NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Michelle Morse, MD, MPH
Acting Health Commissioner

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Acting Health Commissioner

Gotham Center
42-09 28th St.
Long Island City, NY 11101

Via Federal eRulemaking Portal (Regulations.gov)

Re: Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (Docket No. FDA-2024-N-5471)

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

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (NYC Health Department) submits this comment in response to the Food and Drug Administration's (FDA) proposed tobacco product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products. In New York City (NYC), despite decreased smoking prevalence rates over the last 15 years, tobacco use remains a leading cause of premature, preventable death, killing an estimated 12,000 people annually.[1] There are nearly 540,000 adults in NYC who continue to smoke, and there are persistent inequities, with higher smoking rates in some NYC communities.[2] A nicotine reduction approach that reduces the addictiveness of tobacco products has the potential to prevent initiation by young New Yorkers, while also making it easier for adults who smoke to stop.[3,4] Given the need for further progress in tobacco control, the NYC Health Department supports a new tobacco product standard that establishes a maximum nicotine level for all combusted and smokeless tobacco products.

FDA requests comment regarding the scope of products covered by this proposed rule.

All products containing tobacco, including waterpipe tobacco, should be made minimally addictive or nonaddictive by limiting nicotine content.

In NYC, migration to other tobacco products has been observed following the introduction of taxes on cigarettes, especially among youth. For example, after cigarette tax increases and implementation of other tobacco control measures beginning in 2002, the prevalence

of cigarette smoking among NYC high school (HS) students declined by more than 50% from 17.6% in 2001 to 8.2% in 2013. During the same time period, cigar use among HS students increased from 5.1% to 7.7% and smokeless tobacco use increased from 1.1% to 4.4%.[5] Specifically, among HS students who used any tobacco product, the proportion who used cigars doubled, from 22.2% to 45.9%, and the proportion who used smokeless products increased five-fold, from 4.2% to 21.2%. The same phenomenon has been observed in other states following increases in cigarette taxes.[6]

While waterpipe tobacco is not a likely substitute for cigarettes among adults who smoke, it may remain an option for young people initiating tobacco use. Waterpipe or hookah use became increasingly popular in NYC as other tobacco control policies were enacted; the number of establishments serving hookah in 2017 — nearly 400, according to Yelp — was more than four times higher than in 2012.[7] Waterpipe tobacco, which is already more popular among youth than adults, could play an outsized role in creating a new generation of commercial tobacco product consumers if it remains available at current nicotine levels. When NYC began to increasingly regulate hookah like other tobacco products, lifetime use declined among youth from a peak of 13-14% (2012-2014) to 8% (2022).[8] Despite this fact, in 2022, young adults (ages 18 to 24) in NYC were still six times more likely to currently smoke hookah than those ages 45 and older (6% vs. <1%).[9] Further, the modeling data predicting reductions in tobacco dependence presented in the FDA's proposal did not appear to include waterpipe tobacco. Multiple studies have shown that youth can develop symptoms of nicotine dependence, even with infrequent tobacco use,[10] such as might occur with hookah. Therefore, we urge the FDA to expand the scope of this proposed standard beyond just cigarettes and certain other combusted tobacco products and limit the nicotine yield of all products containing tobacco to nonaddictive or minimally addictive levels, including waterpipe tobacco, smokeless tobacco, and heated tobacco.

E-cigarettes and other commercial nicotine products do not need to be nonaddictive or minimally addictive, but they should have a maximum nicotine content level to reduce youth initiation and dependence.

In Canada, the United Kingdom, and the European Union, regulations limit e-cigarette liquids to a nicotine concentration of no more than 20mg/ml and a maximum 2ml reservoir (i.e., a total of 40mg of nicotine in the device at maximum). Meanwhile, e-cigarettes available in the United States (U.S.) continue to increase in both volume and concentration.[11] The vast majority of e-cigarettes sold in the U.S. now have a nicotine concentration of 40mg/mL or higher, and the total nicotine content in vaping products popular among youth rose from about 20mg in 2015 to 650mg in 2023. Notably, high nicotine content does not appear to be necessary for adults who are using e-cigarettes for smoking cessation. In fact, all randomized control trials included in the 2025 Cochrane review, that compared e-cigarettes to nicotine replacement therapy (NRT) for smoking cessation, used e-cigarettes with a nicotine concentration of 25mg/mL or lower; most trials used e-cigarettes with a nicotine concentration of less than 20mg/mL.[12] Further, similar to tobacco products, most adults in the U.S. who vape want to quit, which is more challenging with high-nicotine-content products that facilitate greater levels of nicotine dependence.[13] FDA regulations and enforcement actions can emancipate users from their nicotine addiction.

Similar to vaping products, limiting the nicotine content of other commercial nicotine products (such as pouches, gum and lozenges) would limit youth initiation and development of nicotine dependence. Canadian regulations classify all commercial nicotine products as NRT medications and thus "[r]equire NRTs in new and emerging formats, such as nicotine pouches,

to be sold only by a pharmacist or an individual working under the supervision of a pharmacist, and to be kept behind the pharmacy counter."[14] The only authorized nicotine pouch product has 4mg of nicotine per pouch.[15] In contrast, nicotine pouches in the U.S. are commonly sold in strengths of 6mg-10mg, and higher strength products have shown more rapid increases in sales.[16] People who smoke or vape and want to quit will continue to have access to approved medications for tobacco treatment, including NRT, bupropion and varenicline available. So, there is no need to protect higher nicotine levels in new products to help people quit combustible ones. The U.S. should not treat commercial nicotine products like other consumer products; we should limit their addictive potential.

Nicotine should be more broadly defined to prevent manufacturers from using nicotine analogs to circumvent the spirit of this new standard.
The proposed definition of "nicotine" as the "chemical substance named 3-1(1-methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine, derived from any source" is too narrow. While it addresses synthetic nicotine, it will not prevent the use of nicotine analogs, which also appeared on the market once the FDA began regulating products with synthetic nicotine.[17,18] Products using nicotine analogs could evade regulation altogether, meaning they may continue to have higher and unpredictable levels of substances similar to nicotine and a range of unknown and potentially unsafe ingredients.[19] Therefore, the FDA should prohibit nicotine analogs altogether, given that identifying the appropriate limit for each is likely impossible.

Implementation

We support the FDA's proposal to pursue a single-target approach to implementation, in which nicotine is reduced at once across all tobacco products as quickly as possible.
Although data comparing abrupt and gradual cessation suggests that both approaches may produce similar quit rates, a stepped-down approach to implementation of a new product standard would result in prolonged exposure to higher nicotine content products.[20,21] Moreover, a stepped-down approach would be challenging to implement, and multiple transition periods might cause confusion for consumers and retailers. The availability of intermediate nicotine content products could also present enforcement challenges, given the potential for illicit markets.

Education and strong public health messaging surrounding implementation will be essential to counter misperceptions about low-nicotine content products.
With the development of a new product standard to establish a maximum nicotine level for tobacco products, there is a possibility that adults and youth will perceive these products as being "safer."[22,23] In fact, the tobacco industry has promoted similar beliefs in the past by using descriptors such as "light" and "low tar."[24] Some of these beliefs have persisted for decades, despite the elimination of this messaging, and they continue to influence smoking behavior.[25] Therefore, it is essential to have clear messaging, including through media outlets and other popular venues, which emphasizes the persistent dangers of low-nicotine-content tobacco products. Although the new product standard will mean these products are minimally addictive, they remain dangerous and toxic. Messaging should similarly highlight that secondhand exposure to these products remains just as dangerous as exposure to tobacco products with high nicotine content because the vast majority of harm comes from inhalation of the combusted or heated non-nicotine contents of these products. Ongoing monitoring of tobacco industry advertising will also be necessary to ensure that no false claims are being perpetuated.

Possible Countervailing Effects

We urge the FDA to develop measures to mitigate potential countervailing effects of a new product standard and to ensure that adequate surveillance systems are in place to monitor these effects.

A new product standard will likely have countervailing effects that may diminish its potential population health benefits including migration to, or dual use with, other products as discussed above and increases in illicit trade via illicit manufacturing and distribution, as well smuggling or sales from other countries. It is imperative to put measures in place that can identify and mitigate these effects.

Illicit trade is a concern that should be addressed both prior to implementation and with ongoing enforcement and surveillance. Like many other jurisdictions, NYC currently has a large illicit cigarette market.[26] Consequently, the NYC Health Department strongly encourages the FDA to adopt a track and trace system that would allow the FDA to monitor the flow of tobacco products from manufacturers through point of sale, as noted in a separate comment submitted by the NYC Health Department regarding docket number: FDA-2018-N-0529. Ensuring that FDA-approved tobacco treatment medications are readily available may also help limit the size of any illicit market that develops.

It is difficult to anticipate the exact course of these countervailing effects and other unintended consequences of any new product standard. Therefore, ongoing monitoring is critical. We are concerned that the recent cuts to the Office on Smoking and Health at the Centers for Disease Control and Prevention and the FDA's Center For Tobacco Products, which administer the National Youth Tobacco Survey and other monitoring, will compromise the government's ability to conduct adequate, large-scale surveillance to understand the impact of new regulations on the market and retailers, as well as on use patterns and initiation behavior. Surveillance would ideally assess the impact of new regulations on groups with high smoking prevalence to ensure disparities are not being perpetuated. The regulations should have sufficient flexibility to adapt to any emerging information, especially if there is evidence that the new maximum nicotine level continues to result in reinforcing effects or development of new dependence.

Conclusion

Tobacco use remains a leading cause of premature mortality and significant morbidity in NYC. Making tobacco products nonaddictive or minimally addictive will reduce current tobacco use, prevent future use, and save lives. Thank you for allowing public comment on this proposed product standard.

Sincerely,

[redacted]

Michelle Morse, MD, MPH
Acting Health Commissioner
New York City Department of
Health and Mental Hygiene

[1] Estimate derived from a *SimSmoke* NYC-specific simulation model. For more information regarding SimSmoke, please see: Levy DT, Bauer JE, Lee HR. Simulation modeling and tobacco control: creating more robust public health policies. *American Journal of Public Health* 2006; 96:494–8.

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[8] New York State Youth Tobacco Survey 2008-2022. Internal analysis of data.

[9] New York City Department of Health and Mental Hygiene. Community Health Survey, 2022. Internal analyses of data.

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