



DEPARTMENT OF PUBLIC HEALTH  
CITY OF CHICAGO

September 26, 2013

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Menthol in cigarettes and tobacco products; Docket No: FDA-2013-N-0521**  
(Submitted in response to section entitled to “*C. Other Actions and Considerations*”)

**I. REGULATION OF MENTHOL-FLAVORED CIGARETTES IS BOTH A CRITICAL PUBLIC HEALTH ISSUE AND AN IMPORTANT SOCIAL JUSTICE ISSUE.**

Regulation of menthol-flavored cigarettes is not only a critical public health issue — it is an important social justice issue. Menthol-flavored cigarettes are disproportionately used by populations such as young people, women, racial minorities, the LGBT community, and people of low socio-economic status.<sup>1</sup> Scientists have documented ethnic differences in smoking behavior, and health disparities can be linked to rates of menthol-flavored cigarette use.<sup>2,3</sup>

Moreover, the tobacco industry has a well-documented history of developing and marketing menthol-flavored brands to racial and ethnic minorities and youth.<sup>4,5</sup> For example, a recent study reveals that the tobacco industry engages in predatory targeting of Black youth — by, for example, increasing promotions for Newport cigarettes by as much as 42% in areas surrounding high schools with predominantly African-American students.<sup>6</sup> This research also reveals the industry lowers their prices for menthol-flavored cigarettes near schools where African American students attend.

We know that the populations the tobacco industry aggressively targets are less likely to have health insurance; less likely to see a doctor; less likely to receive a medical intervention; and, even if they are insured, they are less likely to have coverage for tobacco cessation products — all of which means they are more attractive target markets because they are more likely to be life-long customers.

Regulating menthol-flavored cigarettes is essential for protecting the health of all our children, and especially minority children. It is socially unjust to allow the flavored cigarettes that are targeted aggressively to minority communities to remain unregulated years after all other flavored cigarettes were removed from the market.



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**II. REGULATING AND/OR BANNING MENTHOL-FLAVORED TOBACCO WOULD IMPROVE PUBLIC HEALTH.**

If your agency does not move forward with regulating menthol-flavored cigarettes, it is certainly not because of a lack of evidence regarding their negative impact on public health. Derived from the peppermint plant, menthol provides a minty flavor and cooling sensation for smokers, covering up the tobacco taste and reducing the throat irritation associated with smoking, particularly among first-time users. The anesthetic cooling effect of menthol facilitates initiation and early persistence of smoking by youth.<sup>7</sup> Menthol may also inhibit the metabolism of nicotine, resulting in higher rates of addiction.<sup>8</sup> Through suppression of respiratory irritation, menthol may facilitate smoke inhalation and promote nicotine addiction and smoking-related morbidities.<sup>9</sup>

Most importantly, there is substantial evidence that menthol-flavored cigarettes are a “starter” product for youth who begin smoking.<sup>10, 11, 12, 13</sup> The most popular tobacco products among youth are menthol flavored.<sup>14</sup> In fact, kids aged 12 to 17 smoke menthols at a higher rate than any other age group.<sup>15</sup>

The prevalent use of menthol-flavored cigarettes among 12 to 17 year-olds is staggering, with disproportionate rates being evident across the community: 72% of African Americans, 51% of Asians, 47% of Hispanics and 41% of Whites; as well as 71% among young LGBT smokers.<sup>16, 17</sup> The trend continues into young adulthood, with 85% of African American smokers, 38.2% of Hispanics, and 35.8% of Asians using a mentholated brand compared to 28.8% of Whites.<sup>18</sup> At the Federal level, a menthol ban could prevent up to 600,000 smoking-related deaths by 2050, a third of these from the African American community.<sup>19</sup>

Among adult menthol users, menthol cigarette use (vs. non-menthol) is associated with a lower likelihood of a successful quit attempt and higher rates of relapse.<sup>20</sup> In addition, menthol smokers have higher physical nicotine dependence and smoking urge, despite smoking the same number of cigarettes as non-menthol users.<sup>21</sup> The FDA’s most recent report reaffirmed these findings. Specifically, the FDA’s 2013 report on menthol cigarettes found that menthol in cigarettes is likely associated with increased smoking initiation and greater addiction and that “menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking.”<sup>22</sup>

Menthol poses a serious risk to our kids and the public health. The FDA must act to protect the public from these dangerous and addictive products and all options should be on the table — including, but not limited to new regulations, new warning labels that are specific to menthol, as well as an outright ban.



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**III. ALTHOUGH THE TOBACCO INDUSTRY WILL SEEK TO OBSTRUCT OR DELAY IMPLEMENTATION OF NEW RESTRICTIONS ON MENTHOL, THE THREAT OF LITIGATION SHOULD NOT STOP THE FDA FROM MOVING FORWARD WITH STRONG REGULATIONS OR A BAN. MOREOVER, IN ORDER TO PROVIDE A MINIMUM PUBLIC HEALTH RESPONSE, THE FDA SHOULD ALSO PURSUE SHORT-TERM STRATEGIES THAT ARE LESS LIKELY TO BE LITIGATED AND CAN BE IMPLEMENTED IMMEDIATELY.**

The FDA must recognize that Big Tobacco companies will use litigation to resist implementation of any regulation that restricts the sale of menthol-flavored tobacco products — even if that regulation falls short of a ban. The use of litigation is a well-known tobacco industry tactic for resisting public policy on health.<sup>23, 24</sup> The threat of litigation should not stop the FDA from moving forward.

The FDA should proactively attempt to mitigate the negative impact tobacco industry litigation tactics have on public health. With the expected delay in life-saving policies, the City of Chicago urges the FDA to invest additional funds in education and marketing campaigns that direct consumers to tobacco cessation services.

Moreover, the FDA should immediately adopt new warning labels (under authority in 15 U.S.C. 1333) that specifically address the unique public health problems that are created by menthol-flavored tobacco products — including evidence that menthol tobacco products are associated with increased smoking initiation, especially among youth and that menthol cigarettes are more addictive and harder to quit.

The FDA should move forward with creating new warning labels for menthol-flavored tobacco products and smokeless tobacco products even if the agency ultimately decides to remove these products from the market, because doing so will provide a minimum public health response that is less likely to be delayed by years of litigation. The public should not have to wait for years of “intimidation through litigation” strategies to play out before public health protections are implemented. New warning labels specific to menthol should be created immediately.

**IV. THE FDA SHOULD ASSERT JURISDICTION OVER ALL TOBACCO PRODUCTS**

Four years ago, when herb, spice, and flavored cigarettes were banned, the tobacco industry immediately created candy and fruit-flavored little cigars, cigars and e-cigarettes, which are often cheaper and sold individually or in packs of two or three. Some of these new flavored products include Swisher Sweets Sweet Chocolate Blunts, Phillies Sugarillos Cigarillos and White Owl



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grape Blunts Xtra. E-cigarettes now come in dozens of flavors, including cotton candy, gummy bear, bubble gum, Atomic Fireball, cherry cola, cherry limeade, caramel candy and orange cream soda.<sup>25</sup> These products are now advertised on television and have been sold by Groupon.

The tobacco industry has proven time and time again that, absent oversight, it will create new products and manipulate other products to meet any loopholes in the law. The industry is constantly evolving to addict children as their new customers and keep current users hooked. As long as the FDA does not assert its jurisdiction over other tobacco products such as cigars, little cigars, e-cigarettes, hookah, and other tobacco products, the tobacco industry is essentially unchecked when it comes to the marketing and manufacturing of these products.

The *Family Smoking Prevention and Tobacco Control Act of 2009* gave FDA authority over cigarettes and smokeless tobacco products. The *Tobacco Control Act of 2009* also gave FDA the ability to then assert authority or “deem” jurisdiction over all other tobacco products, including cigars, e-cigarettes, hookah and pipe tobacco — the next generation of tobacco products that are being used to target kids.

By asserting its authority over other tobacco products, the FDA could: (1) require authorization of new tobacco products before they could be sold in the U.S., thereby stopping the industry from constantly developing new products, flavors, and marketing to hook kids; (2) prohibit flavored tobacco products; and/or (3) work with states to enforce youth sale, distribution, and access restrictions, which could include a requirement that all tobacco products be located behind the counter in all stores.

**V. CONCERNS ABOUT BLACK MARKET SALES SHOULD BE ADDRESSED BY IMPLEMENTING THE “TRACK AND TRACE” SYSTEM REQUIRED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009**

There is ample evidence that Big Tobacco companies profit from the existence of a multi-billion underground cigarette trade.<sup>26, 27, 28, 29</sup> Official statements, made on the record by Big Tobacco companies, unapologetically confirm that the industry is uninterested in ensuring retailers are not evading taxes by selling illegal cigarettes.<sup>30</sup> In 2008, the Republican staff of the House Committee on Homeland Security issued a report that confirmed that black market sale of tobacco products boosts the bottom line of Big Tobacco companies.<sup>31</sup>

When Mayor Emanuel served in Congress, recognizing that Big Tobacco companies had little interest in ensuring their cigarettes are not smuggled, he strongly supported the *Family Smoking Prevention and Tobacco Control Act of 2009*, which President Obama signed into law. Among other things, the *Tobacco Control Act of 2009* mandates that the FDA implement a national



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track-and-trace system to monitor the manufacture and flow of tobacco products from production through distribution to retail outlets.

The City of Chicago urges the FDA to fulfill this statutory obligation by issuing proposed rules on a track-and-trace system. A track-and-trace system will immediately disrupt the illicit trade, trafficking, and counterfeiting of cigarettes. A national track-and-trace system will increase much needed tax revenue, which will help the government offset the substantial economic and health burdens it bears because of smoking. Most importantly, a national track-and-trace system will decrease smoking among the most price-sensitive consumers — our children.

It is especially important to recognize that, with regard to menthol-flavored cigarettes, if the FDA decides it is appropriate to move forward with a ban of these products, at least in the short term, a black market for these products could only occur if the U.S. tobacco companies were complicit in its existence. Menthol-flavored cigarettes are produced almost exclusively in the United States, which means the only current supplier for a so-called “black market” would be the very companies who are sounding the alarms about smuggling in an effort to avoid regulation.

Let’s be clear — the tobacco industry is not interested in protecting kids. Multi-billion dollar, multi-national tobacco companies must addict a new generation of smokers in order to fulfill their corporate obligation to “maximize shareholder wealth.”

I urge the FDA to take the following actions. First, require tobacco wholesalers to use invoices that are tamper-proof and cannot be photocopied. Similar to tamper-resistant prescription pads, tamper-resistant invoices would provide local inspectors who attempt to crack down on illegal sales with a method of ensuring that the paper trail provided by retailers is authentic. An even better system would require wholesalers to report information regarding business-to-business, wholesale tobacco transactions into a national clearinghouse via electronic filing system. Second, I urge the FDA to issue regulations requiring counterfeit-resistant identifying codes on the labels of the tobacco products, or other designs or devices for the purpose of tracking and tracing tobacco products from the point of manufacture, through the distribution chain to the point of retail sale. Third, require that any implemented track-and-trace system have the capacity to determine the date of manufacture, payment records and shipping information on the smallest unit of tobacco offered for retail sale (*i.e.*, the level of the pack for cigarettes). Finally, it is essential to hold manufacturers, distributors, wholesalers, and retailers accountable for maintaining complete records of their transactions and ensuring legal sales of their products.

In summary, regulating menthol-flavored cigarettes is essential for protecting the health of all our children, and especially minority children. The City of Chicago urges you to act expeditiously. It is socially unjust to allow the flavored cigarettes that are targeted aggressively



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to minority communities to remain largely unregulated years after all other flavored cigarettes were removed from the market. In addition to contemplating new regulations around menthol, or an outright ban, the City of Chicago also urges the FDA to create new warning labels specific to menthol-flavored cigarettes, invest additional funds in education and marketing campaigns that direct consumers to tobacco cessation services, implement a national track-and-trace system, and exercise its authority over all tobacco products in order to best determine how to protect public health.

Sincerely,

Bechara Choucair, M.D.  
Commissioner



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CITATIONS

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- <sup>2</sup> See, e.g., Gandhi KK, Foulds J, Steinberg MB, Lu SE, Williams JM. (2009). Lower quit rates among African American and Latino menthol cigarette smokers at a tobacco treatment clinic. *Int J Clin Pract*. 63(3), 360-7.
- <sup>3</sup> See, also, Murphy AB, Akereyeni F, Nyame YA, Guy MC, Martin IK, Hollowell CM, Walker K, Kittles RA, Ahaghotu C. (2013). *Prostate*. 73(14), 1518-28.
- <sup>4</sup> *United States v. Philip Morris*, 449 F. Supp. 2d 1, 71 (D.D.C. 2006) aff'd, 566 F.3d 1095 (D.C. Cir. 2009).
- <sup>5</sup> Yerger V, et al. (2007). Racialized Geography, Corporate Activity, and Health Disparities: Tobacco Industry Targeting of Inner Cities. *Journal of Health Care for the Poor & Underserved* 18(4), 10-38.
- <sup>6</sup> Henriksen L, et al. (2012). Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods. *Nicotine & Tobacco Research*. 14(1), 116-121.
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- <sup>8</sup> Brody, A.L., et al., (2012). Up-regulation of nicotinic acetylcholine receptors in menthol cigarette smokers. *The international journal of neuropsychopharmacology/official scientific journal of the Collegium Internationale Neuropsychopharmacologicum (CINP)*, p. 1-10.
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- <sup>12</sup> Wackowski O, Delnevo C. (2007). Menthol Cigarettes and Indicators of Tobacco Dependence Among Adolescents, 32 *Addictive Behav*. 1964, 1964-69.
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- <sup>14</sup> German Cancer Research Center. (2012). Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product. *red series tobacco prevention and tobacco control*. 17.
- <sup>15</sup> Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (2009). Use of Menthol Cigarettes. The NSDUH Report. Retrieved from <http://oas.samhsa.gov/2k9/134/134MentholCigarettes.htm>.
- <sup>16</sup> Moodie-Mills, A.C. (2011). Flavored Disease and Death for Minorities: Why the FDA Must Ban Menthol Cigarettes. Washington, D.C.: Center for American Progress. Retrieved from <http://www.americanprogress.org/issues/healthcare/report/2011/05/12/9668/flavored-disease-and-death-for-minorities>.
- <sup>17</sup> Tobacco Control Legal Consortium et al. (2013). Citizen Petition to Food & Drug Administration, Prohibiting Menthol as a Characterizing Flavor in Cigarettes. Available at <http://www.publichealthlawcenter.org/sites/default/files/tclcf-dacitizenpetition-menthol-2013.pdf>.
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- <sup>19</sup> Legacy Foundation (2012). Legacy Foundation Annual Report.
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