To: U.S. Food and Drug Administration

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VIA REGULATIONS.GOV

Re: CASAA comments on FDA’s Proposed Regulations: Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”

Docket No. FDA-2015-N-2002  
Originally assigned RIN 0910-AH19 when docket first opened September 25, 2015

I. Introduction

This comment on Docket No. FDA-2015-N-2002 (originally assigned RIN 0910-AH19 when docket first opened September 25, 2015), “Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ‘Intended Uses,’” 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 NGO and is the leading representative of consumers who use or might in the future use smoke-free tobacco/nicotine products. It is a U.S. membership organization with over 125,000 members. CASAA is not an industry group and does not represent the interests of industry.
Our comments regarding this proposed rule should not be construed as supporting FDA’s proposed rule to deem e-cigarettes and other vapor products (collectively referred to as “e-cigarettes”) as “tobacco products” under the Family Smoking Prevention and Tobacco Control Act (the “TCA”). CASAA continues to strenuously object to FDA’s attempted deeming as a de facto ban on more than 99% of the vapor products currently on the market.¹

II. Comment

We recognize that it is in the best interests of consumers that FDA exercise its legitimate authority to restrict e-cigarette manufacturers from making unapproved claims that are genuinely about e-cigarettes themselves providing cure, mitigation, treatment, or prevention for disease, or providing diagnosis of disease or other conditions. That limitation on commercial speech is already well established and generally adhered to. However, the proposed rule exceeds the legitimate authority of FDA, and in so doing would impose restrictions that are clearly harmful for consumer interests and genuine public health.

Smoking itself is not a disease. It causes disease, but the act of smoking itself is a behavior and a consumer choice. The act of stopping smoking, by whatever means, is not a cure or treatment for disease, even though it is a health-promoting action. This is no different from the act of wearing a seatbelt or the act of substituting vegetable juice for soda. Seatbelts are not considered medical devices, and car manufacturers have often advised people to “buckle up for safety” as a substitute for the less healthy behavior of not doing so. A vegetable juice manufacturer is not selling a drug and is not governed by approved “indications” for their product. While they might not be allowed to say “avoid the diabetes risk from soda by drinking this,” they can certainly suggest you drink it instead of soda (leaving it to the consumer to infer why she might want to make that choice) and can generally use such phrases as “the smart alternative.” Therefore, it is clearly administrative overreach for FDA to assert that statements about using e-cigarettes instead of cigarettes should trigger treatment as a drug/device/combination product under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Due to mission creep (mostly in the form of making sure healthcare providers can bill healthcare funders for smoking cessation services and pharmaceutical companies can receive de facto subsidies for their smoking cessation products), smoking is labeled as a “disease” in some catalogues. But it is always the case that some technical rules that serve specific purposes will define words in ways that torture natural definitions, and that does not change the reality. A “corporation” can be defined to be a “person” for purposes of some laws, but that does not make

¹ CASAA’s comments on the proposed deeming can be found at http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-78335 and is incorporated herein by this reference.
it human. Thus, no list that defines disease conditions for a particular purpose, and that includes the act of smoking, changes the fact that smoking is not a disease for all other purposes.

The proposed rule asserts, “FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction and its symptoms to be within FDA’s ‘disease prong’ jurisdiction.” But smoking cessation in and of itself is not a cure or treatment any more than the act of smoking itself is a disease. E-cigarettes do not “cure” or “treat” nicotine addiction, but, rather, provide an acceptable and satisfying alternative for those who wish to reduce or eliminate their smoking habit. Indeed, many statements by FDA and other supporters of this proposal emphasize the fact that switching to e-cigarettes perpetuates “nicotine addiction and its symptoms” (setting aside the question of what that even means). This means the quoted claim is irrelevant to the use of e-cigarettes for smoking cessation.

Simply stated, general claims of smoking cessation do not meet the “disease prong” of the drug/device definition under the FD&C. Any suggestion that various claims regarding e-cigarettes meet the “structure/function prong” are similarly misguided. Under the analysis provided by FDA, seatbelts, vegetable juice, and coffee could be considered to meet those “prongs.”

Looking at the practical implications rather than legalisms, the effects of this rule would be flatly contrary to the stated goals and missions of FDA. FDA has repeatedly acknowledged that it is better for tobacco users to use low-risk products like e-cigarettes rather than to smoke. But this rule would remove an effective tool for making that happen despite providing no apparent benefit.

There is no claim of any material harm in the world that would be reduced by the imposition of this rule, so it is impossible to identify any benefit that could come from this regulatory overreach. FDA suggests that there is benefit to avoiding confusion between e-cigarettes and smoking cessation pharmaceuticals, but has provided no evidence that any material confusion exists, let alone enough to warrant regulatory action. Indeed, the claim is patently absurd to anyone familiar with consumers and the market: There is no way consumers are going to confuse a product that mimics cigarettes and that is sold alongside cigarettes in a convenience store -- let alone up-market e-cigarette products sold by specialists -- with a product that is marketed, supplied, and labeled as a pharmaceutical. Indeed, the predominant source of confusion on the part of consumers about these products is not realizing they pose risks much closer to those from the pharmaceuticals than from combustible cigarettes, and are a satisfying substitute for many smokers. These allegations of confusion seem more like a blatant attempt at protectionism for the manufacturers of the pharmaceutical products that cannot compete with e-cigarettes in the free market.

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2 Federal Register Volume 80, No. 186, September 25, 2015 at p. 57759 (Section II.A.1).
Perhaps FDA has some evidence of real confusion by consumers that actually has the potential to materially harm consumers (rather than just merely harming influential companies that make competing products). If so, it should be presented. Then FDA must conduct a cost-benefit analysis that shows that (a) the proposed regulation might reduce the alleged harm and (b) the benefits from this warrant the obvious and inevitable costs the regulation would create. In the proposal, FDA disingenuously claims that, “The proposed rule is not expected to impose significant additional costs on manufacturers who make products made or derived from tobacco, or on drug and device manufacturers generally.” Setting aside whether that is even true, it blatantly ignores that the real costs of denying consumers accurate information is borne by consumers.

E-cigarette manufacturers’ statements that their products can be an attractive alternative to smoking, and that many people have successfully used e-cigarettes to reduce or completely replace their smoking, are beneficial to consumers and public health. That message is communicated by many parties who are concerned with public health and are outside FDA jurisdiction, and thus the message could never be fully censored by FDA action (despite the outlandish suggestions of some commenters on this proposal that FDA try to do just that). But manufacturers, due to their ability to mass-advertise and engage in point-of-sale communications to smokers, can often reach consumers who might not hear that message from other parties. This is particularly true since specialty retailers (vape shops and online e-cigarette stores) play a major role in educating consumers and almost all of them likely qualify as “manufacturers” under this rule because most make, modify, or directly import some of the products they sell. Similarly, manufacturers’ point-of-sale communications through non-specialty retailers (e.g., signage in convenience stores) can reach the consumers who are the least likely to quit smoking without such information.

Thus, preventing such communication would cause more people to smoke rather than switch to e-cigarettes. This has potential for serious public health harm, not offset by any apparent material benefit. To provide examples of the benefits that would be lost under this proposal, we have asked some CASAA members to provide their personal testimonials about the role that manufacturer statements about substituting e-cigarettes for smoking had in helping them to quit smoking, and we call your attention to those. See also CASAA’s collection of testimonials.³

We repeatedly hear from our membership about the important role that dedicated vape shops play in helping them become -- and stay -- nonsmokers. In fact, we believe that vape shops are uniquely situated to provide the advice, encouragement, and support necessary for even the most inveterate smoker to successfully replace her smoking habit with vaping. E-cigarettes are indeed a successful tool for smoking cessation or significant smoking reduction for many smokers, and particularly so when they receive information and support from fellow vapers and dedicated vape

³ CASAA’s Testimonials Collection, at http://testimonials.casaa.org/, currently includes more than 7,800 tobacco harm reduction success stories.
shops. To do anything to reduce this phenomenon would be a huge blow to genuine public health interests.

This proposed rule would probably actually foster the consumer confusion that FDA ostensibly is seeking to address. E-cigarette merchants would effectively have to pretend that the reason consumers should buy their products has nothing to do with them being a low-risk substitute for smoking. Meanwhile, as noted above, the message about e-cigarettes as a means of smoking cessation is being communicated by parties outside FDA jurisdiction who will remain free to exercise their free-speech rights to make such claims. Many healthcare practitioners are increasingly recommending e-cigarettes to their smoking patients who have failed using FDA-approved methods.4

We further argue that FDA should not attempt to prevent e-cigarette manufacturers from making non-specific uncontroversial (among honest experts) claims about comparative risk, such as “these products are much less harmful than smoking.” Again, while there are many actors who actively deliver that information to the public, a remarkably large portion of the target population -- adult smokers -- are unaware of it.5 The additional communications reach provided by manufacturers could help remedy these misperceptions and thus improve public health. While FDA arguably has better legal grounds for restricting explicit comparative risk claims than it does for restricting statements about substitution that make no claim about disease (though it is not clear that it has adequate legal ground even for this), such restrictions are a terrible idea. Such a restriction serves no purpose other than appeasing anti-harm-reduction extremists, but it actively harms public health.

In addition to cutting off communication that is beneficial for consumers and genuine public health, the rule would encourage exactly the kind of communication that FDA seems to find objectionable (and certainly the knee-jerk supporters of such restrictions on speech do6). Manufacturers could and would still engage in marketing. But they would not be able to tell consumers that the purpose of the products is to facilitate and maintain smoking cessation. They would probably not even be allowed to say, “This webpage is for adult smokers only.” Instead, they would be left with no options other than highlighting the attractiveness and enjoyability of their products, without any caveats about how these are characteristics that are meant to appeal to smokers. Thus they would be forced to present their marketing messages in terms that might be as attractive to non-users of any tobacco product as they are to smokers.

5 http://www.ajpmonline.org/plosone/article?id=10.1371/journal.pone.0103462
6 See, for example, http://www.tobaccofreekids.org/tobacco_unfiltered/post/2014_02_24_si.
If there really is a problem of consumer confusion, mandatory disclaimers are an established and effective method for dealing with it (as is done, e.g., for dietary supplements). Rather than trying to manipulate consumer beliefs with the overbearing and yet still ineffective approach of censoring the provision of accurate information from some sources, disclaimers provide exactly the accurate information that eliminates the supposed confusion. Thus the requirement for targeted disclaimers would bring about any benefits this proposal supposedly offers far more effectively than censoring accurate information, and without imposing an aggressive regulatory overreach. If the supposed confusion is merely that consumers would not know which products were and were not endorsed by FDA for smoking cessation, a simple disclaimer would solve the problem (e.g., “This is not an FDA-approved smoking-cessation product.”). But justifying even this would still require some evidence that such confusion exists. If there were evidence of some confusion that, unlike the previous example, might actually materially harm consumers, more aggressive disclaimers could be mandated.

It should, however, be noted that “disclaimers” of the type that some manufacturers have felt obliged to use, along the lines of “not intended for smoking cessation,” are terribly counterproductive. If not intended for smoking cessation, is the product intended solely for fun and enjoyment? And if that is the message, this is, again, the very type of marketing that has come under criticism from other quarters.

We respectfully submit that the proposed rule overreaches FDA’s authority under the FD&C Act and will not accomplish its stated goals, in that it will (1) cause or increase consumer confusion, (2) cause fewer smokers to reduce or eliminate their smoking habit, (3) impose substantial health costs on consumers, and (4) work against the interests of genuine public health and the mission of the FDA. We further note that there has been no evidence presented that there is any genuine problem that needs to be fixed. However, if genuine harm resulting from alleged consumer confusion could be demonstrated, it seems likely this harm could be more effectively mitigated by the targeted and less harmful regulatory approach of mandating appropriate disclaimers.