



The Consumer Advocates for Smoke-Free Alternatives Association

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To: U.S. Food and Drug Administration

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RE: Docket No. FDA-2016-N-2527

VIA REGULATIONS.GOV

Introduction.

The following comments are submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA) asking that FDA withdraw the proposed rule, "Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products," Docket No. FDA-2016-N-2527. CASAA is a 501(c)(4) nonprofit public health and education NGO and is the leading representative of consumers who use or might in the future use smoke-free tobacco and nicotine products. It is a U.S. membership organization with over 200,000 members. CASAA advocates on behalf of consumers, and does not represent the interests of industry.

Section 907(a)(3) of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) requires that any tobacco product standard be appropriate for the protection of public health. In the proposed rule, FDA states, "Because products with higher NNN levels pose higher risks of cancer, FDA finds that establishing a NNN limit in finished smokeless tobacco products

is appropriate for the public health.”¹ FDA does not take into consideration the likely effect of this rule would be to decimate the U.S. smokeless tobacco industry and virtually eliminate meaningful consumer choice and access to low-risk, smoke-free tobacco products.

In fact, as more fully discussed in this comment, FDA has not demonstrated that this rule is appropriate for the protection of the public health. To the contrary, we believe that if enacted, this rule will actually work against the interests of genuine public health and result in a net public health loss at the population level. We can only speculate as to why FDA’s first effort at promulgating product standards for tobacco is aimed at the lowest-risk product (which FDA estimates in its proposed rule causes less than 300 deaths per year) instead of high-risk combustible products (which CDC estimates causes more than 480,000 deaths per year).²

If FDA is truly committed to reducing the health burden associated with tobacco use (virtually all of which comes from combustible tobacco products), the single-best thing it could do would be to accurately inform consumers that smokeless tobacco and vapor products are low-risk alternatives to smoking. Instead, it continues to mislead consumers into thinking that all tobacco products carry similar and significant health risks, which leads many people to continue smoking rather than switch to a lower-risk product. Accurately communicating the much lower-risk nature of smokeless tobacco and vapor products would have a far more positive impact on the public’s health and well-being as opposed to enacting a rule that will virtually eliminate consumer choice, drive up costs, and likely create a public health loss as opposed to a benefit.

Errors in data and interpretation result in a fatally flawed analysis and a corruption of good scientific practice.

As noted in several comments already on the docket, FDA made errors in computation, as well as errors in the analysis of data. Specifically, we refer to the comments of (1) Dr. Brad Rodu³, Professor of Medicine at the University of Louisville School of Medicine, where he challenges FDA’s estimates of oral and pharyngeal cancer deaths associated with smokeless tobacco use. To the extent that past studies of dry snuff have been pooled with moist snuff and other types of smokeless tobacco, this artificially and inaccurately drives up the risk for all products in the smokeless tobacco category since the use of moist snuff and chewing tobacco impose minimal risks for oral and pharyngeal cancer.⁴ This is particularly troubling when one considers that dry

¹ Federal Register, Volume 82, No. 13, January 23, 2017, p. 8004. [\[link\]](#)

² We do not necessarily embrace these estimates as accurate, but simply note that this is the information that the FDA considers persuasive and upon which the agency bases its conclusions.

³ Comment by Dr. Brad Rodu dated February 14, 2017. [\[link\]](#)

⁴ Rodu B., Cole P. Smokeless tobacco use and cancer of the upper respiratory tract. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* : US Department of Health and Human Services, Washington, DC; 2002 May 1;93(5):511-5. [\[link\]](#)

snuff (with the highest levels of NNN) currently makes up only a tiny fraction of market share in the U.S. (FDA estimates that dry snuff represents less than 1% of smokeless tobacco sales.⁵)

We also note the comments by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company⁶ and RAI Services Company⁷ where they identify a serious error in FDA's calculation of the wet-weight to dry-weight conversation, which invalidates FDA's estimate that 30% of moist snuff products on the market currently meet the 1 ppm dry-weight limit. This is a significant problem in that this error would result in dramatically overstating the number of products on the market that currently meet the standard (and, obviously, dramatically understating the number of products that do not meet the standard).

Errors such as these significantly invalidate FDA's analysis, and necessitate that the proposed rule be withdrawn for further consideration.

FDA ignored the ANPRM process and failed to obtain relevant information from stakeholders, resulting in a proposed rule that is fatally flawed.

The subject matter of this rule is more appropriately addressed through the Advanced Notice of Proposed Rulemaking (ANPRM) process. ANPRM would have allowed the public and various stakeholders to inform the FDA of critical facts that FDA either ignored or simply got wrong.

The Tobacco Control Act requires FDA to consider technical achievability of compliance with the standard. It is striking that this rule, which imposes product standards that will fundamentally change the entire smokeless tobacco product category, was formulated with no formal input from industry stakeholders to determine whether the product standards were truly achievable in the base case or, if technically achievable for some products, whether those products would be readily accepted by consumers. It appears from several comments made by industry stakeholders that the standard for the most part is not technically achievable for most smokeless products produced in the U.S.⁸

⁵Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis for Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, Docket No. FDA-2016-N-2527, p. 19. [\[link\]](#)

⁶ Comment by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company dated March 3, 2017. [\[link\]](#)

⁷ Comment by RAI Services Company dated [\[link\]](#)

⁸ See, for example, comments by Kentucky Farm Bureau Federation dated April 10, 2017 [\[link\]](#); Eastern Dark Fired Tobacco Growers Association dated April 4, 2017 [\[link\]](#); Dark Leaf Tobacco Dealers and Exporters Association dated March 21, 2017 [\[link\]](#); Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company dated February 13, 2017 [\[link\]](#).

FDA also failed to engage consumer stakeholders in formulating this rule. If they had, they would have understood the importance of consumer preferences and would have given more serious consideration to the ramifications of (1) removing certain products from the marketplace and (2) changing product formulations that impact taste and consumer acceptance. Much of FDA's analysis and assumptions are flawed because they simply failed to take into account important factors regarding consumer use, habits, choice, practice, preferences, and beliefs. This failure is troubling since consumers are directly affected by the rule and are arguably the most important stakeholders.

Moreover, while FDA chose not to seek input from industry or consumer stakeholders, it appears likely that at least six organizations preferentially received information about the proposed rule in advance of its publication. Specifically, we refer to the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco Free Kids, and Truth Initiative, which groups filed a joint comment within hours of the publication of the proposed rule. We agree wholeheartedly with the comment by Brian J. Fojtik, Senior Fellow with Reason Foundation:

Given how little time elapsed between publication of the rule and the filing of the comment, questions arise as to whether there was coordination or consultation by the CTP with these groups prior to publication Even in the most forgiving of lights, the appearance is unseemly and should necessitate the withdrawal of the proposed rule.⁹

Our membership is largely skeptical (if not downright distrustful) of organizations that support the imposition of regulations that have the effect of making low-risk tobacco products less affordable, accessible, or acceptable to adult consumers. Even the suggestion that FDA might have coordinated its activities with these organizations has devastating ramifications in terms of already incredibly eroded consumer trust in the FDA.

The appearance of collusion, together with the significant missteps of FDA resulting from failing to use the ANPRM process, require that the proposed rule be withdrawn.

FDA ignored issues involving consumer choice, preference, practice, habit, and use patterns and their effect on the analysis of the rule's impact on public health.

At the heart of this proposed rule is the notion that reducing NNN levels in all smokeless tobacco will result in significant health benefits. Leaving aside the issue of FDA's flawed

⁹ Comment by Brian J. Fojtik, Senior Fellow with Reason Foundation, dated March 9, 2017, pp. 3-4. [[link](#)]

analysis of the risks associated with smokeless tobacco, we believe there is a strong likelihood that this rule may well result in an overall increase in harm to public health.

While FDA acknowledges that NNN levels vary substantially across subcategories of smokeless tobacco, it fails to acknowledge the significance of the other differences among those subcategories. While Swedish-style snus products may have lower levels of NNN than other types of smokeless tobacco product categories, not all consumers will find Swedish-style snus an acceptable alternative to the American-style product they currently use and enjoy.

FDA does not explore, even in the most cursory fashion, how acceptable consumers will find the mandatorily reduced NNN products, or how they will feel and react to their preferred products being removed from the market or reformulated so as to no longer (1) impart the flavor they enjoy, (2) provide the experience they enjoy, or (3) permit the cultural practices or experiences associated with products they are accustomed to. For example, FDA notes that one of the factors affecting NNN levels is the curing process. It also notes in a rather off-hand manner that the curing process imparts characteristic flavor. But FDA fails to address how effectively eliminating flue- and fire-curing would affect characteristics of the product other than simply NNN levels and how those changed characteristics will be received by consumers.

Consumer acceptance of mandatorily reduced NNN products is a critical issue. If a consumer's preferred product is taken off the market or reformulated in a fashion that makes it no longer acceptable, one cannot assume that the consumer will simply quit using all tobacco products or will switch to using another mandatorily reduced NNA smokeless tobacco product.

FDA explores the question of whether this proposed rule might cause an uptake in smokeless tobacco use if the general public perceives that FDA has made the product category less risky, and notes that they would expect additional reduction in risk to individual users who might choose to switch from smoking to smokeless.¹⁰ FDA also explores the possibility that some non-tobacco users might decide to initiate smokeless tobacco use, but opines that it would still be a net health gain since "the prevalence of smokeless tobacco use would have to nearly triple in order to offset the expected excess cancer risk reduction due to the proposed rule."¹¹

And yet FDA never considers the far more damaging--and far more likely--possibility, namely, that the effect of this rule will be to cause more smoking as smokeless tobacco users' preferred products are removed from the market or rendered unpalatable due to product formulation changes, nor does FDA quantify how many smokeless-tobacco-users-turned-smokers it would take to eliminate any of the anticipated health gains associated with the rule. Given the dramatic

¹⁰ Federal Register, Volume 82, No. 13, January 23, 2017, p. 8025. [\[link\]](#)

¹¹ Federal Register, Volume 82, No. 13, January 23, 2017, p. 8025. [\[link\]](#)

risk differential between smoking and smokeless tobacco, this is a significant issue which could well result in the a massive health benefit loss.

FDA failed to adequately address the issue of reduced risk across product categories and consumer misperceptions, resulting in the likelihood that this rule may actually result in a population-level loss of health benefit.

As noted previously, at the heart of this proposed rule is the notion that reducing NNN levels in all smokeless tobacco will result in significant health benefits. And while FDA has rather cursorily attempted to quantify the impact vis-a-vis the smokeless tobacco category, it failed to consider the possible impact of making the product category less attractive to the current consumers of these products as a result of product withdrawals and mandatory reformulations. Aside from the considerable welfare costs to many consumers of loss of enjoyment, there may well be a move away from the product class by current consumers. And, as discussed previously, we can expect that while some movement may consist of some consumers quitting smokeless tobacco use, we can also expect that some movement may consists of some smokeless tobacco users becoming smokers (or increasing their current smoking habit).

This would be a direct result of consumers failing to understand the risk differential between smoking and smokeless tobacco use. FDA ignores the incredible amount of misinformation in the public arena about the relative risks of smokeless tobacco versus smoking. The public perception is overwhelmingly that smokeless tobacco is as harmful as smoking.¹² This misperception has been fueled by anti-tobacco messaging campaigns by federal and state governmental agencies, and by special-interest nonprofit groups that conflate risks by repeating the unhelpful (and deceptive) mantras that all tobacco products are harmful, no tobacco product is safe, and smokeless tobacco is not a safe alternative to smoking.

To the extent that many smokeless tobacco users see smokeless tobacco as being as risky as smoking, it is likely that a number of those smokeless tobacco users will consider smoking as a potentially acceptable alternative if their preferred products are no longer available. This is especially true given that we know that some smokeless tobacco users smoke (either daily or occasionally).¹³

¹²According to a recent study, approximately 9 out of 10 individuals did not know that smokeless tobacco products were less hazardous than smoking. See Kiviniemi M, Kozlowski L, Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey. *Harm Reduct J.* 2015; 12:21. [[link](#)]

¹³ See, for example, Tomar S., Alpert H., Connolly G. Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys. *Tobacco Control* 2010;19:104-109: “[A]nalyzes

Conclusion.

Based on the foregoing, we submit that FDA must withdraw the proposed rule in order to correct errors in analysis and computation and to consider all relevant information. We are also very concerned to see the elevation of bad science as the basis for national policy making. We urge FDA to methodically and patiently use the rulemaking process and to consider only the highest quality of science when proposing any new standards for low-risk tobacco and nicotine products.

Misleading the public is never good public policy. The public will be better served by receiving accurate information about low-risk alternatives to smoking, such as smokeless tobacco. Rather than proposing a rule that is a de facto ban on nearly all low-risk smokeless tobacco products, FDA must seize this opportunity to empower consumers to make safer choices when consuming nicotine.

of data from four nationally representative surveys indicate that dual use of cigarettes and ST is relatively common among young males.” [\[link\]](#)