NATO

July 16, 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-6189

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 "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes" as published in the Federal Register at 83 Fed. Reg. 11818 on March 16, 2018 (referred to in these comments as "Nicotine ANPRM").

Background on the National Association of Tobacco Outlets

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.

Scope of a Maximum Nicotine Level Tobacco Product Standard

In the Nicotine ANPRM, the Food and Drug Administration states that it is "considering the issuance of a product standard to set a maximum nicotine level in cigarettes" and is also seeking comments on whether such a product standard should cover other combustible products including roll-your-own tobacco, cigars, pipe tobacco, and waterpipe tobacco.

On July 28, 2017, FDA Commissioner Scott Gottlieb announced the agency's new, multi-year approach to regulating tobacco products that would establish a comprehensive nicotine regulatory policy based on the continuum of risk. In the event that the FDA proceeds with a product standard to set a maximum level of nicotine in cigarettes and potentially other

combustible tobacco products, then consistent with Commissioner Gottlieb's announcement and stated goals, the FDA should allow sufficient time for further establishment of a market for authorized, non-combustible, reduced risk products such as electronic cigarettes, e-vapor alternatives, heat-not-burn products, and oral nicotine-containing products. This is important because if the FDA adopts a very low level of nicotine for cigarettes and possibly other combustible tobacco products, then consumers may seek out alternative, non-combustible tobacco products that contain nicotine. However, without a regulatory approved and established market for these alternative, non-combustible tobacco products, then consumers could seek out combustible tobacco products from illicit sources (see comment below regarding the creation of an illicit tobacco product market as an unintended consequence of adopting a nicotine level product standard).

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

In the Nicotine ANPRM, the FDA states that one reason for considering a product standard to set a maximum level of nicotine for cigarettes and other combustible tobacco products is because 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. Rather than implementing a new product standard involving maximum nicotine levels, 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 which is one of the primary goals of the FDA's new regulatory approach.

Prohibition on Reducing Nicotine Yields to Zero

The Nicotine ANPRM states that another goal of the FDA's new regulatory approach is to set a maximum nicotine level to make cigarettes, and potentially other combustible tobacco products, "minimally addictive or non-addictive" and that "FDA is particularly interested in comments about the merits of nicotine levels like 0.3, 0.4, and 0.5 mg nicotine/gram of tobacco filler." Converting milligrams to grams, 0.3 milligrams equals 0.0003 grams, or three ten thousandths of a gram. This amount or content of nicotine is very low and for all intents and purposes could be considered "zero." However, Section 907(d)(3)(B) of the Family Smoking Prevention and Tobacco Control Act states that the Secretary of the Department of Health and Human Services is prohibited from "requiring the reduction of nicotine yields of a tobacco product to zero." This focus by the FDA on such a low nicotine level could, for all intents and purposes, violate the "zero" nicotine prohibition passed by Congress.

Moreover, a product standard that sets a very low maximum level of nicotine yield could raise various questions about the commercial feasibility and consumer acceptance of such tobacco products. These questions include the ability of farmers to change agricultural practices to grow a tobacco leaf plant that has low levels of nicotine, the feasibility of tobacco product manufacturers to produce cigarettes or other tobacco products that comply with a nicotine level so close to zero, and the acceptability of very low nicotine cigarettes and other tobacco products by consumers. All of these questions should be thoroughly studied and answered before the FDA proposes a product standard to set a maximum level of nicotine.

Substantial Illicit Market Could Be Created Due to a Nicotine Product Standard

A product standard that sets a very low level of nicotine for cigarettes and possibly other tobacco products could result in the creation of an illegal market for cigarettes and tobacco products that have a higher level of nicotine. The demand for cigarettes and other tobacco products with the current level of nicotine will continue even if a maximum level of nicotine is required. Consumers that are accustomed to the levels of nicotine in cigarettes and other tobacco products would likely seek out sources of these products that do not have lower levels of nicotine.

In one scenario, criminal elements could respond to this demand by smuggling back into the United States cigarettes and other tobacco products that are manufactured domestically but designated for export to other countries. 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 cigarettes and other 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 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, the statement in the Nicotine ANPRM that "[l]arge, commercial, tobacco product manufacturers have the resources, sophistication, and ability to manufacture illicit tobacco products" is unfounded when domestic manufacturers are working to comply with FDA tobacco regulations. The culprits will not be domestic manufacturers, but those persons who decide to take advantage of a demand that would be created by a government regulation for otherwise banned legal tobacco products by smuggling cigarettes and other tobacco products into the country.

In addition, before implementing any maximum nicotine level requirement, the FDA should study the resources that law enforcement agencies would need to respond to the potential for nationwide smuggling of cigarettes and tobacco products. The law enforcement response would involve local, state and federal police and law enforcement agencies since the smuggling of cigarettes 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 cigarettes and 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 nicotine level product standard? These kinds of questions need to be answered before a nicotine product standard is adopted.

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

If an illegal market for cigarettes and other tobacco products with higher nicotine yields develops and expands, legitimate and lawful retail sales of cigarettes and other tobacco 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 a product standard setting a maximum level of nicotine. It is incumbent upon the FDA to conduct a fiscal impact analysis of a nicotine level product standard 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.

Public Misperception of Very Low Nicotine Content Cigarettes

In a study published in January 2018 in *Tobacco Control*, researchers found that many current smokers had the misperception that smoking very low nicotine content (VLNC) cigarettes are less likely to cause cancer and some smokers indicated that they would be less likely to quit smoking if they smoked VLNC cigarettes ("Public Misperception that Very Low Nicotine Cigarettes Are Less Carcinogenic", Byron, Jeong, Abrams and Brewer, *Tob Control,* 2018). Specifically, almost one-half of the smokers surveyed (47.1%) believed "that smoking VLNC cigarettes for 30 years would be less likely to cause cancer than smoking current cigarettes." Additionally, "23.9% of smokers reported that they would be less likely to quit if the USA adopted a VLNC standard." In fact, the belief that VLNC cigarettes would be less carcinogenic "was associated with smokers reporting they would be less likely to quit."

These misperceptions about VLNC cigarettes among almost half of current smokers and the finding that one-fourth of smokers would be less likely to quit because of the misperceptions raise significant public health questions about the efficacy of proceeding with a nicotine level product standard. While the authors of this study also suggested that a VLNC standard may be more effective if accompanied by an educational campaign, changing perceptions and attitudes among smokers is a long-term measure that may not prove successful even if a nicotine level product standard is adopted by the FDA.

This suggestion for an educational campaign about VLNC cigarettes is analogous to NATO's on-going recommendation to the FDA that the agency create and conduct an educational campaign to urge individuals not to be a social source of tobacco products for underage youth. If the FDA were to proceed with a nicotine level product standard accompanied by an educational campaign in an attempt to change smokers' misperceptions about VLNC cigarettes, then likewise the agency should proceed with a social sources educational campaign to address the problem of youth access to tobacco products at its source.

Impact of a Nicotine Product Standard on the Public Health

The adoption of a maximum level of nicotine in cigarettes and other 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 the overall goal of the Family Smoking Prevention and Tobacco Control Act and the FDA's announcement last year regarding a regulatory approach that focuses on nicotine. Second, adult smokers could smoke more very low nicotine cigarettes or use other lower nicotine combustible tobacco products at a higher consumption rate to achieve the same level of nicotine. Third, consumers may attempt to add nicotine to cigarettes or other combustible tobacco products to artificially raise the nicotine level. All of these potential outcomes fail to achieve a positive health benefit and argue against adopting a product standard setting a maximum level of nicotine.

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

Sincerely,

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NATO Executive Director and Legal Counsel