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FDA Issues Advanced Notice of Proposed Rulemaking on Potentially Lowering Nicotine Levels in Combustible Cigarettes to Minimally or Non-Addictive Levels

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In the U.S. Food and Drug Administration's (FDA's) latest effort to implement its comprehensive regulatory plan[1]to shift the trajectory of tobacco-related disease and death, the Agency issued, on March 15, 2018, an advanced notice of proposed rulemaking (ANPRM) to obtain information for consideration in developing a tobacco product standard to set a maximum nicotine level for cigarettes.[2] As described in a contemporaneous statement issued by FDA Commissioner Scott Gottlieb, M.D., the ANPRM provides a wide-ranging review of the current scientific understanding about the role nicotine plays in addiction.[3] Moreover, the ANPRM clarifies that FDA is considering "issuance of a product standard to set a maximum nicotine level in cigarettes so that they are minimally addictive or nonaddictive."[4]

As detailed below, FDA requests in the ANPRM comments on, among other topics, the following:

- *Scope*: Should the potential maximum nicotine level apply only to cigarettes or should it include other combustible tobacco products as well?
- *Maximum Nicotine Level*: What is the maximum nicotine level that should be used as the threshold for "minimally addictive" or "non-addictive" levels?
- *Implementation*: Should the maximum nicotine level for cigarettes propose a single target (where nicotine is reduced all at once or a stepped-down approach (where nicotine is reduced gradually over time through a sequence of incremental levels)? Relatedly, what is the proper timeframe to implement a possible maximum nicotine level?
- *Analytical Testing Method*: Should FDA specify a method for manufacturers to use to detect the level of nicotine in their products? If so, which method should be used?

Comments are due by June 14, 2018.

Scope of FDA's Proposed Tobacco Product Standard

In the ANPRM, FDA seeks comments on whether the standard should cover any or all of the following products: combusted cigarettes (which FDA has previously interpreted to include kreteks and bidis), cigarette tobacco, roll-your-own (RYO) tobacco, some or all cigars (*e.g.*, including large and "premium" cigars), pipe tobacco, and waterpipe tobacco.[5] Importantly, the Agency explains that

"any nicotine tobacco product standard would cover all brands in a particular product category and, therefore, those products currently on the market and any new tobacco products would be expected to adhere to the standard."[6] Key questions raised by the ANPRM also include whether so-called "premium" cigars should be regulated differently from other cigars and whether waterpipe tobacco products should be excluded because they are unlikely to be migration substitutes or dual use candidates.[7]

Identification and Implementation of Appropriate Maximum Nicotine Level

With respect to nicotine levels in cigarettes, FDA requested comments on a potential maximum nicotine level that would be "minimally addictive" or "non addictive" and appropriate for the protection of public health, recognizing that the Family Smoking Prevention and Tobacco Control Act specifically prohibits FDA from "requiring the reduction of nicotine yields of a tobacco product to zero."[8] Indeed, FDA is particularly interested in comments concerning the merits of nicotine levels of 0.3, 0.4, and 0.5 mg nicotine/g of tobacco filler.[9] In addition, the ANPRM requests comments on how any potential maximum nicotine level should be measured (*e.g.*, nicotine yield, nicotine in tobacco filler, something else), how the threshold of nicotine addiction should be measured, and whether the product standard should specify a method for manufacturers to use to detect the level of nicotine in their products.[10] Further, FDA requests comments on whether a maximum nicotine level for cigarettes should propose either a single target (where the nicotine is reduced all at once) or a stepped-down approach (where the nicotine is reduced gradually over time through a sequence of incremental levels and implementation dates).[11]

Technical Challenges Associated with Implementation

The ANPRM also acknowledges the technical challenges associated with implementation of a maximum nicotine standard. Indeed, FDA explains that "significant nicotine reductions in cigarettes and other combusted tobacco products can be achieved principally through tobacco blending and cross-breeding plants, genetic engineering, and chemical extraction."[12] Similarly, FDA notes that "agricultural practices (*e.g.,* controlled growing conditions, fertilization, and harvest) as well as more recent, novel techniques also can help to reduce nicotine levels." With that in mind, FDA explains that it is considering the proper timeframe to allow adequate time for industry to comply with a possible tobacco product standard setting a maximum nicotine level. Relatedly, the ANPRM requests data and information regarding the potential costs, including the potential costs to farmers, to implement such a standard.

Countervailing Effects of Potential Nicotine Standard

Notably, the ANPRM also outlines several possible countervailing effects of a potential nicotine tobacco product standard, including: (1) continued combustible tobacco product use (*e.g.*, current users switching to, or using simultaneously (*i.e.*, dual use), a different combusted tobacco product to maintain their nicotine dependence; (2) continued very low nicotine cigarette smoking with altered behaviors (*e.g.*, increase in number of cigarettes smoked, increased depth of inhalation); (3) cigarette users adding nicotine in liquid or other form to their combusted tobacco product; and (4) increased illicit trade of tobacco products.[13] FDA plans to consider each of these potential unintended consequences before moving forward with issuing a potential maximum nicotine level for combustible tobacco products.

Projected Health Benefits

As explained in FDA Commissioner Gottlieb's statement accompanying the ANPRM, new estimates included in the ANPRM and to be published in the New England Journal of Medicine, evaluate a potential policy scenario whereby a maximum nicotine level is implemented. By the year 2100, the median estimate from the model, based on the experts' estimates of potential initiation rates because of the policy, is that more than 33 million youth and young adults who would have otherwise initiated regular smoking would not start as a result of the hypothetical policy scenario.[14] Further, using expert estimates for the percent of current smokers who would quit smoking after implementation of the policy, approximately 5 million additional smokers are estimated to quit smoking within one year after implementation of the standard.[15] Under the same model, by 2060, it is estimated that a median value of almost 3 million deaths due to tobacco would be avoided.[16]

Impact of Potential Maximum Nicotine Level on Electronic Nicotine Delivery Systems (ENDS)

Of note for the vapor industry, in the Agency's discussion of the effects of FDA's potential tobacco product standard establishing a maximum nicotine level for cigarettes, FDA essentially acknowledges, as it has in the past, that ENDS products are less harmful than cigarettes. Indeed, FDA explains "former smokers that choose to switch completely to a potentially less harmful nicotine product (*e.g.*, electronic nicotine delivery systems (ENDS)) to maintain their nicotine dose also would, to the extent that those products result in less harm, significantly reduce their risk of tobacco-related death and disease."[17] By implication, this statement appears to tacitly accept that current combustible tobacco product users are likely to switch to ENDS products not covered by the potential maximum nicotine level rule.

Indeed, this result was recognized in a 2018 update (discussed in the ANPRM) to a previously published discrete system dynamic population model that compared projected outcomes for a status quo scenario (in which no maximum nicotine level is implemented) with outcomes for a policy scenario in which a hypothetical regulation lowering nicotine in cigarettes and selected other combusted tobacco products, to minimally addictive levels.?[18] Importantly, the model of the potential effects of the maximum nicotine level for cigarettes projected a simultaneous reduction in cigarette smoking and an *increase* in non-combusted tobacco product use.[19] Lastly, in an industry conference call held on March 15, 2018 to announce the ANPRM, Mitch Zeller, the Director of the Center for Tobacco Products, expressly acknowledged the Agency's obligation under Commissioner Gottlieb's new comprehensive plan to ensure that nicotine remains on the market in less harmful forms as FDA works to implement a potential maximum nicotine level for combustible cigarettes.

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[1] FDA News Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of tobacco-related disease and death (July 28, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm.

[2] FDA, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes Advanced Notice of Proposed Rulemaking (ANPRM), *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-05345.pdf(pre-publication copy), at 1.

[3] FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on Pivotal Public Health Step to Dramatically Reduce Smoking Rates by Lowering Nicotine in Combustible Cigarettes to Minimally or Non-Additive

Levels, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM601039.htm?utm_campaign=Statement_ANPRM%20to%20reduce%20nicotine%20in%20cigs&utm_medium=email&utm_source=Eloqua.

[4] *Id.*, at 6

[5] *Id.*, at 7.

[6] *Id.*, at 8.

[7] *Id.*, at 33.

[8] 21 U.S.C. § 387g(d)(3)(B)

[9] Tobacco Product Standard for Nicotine Level of Combusted Cigarettes Advanced Notice of Proposed Rulemaking (ANPRM), at 9.

[10] *Id.*, at 9.

[11] *Id.*, at 9

[12] *Id.*, at 10.

[13] *Id.*, at 10-12; *See also* FDA, Draft Concept Paper, "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard (Mar. 15, 2018), *available at* https://www.fda.gov/downloads/tobaccoproducts/newsevents/ucm601047.pdf.

[14] *Id.*, at 74.

[15] *Id.*, at 75.

[16] *Id.*, at 75.

[17] *Id.*, at 26.

[18] *Id.*, at 69.

[19] *Id.*, at 74.

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