FDA's Proposed Exception for Premium Cigars (Option 2) Does Not Protect the Public Health and Should Be Rejected

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In its proposed deeming rule, FDA solicits public comment on a proposal (Option 2) to exempt a subset of cigars ("premium cigars") from regulation. Option 2 is not appropriate for the protection of the public health, and would result in negative public health consequences. **Indeed, all the scientific evident that the FDA summarizes in the draft rule makes a compelling case for rejecting Option 2 and including all cigars among deemed products that will be subject to uniform regulations.**

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) currently gives FDA the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, and any other tobacco products that the FDA by regulation deems to be subject to the law. FDA proposes to deem products in addition to those already regulated that meet the statutory definition of "tobacco product," which the Tobacco Control Act defines to mean "any product made or derived from tobacco that is intended for human consumption…". Option 1 of the proposed rule would extend FDA's authority to all products that meet this statutory definition, but Option 2 would exclude a subset of cigars (so-called "premium cigars") from regulation (79 FR 23142 at pp. 23150-23152, 23202-23207).

An unregulated premium cigar under Option 2 is defined as: "a cigar that (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less that $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for price increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units" (p. 23150).

All combustible tobacco products deliver nicotine and large levels of the toxins that are produced by burning tobacco. Since large cigars have more tobacco, the dose of toxins delivered is correspondingly higher. For this reason, large cigars should be regulated the same way as other cigars.

Indeed, the FDA itself recognizes this fact in the draft rule when it reports that:

- "all cigars are harmful and potentially addictive" (p. 23150, 23151, Section VII.E, p. 23167-23170),
- "a large cigar may contain as much tobacco as a whole pack of cigarettes" (p. 23151, 23154) with nicotine levels in cigar smoke up to 8 times higher than levels in cigarette smoke (p. 23154)
- all cigars, regardless of size, produce higher levels of carcinogenic TSNAs (p. 23151)
- cigar smoke may be even more toxic and carcinogenic than cigarette smoke (p. 23151)
- a recent analysis derived from National Adult Tobacco Survey data showed that the percentage of young adults using premium cigars was just as high as the percentage using little filtered cigars (p. 23151).

Despite providing this compelling case for regulating large cigars the same as other similar tobacco products, the FDA proposed Option 2 because "it has been suggested that different kinds of cigars (e.g., small cigars, cigarillos, large cigars, premium cigars) may have the potential for varying effects on public health" (p. 23150).

FDA seeks comments on whether there is any evidence that premium cigars are used in a way that would have less health consequences than other cigars. We know of no such evidence. Indeed, as the FDA itself reported, the fact that so-called premium cigars contain more tobacco than other cigars, cigarettes, and other tobacco products means that smokers of premium cigars would be subjected to *higher* amounts of toxins. Thus, if any distinction were to be made between premium and other cigars, an argument could be made that the potentially higher toxicity of premium cigars should require stronger, rather than weaker, regulations. **FDA provides no reasonable justification for excluding one type of cigar from its proposed regulations (Option 2), and there is no science-based evidence for creating such a huge loophole.**

Option 2 would leave the current population of "premium cigar" smokers unprotected, and would drive youth and young adults, who would theoretically be facing tighter restrictions for purchasing smaller cigars as well as warning labels and potentially other restrictions, to initiate premium cigar use.

FDA's own research supports this conclusion. In its background section for deeming all tobacco products to be subject to the Act, FDA states:

> When similar products are taxed or regulated differently, substitutions across products occur. For example, industry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop small cigars that cigarette smokers would smoke (Refs. 20 and 21). Sales of small cigars quadrupled in the early 1970s, when cigars were taxed at a much lower rate than cigarettes and cigarette (but not small cigar) advertisements were banned from television and radio (Ref. 21).
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> This substitution is evidenced in the recent trends regarding cigarette consumption compared to the use of other combustible tobacco products (e.g., small and large cigars, pipe tobacco, and roll-your-own tobacco). For example, the Centers for Disease Control

> and Prevention (CDC) reported a 32.8 percent decrease in cigarette consumption between 2000 and 2011, while the consumption of non-cigarette combustible products increased from 15.2 billion "cigarette equivalents" (i.e., small cigars and large cigars, and per-cigarette equivalents for pipe tobacco and roll-your-own tobacco) to 33.8 billion—a 123.1 percent increase over the same time period (Ref. 22). Pipe tobacco consumption during this period increased 482.1 percent, and consumption of large cigars increased 233.1 percent (id.). This research suggests that recent changes in consumption of non-cigarette combustible products, particularly increases in large cigar and pipe tobacco use, are associated with a decline in cigarette consumption, and indicate that certain cigarette smokers may switch to non-cigarette combustible products (id. at 567). While researchers posited that this change in prevalence rates is likely due to the lower taxes (and ultimately lower cost to the consumer) (id. at 566), the lack of regulation over certain tobacco products may be a contributing factor. ***Without a common regulatory framework, tobacco firms can exploit differences in regulatory requirements to drive consumers to different product markets.*** (p. 23147) [emphasis added]

FDA provides ample scientific evidence demonstrating that regulating one subset of tobacco products differently from another causes consumers to substitute the product with no or less stringent regulations for the more tightly regulated product. Nevertheless, FDA proposes in Option 2 to regulate one subset of cigars differently from other cigars and other tobacco products, despite FDA's acknowledgement that large and so-called "premium cigars" are at least as addictive, toxic, carcinogenic, and attractive to youth as cigarettes (p. 23150, 23151, 23254, Section VII.E, 23167-23170). FDA provides no scientific justification for this illogical proposal. Indeed, all the evidence that FDA cites is *against* this proposal.

Even if it were true that only "adults" smoke premium cigars, the FSPTCA's mandate is to protect "the population as a whole," not only youth.

If the FDA was to adopt Option 2 exempting premium cigars from regulation, these cigars could be legally marketed to youth since the minimum age restrictions that apply to other tobacco products would not apply, tobacco companies could legally drive youth to this easily available nicotine delivery product. In particular, failing to include premium cigars in the final regulation would allow tobacco companies to legally take advantage of the fact, as they did when cigarillos were excluded from regulation, and make premium cigars even more attractive by using kid-friendly flavors and marketing techniques that will attract youth and other vulnerable populations. Thus, Option 2 would increase the likelihood that nonusers will initiate using these products, and will decrease the likelihood that current users will quit using these products.

A $10 price point for premium cigars would be neither meaningful nor effective to deter youth or other vulnerable populations from using these lethal tobacco products. Manufacturers have demonstrated great resourcefulness in finding ways around price points, and would certainly figure out a way to make this work to their advantage. Also, with a pack of cigarettes costing more than $14 in New York and $10 per pack in at least six other states, and with at least 38 states hitting the $6 per pack mark;[*] a $10 price point for cigars would not be a deterrent to

[*] http://www.theawl.com/2013/07/what-a-pack-of-cigarettes-costs-now-state-by-state (accessed May 31, 2014)

smokers. (Indeed, premium cigars could become the low cost alternative for smokers regardless of age.)

Arcane volume/rate restrictions would be very difficult to enforce, and tobacco companies have already devised ways to work around weight restrictions to evade taxes and other regulations; therefore, all of these proposals would be ineffective.

Option 2 would also exclude a category of cigars from the health warning label requirements, which would have public health implications for adults and youth. Additionally, by creating this Option 2 exemption for some cigars, FDA gives tobacco manufacturers an opportunity to game the system to make sure that their cigar products meet the definition of "premium cigars" (p. 23150, 23203, 23204) that would evade FDA regulation.

The proposed rule requires warning statements to appear on the packages and in the advertisements for all proposed newly covered tobacco products. However, since some large and premium cigars are sold in cellophane wrappers and not in boxes or packages, and since warning labels are required for the packages only, many products will not be required to include warning labels. Section 1143.5 requires packages of cigars to bear certain warning statements. Option 1 would require the warnings on all cigars, but **Option 2 would exclude "premium cigars" from the warning label requirements, something clearly not appropriate for the public health.**

Even under Option 1, cigars that are sold individually and not in a product package are not required to bear a warning statement; instead, the required warning statements "must be posted at the retailer's point-of-sale" in accordance with certain specifications (section 1143.5(3), p. 23206). Specifically, the proposed rule describes the size of the sign being a minimum of 8.5 x 11 inches and requires placement within 3 inches of each cash register. This warning is inadequate. **Since the cigars are sold in cellophane wrappers, the warning labels could and should be affixed to or inside the wrappers in a way that is clearly visible to potential purchasers.**

Failing to include warning labels on premium cigars could also put the FDA in the position of misleading consumers into thinking that premium cigars are safe, or at least safer than other tobacco products. An absence of warning on a tobacco product, especially coupled with the presence of warning labels on all other tobacco products, might be interpreted by the consumers as a tacit approval of the product by the agency or as the product being "safe." In one qualitative study with older adults (45+ years old) it was found that older smokers see current warning labels on cigarettes as "totally ineffective" and see the lack of warnings on e-cigarettes as an endorsement of their safety. (Cataldo, J.K. Sheon, N., Hunter, M., Petersen, M.A. (2014) Risk and Benefit Perceptions in the Use of Conventional and Emerging Tobacco Products Among Older Smokers, NIH/FDA Tobacco Regulatory Science Conference, Bethesda, MD, April 28,2014)

While not dealing with tobacco, one study of the effects of the FDA disclaimer used since passage of the Dietary Supplement Health and Education Act which exempted the supplement industry from stricter regulation required of foods and drugs illustrates the consumer misinformation that Option 2 could create. To foster consumer understanding that the FDA was not regulating dietary supplements, the FDA requires a disclaimer to be included which explains that the FDA has not evaluated the claim and the product is not intended to treat or cure any disease. Mason and Scammon* conducted a conducted thirty in-depth interviews conducted among a diverse sample of product users in order to attain a contextualized view of consumer responses to how the FDA disclaimer was perceived by consumers. They reported:

> Informants also reacted with disbelief about the disclaimer. Their disbelief stems partially from familiarity with the marketplace regulations for foods and drugs. ... a general absence of warnings on supplement labels (as there is no requirement for safety testing, there is often no basis for warnings) apparently implies for some consumers a sense of product safety. When discussing the risks of health products, several informants made direct comparisons to the warnings and potential side effects listed on drug products and advertising, and the absence of these items on supplements. *They did not attribute this dissimilarity to different regulatory standards, but rather differences in product safety.* Many informants expressed an "expectation of protection" in their market interactions and assumed health-related products and messages to be overseen by regulatory authorities despite the contradictory information in the disclosure:
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> The truth is anything that's on the shelf has been checked by the FDA. It wouldn't be there if it weren't safe. #13, female, 43 yrs.
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> If it's on the shelf and it has this percentage on it [FDA mandated fact panel listing nutrition content], it's been tested. If it hasn't been tested, it will be tested…I can't remember what governs all the supplements, but they will have it tested. #7, male, 22 yrs.
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> It [the disclaimer] means it's [the supplement] not very strong. You don't have to worry about it, otherwise the FDA would regulate it… Supplements aren't dangerous or I'd need a prescription. Wal-Mart, GNC, they sell it. It isn't going to hurt you or the companies would have been put out of business. #27, male, 38 yrs.

While this was a study of a different product, it is reasonable to conclude that Option 2 would result in the FDA misleading consumers of all ages into thinking that premium cigars were safe or at least much less dangerous than other tobacco products.

There are no specific instructions for internet sales, but since the proposed rule describes the size of the sign being a minimum of 8.5 x 11 inches and requires placement within 3 inches of each cash register, clearly internet sales were not considered in the drafting of this provision. Therefore, any cigars sold on the internet that are sold in individual packages would not bear health warnings, unless the internet sales website is considered an "advertisement" under section 1143.5(b). **These provisions are unclear at best, and most likely would allow cigars sold individually on the internet to evade any kind of health warning label.**

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* MARLYS J. MASON and DEBRA L. SCAMMON. Unintended Consequences of Health Supplement Information Regulations: The Importance of Recognizing Consumer Motivations. *Journal of Consumer Affairs* 2011; 45 (2): 201–223. Article first published online: 3 JUN 2011 | DOI: 10.1111/j.1745-6606.2011.01200.x. http://onlinelibrary.wiley.com/doi/10.1111/j.1745-6606.2011.01200.x/abstract

For these reasons, the FDA should act consistently with the scientific evidence it presents in the draft rule and reject Option 2. All cigars should be treated equally in the regulation of tobacco products.