

June 19, 2018

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

To Whom It May Concern:

**RE:**

**Johns Hopkins Bloomberg School of Public Health Response to the United States (U.S.) Department of Health and Human Services, Food and Drug Administration, Docket No. FDA-2017-N-6565**

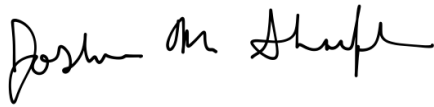
The Institute for Global Tobacco Control (IGTC) at the Johns Hopkins Bloomberg School of Public Health appreciates the opportunity to provide comments in response to the Food and Drug Administration (FDA) public docket published in the Federal Register on March 21, 2018, requesting public comments on the role that flavors play in tobacco products. The public docket is seeking comments, data, research results, or other information about the role of flavors and how flavors attract youth to initiate tobacco product use, and about whether and how certain flavors may help adult cigarette smokers reduce cigarette use.

Research conducted at IGTC indicates that globally, flavored tobacco product availability, including menthol, is increasing. Efforts to ban all flavored cigarettes, including menthol, have been gaining momentum. Canadian provinces have already implemented bans on menthol tobacco products, and Canada will implement its own ban on menthol by the end of 2018, complementing an existing ban on all other flavored cigarettes. Domestically, Chicago has implemented a partial menthol cigarette ban targeted around high schools. More recently, San Francisco voters approved a comprehensive flavored tobacco product ban. Our data show that tobacco manufacturers will use persuasive marketing and packaging to circumvent or exploit loopholes in policy requirements.

Thank you for this opportunity to share comments, published and unpublished research regarding flavored cigarettes and efforts to regulate these products globally. IGTC is

providing the following comments with the aim of informing the FDA on evidence-based measures to reduce cigarette use broadly, and among children specifically.

Sincerely,



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## I. Introduction

The Surgeon General's report of 2012 correctly outlines the role flavors play in the initiation of tobacco product use and dependence and it is detailed well in this advanced notice of proposed rulemaking.[1] The Tobacco Control Act (Pub. L. 111-31) enacted in 2009 made great progress in limiting the availability of flavors (excluding menthol) in combustible cigarettes. However, FDA acknowledges the limitation of the current flavored tobacco ban in reducing adolescent tobacco product use with the continued availability of menthol cigarettes and other flavored tobacco products. The prevalence of past 30 day use of flavored e-cigarettes, hookah tobacco, cigars, pipe tobacco, or smokeless tobacco products, and menthol cigarettes, among middle- and high-school students continues to be a public health concern.[2] While overall smoking prevalence declined from 2004 to 2014, menthol cigarette prevalence increased in white, Asian, and Hispanic smokers during the same time period.[3]

Menthol continues to be a particularly important additive for tobacco manufacturers, as evident by the census of cigarette products purchased as part of our Tobacco Pack Surveillance System (TPackSS) project. Internal tobacco industry studies confirm that menthol increases product appeal to initiators by masking the taste of tobacco, reducing throat irritation, and making smoking easier to inhale.[4] Additionally, menthol cigarettes are perceived to be less harsh, less harmful, and easier to smoke.[5-7]

## II. Tobacco companies' use of flavors in tobacco products around the world

### *Flavor variants are proliferating, with a wide range of flavor descriptors*

One way tobacco companies market and promote cigarettes is by using flavors. Flavors are communicated on the pack either through words (descriptors), imagery, or both. With data collected by TPackSS, 26% (n=1266) of country-unique cigarette packs collected across 14 low- and middle-income countries in 2013 and between 2015-2017 advertised a flavor descriptor, and 2.6% (n=126) displayed flavor imagery.[8] Broadly, the flavors presented fell into three categories: mint or menthol, fruit or citrus, and beverages (including alcohol). Recently, packs are promoting non-characterizing flavors on cigarette packaging, including experiences and emotions like "Ibiza sunset" and "Tokyo midnight," as well as simply using colors or words to promote flavor (e.g. "ruby burst" and "double burst").[8]

Using the same data set, colleagues reviewed cigarette products from six countries (Brazil, Indonesia, Philippines, Russia, Thailand, and Vietnam) between 2013 and 2015-2016. Among the cigarettes in these six countries, flavor capsule variants, as defined as a liquid-filled capsule within a cigarette filter, were identified by visual inspection of the cigarette sticks. In 2013, 18 country-unique flavor capsule variant cigarette products were purchased among 1,083 total cigarette packs. When we returned to these six countries in

2015-2016, the prevalence of unique flavor capsule variants on the market doubled (34 of 1,216 country-unique packs). Each of the six countries, with the exception of Russia, saw an increase in the number of unique flavor capsule variant products available on the market.[9] Menthol or mint flavored cigarette flavor capsule variants were most prevalent on the market (n=15, 44%).[9] The flavor capsule variant market also consisted of characterizing flavors, such as menthol, mint, ice coffee, and lime, as well as non-characterizing flavors such as purple, boost, iMix, or simply colors or graphical symbols that indicate a product's ability to modify the flavor during smoking.[9]

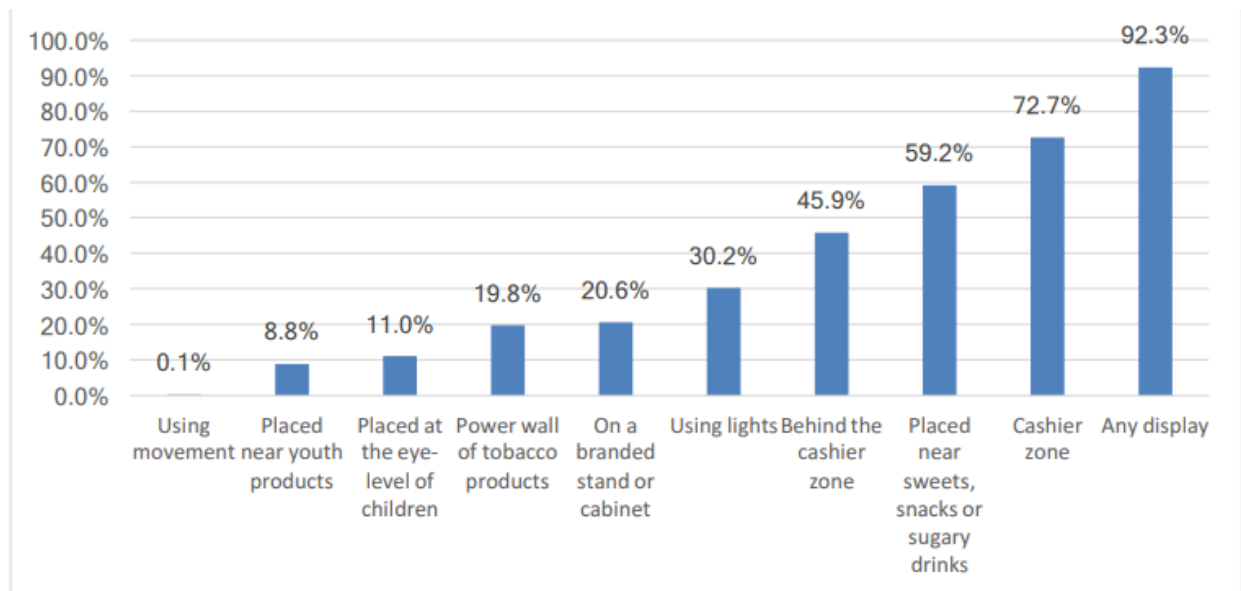
***Flavored cigarettes are being advertised near schools in Latin America***

Advertising of flavors goes beyond the cigarette package. In a five-country study conducted in Latin America (Argentina, Bolivia, Brazil, Chile, and Peru) in 2017, 85% (n=703) of cigarette retailers observed sold cigarettes with menthol or other flavor descriptors, and 71% (n=589) sold cigarettes with flavor capsules.[10] Of the 703 retailers observed that sold cigarettes with menthol or other flavor descriptors, 92% (n=649) actively displayed these products on their shelves, with over a third (n=241) displaying advertising (Figure 1).[10] Special promotions were offered in 51 of the retailers.[10] The placement of cigarettes and advertising can have a highlighting effect: in this study, nearly 60% (n=416) of the cigarettes were displayed near sweets, snacks, or sugary beverages.[10]

**Figure 1:** Print signage for cigarettes with flavor capsules at the point-of-sale, La Paz, Bolivia, 2017[10]



**Figure 2:** Point of sale display of cigarettes with menthol and other flavor descriptors across 5 countries (n=703), 2017[10]



### III. Public health efforts to restrict the sale or distribution of menthol cigarettes

#### *Canada menthol ban*

The Canadian provinces of Nova Scotia and Alberta became the first jurisdictions to implement a ban on menthol tobacco products in May and September of 2015, respectively. These bans extended the already existing flavored tobacco products banned in Canada. In a study assessing the compliance of the menthol cigarette ban in these provinces, it was found that tobacco manufacturers were complying with the ‘letter of the law;’[11] no products purchased post-ban carried a menthol descriptor on the pack. However, tobacco companies instead used the exterior packaging to connote products that were menthol replacements,[11] reminiscent of how tobacco manufacturers responded to the ban on using “light” and “low-tar” descriptors on cigarette packs.[12] Before the ban was implemented, the ‘menthol’ label on the package and the prominent display of the color green easily identified all menthol products. Post-ban, however, showed that the tobacco industry simply used repackaged products with the same green branding to communicate menthol-like flavoring.[11] Additionally, advertising for some brands included “Smooth Taste – Redesigned without Menthol” on the cellophane covering cigarette packs; this was also communicated in business-to-business marketing (Figure 3).[11] The rebranding of menthol products into ‘smooth’ tasting products has the potential to undermine the menthol ban. Learning from the “light” and “low-tar” descriptor ban aftermath, a more encompassing ban on menthol that included restrictions

on pack advertising, promotion or descriptors of menthol alternative or replacement products would better serve the public health.

**Figure 3:** Business-to-business marketing materials from Rothman, Benson & Hedges (owned by Philip Morris International), highlighting the messages on cellophane wrapping on new packs.[11]



The province of Ontario, Canada, in January 2017 instituted its own menthol cigarette ban. In a study looking at the menthol cigarette market before the ban went into effect, it was found that there was a proliferation of flavor capsule cigarettes. Of the 30 unique menthol cigarette packs purchased, 14 (47%) contained flavor capsules.[13] These 14 flavor capsule containing cigarettes were all introduced to the market after the ban was announced in May 2015.[13] These findings suggest that tobacco manufacturers introduced menthol-flavored capsules or other flavored capsules to cigarettes, encouraging current menthol smokers to switch once the ban went into effect. Smoking behaviors did change in the short-term following implementation of the ban. In a sample of 206 menthol smokers, 29% (n=60) of smokers had attempted to quit post-ban;[14] this was a substantial increase compared to 15% (n=30) who indicated before the ban was implemented that they would quit.[14] Before the ban was implemented, 6% (n=12) of menthol smokers indicated they intended to switch to alternatively flavored products (i.e. e-cigarettes, cigars, or other flavored tobacco products);[14] however, one month after the ban was in place, 29% (n=60) of smokers were using alternatively flavored



products.[14] These results suggest that the menthol cigarette ban substantially increased quit attempts among current menthol smokers and is a feasible tobacco control strategy to influence cessation behavior.

### ***Partial menthol ban in Chicago***

In February 2017, Chicago, Illinois became the first major US city to implement a ban on the sale of menthol cigarettes as part of a larger flavored tobacco product ban in stores within 500 feet of high schools. A recent study (in press, *Tobacco Control*) investigated compliance with Chicago's ban in a random sample of 90 of the 154 affected stores across the city.[15] Compliance was determined by whether a menthol cigarette pack was purchased. The study also assessed the presence of menthol cigarette replacement packs, which were previously observed in Alberta, Canada.[11] Multivariable logistic regression modeled compliance by neighborhood-level factors (poverty level, proportion of non-White residents). Prior studies suggest that stores are largely compliant with comprehensive flavored tobacco bans and other tobacco control regulatory efforts.[11,16-18] This study found that compliance with Chicago's partial ban on menthol cigarette sales was poor and slightly over half of stores complied (57% compliance, [weighted, n=53]). No replacement packs were observed in this setting, likely because menthol cigarettes were still widely available in affected and unaffected stores in Chicago.

Neighborhood factors were not associated with compliance, suggesting that partial bans are not less effective in reducing access to menthol cigarettes in low-income, non-White neighborhoods disproportionately exposed to menthol cigarette advertising and sales.[19-21] This finding is encouraging and suggests that partial bans do not appear to increase already existent health disparities in this particular study setting. However, the overall results of the compliance study suggest that partial bans may not be the most effective policy solution to decrease access to menthol cigarettes. In fact, preliminary qualitative interviews with retailers in stores affected by Chicago's partial ban suggest that perceived profit loss is a concern of retailers implementing the ban, many of who claimed to lose customers who can purchase menthol cigarettes in other stores nearby.[22] Further, some retailers express the belief that a comprehensive ban would be more equitable for stores and a more efficient way to reduce access to menthol cigarettes.[22] Clearly, tobacco manufacturers recognize the potential impact of a complete tobacco product flavor ban on tobacco prevalence, as evidenced by RJ Reynolds' \$11+ million investment in advertising against one in San Francisco.[23-24] However, the public understands the importance of a comprehensive tobacco product flavor ban, and supports it: on June 5 San Francisco voters upheld the city's ban on flavored tobacco products, including menthol, supported by over two-thirds of voters.

### ***Global policies on e-cigarette flavors***

In our ongoing global e-cigarette policy scan (<https://www.globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes>),[25] the only jurisdictions that attempt to



regulate flavors contained in e-cigarette liquids, is the European Union's (EU) Tobacco Products Directive (TPD) 2014.[26] Under the TPD, the twenty-eight member states of the European Union prohibit the following additives in e-cigarette liquids: vitamins or other additives that suggest a health benefit; caffeine, taurine, or other stimulants; or additives that pose a risk to human health in heated or unheated form.[26] Any further regulations is at the discretion of member states. The EU offers suggestions in the TPD and cautions member states to take into account the potential attractiveness of flavors to youth and nonsmokers in any additional regulations they may put forth. The scan shows to date, only Finland has gone further to prohibit candy and fruit flavors specifically in e-cigarette liquids.[26]

#### **IV. Any other tobacco product standard, regulatory action, or other action FDA could implement to effectively reduce harm caused by flavors**

In one experimental study, researchers found that youth (aged 14-17) when compared to older adults (aged 25-65) were more likely to report that smokeless tobacco products that carried a flavor descriptor were more appealing and were associated with a reduced health risk than those without.[27] Comprehensive flavors bans are critically important, but care must be made in addressing how tobacco manufacturers communicate about their products through packaging.

The FDA has the necessary authority and tools to implement one of the most cost effective tobacco control measures available: graphic health warning labels on packages. The United States remains one of the few OECD countries that do not display graphic health warning labels on tobacco products. Very little has changed with regard to health warning labels since 1966, when the United States became the first country in the world to display a health warning label on cigarette packages.[28]

The evidence is clear that health warning labels on packs are effective in communicating knowledge of harms of tobacco.[29-30] Compared to text-only warnings, graphic warnings are more likely to be noticed [30-34], be more effective in educating the public about the dangers of smoking [33-35] and increase intentions to quit.[30,32-33, 35-37] Graphic health warning labels would more effectively reduce the harm caused not only by flavors, but cigarettes broadly.

#### **V. Recommendations**

FDA acknowledges the limitations of the current flavored tobacco product ban, including the continued availability of menthol cigarettes. When reviewing the data on the menthol ban in Canada, Chicago, and the recent move to ban menthol and other flavorings in San Francisco, key themes emerge. In Chicago, the limited scope of the menthol ban hindered any real progress on reducing menthol cigarette availability. We have shown that the limited scope of the ban in Chicago creates winners and losers among the retailers

affected by the ban, thus impacting retailer compliance with the ban. This underscores the importance of comprehensive bans.

As demonstrated in San Francisco, where the city council unanimously passed a comprehensive, city-wide menthol and flavored e-cigarettes ban that was recently upheld by voter referendum, proves that the public supports these measures despite vigorous campaigning by R.J. Reynolds. The scope and coverage of the ban will ensure products remain out of reach for all citizens.

The menthol product ban in Canada, first introduced in Nova Scotia and Alberta, and later in Ontario, demonstrated that tobacco manufacturers continued to roll out novel products in order to keep their customers smoking by using new words to connote flavoring or flavor sensations on tobacco packaging. However, the increase in smoking quit attempts after the menthol ban was implemented in Ontario demonstrates the real results that can be expected following comprehensive bans.

The FDA should ban fruit and candy flavors as they appeal to adolescents. Menthol tobacco products should also be banned. To ensure bans are as effective as possible, companies should not be able to signal flavors by other means, including images, designs, or words. Any use of flavorings to assist with smoking cessation should be done so based on evidence and a clear plan with oversight to minimize access to children.

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