



The Consumer Advocates for Smoke-free Alternatives Association

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To: U.S. Food and Drug Administration

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Re: CASAA comments on FDA's Advance Notice of Proposed Rulemaking ("ANPRM"), "Tobacco Product Standards for Nicotine Level of Combusted Cigarettes," Docket No. FDA-2017-N-6189

This comment on Docket No. FDA-2017-N-6189, "Tobacco Product Standards for Nicotine Level of Combusted Cigarettes," is submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA). CASAA is a 501(c)(4) nonprofit public health and education organization and is the leading representative of consumers who use--or may in the future choose to use--low-risk, smoke-free alternatives to smoking. CASAA is a U.S. membership organization with an all-volunteer Board of Directors and a grassroots membership of more than 200,000 members. CASAA is not an industry group and does not represent the interests of industry. Rather, CASAA represents consumers and is dedicated to ensuring the availability of a wide variety of reduced harm alternatives to smoking and to ensuring that smokers and non-smokers alike receive honest information about those alternatives so that they can make informed choices.

These low-risk smoking alternatives at present primarily include vapor products (sometimes referred to as e-cigarettes), low-risk smokeless tobacco products (including snus), and heated

tobacco products (which are currently not available in the U.S. market). These products are collectively referred to as “tobacco harm reduction products” or “THR products.”

Because CASAA is a tobacco harm reduction organization, we generally do not take a position on regulation of combustible products. However, since CASAA represents current smokers who may in the future choose to use THR products, we are commenting on this ANPRM because we are concerned about the unintended consequences of dramatically reducing nicotine levels in combustible cigarettes and how that may actually harm smokers instead of reducing their risks.

I. Serious Consideration of Mandatorily Reducing Nicotine in Combustible Cigarettes is Premature

Mandatorily reducing nicotine in combustible cigarettes would be an incredibly intrusive policy. Many smokers will view this as an example of brute force by FDA to deliberately lower the pleasure (but not the risk) of the products they enjoy, all in an effort to manipulate their behavior. Even more perversely, FDA is considering mandatorily reducing nicotine in combustible cigarettes at a point in time when there is not yet a clear path forward through the prohibitively burdensome regulatory maze for new low-risk smoking alternatives such as vapor products.

Until FDA creates a clear path forward for low-risk products so that smokers have acceptable alternatives that are readily available, enjoyable, effective and affordable, it is premature and inhumane to consider mandatorily reducing nicotine content of combustible cigarettes.

II. Unintended Consequences

It is concerning that FDA seems intent on pursuing such a dramatic and far-reaching policy without massive research and observation. We find the current scientific data on this issue lacking and not particularly compelling.

A. An Increase in Compensatory Smoking

We are particularly concerned that not nearly enough attention has been paid to the very real possibility (if not likelihood) that a good number of smokers will actually increase their smoking habit in an effort to compensate for the reduction in nicotine, similar to what happened with the low tar cigarette boondoggle.¹

¹ See, for example, Andrew A. Strasser, Caryn Lerman, Paul M. Sanborn, Wallace B. Pickworth, Eric A. Feldman, “New lower nicotine cigarettes can produce compensatory smoking and increased carbon monoxide exposure,” *Drug and Alcohol Dependence*, Volume 86, Issues 2–3, 2007, Pages 294-300, (<http://www.sciencedirect.com/science/article/pii/S0376871606002791>) and Lynn T. Kozlowski and Janine L. Pillitteri, “Compensation for Nicotine by Smokers of Lower Yield Cigarettes,” *Monograph 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes*, 1996, Chapter 12 (https://cancercontrol.cancer.gov/BRP/TCRB/monographs/7/m7_12.pdf)

Moreover, while many smokers do indeed cite nicotine as the reason for smoking, we know without a doubt that nicotine is not the only reason many smokers choose to smoke. If nicotine were the only factor involved with smoking, the vast majority of smokers could simply use over-the-counter nicotine replacement therapies (NRTs) and completely eliminate their smoking habit. But we know that the long-term success rate associated with using NRTs to quit smoking, by any measure, is not particularly high, somewhere between 7% and 10%.² Not enough attention has been paid to this issue and how mandatorily reducing nicotine might affect various populations of smokers.³

B. Miscommunication of Risks Associated with Nicotine

Recent survey data confirms that most people believe that nicotine is a source of harm. Specifically, >52% of respondents falsely believe that nicotine is a carcinogen⁴. Even more disturbing, many medical professionals share these misperceptions.

CASAA believes that the FDA has not sufficiently studied the effect of lowering nicotine content in cigarettes on consumers' perception of risk associated with smoking or using any nicotine product. Considering current misperceptions of risk associated with nicotine, there is concern that smokers and never-smokers will see low-nicotine cigarettes as safer than other tobacco products (even though low-nicotine cigarettes would continue to be as risky as combustible cigarettes currently are). Indeed, section IV, F. *Countervailing Effects* in the ANPRM does not consider this scenario at all. FDA must address the question of whether the public will view low-nicotine cigarettes as potentially less harmful than NRT or other nicotine-containing products.

C. Black Market

CASAA is also concerned about the inevitable increase in black market sales of contraband cigarettes and the very real risk of prohibition causing otherwise law-abiding citizens to become criminals. Historically, illicit markets for cigarette sales have been driven by excessive taxes on

² Etter J, Stapleton JA. Nicotine replacement therapy for long-term smoking cessation: a meta-analysis. *Tobacco Control*. 2006;15(4):280-285. doi:10.1136/tc.2005.015487.

³ See, for example, Neil McKeganey and Tiffany Dickson, "Why Don't More Smokers Switch to Using E-Cigarettes: The Views of Confirmed Smokers," *International Journal of Environmental Research and Public Health*, Volume 14(6) (2017) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486333/>) where in response to the query of why the respondent, a smoker, chose to continue smoking rather than use vapor products: "I do not think that I derive enjoyment from the nicotine alone. I think there are other substances in tobacco that are beneficial and enjoyable besides the nicotine." The authors note that this was a common response.

⁴ PinneyAssociates (2018). Most Adults Fail To Understand That Nicotine Does Not Cause Cancer.

[online] Available at:

<https://www.prnewswire.com/news-releases/most-adults-fail-to-understand-that-nicotine-does-not-cause-cancer-300603709.html> [Accessed 16 Jul. 2018].

tobacco products, which provide a profit motive for smugglers and organized crime to move cheap cigarettes from a low-tax jurisdiction to a high-tax one. Such opportunities are limited because tobacco tax policy varies from state to state and among municipalities. But enacting a federal tobacco standard that effectively bans the sale of “full strength” cigarettes opens up the entire country to enterprising black marketeers seeking to meet the new demand.

While the FDA seems to have contemplated responses to several means of illegal manufacture, importation, and distribution of illicit tobacco products, Australia’s experience with an increase in sales of contraband cigarettes highlights flaws in the agency’s analysis. As with other highly coercive anti-tobacco policies, a low nicotine standard relies on limiting access to achieve an increased smoking cessation rate and to prevent initiation. But demand for full strength cigarettes will still exist and meeting this demand would be highly profitable, despite severe penalties for breaking the law. Indeed, over half of the illicit cigarettes sold in Australia are contraband cigarettes imported from outside of the country. Sales of domestically manufactured illegal cigarettes and counterfeits are rapidly shrinking. Concurrently, the decline in the number of smokers in Australia has recently slowed in spite of the government’s aggressive anti-smoking policies.

And as noted by FDA, there are various mechanisms by which consumers can seek to circumvent the prohibition by rolling their own cigarettes, by removing the filter, or by adding high nicotine e-liquid to the tobacco, to name a few.⁵ In order to combat these potential problems created by prohibition, FDA hints at the possibility of even greater prohibition on other low-risk tobacco products by, for example, eliminating the sale of higher nicotine content liquid for e-cigarettes.⁶ (We note for the record that the availability of higher nicotine content liquid plays an important role in allowing some smokers to successfully transition to low-risk vaping and in keeping many current vapers smoking abstinent. Also, using higher nicotine content liquid to alter the nicotine content of cigarettes is impractical and would most likely lead to an unsatisfying experience for smokers.)

D. Erosion of Trust

There is a general mistrust in people of government interventions enacted for their own good. It does not help that people (in this case, people who use tobacco and nicotine products) perceive many of those who would impose such policies as also being dishonest about the factual support for these policies. Government agencies and a distressing number of public health organizations and activists are deliberately conflating the lower risks of noncombustible tobacco products with the considerably higher risk of combustibles. People who use vapor products can easily see this going on, and they are rightfully concerned that an intervention as dramatic as

⁵ Center for Tobacco Products, U.S. Food and Drug Administration, “Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard,” March 15, 2018, (<https://www.fda.gov/downloads/tobaccoproducts/newsevents/ucm601047.pdf>)

⁶ *Id.*, p. 9.

mandatory reduction of nicotine being imposed on cigarette smokers suggests they will be the next target when the intention inevitably turns to making vapor products “safer” by making them “less addictive.”

Moreover, any potential success could easily be dwarfed by the lasting damage to the reputation of FDA as a paternalistic state apparatus that believes it has the right to trample the freedom of others if its noble goals arbitrarily justify it. People want to live their lives as they see fit. They do not see the relentless hand of government forcing them to behave in a healthier manner as helpful. They resent their choices being taken away, even if they know their choice is an unhealthy one.

III. Less Draconian Efforts Should be Explored

CASAA believes that consumers should be given the means to make healthier choices and assistance in achieving their goals. It is not the proper role for the FDA or the government in general to choose goals that people must accept, much less compel them to achieve those goals against their wishes. We believe that mandatorily reducing nicotine content in combustibles is coercive and--if considered at all--should be a policy decision only explored after all less draconian options have been employed.

First, FDA should test real-world effects of reduced nicotine content combustibles and should therefore consider making low-nicotine cigarettes optional before considering making them mandatory. Making these products available as a permissible option for smokers who wish to voluntarily use them in an effort to reduce their nicotine dependence is not coercive. Moreover, it would provide real-world data to FDA in connection with its exploration of the possible role of reduced nicotine content combustibles in helping smokers eliminate or reduce their smoking habit.⁷

In the final analysis, though, it seems to us that that the most reasonable and ethical approach is to try the simplest solution first: Tell people the truth about the low-risk nature of noncombustible nicotine-containing products and do not seek to regulate the low-risk products with the same heavy hand being levied against the high-risk products. If smokers were told the truth about how completely switching to vapor products and smokeless tobacco could dramatically reduce their risk--and if vapor products are regulated with a light hand so that they remain enjoyable (and therefore effective)--we firmly believe that we would see a significant decline in smoking, accomplished without need for coercion.

For the foregoing reasons, CASAA respectfully submits that discussions about mandatorily reducing nicotine in combustible cigarettes is, at best, premature and implementation of any such policy carries significant risks that could create a great deal of harm.

⁷ Lynn T. Kozlowski, *Addiction*, Volume 112, Issue 1, pp. 3-5 (2007), “Let actual markets help assess the worth of optional very-low-nicotine cigarettes before deciding on mandatory regulations,” (<https://doi.org/10.1111/add.13515>)