



July 19, 2018

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

RE: Docket No. FDA-2017-N-6565

Dear FDA Representative:

The National Association of Tobacco Outlets, Inc. (NATO) submits these comments in response to the Food and Drug Administration's Advanced Notice of Proposed Rulemaking titled "Regulation of Flavors in Tobacco Products" as published in the Federal Register at 83 Fed. Reg. 12294 on March 21, 2018 (referred to in these comments as "Flavor ANPRM").

Background on the National Association of Tobacco Outlets

NATO is a national retail trade association with approximately 60,000 member stores nationwide including tobacco stores, convenience stores, gasoline service stations, grocery stores, and liquor stores. These retail members sell cigarettes and tobacco products and understand the responsibility of selling an age-restricted product to legal age adults.

The Role of Flavors in Tobacco Products

Adult consumers prefer flavors in a variety of products from soft drinks, to coffee, to alcoholic beverages, to tobacco products. Flavoring is commonplace throughout these and many other consumable goods. From one perspective, the use of flavorings in products is about consumer choice, the freedom to choose the kind of products with specific flavors that appeal to a person's senses. This freedom of choice extends to adult, age-restricted products including alcohol and tobacco products.

A 2014 study conducted by The Nielsen Company found that 58% of men surveyed preferred flavored alcoholic beverages and that 73% of women surveyed enjoy flavored alcoholic products. (See: The Nielsen Company (US) LLC, Nielsen QuickQuery Survey, <http://www.nielsen.com/us/en/insights/news/2015/americans-have-the-fever-for-flavor->

alcoholic-beverages-and-creative-taste-profiles.html, 2015). This means that a majority of men and women prefer flavored alcoholic products based on their personal likes and tastes and there are no barriers or restrictions imposed by government on the ability of legal age adults to purchase and consume these products.

Similarly, adult consumers have demonstrated a desire for flavored tobacco products. This preference for flavored tobacco products extends from menthol cigarettes, to mint and wintergreen smokeless tobacco products, to flavored cigars, to pipe tobacco, to flavored electronic cigarette cigarettes/vapor products, and to hookah tobacco. Just as adults have the freedom to purchase and consume age-restricted flavored alcoholic beverages, so too should legal age adults be allowed to continue to buy and use their preferred flavored tobacco products without restrictions by a government agency.

Banning Flavored Tobacco Products Violates Congressional Limitation on FDA Authority

In Section 907(d)(3)(a) of the Family Smoking Prevention and Tobacco Control Act, Congress limited the authority of the Secretary of Health and Human Services by prohibiting the Secretary and thus the U.S. Food and Drug Administration from banning the sale of entire classes of tobacco products. Specifically, Section 907(d)(3)(a) reads as follows:

(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION. Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act.

Despite this prohibition on banning classes of tobacco products, the Flavor ANPRM requests comments on the level of restrictions that should be applied to flavors in tobacco products and whether the FDA should adopt “a tobacco product standard prohibiting” flavors. At its most restrictive, a prohibition by the FDA of all flavors in tobacco products would for all intents and purposes ban the sale of entire classes of tobacco products and result in the removal of hundreds of tobacco product SKUs from retail store shelves.

Since virtually all pipe tobacco is flavored and always has been, a ban on flavors would eliminate the pipe tobacco category. Also, it is important to note that the average pipe smoker is 54 years old and studies have shown that underage youth do not purchase nor use pipe tobacco. This means that pipe tobacco does not play a role in youth initiation of tobacco use and, for this reason, flavors in pipe tobacco should not be restricted or prohibited.

Moreover, an across the board ban on flavors will also eliminate entire categories of cigars, electronic cigarettes, vapor products, and hookah tobacco. Any FDA regulation that prohibits flavors, and in turn eliminates an entire category of tobacco products, would be contrary to the

limitation placed on the agency by Congress.

Advertising Restrictions on Flavored Tobacco Products Would Be Unconstitutional

The Flavor ANPRM states that the FDA may consider possible restrictions on the advertising and promotion of flavored tobacco products. A restriction or prohibition on flavored tobacco product advertising would be contrary to and violate the protection afforded product advertising under the First Amendment of the U.S. Constitution.

It is important to understand that the U.S. Supreme Court has held that product advertising, including the advertising of tobacco products, constitutes “free commercial speech” and is protected by the First Amendment. In 2001, the U.S. Supreme Court issued a decision in *Lorillard Tobacco Company v. Reilly*, 533 U.S. 525 (2001). In *Lorillard*, the U.S. Supreme Court overturned regulations adopted by the Massachusetts Attorney General banning outdoor tobacco advertising and tobacco advertising displayed in a retail store that is visible from outside the store, if the store was located within 1,000 feet of a school or playground.

Subsequently, on March 31, 2012, a U.S. Federal District Court judge in Massachusetts cited the *Lorillard* decision in ruling that an outdoor and in-store tobacco advertising ban ordinance adopted by the Town of Worcester, Massachusetts was unconstitutional on First Amendment free speech grounds (see *National Association of Tobacco Outlets, Inc., et. al, v. Town of Worcester, Massachusetts, et. al.*, 851 F.Supp.2d 311, (2012)).

These specific court rulings, as well as other U.S. Supreme Court decisions establishing the commercial speech doctrine protecting product advertising under the First Amendment, including tobacco product advertising, would invalidate any regulation that the FDA might adopt to restrict or prohibit flavored tobacco product advertising.

Substantial Illicit Market Could Be Created Due to Restrictions on Flavored Products

A product standard that restricts or prohibits menthol cigarettes or flavored tobacco products could result in the creation of an illegal market for these products. Consumer demand for menthol cigarettes and flavored tobacco products will continue even if these flavored products are restricted or banned. This on-going demand would cause consumers to seek out alternative sources for these products, even if such sources are acting illegally.

This demand would likely be met by criminal elements smuggling menthol cigarettes and flavored tobacco products into the United States. In the late 1990’s and early 2000’s, there was widespread smuggling of what are known as “gray market” cigarettes into the United States. These “gray market” cigarettes were domestically manufactured for export to foreign countries, but smugglers diverted these cigarettes for distribution in the United States. A search on the Internet for “gray market cigarettes” will result in a plethora of articles about the diversion and smuggling of these kinds of cigarettes.

This same kind of scenario could arise where domestically produced menthol cigarettes and other flavored tobacco products intended for export are obtained by criminal elements and diverted for distribution in the U.S. marketplace. Moreover, these criminal elements that

smuggle cigarettes and tobacco products into the country would not be concerned with verifying the legal age of individuals, which could allow underage youth to have more easy access to cigarettes and tobacco products.

The FDA should not adopt a regulation that promotes the illegal sale of menthol cigarettes and flavored tobacco products in the marketplace. That is, a government agency should work to minimize crime, not create an opportunity for individuals to engage in illegal tobacco product trafficking.

In addition, before implementing restrictions on or a prohibition of flavored tobacco products, the FDA should study the resources that law enforcement agencies would need to respond to the potential for nationwide smuggling of these banned products. The response would involve local, state and federal police and law enforcement agencies since the smuggling of tobacco products would violate state and federal laws and regulations. How would these various law enforcement agencies collaborate to investigate, intervene and prosecute those that engage in smuggling of flavored tobacco products? What level of resources would law enforcement agencies need to devote to respond to criminal tobacco product smuggling as a result of a FDA restriction on, or prohibition of, flavored tobacco products? These kinds of questions need to be answered before any restrictions are proposed for flavored tobacco products.

Social Sources Need to be Addressed as a Part of the FDA’s New Regulatory Approach

In the Flavor ANPRM, the FDA states that one reason for considering restrictions on flavored tobacco products is that flavors attract youth to initiate tobacco use. In addition, the FDA asks for information or recommendations on any “other activity that FDA could pursue that would complement or increase the effectiveness” of potential restrictions on flavored tobacco products.

In response to these statements and requests in the Flavor ANPRM, it is important to understand that youth obtain tobacco products from a variety of non-retail sources, including giving others money to buy them, obtaining them from other youth or adults, or stealing. This reliance on these non-retail “social sources” was confirmed by the FDA’s Population Assessment of Tobacco and Health (PATH) study. According to the findings of the PATH study, and as summarized in the table below, minors rely on social sources and use various methods to obtain access to cigarettes 86.1% of the time, to obtain access to electronic cigarettes 89.5% of the time, and to obtain access to cigars 75.6% of the time.

Product	Gave Someone Money to Buy	Bought From Someone Else, Stole From a Person or Store	Asked Someone for a Tobacco Product or Someone Offered a Tobacco Product	Other or Don’t Know or Refused to Answer	Social Sources Percentage	Bought at a Retail Store
Cigarettes	32%	6.6%	42.5%	5%	86.1%	13.8%
E-Cigarettes	17.3%	5.8%	56.7%	9.7%	89.5%	10.5%
Cigars	34.2%	4.1%	37.3%	NA	75.6%	21%

For several years, NATO has been urging the FDA to undertake a media campaign to educate youth and adults about the prevalence of the social sources problem and to change societal attitudes so that adults do not serve as a source of tobacco products for underage youth. This educational effort could have a significant impact on further reducing the ability of minors to obtain tobacco products, including flavored tobacco products. Rather than restricting or prohibiting flavored tobacco products, the FDA should give serious consideration to a conducting a nationwide educational campaign focused on the issue of social sources in order to achieve further reduction in underage tobacco initiation and use.

Impact on Legal Retail Sales and State/Federal Excise Tax Collections

If an illegal market for menthol cigarettes and flavored tobacco products develops and expands, legitimate and lawful retail sales of these products will decline. This decrease in legal sales will reduce the amount of federal and state cigarette and tobacco product excise taxes plus reduce the amount of state sales tax collected. The magnitude of lost excise tax and sales tax revenue will depend on the scope of the illicit market that develops due to FDA restrictions or prohibitions on flavored products. It is incumbent upon the FDA to conduct a fiscal impact analysis of banning menthol cigarettes and flavored tobacco products so that state and federal lawmakers are informed of potential excise tax and sales tax revenue shortfalls since that lost revenue would need to be made up from other sources.

Impact of Restricting or Prohibiting Flavored Tobacco Products on the Public Health

The adoption of restrictions or prohibitions on menthol cigarettes or flavored tobacco products may lead to several negative impacts on the public health. First, the creation and expansion of an illicit market will allow underage youth easy access to tobacco products as those engaged in smuggling will not be concerned about complying with laws and regulations that prohibit the sale of tobacco products to underage individuals. This greater accessibility to cigarettes and tobacco products by minors runs counter to one of the overall goals of the Family Smoking Prevention and Tobacco Control Act to reduce underage youth tobacco initiation and use. Second, this same illicit market will allow consumers to continue to obtain the kinds of flavored tobacco products that they prefer. Third, consumers may even attempt to add aftermarket flavors to cigarettes or other tobacco products. All of these outcomes would undermine an attempt by the FDA to restrict or prohibit the sale of menthol cigarettes or flavored tobacco products and fail to achieve a positive health benefit. In short, these potential outcomes argue against restricting or banning menthol cigarettes or flavored tobacco products.

NATO appreciates the opportunity to submit these comments in response to the Flavor ANPRM.

Sincerely,

Thomas A. Briant

NATO Executive Director and Legal Counsel