

May 17, 2017

The Honorable Thomas E. Price, M.D.
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Price:

We write to express our concern that the administration appears to be taking steps to reconsider the U.S. Food and Drug Administration (FDA) “deeming rule” extending the agency’s regulatory jurisdiction to electronic cigarettes, cigars and other tobacco products not previously regulated and is delaying implementation of important provisions of the rule, to the detriment of public health.¹ The deeming rule was the product of a multi-year rulemaking proceeding and is supported by overwhelming evidence in the administrative record at the FDA and strongly defended as essential to public health by the U.S. Department of Justice (DOJ) in *Nicopure Labs LLC v. FDA*, a pending industry challenge to the rule. The public health justification for regulation is as compelling now as it was a year ago, when the FDA issued the final deeming rule. There is, therefore, no basis for a reconsideration of the rule or a failure to defend it strongly in court. Every day of delay in its full implementation subjects the public to the continuing public health threat of unregulated, highly addictive and dangerous tobacco products, many of which come in sweet or candy flavors which are designed and marketed to appeal to children.

Twice in recent months the DOJ has requested extensions of time to file motions for summary judgment dismissing pending tobacco industry legal challenges to the deeming rule, citing the change in administration and new leadership at the U.S. Department of Health and Human Services (HHS) as requiring additional time to “more fully consider” the issues raised by these challenges. The first such motion was filed, with the industry plaintiffs’ consent, on March 1, 2017, in *Cyclops Vapor 2, LLC v. FDA*, resulting in a 60-day extension of time to file the government’s summary judgment papers. A motion for an extension of time was also filed at that time by the government jointly with the industry plaintiffs in *Cigar Association of America v. FDA*. That extension also was granted, as was an extension in *Sanchez Icaza and Global Premium Cigars v. FDA*. Then, on May 1, 2017, facing new deadlines for its summary judgment

¹ See Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. at 28973 (May 10, 2016) (the “deeming rule”).

motions, the DOJ filed joint motions with the industry plaintiffs seeking another three-month extension of all pending deadlines in the three cases.

Significantly, the FDA announced on May 1 that it will defer enforcement of all future compliance deadlines for e-cigarettes, cigars and all other products affected by the deeming rule, for three months, to “allow new leadership at the FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the final rule that are now the subject of multiple lawsuits in federal court.” The FDA announcement states that its action will extend compliance dates for such fundamental requirements as the submission of plans for implementation of cigar health warning labels, ingredient listing, the production of documents on the health effects of products, substantial equivalence and premarket tobacco applications and the reporting of harmful and potentially harmful product constituents.

There is no legal or policy reason to delay implementation of any provision of the deeming rule, or to reconsider the government’s strong legal defense of the rule. As the following discussion demonstrates as to e-cigarettes and cigars, the two primary tobacco products at issue in the pending cases, the importance of the rule for the protection of public health is evident from both the extensive administrative record compiled by the FDA as well as the record evidence cited in the DOJ summary judgment brief in the *Nicopure Labs* case.

As to e-cigarettes and related products, the record cited by the FDA in the May 2016 final rule, and the record cited by the government in the DOJ brief in support of its summary judgment motion in the *Nicopure Labs* case, make a compelling case for regulation.² According to the DOJ, the recent “explosion in virtually unregulated [e-cigarette] products raises significant public health concerns.”³ These concerns include the growing prevalence of e-cigarette use among youth, their addictiveness due to nicotine delivery comparable to conventional cigarettes, the toxicity of nicotine and its significant risk of adverse effects on pregnant women and the still-developing adolescent brain, the divergence of actual nicotine content from labeled content, the inhalation risks of certain e-liquid ingredients, including certain flavorings, the risk of battery explosion and resulting injury, and the potential harm to nonusers of secondhand aerosol containing nicotine.⁴

The DOJ brief also cited the record evidence that “[i]n contrast to conventional cigarettes, which are permitted in only two characterizing flavors – tobacco and menthol – a staggering 4,000 to 8,000 different varieties of e-liquid ... are now sold in the United States” and “[m]any of these are fruit or candy flavored, magnifying ‘their appeal to youth and young adults.’”⁵ The DOJ also cited evidence that 73 percent of brands offer fruit flavors and 71 percent offer candy

² See Memorandum in Opposition to Plaintiffs’ Motions for Summary Judgment and in Support of Defendants’ Cross-Motion for Summary Judgment, *Nicopure Labs, LLC v. FDA and Right to be Smoke-Free Coalition v. FDA* (consolidated), CA Nos. 16-878, CA No. 16-1210 (D.D.C. filed August 16, 2016) (“DOJ Brief”).

³ DOJ Brief at 10.

⁴ *Id.* at 9-15.

⁵ *Id.* at 10 (citing 81 Fed. Reg. at 29,011).

flavors; indeed, the three top-selling flavors at e-liquids.com, a large online retailer, are “Unicorn Milk” (strawberries and cream), “TNT” (strawberry, apple and peach) and “I Love Donuts” (blueberries and pastry).⁶ According to the FDA’s Population Assessment of Tobacco and Health (PATH) study, 85.3 percent of current e-cigarette users aged 12-17 had used a flavored e-cigarette in the past month and 81.5 percent of current youth e-cigarette users said they used e-cigarettes “because they come in flavors I like.”⁷

The appeal of these flavored products to young people has been magnified by e-cigarette marketing. The DOJ brief cites abundant evidence of record that “e-cigarette advertising specifically targets youth, mimicking the strategies previously used by ‘Big Tobacco’ – to devastating effect – and thus banned for conventional cigarettes.”⁸ The DOJ cites several examples, including advertising during events and programming with high levels of youth viewership, advertising using celebrity endorsements to depict e-cigarette use as “glamorous, rebellious, sexy, and masculine,” and the distribution of free samples at events geared toward youth, including concerts, music festivals, parties and sporting events.⁹

Given the proliferation of flavored products and these youth-targeted marketing strategies, it is hardly surprising that, as the DOJ points out, the record evidence demonstrates a dramatic spike in youth usage of e-cigarette products: from 2011 to 2014, current use by high school students rose eight-fold, from 1.5 to 13.4 percent.¹⁰ By 2014, e-cigarettes had eclipsed conventional cigarettes as the most widely used tobacco product among youth, with more than 2.4 million current users in middle and high school alone.¹¹

As to cigars, the FDA also found compelling evidence that cigars pose significant health risks, including the risk of addiction, and that they are increasingly available in candy and fruit flavors that appeal to children, predictably resulting in rates of cigar smoking among young people that remain high, despite declining rates of cigarette smoking. The FDA found that cigar smoke contains many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds.¹² All cigar smokers have an increased risk of oral, esophageal, laryngeal and lung cancer compared with non-tobacco users, as well as a higher risk of chronic obstructive pulmonary disease (COPD) and stroke as compared with non-smokers. Moreover, cigars emit harmful secondhand smoke.¹³ Cigars also are powerfully addictive, due to their delivery of nicotine. A single cigar can contain as much tobacco as an entire pack of cigarettes and nicotine yields from smoking a cigar can be up to eight times higher than yields

⁶ *Id.* at 10.

⁷ Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015. Study cited at 81 Fed. Reg. at 29014.

⁸ DOJ Brief at 15.

⁹ *Id.* at 15-16.

¹⁰ *Id.* at 9.

¹¹ *Id.*

¹² 81 Fed. Reg. at 29020.

¹³ *Id.*

from smoking a cigarette.¹⁴ Citing the conclusions of the Surgeon General, the FDA also concluded that all cigar products, including so-called “premium cigars,” pose serious risk of disease and are addictive.¹⁵

The FDA also found the prevalence of cigar smoking among young people to be of particularly serious concern. National surveys show that 8.2 percent of high school students and 1.9 percent of middle school students had smoked cigars in the past 30 days.¹⁶ In fact, more than 2,500 persons under the age of 18 smoke their first cigar each day.¹⁷ Because cigar smoking prevalence has declined much less dramatically than cigarette smoking among youth, the prevalence rates are now comparable. In 2014, for example, the prevalence of current cigar smoking was slightly greater than cigarette smoking among high school boys.¹⁸ There is little doubt that the continuing high rates of youth cigar smoking are largely due to the industry’s successful strategy of flavoring their products to make them appealing to kids. According to the FDA’s PATH study, 71.7 percent of current cigar smokers aged 12-17 had used a flavored cigar in the last month; 73.8 percent of these current youth cigar smokers said they smoked cigars “because they come in flavors I like.”¹⁹

In light of the overwhelming record evidence compiled by the FDA, persuasively presented as to e-cigarettes by the DOJ in the *Nicopure Labs* case, there is no public health justification for the FDA to reconsider the deeming rule, or to postpone the implementation of its provisions. We urge you to ensure that the deeming rule is implemented in accordance with its provisions, as well as to make certain that a strong defense of the rule is maintained against industry attack in court.

Sincerely,

¹⁴ *Id.* at 29022.

¹⁵ *Id.* at 29020-29022.

¹⁶ *Id.* at 28985.

¹⁷ *Id.*

¹⁸ *Id.* at 29023.

¹⁹ Ambrose, *supra* at note 9.

Action on Smoking & Health
 American Academy of Family Physicians
 American Academy of Oral and
 Maxillofacial Pathology
 American Academy of Pediatrics
 American Association for Cancer Research
 American Association for Dental Research
 American Association for Respiratory Care
 American Cancer Society Cancer Action
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 Gynecologists
 American Dental Association
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 Society for Public Health Education
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 The Society of State Leaders of Health and
 Physical Education
 Tobacco Control Legal Consortium
 Trust for America's Health
 Truth Initiative
 United Methodist Church- General Board of
 Church and Society

CC: Scott Gottlieb, M.D., Commissioner of Food and Drugs