throat irritation, coughing) that can deter new and inexperienced users from repeated experimentation."[25] The report continues to note that "[r]epeated exposure to nicotine, particularly during adolescence, increases the likelihood of addiction. Consequently, youth who initiate smoking with menthol cigarettes may be at greater risk for progression from experimentation to established smoking and nicotine dependence than youth who initiate with non-menthol cigarettes."[26]

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[19] U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General; 2012.
[20] 87 FR at 26464.
[21] Truth Initiative. Menthol Cigarettes: Attitudes, Beliefs, and Policies. See https://truthinitiative.org/research/menthol-cigarettes-attitudes-beliefs-and-policies
[22] TPSAC Report.
[23] Le TT, Mendez D. An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018 Tobacco Control Published Online First: 25 February 2021. doi: 10.1136/tobaccocontrol-2020-056256
[24] Ibid.
[25] Food and Drug Administration. Scientific Review of the Effects of Menthol on Tobacco Addiction: 1980-2021. April 2022.
[26] Ibid.

A recent study illustrates the im

cigarette smokers have declined more slowly.[33] Even though menthol cigarette smokers make more quit attempts than non-menthol smokers, they have a significantly lower success rate.[34] One study using data from the Population Assessment of Tobacco and Health (PATH) found that daily menthol smokers were 24% less likely to quit compared to non-menthol smokers.[35] Another study, which compared 30+ day and 12-month abstinence rates by menthol use, found that using menthol prior to a quit attempt reduced the probability of success by 28%. Conversely, switching from menthol to non-menthol use increased the probability of 30+ day and 12-month abstinence by 58% and 97% respectively.[36]

experience.[43]

For example, the tobacco industry began advertising heavily in Black publications, such as Ebony, Jet, and Essence magazines. In 1962, Ebony contained twice as many cigarette advertisements as

advertisements compared with White neighborhood thoroughfares.[67] An analysis of billboards in St. Louis also found that tobacco advertisements were more common in Black neighborhoods than in White ones.[68] Similarly, a 1986 industry memorandum showed that one company intentionally advertised menthol cigarettes in the interior of buses that had "a high percent of Black ridership," but chose not to put those advertisements on the exterior of buses that passed through neighborhoods with a higher percentage of White residents or

In addition to advertisements and brand associations with community events, the tobacco industry relied heavily on free samples and coupons to attract new users. Industry documents from 1967 describe "handing out free samples to those who were the 'kingfish' in the community and building brand following through barbers, bellhops, and taxi drivers, who also distributed free samples."[78] In the 1970s and '80s, tobacco companies used mobile vans to pass out coupons for free samples of menthol products in predominantly Black,

LQBT (36%) smokers, but at lower rates.[97,98] Menthol use is also higher among people with low levels of income or education[99] or with mental health conditions.[100]

Some of this popularity can be attributed to targeting of these populations. As with Black communities, the tobacco industry tends to advertise more heavily in communities of color and underserved populations. As described above, the tobacco industry supported Hispanic media and advertised more heavily in Spanish-language magazines, placed more billboards in areas with Hispanic or Asian residents, and sponsored Hispanic athletic, civic, cultural, and entertainment events. In the 1980s, industry began to apply some of the same strategies it had been using to target Black and Hispanic communities to Asian Americans and American Indian/Alaska Native (AI/AN) consumers. For example, some tobacco companies began appropriating American Indian imagery and language to associate their products with positive American Indian stereotypes (e.g., that products were natural, traditional, mystical, or spiritual), evoke a sense of pride among American Indians, and blur the lines between commercial and traditional tobacco use.[101]

Because menthol has a disproportionate impact on minorities and other underserved communities, removing menthol cigarettes from the market and lowering tobacco use would advance health equity.

Benefits of Removing Menthol Cigarettes

Reduce Initiation and Use, Increase Cessation

AHA agrees with the FDA's assessment that prohibiting menthol as a characterizing flavor in cigarettes would reduce cigarettes' appeal, particularly for youth and young adults. Young people would be less attracted to cigarettes, less likely to initiate smoking, and less likely to continue experimenting and progress to regular use.

We also agree that prohibiting menthol would increase the number of smokers who stop using cigarettes. Almost 70% of smokers want to quit smoking,[102] and studies have shown

[97] U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2019.
[98] Fallin A, et al. Menthol Cigarette Smoking Among Lesbian, Gay, Bisexual and Transgender Adults. Am J Prev Med. 2015 Jan;48(1):93-7. doi: 10.1016/j.amepre.2014.07.044.
[99] FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol

that many current menthol smokers would quit tobacco altogether if menthol cigarettes were removed from the market. For example, data from the 2011 National Youth and Adult Health Survey found that 65.7% would quit, while 18.4% would switch to non-menthol cigarettes, and 16% would switch to another tobacco product.[103] A 2021 expert elicitation estimated that a federal menthol cigarette and cigar ban would reduce combustible tobacco use by 30% among menthol smokers ages 12-24 and by 20% among menthol smokers ages 35-54, as well as prevent 39% of young people ages 12-24 who would have initiated menthol cigarette use absent a menthol ban, from initiating tobacco use.[104]

These data are supported by real-world evidence that shows many menthol cigarette smokers do attempt to quit after menthol cigarettes are banned. Only one month after Ontario, Canada banned menthol cigarettes in January 2017, a small study found that 29.1% had already attempted to quit.[105] While a larger, more recent study conducted after Canada implemented a country-wide menthol cigarette ban found that menthol cigarette smokers were significantly more likely than non-menthol smokers to attempt to quit; daily menthol smokers were also significantly more likely to quit (22%) compared to non-menthol smokers (15%).[106] When the study's authors applied Canada's experience to the U.S., they projected that if the U.S. were to remove menthol cigarettes from the market, an additional 1,337,988 smokers would quit, including 381,272 Black smokers.[107]

These data add to the evidence base in support of a menthol ban.

Improve Public Health

If menthol cigarettes are removed from the market, it will have a tremendous impact on public health, reducing tobacco-related morbidity and mortality. As the Agency is well

well as a number of serious health conditions in children and adolescents. Almost half a million Americans die because of smoking and more than 41,000 die of secondhand smoke exposure in the U.S. each year. On average, male smokers die 12 years earlier and female smokers die 11 years earlier than never-smokers.[110]

The good news is that quitting cigarette smoking has "immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general."[111] For example, heart rate and blood pressure drop 20 minutes after finishing an acute episode of smoking.[112] As early as two weeks after quitting,

Lower Health Care Costs

A reduction in menthol cigarette use would also result in lower health care costs. Between 2010 and 2014, cigarette smoking was estimated to account for 11.7% of annual health care spending, or $225 billion per year.[116] More than half of this spending was funded by Medicare and Medicaid. Cigarette smoking also costs the U.S. more than $150 billion in lost productivity attributable to premature death and exposure to secondhand smoke.[117]

While AHA is unable to quantify the specific cost savings that would result from a menthol cigarette ban during this comment period, it is evident that fewer cigarette smokers would result in lower health care costs. Former smokers and never smokers require fewer medical services during their lifetime.[118]

Advance Health Equity

AHA agrees with the Agency that removing menthol cigarettes from the market is an important step to advance health equity. Menthol cigarettes take the greatest toll on the Black community. Black Americans smoke menthol cigarettes at disproportionately high rates, have the highest levels of exposure to secondhand smoke, suffer some of the highest burden of tobacco-related disease and death, have less access to comprehensive cessation services, and are less likely to successfully quit despite being more likely to try. Consequently, menthol cigarettes are largely responsible for tobacco-related health disparities in this population.

The best way to address tobacco-related health disparities is to eliminate menthol as a characterizing flavor in cigarettes. Because menthol use is heavily concentrated in Black and other underserved communities, menthol cigarette use and adverse tobacco-related health effects in these populations would likely decrease significantly. For example, one recent study that examined the impact of the FDA's proposed menthol cigarette ban on Black Americans, projected that smoking by Black adults would decrease 35.7%, avert 255,895 premature deaths, and result in an increase of 4 million life-years over a 40-year period.[119] According to the study's authors, a menthol cigarette ban would have a disproportionately greater health impact on Black Americans, who would receive approximately one-third of the gains in averted deaths and life years lost, even though they only represent 12 to 13% of the overall U.S. population.[120]

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[116] Xin Xu, et al. U.S. healthcare

Scope of the Proposed Product Standard

No Cigarette Should Be Exempt from the Product Standard

Under the proposed rule, all tobacco products that meet the definition of a "cigarette" would be subject to the new productstandard prohibiting menthol as a characterizing flavor. However, the FDA is requesting comments on whether certain products should be eligible to apply for an exemption. Two examples the FDA provides are noncombusted and reduced nicotine cigarettes.

AHA strongly opposes creating an exemption process; all cigarettes should be required to comply with the menthol product standard. Allowing any menthol cigarettes to remain on the market would undermine the public health purpose of this rule.

As the FDA itself explains in the Federal Register notice, "Menthol's flavor and sensory effects increase

We also have specific concerns with the two types of cigarettes the FDA is considering.

Noncombusted Cigarettes

For the reasons described above, we do not believe any menthol cigarette should be allowed to remain on the market, including noncombusted cigarettes like IQOS or similar heated tobacco products (HTP).

With IQOS specifically, we are concerned about the lack of research examining this product's appeal to youth and to communities of color, two populations that heavily use menthol cigarettes. It is our understanding that Philip Morris did not provide FDA data on the impact of "Smooth Menthol" or "Fresh Menthol" IQOS heat sticks for either population. However, a study examining interest in IQOS in the U.S., Canada, and England found that 38.6% of youth expressed interest in trying the product, including 40.9% of youth respondents in the U.S.[22] Susceptibility to trying IQOS was 21.8% among youth never smokers or never vapers in the U.S., higher than the rate for conventional cigarettes (19%). This shows that youth interest in IQOS is high. And as the study's authors point out:

toxic chemicals and put users at risk for the same tobacco-related diseases and premature death. As we discuss above, we are concerned that consumers may erroneously believe that these cigarettes are safe if they are the only menthol cigarettes that remain on the market, especially if, like VLN, they bear a reduced exposure claim. And, because youth and young adults prefer menthol flavor, it may lead to increased initiation. There is also the potential that youth may start with a reduced nicotine menthol cigarette but later switch to a combustible tobacco product with higher nicotine, sustaining their addiction and risk for morbidity and mortality.

We are also concerned that the availability of reduced nicotine menthol cigarettes may lower cessation rates. Smokers may switch to these products rather than attempt to quit. In

- Any other means that impart flavor or represent that the tobacco product has a characterizing flavor

We understand the Agency's decision to utilize these "specific, flexible factors"[127] rather than one rigid definition. It would be difficult to develop one definition that adequately covers all the methods the tobacco industry can utilize to produce a flavored product or the sensation of one. It would also be difficult to capture new ingredients or innovations that the tobacco industry may develop in the future. In addition, providing one specific definition might actually make it easier for the tobacco industry to evade the flavoring restriction.

That said, we are still concerned that the tobacco industry will attempt to evade the four factors identified by the FDA. The tobacco industry has a long history of exploiting any loophole it can find. Therefore, we strongly encourage the FDA to consider ways to strengthen and apply the proposed factors. This may include flagging, limiting, or prohibiting the use of ingredients that are not traditionally thought of as flavors but provide some of the same sensory effects as menthol, such as sweeteners, ingredients that have anesthetic properties or that provide a cooling sensation, such as menthol analogs or alternatives. It could also include the use of multiple flavor additives but each in small amounts to evade any specific flavor limit, or the use of a small amount of menthol in conjunction with other ingredients that amplify its flavor or effects.

The factors the FDA ultimately selects must be able to withstand the innovative, persistent, and perpetual efforts the tobacco industry will undoubtably employ.

Possible Countervailing Effects

Illicit Trade Market

In the Federal Register notice, the FDA examines possible countervailing effects that may occur if a menthol product standard is adopted, including an illicit trade market. We agree with the FDA's assessment that a menthol standard is unlikely to create a significant illicit market, that a large number of illicit menthol cigarettes would be available, or that a substantial number of smokers would utilize such products. We also agree that the risks of a potential illicit market do not outweigh the benefits created by this rule.

It is important to recognize that the argument that a menthol cigarette ban will create an illicit market is largely driven by the tobacco industry itself. The tobacco industry has a history of using the threat of an illegal market to argue against tobacco regulations, such as flavor restrictions and increased

It is unlikely that a large illicit market of menthol cigarettes would develop in the U.S. because the product standard would prohibit the manufacture, distribution, or sale of these products. Cigarette manufacturers would no longer be producing menthol cigarettes for a U.S. market, and it is unlikely that manufacturers would be willing to engage in large scale manufacturing of illegal products. In addition, because the menthol standard would apply nationwide, would-be participants in an illicit market would not be able to obtain menthol cigarettes simply by crossing state lines. Therefore, it would be difficult for entities to secure large quantities of menthol cigarettes to distribute and sell in an illicit market.

In addition, we are unaware of any evidence that other flavor restrictions have led to a significant increase in illicit tobacco. For example, after flavored cigarettes (other than menthol) were removed from the

e in illicit flavored cigarettes. Instead, as the FDA describes in the proposed

va Scotia banned menthol

cigarettes, a study found "there was no surge in illicit cigarettes after the 2015 ban on

cigarettes should remain on the market legally because they are safer for having undergone FDA review is seriously flawed and should not be considered.

Again, we do not believe a menthol product standard will result in a significant illicit market, but, if an illicit market emerges, any potential adverse effects will be outweighed by the substantial public health benefit.

Potential

criminalization.[139] RJR provides financial support to Rev. Sharpton's organization, the National Action Network, which notably has come out against menthol cigarette restrictions.[140] A recent investigation by the L.A. Times and The Bureau of Investigative Journalism found that RJR also funds police organizations, such as the Law Enforcement Action Partnership (LEAP), and sponsored a luncheon at a National Black Caucus of State Legislators conference where a LEAP official served as the luncheon's speaker and warned attendees that "prohibiting menthol cigarettes would increase policing in Black communities and create a new layer of racism."[141] That investigation also identified other tactics, such as donating to the Congressional Black Caucus (CBC), enlisting lobbyists to fight menthol restrictions or write op-eds without acknowledging their client or the source of their funding, and paying protestors to attend a rally.[142] The tobacco industry has also used television and social media ads to oppose local flavored tobacco restrictions, claiming that it will increase racial profiling by law enforcement.[143] Most recently, the industry has tried to associate itself with the Black Lives Matter movement and concerns about police brutality.

However, the proposed rule is specifically designed not to increase law enforcement interactions with the community. The FDA is clear that the rule will only apply to manufacturers, distributors, wholesalers, importers, and retailers; it will not include a prohibition of individual consumer possession or use.[144] According to the Agency, "FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes."[145] In addition, the FDA has clarified that state and local law enforcement entities do not and cannot take enforcement action on FDA's behalf for violations of this restriction. Therefore, a federal ban on menthol cigarettes should not increase the risk of police abuse or racial discrimination within particular communities.

It is also important to recognize that the FDA is not "singling out" menthol cigarettes or purposely targeting the tobacco product many Black smokers prefer. Menthol cigarettes are the only flavored cigarette currently on the market; all other flavored cigarettes were removed in 2009 under the Tobacco Control Act, but menthol cigarettes were allowed to remain due to a massive lobbying campaign by the tobacco industry. That decision allowed tobacco companies to continue targeting communities of color, youth, LGBTQ, and others

[139] Truth Initiative. Menthol: Facts, Stats and Regulations. April 22, 2022. https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations

[140] Baumgaertner E, et al. How Big Tobacco Used George Floyd and Eric Garner to Stoke Fear Among Black Smokers. Los Angeles Times, April 25, 2021.

with these deadly, addictive products. The FDA's proposal would "just add menthol to the existing list of prohibited flavors"[146] and put an end to that discrimination.

The important public health benefits of the proposed rule have also been recognized by many members of the Black community. The African American Tobacco Control Leadership Council, Association of Black Cardiologists, Black Women's Health Imperative, Center for Black Health and Equity, NAACP, National Black Nurses Association, National Caucus and Center on Black Aging, and National Medical Association, among others, have all voiced strong support for removing menthol cigarettes from the market. In a letter to HHS Secretary Becerra in April 2021, the groups described how "The industry's successful campaign to hook Black/African Americans on a more addictive cigarette has had devastating consequences" and noted that:

> The tobacco industry's spokespeople have attempted to stoke fears that prohibiting menthol cigarettes is discriminatory, but this could not be further from the truth. The industry has mischaracterized a prohibition on menthol cigarettes as criminalizing Black/African American smokers when the tobacco industry is directly responsible for this disparity in menthol use. There in lies the true injustice. There are undoubtedly racial injustices in our criminal justice system, but FDA's rulemaking process should clarify that just as it enforces other tobacco regulations, a prohibition of menthol cigarettes will focus enforcement efforts on manufacturers and retailers, not individual consumers.[147]

A menthol ban is also supported by many Black policy makers. For example, in 2020, a majority of the CBC voted for legislation that would prohibit flavors in tobacco products, including menthol cigarettes. And last year, the CBC Health Braintrust called on HHS to remove menthol cigarettes from the market, stating that "[t]he tobacco industry must no longer be permitted to use menthol cigarettes to profit at the expense of the health of Black Americans."[148] Support among the general community is also high. A survey of 2,871 adults between the ages of 18 and 64 found that 56.4% support a government policy to ban menthol cigarettes, including 60.5% of Black, 62.5% of Hispanic/Latino, 65.8% of non-Hispanic other, and 50.4% of non-Hispanic White respondents.[149]

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[146] Public Health Law Center. Menthol Ban: Highlighting the Facts and Rebutting Tobacco Industry Misinformation. Menthol Ban Highlighting the Facts and Rebutting Tobacco Industry Misinformation.pdf (publichealthlawcenter.org)

[147] African American Tobacco Control Leadership Council, et al. Letter to HHS Secretary Becerra. April

Sell-Off Period

The FDA requests comment on whether it should include a sell-off period, such as 30 days after the effective date of a final rule, to give retailers time to sell through their current inventory of menthol cigarettes. AHA strongly opposes a separate sell-off period. A one-year effective date will provide retailers sufficient time to plan, adjust their orders for menthol cigarettes, and sell any remaining inventory by the time the rule takes effect. There is no justification for a separate sell-off period.

Regulatory Impact Analysis

Consumer Surplus

AHA is disappointed that the Regulatory Impact Analysis (RIA) contains a discussion of "consumer surplus" or what is loosely defined as how much a consumer values or benefits from a product. As we have expressed to FDA previously, we do not believe that "consumer surplus" should be applied to tobacco use.

The concept of lost consumer surplus should only be considered when individuals are able to make fully rational and fully informed decisions. However, nearly nine out of 10 smokers start smoking before age 18 and 99% start before age 25.[150] Adolescents are not fully aware of the health consequences of tobacco use, have little concept of their own mortality, and heavily discount the threat of addiction, making their decisions neither fully informed nor rational. It is this premise – that youth may not be able to make fully rational decisions – that led policymakers to create and later raise the minimum sales age for tobacco products.

In addition, tobacco is addictive and once an individual becomes addicted, the decision to continue buying tobacco products is no longer rational. This is particularly true for menthol cigarettes since menthol enhances 5p 0 TD -.e -. -1.h6pro0ievea

other targeted populations and are designed to maximize addictiveness.[152] That means that

and Hispanic youth and adults using these products remained high. We fear that any additional delay will have real, and continuing, public health consequences. Therefore, we urge you to release the final rule by the end of this calendar year.

Prohibiting menthol cigarettes is one of the most important actions the FDA can take "to ensure that tobacco-related disease and death is a part of America's past, not America's future."[155] We look forward to continuing to work with you to achieve this mutual goal.

Thank you for your consideration of our comments.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Senior Regulatory Affairs Advisor, at 202-785-7908 or susan.k.bishop@heart.org.

Sincerely,

Nancy A. Brown
Chief Executive Officer
American Heart Association

[155] @FDATobacco. May 20, 2002. https://twitter.com/FDATobacco/status/1527689609261506560