

August 8, 2014

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Docket No. FDA-2014-N-0189

Dear Commissioner Hamburg:

The Tobacco Control Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the proposed deeming regulation to assert jurisdiction over non-cigarette tobacco products. The Tobacco Control Legal Consortium is a national network of nonprofit legal centers providing technical assistance to public officials, health professionals and advocates concerning legal issues related to tobacco and public health.¹ The Consortium is joined in submitting these comments by the Tobacco Technical Assistance Consortium² and Boston Public Health Commission.

As a result of five decades of increasingly stringent regulation and effective education, mostly at the state and local level, cigarette sales have declined steadily.³ Unfortunately, the tobacco industry has been quick to adapt to keep consumers addicted. Proving their business savvy, manufacturers have been adding to their product lines tobacco products designed to escape the more effective regulations applicable to cigarettes and smokeless tobacco. Other businesses have

¹ Other affiliated legal centers include ChangeLab Solutions in Oakland, California; the Legal Resource Center for Tobacco Regulation, Litigation & Advocacy at the University of Maryland School of Law in Baltimore, Maryland; the Tobacco Control Resource Center, a project of the Public Health Advocacy Institute at Northeastern University School of Law in Boston, Massachusetts; the Smoke-Free Environments Law Project at the Center for Social Gerontology in Ann Arbor, Michigan; the Public Health Law Center at the William Mitchell College of Law in Saint Paul, Minnesota; the Tobacco Control Policy and Legal Resource Center at New Jersey GASP in Summit, New Jersey; and the Center for Public Health and Tobacco Policy at New England Law in Boston, Massachusetts, which provides technical assistance to communities in the states of New York and Vermont.

² Now part of the Emory Centers for Training and Technical Assistance at the Rollins School of Public Health, Emory University.

³ Gregory Connolly, *Trends in the Use of Cigarettes and Other Tobacco Products, 2000-2007*, 299 JAMA 2629 (2008); see also, FED. TRADE COMM'N, CIGARETTE REPORT FOR 2009 AND 2010 (2012), available at <http://ftc.gov/os/2012/09/120921cigarettereport.pdf>.

also entered the market with their new, non-cigarette tobacco products. As sales of these products increase and expose the public to the harms that they cause, the need for federal regulation has become critical. FDA action is overdue. The agency must take steps to regulate the manufacturing, marketing and sale of currently unregulated tobacco products that have already secured a place on the market and must prevent new products – particularly those marketed with youth-attractive flavors – from eroding public health gains achieved by existing tobacco product regulation. The proposed regulation must fulfill the FDA’s congressional mandate to protect the public health by preventing initiation by non-users and increasing cessation among users of tobacco products.⁴

Current trends in tobacco product development underscore the need for effective federal regulation. Some non-cigarette tobacco products, such as cigars and “little cigars,” have an established presence in the marketplace and have enjoyed steady or increasing sales as cigarette sales decline.⁵ Emerging tobacco products, such as dissolvable tobacco products, e-cigarettes, and hookah, enter the market unencumbered by restrictions designed to limit the enticement of youth, reduce youth access or deter adult consumption. These products, often sold in flavors designed to attract youth, present the threat of addiction disease, and death, requiring federal regulators to take action. While state and local jurisdictions have adopted some restrictions to address the threat posed by the unregulated tobacco products,⁶ the FDA has the power, ability, and duty to adopt broad regulations to protect public health throughout the United States.

Continued failure to implement comprehensive regulation of these products will provide the tobacco industry with free reign in designing, marketing and selling tobacco products that entice and addict young people through many of the tactics long-forbidden with respect to cigarettes. The proposed deeming regulation is inadequate. The public health community insists that FDA strengthen the regulation now rather than creating further delays by leaving critical issues for a subsequent rule-making process;⁷ a piecemeal approach jeopardizes public health and benefits the tobacco industry. This sentiment is shared by members of both houses of Congress.⁸ In addition, the FDA must use its enforcement discretion to curb the health harms in the near term, while the developing robust regulations for long-term protection of the public’s health.

⁴ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776, 1796 (2009) (codified at 21 U.S.C. § 387f(d)(1)) [hereinafter Tobacco Control Act].

⁵ Connolly, *supra* note 1, at 2629; *see also*, FED. TRADE COMM’N, CIGARETTE REPORT FOR 2009 AND 2010 (2012), available at <http://ftc.gov/os/2012/09/120921cigarettereport.pdf>; Letter from Henry Waxman, Ranking Member of the U.S. House of Representatives Comm’n on Energy & Commerce, to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (Aug. 27, 2012), available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Hamburg-Cigar-Use-Study-2012-8-27.pdf>.

⁶ *See, e.g.*, SANTA CLARA CNTY., CAL., ORDINANCE CODE, tit. A, ch. XXIII, § A18-369(h); N.Y.C., N.Y., ADMIN. CODE, tit. 17, 17-713–17-718 (2013); PROVIDENCE, R.I., CODE OF ORDINANCES, § 14-309.

⁷ The Citizens' Commission to Protect the Truth has similarly requested the FDA to "bring all tobacco products within the regulatory regime established by the Family Smoking Prevention and Tobacco Control Act" and expressed frustration with the agency's public statement of intent to regulate without any such action. *See* Letter from Joseph A. Califano, Jr., Chairman, Citizens' Comm’n to Protect the Truth, to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (Oct. 1, 2012), available at www.protectthetruth.org/downloads/20121001commltr.pdf.

⁸ Letter from Richard J. Durbin, et al., U.S. Senators, to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (April 16, 2013) available at http://www.durbin.senate.gov/public/index.cfm/files/serve?File_id=90eae776-6b4f-471b-a2d2-fe1525d2ed74; Waxman letter, *supra* note 3.

In recognition of the ongoing devastating health harms and economic burdens caused by tobacco use⁹ and the failure of previous tobacco control efforts to adequately curb tobacco use among young people,¹⁰ Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) in 2009, granting the FDA the jurisdiction to regulate the manufacture, sale, distribution, advertising, and promotion of tobacco products.

The Tobacco Control Act grants the FDA the authority to regulate all tobacco products, including all tobacco products currently marketed in the United States. However, in its charge to the FDA, Congress only required the FDA to regulate cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. To tackle the substantial public health harms of all other tobacco products, the FDA must take an affirmative step and issue a rule asserting jurisdiction over those products. This jurisdiction includes the authority to adopt tobacco product standards and establish restrictions on the sale, distribution, advertising and promotion of tobacco products that are “appropriate for the protection of the public health.”¹¹ In finding that a product standard is appropriate for the public health, the FDA is required to take a broad, population-level view that takes into consideration “the increased or decreased likelihood that those who do not use tobacco products will start using such products;” “the increased or decreased likelihood that existing users of tobacco products will stop using such products;” and, ultimately, “the risks and benefits to the population as a whole, including users and nonusers of tobacco products.”¹²

The significant health harms caused by some newly-covered products are well-documented, as is their impact on initiation and use in combination with other products (known as “dual-use”). The scientific evidence regarding the prevalence of use of these products and the harms caused by these products compel FDA regulation. For other newly-covered products, there is less information available regarding their impact on both individual- and population-level harm. While opponents of regulation have taken this lack of evidence of harm as evidence of safety and argued that the situation calls for no federal oversight, the lack of information underscores the need for FDA action because regulation allows the agency to gather more information, including information from the manufacturers who would not otherwise disclose it.

The lack of federal regulation to date has allowed tobacco companies and retailers to market these harmful products to children including by adding fruit and candy flavors, and to make false and unfounded claims about reduced harm. Unfortunately, the FDA’s proposed regulation fails to effectively address many of these problems. Instead, it caters to the interests of the very same businesses that prey on children. The FDA must not only assert jurisdiction over and regulate all tobacco products, it must significantly strengthen the current proposal to protect public health.

I. The proposed deeming regulation fails to adequately protect public health.

While finalizing the deeming regulation is an important first step toward fulfilling the promise of the Tobacco Control Act, there are significant failures and flaws in the proposed deeming

⁹ Tobacco Control Act, § 2 (1)-(2),(13)-(14), 123 Stat. 1776, 1777 (codified at 21 U.S.C. § 301).

¹⁰ Tobacco Control Act, § 2 (6)-(7), 123 Stat. at 1777 (codified at 21 U.S.C. § 301).

¹¹ Tobacco Control Act § 907(a)(3)(A), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(A)); Tobacco Control Act § 906(d)(1), 123 Stat. 1796 (codified at 21 U.S.C. § 387f(d)(1)).

¹² Tobacco Control Act, §907(a)(3)(B)(i)(I)-(III), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)-(III)).

regulation that must be addressed before a final rule is adopted. First, the proposed regulation fails to protect youth. It does this first by omitting any restriction on flavors in the newly-covered tobacco products, despite significant evidence of the appeal to youth and a restriction on flavored cigarettes. In addition, the regulation fails to protect youth by proposing utterly anemic warning labels, ignoring the urgent need for marketing and advertising restrictions, neglecting to prohibit self-service access to the newly-covered products, and overlooking child-resistant packaging requirements. Second, the FDA's proposed regulation fails to address the exploding market for e-cigarettes, omitting critical product definitions and disregarding burgeoning mix-your-own e-cigarette retailer practices completely. Finally, the FDA's proposed regulation prioritizes private business interests over public health by proposing unnecessarily lengthy implementation timelines for the new requirements and creating a loophole in the product approval process that will allow unapproved tobacco products to be marketed and sold for years while product applications languish at the FDA.

II. FDA authority under the Family Smoking Prevention and Tobacco Control Act

Under the Tobacco Control Act, Congress gave the FDA broad regulatory authority over all tobacco products.¹³ In the Act, Congress established requirements applicable “to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.”¹⁴ To date, the FDA has regulated only the products that it is required to by the Tobacco Control Act – cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. To regulate other tobacco products, the FDA must adopt a regulation that deems those products to be subject to regulation.¹⁵ On April 25, 2014, nearly five years after the passage of the Tobacco Control Act, the FDA finally proposed a regulation asserting jurisdiction over other tobacco products, taking a first step to address the public health hazards posed by products such as cigars, dissolvables, e-cigarettes and hookah. The authority to subject these other products to FDA regulation is made explicit in the Tobacco Control Act and is limited only by the very broad definition of “tobacco product.” Under the Food, Drug, and Cosmetic Act, as revised by the Tobacco Control Act, a tobacco product is, “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product. . . .”¹⁶

While the public health community supports the FDA's first step to regulate additional tobacco products, the agency must do more than is proposed to fulfill its clear mandate from Congress to protect public health.¹⁷ This requires a new approach at the FDA, an agency that has traditionally used a “safe and effective” standard to evaluate drugs and medical devices.¹⁸ Congress recognized the impossibility of applying this standard to tobacco, so the Tobacco Control Act establishes a public health standard of review that is entirely different from the “safe and effective” standard described above. In establishing new tobacco product regulations, Congress directs the FDA to determine that a regulation is “appropriate for the protection of public health”

¹³ See Tobacco Control Act 123 Stat. 1776, 1786-87 (2009) (codified at 21 U.S.C. § 387).

¹⁴ Tobacco Control Act, § 901(b), 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)).

¹⁵ Tobacco Control Act, § 901(b), 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)).

¹⁶ Tobacco Control Act, § 101(a), 123 Stat. at 1783 (codified at 21 U.S.C. § 321(rr)(1)).

¹⁷ Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)).

¹⁸ H.R. REP. NO. 111-58, pt. 1, at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488, *available at* <http://www.gpo.gov/fdsys/pkg/CRPT-111hrpt58/pdf/CRPT-111hrpt58-pt1.pdf>.

and frames this requirement in terms of “risks and benefits to the population as a whole” and “increased or decreased likelihood” of tobacco product cessation or initiation.¹⁹ Congress intended this new “public health standard” to be a “flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products.”²⁰ Because the products that would now be regulated pose risks of death and disease, the FDA must not only assert jurisdiction over these products but also impose additional requirements. An assessment of what is “appropriate for the public health,” as defined by the Tobacco Control Act, involves broad considerations,²¹ requiring: 1) consideration of the *likely* impact of a product standard on smoking initiation and cessation, analyzed in the context of the serious health effects of tobacco use, and 2) a weighing of the anticipated risks and benefits to the entire population, including nonusers of tobacco.²²

III. The proposed deeming regulation fails to protect youth.

a. The FDA should establish a product standard prohibiting all flavors – including menthol – in all tobacco products.

The Tobacco Control Act explicitly prohibits all characterizing flavors in cigarettes except menthol and tobacco.²³ While Congress focused its attention on the wide range of fruit- and candy-flavored cigarettes, it did not expressly extend the flavor prohibition to other tobacco products.²⁴ This is an obvious gap that could be closed by agency regulation.

The FDA can and should prohibit all flavors in all tobacco products, including menthol. There is no limitation in the Act that would prevent the FDA from prohibiting the use of mint and menthol flavoring in all tobacco products and there is no rational basis for excluding them from such a prohibition.²⁵ Rather, there is extensive evidence showing that menthol cigarettes are the

¹⁹ Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)); *see also* Tobacco Control Act, §907(a)(3)(B)(i)(I)-(III), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)-(III)).

²⁰ H.R. REP. NO. 111-58, pt. 1, at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488, *available at* <http://www.gpo.gov/fdsys/pkg/CRPT-111hrpt58/pdf/CRPT-111hrpt58-pt1.pdf>.

²¹ Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)). For example, the 2004 Surgeon General Report separated causal conclusions from public health recommendations, “decoupling [that] is necessary, as decision-making in the face of uncertainty involves different issues than those that pertain to the uncertainty itself. . . .” U.S. DEP’T OF HEALTH & HUMAN SERVS., *THE HEALTH CONSEQUENCES OF SMOKING: A REPORT OF THE SURGEON GENERAL* 24 (2004), *available at* <http://www.surgeongeneral.gov/library/reports/smokingconsequences/index.html>. The report notes that public health recommendations are necessarily informed by broader considerations than “conclusions regarding causality”: “The proportion of cases in the population as a result of exposure (the population attributable risk), along with the total prevalence and seriousness of a disease, are more relevant for deciding on actions than the relative risk estimates typically used for etiologic determinations.” *Id.* at 18.

²² Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1))(emphasis added).

²³ Tobacco Control Act § 907(a)(1)(A), 123 Stat. at 1799 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)).

²⁴ This was the first substantive provision of the Tobacco Control Act to become effective Sept. 22, 2009 and the FDA acted promptly in giving industry notice and guidance and in conducting enforcement. Press Release, U.S. Food & Drug Admin., *FDA Warns Companies Against Marketing Illegal Flavored Cigarettes* (Nov. 6, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm189436.htm>. Although menthol and tobacco flavorings were excepted, there are no other exceptions and no existing products were grandfathered in, regardless of how long they had been on the market and regardless of the demographics of users. *Id.*

²⁵ Although Congress chose to exempt menthol cigarettes from the prohibition—after a hard-fought political battle—it gave the FDA power to prohibit menthol cigarettes. Congress also mandated that TPSAC undertake a

source of addiction for nearly half of all teen smokers.²⁶ Menthol increases the palatability of smoking, especially among youth and members of racial and ethnic populations, and menthol increases the difficulty of quitting. There is also evidence that trying flavored non-cigarette tobacco products is related to increased rates of youth smoking. A recent study of flavored tobacco product sales concluded: “Ever trying flavored tobacco products were strongly associated with current smoking among teens. The findings from this study suggest that regulations prohibiting sales of flavored tobacco products could decrease youth smoking.”²⁷

The reasons that support prohibiting the sale of sweet or candy-flavored cigarettes also apply to flavored non-cigarette tobacco products. As the FDA’s own *Parental Advisory on Flavored Tobacco Products* states, flavored tobacco products:²⁸

- Appeal to kids.
Young people are much more likely to use flavored tobacco products than adults, and tobacco industry documents show that companies have designed flavored cigarettes with kids in mind. For example, one tobacco company suggested creating a honey-flavored cigarette to attract teenagers who like sweet products.
- Disguise the bad taste of tobacco.
Candy and fruit flavors mask the bad taste of tobacco, making it easier for kids to start using tobacco products. Once they start using one tobacco product, however, they are more likely to experiment with others.
- Are just as addictive as regular tobacco products.
Scientists have found that many kids think flavored tobacco products are safer and less addictive than regular tobacco products. This is not true. All tobacco products

study of certain questions related to menthol cigarettes. In its report, TPSAC concluded that “menthol is not simply a flavoring agent but has drug-like characteristics that modulate the effects of nicotine on the smoker.” TOBACCO PRODS. SCIENTIFIC ADVISORY COMM., MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS 24 (2011), *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>. TPSAC expresses concern over the use of menthol to entice new smokers and sustain addiction in current smokers, particularly in some vulnerable populations. *Id.* at 23-27. And the Committee finds that marketing of menthol cigarettes contributes to consumers’ misperception of menthol products as less harmful. *Id.* at 91-92. Although research is nascent on the impact of menthol in OTPs, it is logical to conclude that these same concerns apply to the use of menthol in OTPs. When viewed through the public health lens and in light of the breadth of the FDA’s power, any flavored prohibition for OTPs ought to include menthol and mint flavorings. Hence, throughout this comment, the request for a prohibition on flavored non-cigarette tobacco products includes menthol and mint. The Tobacco Control Legal Consortium has filed a Citizens’ Petition requesting that the FDA prohibit the sale of menthol cigarettes. TOBACCO CONTROL LEGAL CONSORTIUM ET AL., CITIZEN PETITION: ASKING THE U.S. FOOD AND DRUG ADMINISTRATION TO PROHIBIT MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES, Docket No. FDA-2013-P-0435 (May 15, 2013) [hereinafter Menthol Citizen Petition], *available at* <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fdacitizenpetition-menthol-2013.pdf>. That petition contains a more thorough description of the scientific and public health reasons for prohibiting mint and menthol flavoring in tobacco products. Therefore, that petition is incorporated by reference in this comment.

²⁶ Menthol Citizen Petition, *supra* note 23.

²⁷ Shannon M. Farley, et al, *Teen Use of Flavored Tobacco Products in New York City* NICOTINE TOBACCO RES. 1 (published online ahead of print) doi:10.1093/ntr/ntu126 (2014).

²⁸ U.S. FOOD & DRUG ADMIN., FDA ADVISORY, FLAVORED TOBACCO PRODUCTS—WHAT YOU NEED TO KNOW, *available at* www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/UCM183262.pdf.

contain nicotine, the primary addictive chemical that makes it so hard to quit using tobacco.

- Have the same harmful health effects as regular tobacco products. Flavored cigarettes, cigars and pipes are not less dangerous than regular tobacco products. Smoking any kind of tobacco product increases your risk of developing serious health problems, including lung cancer, heart disease and emphysema. Tobacco products that you don't smoke, like snuff and chewing tobacco, have also been shown to cause gum disease and cancers of the mouth.

The FDA's advisory committee's conclusions regarding the appeal and harm of flavored tobacco products are strongly supported by scientific research.²⁹ While adults use flavored products as well, these products are clearly designed to appeal to youth. This intent is made more obvious by the marketing, which is designed to entice young people to try the product, and the flavors, which make it easier for youth to smoke or use smokeless products.³⁰ Internal tobacco industry documents have established a long history of the use of flavored cigarettes to attract children.³¹ Failing to extend a prohibition on flavors to other products ignores this blatant industry tactic to hook youth on tobacco products.

Flavorings also form the basis of youth-enticing marketing campaigns. For example, Apple Blend Skoal Chew promotions assert that the product will “combine rich, premium tobacco with the crisp flavor of juicy apples,”³² available in a pouch similar to a tea bag. One manufacturer's little cigar is marketed as containing “a nice punch of ‘wild raspberry’ to tantalize the taste buds.”³³ Advertisements and packaging employ stylish designs and bright colors that further emphasize the flavor and entice youth.³⁴ In fact, nearly every aspect of the marketing for these flavored tobacco products is strikingly similar to the marketing used for similarly flavored candies and sweetened beverages. That kids like flavored tobacco products is supported by the target audience itself. One teen described Cherry Skoal as “a beginner's product that helped me

²⁹ Carrie M. Carpenter et al., *New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies*, 24 HEALTH AFF. 1601, 1608 (2005); see also Joseph A. Califano, Jr. & Louis W. Sullivan, Editorial, *The Flavor of Marketing to Kids*, WASH. POST, June 29, 2006, at A27 (“By masking the regular tobacco flavor and scent, flavored cigarettes make it even more appealing for a 12- or 13-year old to take that initial puff and keep smoking until he or she gets hooked.”).

³⁰ Stacy M. Carter & Simon Chapman, *Smokers and Non-smokers Talk About Regulatory Options in Tobacco Control*, 15 TOBACCO CONTROL 398 (2006).

³¹ Memorandum on New Flavors Sensations from A.B. Hudson to P.T. Sherman (July 3, 1978), available at <http://legacy.library.ucsf.edu/tid/tlp76b00/pdf>; Memorandum on Unique Flavored Cigarettes from Kenneth W. Swicegood to Susan McReynolds (June 27, 1979), available at <http://legacy.library.ucsf.edu/tid/htr76b00/pdf>; Memorandum on New Products-Flavored Cigarettes from Tom H. Mau to Andrew H. Tisch (Sept. 6, 1972), available at <http://legacy.library.ucsf.edu/tid/nes46b00/pdf>; Memorandum from Marketing Innovations Corp. to Brown & Williamson Tobacco Corp. on Youth Cigarette – New Concepts (Sept. 1972), available at <http://legacy.library.ucsf.edu/tid/xfq76b00/pdf>.

³² Press Release, U.S. Smokeless Tobacco Co., Skoal Pouches Line Expands with Apple Blend Pouches (May 23, 2005), available at <http://www.csnews.com/%25cat%25skoal-apple-blend-pouches>.

³³ *Pipe Tobacco: Dean's Wild Berry Wide Cigars*, PIPE TOBACCO PLACE, <http://www.pipetobacco.com/deans-wild-berry-wide-cigars-100mm.html> (last visited Aug. 4, 2014, 2:30 PM).

³⁴ Michael Gormley, *Flavored Tobacco Ban in NY Convenience Stores? Cancer Society Says Products Aimed at Kids*, HUFFINGTON POST (May 31, 2013), http://www.huffingtonpost.com/2013/06/01/flavored-tobacco-ban-in-ny-convenience-stores-cancer-society-says-products-aimed-at-kids_n_3371834.html.

gradually go up the ladder.”³⁵ “Cherry is like the kindergarten for Copenhagen,” said another high school boy.³⁶

In addition to flavored product use by youth, many adults and subpopulations of adults are also attracted to flavored products. The attractiveness of flavored tobacco products is supported by a recently published report from the Centers for Disease Control and Prevention (CDC), which found that a substantial proportion, 42.8%, of adult cigar smokers report using flavored cigars. Even more troubling is the CDC’s findings that the prevalence of flavored cigar use among smokers increases with decreasing age, with 57.1% of 18-24 year old smokers reporting use of flavored cigars in comparison to 43.2% of smokers age 25-44, 28.9% of smokers age 45-64, and 13.4% of smokers over age 65.³⁷ It is clear that younger smokers who are in the early stages of developing addiction are the most attracted to flavored products. Moreover, the CDC report found that there are notable disparities in flavored cigar use across subpopulations of cigar smokers, with flavored cigar use higher among female than male cigar smokers (60.8% vs. 39.2%), higher among Hispanic than non-Hispanic white cigar smokers (61.7% vs. 37.9%), and higher among lesbian, gay, bisexual and transgendered individuals than heterosexual cigar smokers (67.0% vs. 41.8%).³⁸ Flavored cigars are used by populations with greater health disparities, making swift action on flavored cigars particularly important.

Additionally, there is evidence suggesting that flavors are contributing to the popularity and growth of the smokeless tobacco market. A study of smokeless tobacco users seeking cessation treatment found that a majority of the subjects currently used a mint-flavored smokeless tobacco product (58.7%) and had initiated smokeless tobacco use with a mint-flavored product (57.7%).³⁹ This study also observed that the likelihood of switching to a flavored smokeless tobacco product after initiating with a non-flavored product was higher than the likelihood of switching to a non-flavored product after initiating with a flavored product.⁴⁰ The importance of flavoring to the prevalence of smokeless tobacco product use is further supported by data indicating that sales of flavored moist snuff products not only increased 72.1% from 2005 to 2011, but also contributed to about 60% of growth in sales in the moist snuff category overall.⁴¹ Each year from 2005 to 2011, flavored products comprised at least 54% of the overall moist snuff market share.⁴² The market share of flavored products is even higher for the subcategory of snus – 79.6% in 2011.⁴³

³⁵ Alex M. Freedman, *Juiced Up: How a Tobacco Giant Doctors Snuff Brands to Boost Their “Kick”*, WALL ST. J., Oct. 26, 1994, at A1.

³⁶ *Id.* Also underscoring the fact that flavored products are marketed to kids is the fact that in 2006, in response to the threat of litigation for violating the Master Settlement Agreement’s prohibition on targeting youth in marketing, R.J. Reynolds agreed to stop selling flavored cigarettes. See R.J. REYNOLDS SETTLEMENT AGREEMENT ON FLAVORED CIGARETTES (2006), available at <http://www.naag.org/assets/files/pdf/20061011.FlavoredTobaccoSettlement.pdf>.

³⁷ Brian A. King et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, 15(9) NICOTINE & TOBACCO RES. 1623, 1625 tbl.1 (2013).

³⁸ *Id.*

³⁹ Andrew J. Oliver et al., *Flavored and Nonflavored Smokeless Tobacco Products: Rate, Pattern of Use, and Effects*, 15(1) NICOTINE & TOBACCO RES. 88, 90 tbl.1 (2013).

⁴⁰ *Id.*

⁴¹ Cristine D. Delnevo et al., *Examining Market Trends in the United States Smokeless Tobacco Use: 2005-2011*, 23 TOBACCO CONTROL 107, 2 (2014).

⁴² *Id.*

⁴³ *Id.* at 4.

Unchecked, the market for flavored tobacco products will continue to grow, leading to an increase in youth initiation and diminishing cessation.

Some state and local governments have taken action to prohibit the sale of flavored tobacco products. The only state that has passed legislation prohibiting the sale of flavored cigars is Maine; that statute is comprehensive and is currently being enforced by the Attorney General of Maine.⁴⁴ New York City passed an even more expansive bill restricting the sale of flavored non-cigarette tobacco products, but exempt menthol, mint and wintergreen.⁴⁵ The prohibited products include flavored cigars and smokeless tobacco products, but the law exempts sales in adult-only facilities.⁴⁶ The City Council's action was prompted by city officials' alarm at the wide array of cigar flavors, like cookie dough, chocolate chip and pink berry, which appeared to target minors.⁴⁷

Other jurisdictions, including Providence, Rhode Island, and Santa Clara County, California, have followed suit with even more comprehensive flavored tobacco product sales restrictions that protect youth.⁴⁸ Both Providence and New York City successfully defended their flavored product provisions against legal challenges brought on the grounds that only the federal government has this authority.⁴⁹ This developing case law provides helpful guidance to other communities considering a sales restriction on flavored tobacco products. However, a piecemeal approach cannot match the public health impact that a nationwide prohibition on flavored tobacco products would have both with respect to decreasing youth initiation and reducing adult tobacco use.

⁴⁴ Me. Rev. Stat. tit. 22, § 1560-D(2) (2011). In addition, Illinois prohibits the sale of flavored wrapping papers, defined as "cigarette papers, blunt wraps, cigar wraps, or tubes of paper or leaf, or any similar device," that have a flavor, other than tobacco or menthol, including "alcoholic or liquor flavor, chocolate, fruit flavoring, vanilla, peanut butter, jelly, or any combination of said flavors or similar *child attractive* scent or flavor." 720 ILCS 685/4 (emphasis added).

⁴⁵ N.Y.C., N.Y., ADMIN. CODE, tit. 17, 17-713 —17-718 (2013). The ordinance is not being enforced with respect to e-cigarettes.

⁴⁶ N.Y.C., N.Y., ADMIN. CODE, tit. 17, 17-713 —17-718 (2013) (regulating the sale of herbal cigarettes and flavored tobacco products, excluding menthol, mint and wintergreen). The New York City provision was challenged on the basis that the provision is preempted by the Tobacco Control Act, but the city prevailed. *U.S. Smokeless Tobacco Manufacturing Co. v. City of New York*, 708 F.3d 428 (2d Cir. 2013) (upholding the ordinance).

⁴⁷ See Testimony of Anne Pearson, Senior Legal Counsel for Policy, Bureau of Tobacco, NYC Dep't of Health & Mental Hygiene, to the NYC Council Comm. on Health (May 21, 2009), available at <http://www.nyc.gov/html/doh/downloads/pdf/public/testi/testi20090521.pdf>.

⁴⁸ SANTA CLARA, CA., ORDINANCE CODE, ch. 23, § A18-369 (2013); PROVIDENCE, R.I., CODE OF ORDINANCES §§ 14-308 *et seq.* (2012). Legislation is pending in other localities. For example, the Board of Commissioners for Miami-Dade County, Florida, took initial steps to gain passage of a flavored tobacco restriction and the legislation remains pending in that county. See Miami-Dade Legislative Item, File No. 121838, Memorandum from R.A. Cuevas, Jr., Cnty. Attorney, to Honorable Chairwoman Rebeca Sosa & Members, Bd. of Cnty. Comm'rs (Oct. 23, 2012), available at <http://www.miamidade.gov/govaction/matter.asp?matter=121838&file=true&yearFolder=Y2012> (indicating passage of the first reader version on May 12, 2012 by a vote of twelve to one).

⁴⁹ *Nat'l Ass'n of Tobacco Outlets v. City of Providence, R.I.*, 731 F.3d 71 (1st Cir. 2013); see also Brief for Public Health Law Center as Amicus Curiae Supporting Defendants, No. 12-96-ML, 2012 WL 6128707 (D.R.I. Dec. 10, 2012)(No. 10-1353), available at <http://www.publichealthlawcenter.org/sites/default/files/resources/amicus-NATO-providence-2012.pdf>; AM. LUNG ASS'N OF CAL., CENTER FOR TOBACCO POL'Y & ORGANIZING, THE NAT'L ASS'N OF TOBACCO OUTLETS (NATO) AND LOCAL ORDINANCES RELATED TO TOBACCO RETAILERS (2012), available at <http://center4tobaccopolicy.org/wp-content/uploads/2013/06/The-National-Association-of-Tobacco-Outlets-and-Ordinances-Related-to-Tobacco-Retailers-July-20121.pdf> (describing this and similar challenges).

Each of the products that the FDA proposes to now regulate are available in flavors that are undeniably attractive to young people as well as adults and present all of the hazards of flavored cigarettes. The FDA must take action to prevent the attraction and addiction of young people to these products that contribute to chronic disease and premature death. Therefore, the agency must immediately prohibit the sale of all flavored tobacco products. This could be accomplished by using language which mirrors the language prohibiting flavored cigarettes from the Tobacco Control Act:

No tobacco product or any component of a tobacco product (including the tobacco, filter, paper, liquid nicotine, or pouch) may contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol⁵⁰) or an herb or spice, including strawberry, grape, orange, mint, menthol, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.⁵¹

The FDA has the authority, evidence base, and congressional mandate to act to prohibit flavored tobacco products. There is no public health rationale for further delay. There is ample evidence that flavored tobacco products appeal to youth and lead to initiation into tobacco product use. If the FDA's goal with this regulation is to reduce youth use of tobacco products – as it should be given the public health standard's focus on initiation – it cannot justifiably defer prohibiting the sale of flavored tobacco products.

Such a prohibition is not only obviously within the FDA's authority to establish product standards⁵² and to restrict the sale and distribution⁵³ of tobacco products, a prohibition on flavors would be a logical outgrowth of the FDA's current proposal. The proposed deeming regulation recognizes the youth appeal of flavors⁵⁴ and specifically solicits information regarding “what additional actions, if any, should FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults?”⁵⁵ The simplest action is a prohibition of all flavors in all tobacco products with the exception of the flavor of tobacco. Any flavor additive to a tobacco product serves only to mitigate the harsh flavor of tobacco, making tobacco product

⁵⁰ As explained above, we urge that the flavored restriction for OTPs not contain the menthol exception that currently exists for cigarettes. This is consistent with the Tobacco Control Legal Consortium's companion request in a citizen petition to remove the menthol exception from the flavored restriction for cigarettes which is discussed earlier in this comment. See Menthol Citizen Petition, *supra* note 23.

⁵¹ Tobacco Control Act §907(a)(1)(A), 123 Stat. at 1799 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)) (strike through shown to demonstrate removal of those words).

⁵² Tobacco Control Act §907(a)(1)(A), 123 Stat. at 1799 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)).

⁵³ Tobacco Control Act, §906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)).

⁵⁴ 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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule, 79 Fed. Reg. 23,142, 23,144-23,146 (proposed April 25, 2014) (to be codified at 21 C.F.R. pt. 1100, 1140, and 1143) [hereinafter Deeming Regulation].

⁵⁵ Deeming Regulation, 79 Fed. Reg. at 23,147.

use easier and thus increasing initiation and decreasing cessation. The FDA has deferred meaningful action on flavors long enough. The time for a flavor prohibition is now.

b. The FDA must restrict advertising and marketing of newly-covered tobacco products.

The FDA has proposed extending certain advertising and marketing regulations that currently only apply to cigarettes and smokeless tobacco, such as prohibiting free samples and requiring warning labels, to newly-covered products. While these regulations should apply to all tobacco products, especially cigars,⁵⁶ hookah and e-cigarettes, the proposed regulation's silence on other important marketing and advertising restrictions for newly-covered tobacco products is a major oversight with enormous public health consequences.

The FDA should extend the following advertising and marketing restrictions that currently only apply to cigarettes and smokeless tobacco to all tobacco products: 1) prohibit tobacco product brand and trade names of non-tobacco products;⁵⁷ 2) prohibit brand and trade name sponsorship of sporting and cultural events;⁵⁸ 3) require notice of all advertising in any non-traditional medium.⁵⁹ Each of these marketing techniques is recognized as a tactic to increase youth initiation. In addition, the FDA must address the now-common practice of advertising e-cigarettes on television and radio. Cigarettes and smokeless tobacco product advertisements have been prohibited on television and radio for decades. The growing number of e-cigarette advertisements is renormalizing tobacco product advertisements in these mediums. The FDA cannot simply sit on the sidelines while e-cigarette advertisements are being broadcast to millions of people, many of whom are youth and young adults. There are a range of options available to the FDA. Given the ubiquitous and irresponsible marketing of tobacco products, and e-cigarettes in particular, it is important for the FDA to take the necessary steps to protect children from predatory marketing practices.⁶⁰

⁵⁶ A previous citizen petition filed with the FDA makes clear that these regulations should apply to the sale of cigars; we do not repeat those specifics here. *See* CITIZEN PETITION: ASSERT JURISDICTION OVER CIGARS AND SUBJECT CIGARS TO CERTAIN SALES AND DISTRIBUTION REGULATION THAT APPLY TO CIGARETTES AND SMOKELESS TOBACCO, Docket No. FDA-2011-P-0356 (May 31, 2011).

⁵⁷ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.16(a) (2013). The FDA has agreed not to enforce this regulation against some manufacturers until amendments are made to the regulation. The FDA has yet to promulgate a rule making any such amendments. *See* Stipulation of the Parties, *Renegade Tobacco Co. v. U.S. Food & Drug Admin.*, No. 3:10-cv-00265-HEH (E.D. Va. May 19, 2010)(stipulating that the litigation should be stayed pending the FDA's consideration of amendments to 21 C.F.R. § 1140.16(a)).

⁵⁸ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.34(c) (2013).

⁵⁹ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.30(a) (2013).

⁶⁰ Letter from Henry Waxman et al., United States Congressman, to Kamala Harris et al., Attorneys General (Feb. 12, 2014), available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Harris-Miller-Sorrell-Master-Settlement-Agreement-Tobacco-2014-2-12.pdf>; *Full Committee Hearing – Progress and Challenges: The State of Tobacco Use and Regulation in the U.S.*, 113th Cong. (2014), available at <http://www.help.senate.gov/hearings/hearing/?id=a0a14829-5056-a032-526d-3bc1bfd96586>; *Aggressive E-cigarette Marketing and Potential Consequences for Youth*, 113th Cong. (2014), available at http://www.commerce.senate.gov/public/index.cfm?p=Hearings&ContentRecord_id=42af91a8-6308-45b5-9842-74bc5833be73&ContentType_id=14f995b9-dfa5-407a-9d35-56cc7152a7ed&Group_id=b06c39af-e033-4cba-9221-de668ca1978a&MonthDisplay=6&YearDisplay=2014; *Protecting Children from Electronic Cigarette Advertising Act of 2014*, S. 2047, 113th Cong. (2014), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113s2047is/pdf/BILLS-113s2047is.pdf>; *see also* H.R. 4325, 113th Cong. (2014)(companion bill), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113hr4325ih/pdf/BILLS-113hr4325ih.pdf>; *Smoke Act*, H.R. 5010, 113th

The justification underlying the application of these restrictions to cigarette and smokeless tobacco advertising applies to all tobacco products. The tobacco industry has a long history of marketing its products to young adults and children to get them addicted to nicotine at a young age.⁶¹ These restrictions do not prevent the tobacco industry from communicating about its products to adult consumers but do restrain the industry from preying on children. Given the increasing appeal of these products to youth and young adults and the amount of experimentation that is already underway, there is clearly a need to implement these restrictions to curb youth initiation of tobacco use as is the FDA's charge from Congress. The restrictions proposed by the FDA represent a small step in the right direction. However, the FDA must extend all of the current advertising and marketing restrictions concerning cigarettes and smokeless to these newly-covered products.

c. The FDA must strengthen the warning label requirements in the proposed regulation.

Warning labels are one of the oldest and most basic public health measures to attempt to mitigate the negative health effects of smoking.⁶² Since the first warning labels appeared on cigarette packages in 1965, warning labels have been an important source of information for tobacco users.⁶³ While there is evidence that warning labels can go stale,⁶⁴ and the need for large graphic warning labels is clear,⁶⁵ the newly-covered products are typically marketed with no warning labels whatsoever. This contributes to the state of confusion surrounding the health effects of these new products.⁶⁶ At the very least, these products must display textual warnings; but to use the full extent of its authority and to provide the strongest protection for public health, the FDA should require large graphic warnings for all tobacco products. The FDA must establish warning

Cong. (2014), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113hr5010ih/pdf/BILLS-113hr5010ih.pdf>; Child Nicotine Poisoning Prevention Act of 2014, S. 2581, 113th Cong. (2014), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113s2581is/pdf/BILLS-113s2581is.pdf>.

⁶¹ U.S. v. Philip Morris USA Inc., 449 F.Supp.2d 1, 561-692 (D.D.C. 2006).

⁶² Ctrs. for Disease Control & Prevention, *Cigarette Package Health Warnings and Interest in Quitting Smoking—14 Countries, 2008-2010*, 60(20) MORBIDITY & MORTALITY WKLY. REP. 645 (2011), available at <http://www.cdc.gov/mmwr/pdf/wk/mm6020.pdf>; U.S. DEPT. OF HEALTH & HUMAN SERVS., ORAL HEALTH IN AMERICA: A REPORT OF THE SURGEON GENERAL (2000) [hereinafter, SGR 2000], available at <http://silk.nih.gov/public/hck1ocv.@www.surgeon.fullrpt.pdf>; Heikki Hiilamo et al., *The Evolution of Health Warning Labels on Cigarette Packs: The Role of Precedents, and Tobacco Industry Strategies to Block Diffusion*, 23(2) TOBACCO CONTROL 1 (2014) (published online ahead of print), doi:10.1136/tobaccocontrol-2012-050541.

⁶³ SGR 2000, *supra* note 60, at 163.

⁶⁴ INST. OF MED., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION (Richard J Bonnie et al. eds., 2007), available at http://books.nap.edu/openbook.php?record_id=11795.

⁶⁵ U.S. DEP'T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 203, 718-19 (2012), available at <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>; Sunday Azagba, *The Effect of Graphic Cigarette Warning Labels on Smoking Behavior: Evidence from the Canadian Experience*, 15(3) NICOTINE & TOBACCO RES. 708 (2013); Jennifer Cantrell et al., *Impact of Tobacco-Related Health Warning Labels Across Socioeconomic, Race and Ethnic Groups: Results from a Randomized Web-Based Experiment* 8(1) PLOS ONE e52206 (2013), available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0052206>; A.A. Strasser et al., *Graphic Warning Labels in Cigarette Advertisements: Recall and Viewing Patterns*, 43(1) AM. J. PREV. MED. 41 (2012).

⁶⁶ See, e.g., *Reclassify Nicotine Vaporizers (E-cigarettes) from "Drug-Device Combination" to "Tobacco Product"*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=FDA-2010-P-0095> (Showing the confusion, given the number of comments).

labels for cigars, hookah, and e-cigarettes and recognize that dissolvable tobacco products are smokeless tobacco products for the purpose of warning label regulation.

Although the proposed deeming regulation includes a warning label requirement, the proposed warning is anemic and likely to be ineffective. The proposed warning label for the deemed tobacco products is: “This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”⁶⁷ There are several problems with this label. First, a warning that focuses only on the possibility of addiction is meaningless to consumers. There are a variety of products perceived as harmless that are also addictive, such as caffeine, so a warning containing only this statement is unlikely to resonate with consumers.

There is no need to use such an underwhelming warning, there is significant evidence of the specific health harms of cigars, pipe tobacco, roll-your-own tobacco and hookah. In particular, there is evidence regarding the specific health harms caused by nicotine that support stronger, more specific warnings. For the evidence base supporting stronger warning labels, the agency needs to look no further than the 2014 U.S. Surgeon General’s Report: *The Health Consequences of Smoking—50 Years of Progress*. The Report, discussed further below, includes significant findings regarding the health harms of nicotine beyond addiction.

Neglecting to address these significant harms in the form of a warning label for these products is a significant missed opportunity to protect public health. At the very least, the FDA should extend the current warnings for cigarettes that reference tobacco smoke to all other combusted tobacco products. Those warnings are:

- WARNING: Tobacco smoke can harm your children.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

Second, the proposed regulation also fails to require multiple warnings for newly-covered tobacco products. Establishing multiple warnings will allow for rotation, maintaining the effectiveness of the warning labels.

Effective warning labels are an important tool in the FDA’s arsenal to protect public health. The agency’s proposed warning label requirements for newly-covered tobacco products are underwhelming and must be improved in a final regulation. The public health standard requires the agency to establish warning labels that will reduce initiation and increase cessation. Stronger warning labels are needed to adequately protect public health.

⁶⁷ Deeming Regulation, 79 Fed. Reg. at 23,162. There are additional warning labels proposed for cigars. *Id.* at 23163.

d. The FDA must prohibit self-service access to all newly-covered tobacco products.

Under the Tobacco Control Act, retailers cannot provide self-service access to cigarettes and smokeless tobacco or sell these products in vending machines, unless the retailer is an adults-only establishment.⁶⁸ The Supreme Court upheld a similar restriction implemented by the Massachusetts Attorney General, finding that self-service displays of cigarettes may be prohibited because “[u]nattended displays of tobacco products present an opportunity for access without the proper age verification required by law.”⁶⁹ Similarly, when the FDA first proposed the prohibition on self-service access to cigarettes, it relied on evidence such as the Institute of Medicine (IOM) Report *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths* (1994), which referred to surveys in two communities that found over 40% of daily smokers in grade school shoplifted cigarettes.⁷⁰ The public health rationale for this restriction extends to the newly-covered tobacco products: eliminating self-service access where youth are permitted reduces youth access to those products. There is no public health rationale for refusing to extend the prohibition on self-service access to the newly-covered tobacco products. While some state and local governments prohibit self-service access for all tobacco products, many are unable to do so because of a lack of local authority, state preemption of local authority, or other barriers. Self-service access can play a significant role in youth initiation and the FDA must act to limit this avenue for youth access to all tobacco products.

e. The FDA should establish minimum pack sizes for newly-covered tobacco products.

Increasing the price of tobacco products has a number of desirable public health outcomes, including reducing youth and adult consumption and decreasing initiation rates.⁷¹ Regulating the sale or the price of tobacco products based on minimum packaging requirements is one way to reduce tobacco use by raising prices. A single cigarette, cigar, or pouch can be sold at a fraction of the price of a “pack.” This makes the product more accessible to all users, but especially appealing to youth who might be experimenting with different tobacco products and are extremely price sensitive. Larger packs likely reduce rates of youth purchasing the products. Additionally, while appropriate health warnings and ingredient disclosures may be placed on packs, it is impossible to give consumers this important information on a single cigar or other singly-sold product. Larger packs are also easier to monitor for tax and trade enforcement purposes.

For these reasons, the FDA requires that cigarettes be sold in packs of at least twenty.⁷² Unfortunately, the proposed deeming regulation fails to extend this requirement to non-cigarette tobacco products, allowing the products to be sold at cheaper and more tempting prices. The

⁶⁸ 21 C.F.R. §§ 1140.14(c), 1140.16(c)(2)(ii) (2010).

⁶⁹ *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 569 (2001).

⁷⁰ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,441 (Aug. 28, 1996).

⁷¹ Kurt Ribisl et al., Ctrs. for Disease Control & Prevention, *State Cigarette Minimum Price Laws--United States, 2009*, 59(13) MORBIDITY & MORTALITY WEEKLY REPORT 389, 389 (2009), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5913a2.htm>.

⁷² 21 C.F.R. § 1140.14 (2009).

results are predictable; while cigarette use is going down, use of non-cigarette tobacco products remains high.⁷³

- Among youth surveyed, 14% smoked cigars, cigarillos, or little cigars on at least 1 day during the 30 days before the survey and 9% used chewing tobacco, snuff, or dip.⁷⁴
- Between 1997 and 2007, sales of little cigars increased by 240% while cigarillo sales increased by almost 150%.⁷⁵
- More than half of teens surveyed by the CDC in a national study admitted to smoking a cigar at some point in their lives.⁷⁶

While many non-cigarette tobacco products can be sold in a single “dose,” enjoy a relatively low tax as compared to cigarettes, and are available in fruit, candy, and alcohol flavors, data show that cigars and cigarillos are most popular among youth.⁷⁷

Several jurisdictions have passed laws that restrict sales of tobacco products, such as cigars, that do not meet minimum pack size standards.⁷⁸ These laws establish a minimum weight or minimum number of units that must be sold per transaction. Communities may also restrict the types of locations where certain tobacco products, such as unpackaged cigars, may be sold. For example, Boston prohibits the sale of cigars in packages of less than four at convenience stores, gas stations, grocery stores, and pharmacies.⁷⁹

Establishing minimum pack sizes for newly-covered tobacco products will keep cheap tobacco products out of the hands of youth and reduce impulse-buying by adults. Both effects reduce initiation into tobacco product use and would serve to uphold the public health standard as required for FDA action.

⁷³ Jennifer Cullen et al., *Seven-Year Patterns in US Cigar Use Epidemiology Among Young Adults Aged 18-25 Years: A Focus on Race/Ethnicity and Brand*, 101 AM. J. PUB. HEALTH 1955, 1955-1962 (2011).

⁷⁴ Danice K. Eaton et al., Ctrs. for Disease Control & Prevention, *Youth Risk Behavior Surveillance – United States, 2009*, 59 MORBIDITY AND MORTALITY WEEKLY REPORT 11, 12 (Jun. 4, 2010), available at <http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf>.

⁷⁵ *Id.*

⁷⁶ *Id.* at 11.

⁷⁷ *Id.* at 12.

⁷⁸ D.C. CODE § 7-1721.06(c) (2011); BOSTON, MA., A REGULATION LIMITING TOBACCO AND NICOTINE ACCESS BY YOUTH (hereinafter “Youth Access Regulation”) (Dec. 1, 2011), available at

http://www.bphc.org/boardofhealth/regulations/Documents/Tobacco_Control_Youth_Access_Regulation.pdf

⁷⁹ Youth Access Regulation, *supra* note 76.

f. The FDA should extend the prohibition on free samples to include smokeless tobacco products provided in adult-only facilities.

Under current federal regulations, the distribution of free samples of cigarettes and smokeless tobacco is prohibited,⁸⁰ with an exception for a “qualified adult-only facility.”⁸¹ Rather than leaving this issue to local communities to patch together a solution to protect public health, the FDA should prohibit free samples of smokeless tobacco in adult facilities as well, treating free samples of this product like samples of other tobacco products. This restriction should be extended to apply to roll-your-own and all newly-covered tobacco products. There is no logical reason to continue to allow free samples of smokeless tobacco products. If the restrictions on free samples in this proposed rule are finalized, this is the only product that can be sampled. This is an illogical loophole that must be closed.

g. The FDA should require child-resistant packaging for liquids containing nicotine.

The final rule for this proposal must include a provision regulating the packaging of e-cigarettes and e-cigarette liquid. The lack of e-cigarette packaging standards has led to product designs for the containers for liquid nicotine that may encourage children to ingest the product’s poisonous content.⁸² Some labels include cartoons, have colorful labeling, or depict edible ingredients indicating a bottle’s particular flavor, such as cherry, chocolate, or bubble gum. The contents themselves can have the aroma of the edible ingredient pictured on the label.⁸³ Any of these factors could be enticing enough for a child to investigate, cumulatively they are a lethal combination.

As the use of e-cigarettes increases, so too does the risk of accidental poisoning. The CDC analyzed calls to U.S. poison centers from September 2010 to February 2014 regarding e-cigarette exposure related incidents. The results show that e-cigarettes accounted for 0.3% of the exposure calls in September 2010 and 41.7% of the calls in February 2014.⁸⁴ Just over half of the calls made regarding exposure were for incidents involving children ages 0–5.⁸⁵ The prevalence of poisonings and the potential danger to young children prompted the American Association of Poison Control Centers and its fifty-five member centers to issue a statement urging e-cigarette

⁸⁰ Although the regulation refers to “cigarettes, smokeless tobacco, or other tobacco products,” the FDA has not yet enforced this restriction with respect to “other tobacco products.” See 21 C.F.R. § 1140.16(d)(1); UNITED STATES FOOD & DRUG ADMINISTRATION, DRAFT GUIDANCE FOR INDUSTRY: COMPLIANCE WITH REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS [REVISION TO DRAFT GUIDANCE] (2011), available at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252758.htm>.

⁸¹ 21 C.F.R. § 1140.16(d)(iii) (2010).

⁸² Robert A. Bassett, *Nicotine Poisoning in an Infant*, 370 NEW ENG. J. MED. 2249, 2249–50 (2014), available at <http://www.nejm.org/doi/full/10.1056/NEJMc1403843>.

⁸³ Tony Leys, *E-Cigarette Liquid Refill Warning*, DES MOINES REGISTER Mar. 25, 2014 (included in Iowa Poison Center’s Media Packet), available at <http://www.iowapoisson.org/news-and-recalls/e-cigarette-liquid-refill-warning/>.

⁸⁴ Kevin Chatham-Stephens, et al., Ctrs. for Disease Control & Prevention, *Notes from the field: Calls to Poison Centers for Exposures to Electronic Cigarettes* 63(13) MORBIDITY AND MORTALITY WEEKLY REPORT 292, 292-93 (2014), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm>.

⁸⁵ *Id.*

users to keep the devices and liquids away from children.⁸⁶ One teaspoon (5 ml) of a 1.8% nicotine solution could be lethal to a 200-pound person.⁸⁷ Most liquid nicotine levels vary in range from 1.8% to 2.4%.⁸⁸ Considering that most refill bottles contain between 10–30 milliliters, there are at least enough doses in each bottle to kill between two and six full-grown adults. There is an even greater danger to small children as it takes proportionally less nicotine to create a lethal dose as body weight decreases.

There have not yet been any fatal incidents reported. However, there are other harms associated with nicotine exposure. The effects of exposure can vary depending on the size of the person and the amount of nicotine ingested or absorbed. Common effects that have been reported include eye irritation, nausea, and vomiting.⁸⁹ As exposure increases, the effects worsen and can include seizures, neuromuscular blockade (muscle weakness or paralysis) and respiratory failure.⁹⁰ There are several means of accidental exposure. Nicotine can be inhaled, ingested, absorbed through the skin, lips, mouth or eyes.⁹¹ Most reported exposure cases having been from ingestion.⁹²

Due to the obvious danger and the alarming increase in calls to poison control centers, some state legislatures have already taken precautions. Legislators in Minnesota and Vermont passed laws this year that will require child-resistant packaging on all liquid nicotine refillable bottles. Some retailers have also voluntarily begun selling only those refills that have child-resistant caps.⁹³

As reflected in the increase of poisoning incidents reported nationwide, the dangers of liquid nicotine to children are clear. The lack of regulation concerning labelling and packaging has resulted in a product that is not only easy for children to open but invites children to do so. When considering the small amount of liquid nicotine necessary to be fatal, it is clear that there is a public health danger that needs to be addressed before it leads to the death of an adult or small child.

Although there have been no confirmed poisoning deaths in the United States due to the ingestion of liquid nicotine, the FDA must not wait for tragic consequences before acting. The public health standard allows the FDA to protect not only the users of tobacco products but non-users as well. The FDA must require child-resistant packaging to protect the most vulnerable non-users who are in significant danger as long as there are no standards for nicotine liquid

⁸⁶ News Release, American Association of Poison Control Centers, AAPCC and Poison Centers Issue Warning About Electronic Cigarette Devices and Liquid Nicotine (March 25, 2014), *available at* https://aapcc.s3.amazonaws.com/pdfs/releases/E-cigarette_Release.pdf.

⁸⁷ Robert A. Bassett, *Nicotine Poisoning in an Infant*, 370 NEW ENG. J. MED. 2249, 2249–50 (2014), *available at* <http://www.nejm.org/doi/full/10.1056/NEJMc1403843> (“[A]n estimated median lethal dose between 1 and 13 mg per kilogram of body weight, 1 teaspoon (5 ml) of a 1.8% nicotine solution could be lethal to a 90-kg person.”).

⁸⁸ Matt Richtel, *Selling a Poison by the Barrel: Liquid Nicotine for E—Cigarettes*, N.Y. TIMES, Mar. 24, 2014, at A1, *available at* <http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html>.

⁸⁹ Chatham-Stephens et al., *supra* note 82, at 292-93.

⁹⁰ Robert A. Bassett, *Nicotine Poisoning in an Infant*, 370 NEW ENG. J. MED. 2249, 2249–50 (2014), *available at* <http://www.nejm.org/doi/full/10.1056/NEJMc1403843>.

⁹¹ E.J. Mundell, *Nicotine Poisoning of Infant highlights ‘E-Cig’ Dangers, Docs Report*, HEALTHDAY, <http://consumer.healthday.com/public-health-information-30/poisons-health-news-537/nicotine-poisoning-of-infant-highlights-new-e-cig-dangers-687620.html> (last updated May 7, 2014).

⁹² Chatham-Stephens et al., *supra* note 82, at 292-93.

⁹³ Richtel, *supra* note 86, at A1.

packaging. Every day that these products are sold without packaging requirements is a day that public health is at risk.

IV. The proposed deeming regulation fails to adequately address the quickly changing e-cigarette marketplace.

It is rare that the invention of a product can so thoroughly disrupt the marketplace and the regulatory and taxation infrastructure for an entire category of products. The e-cigarette has done just that in the tobacco product market. It is equally rare that a federal regulatory agency has the ability to begin regulating a product with an entirely clean slate. The FDA has that opportunity, although its delays are eroding the potential benefits of this opportunity. Given what is at stake with e-cigarette regulation, the ongoing struggle of state and local governments to keep them out of the hands of children, how little is known about the long-term health effects, the scant information available regarding their effects on initiation and cessation, the ubiquity of the devices in stores and in the media, their obvious inherent and designed appeal to youth and young adults, bold action is necessary to protect public health.

It is not enough to simply assert its jurisdiction, establish minimum purchase age requirements to only the parts and components of the devices that contain nicotine, and mandate the blandest of warning labels. We urge the agency to revise the proposed regulation to do much more in the face of the exploding market for e-cigarettes and the resulting risk to public health.

a. While some questions remain with regard to the effects of e-cigarettes on individual and public health, there is a significant and growing body of evidence about the use of the product and the health effects of nicotine that should inform FDA decision making.

The surprisingly lax regulation of e-cigarettes proposed by the FDA seems to willfully ignore all that is known about e-cigarettes in favor of a hope that e-cigarettes could someday prove to be an effective harm reduction tool. Even accepting the premise that e-cigarettes can safely and effectively end the use of combustible tobacco products, the FDA must also consider what is known about the dangers of the product, including the scientific evidence regarding the harmful effects of nicotine, data concerning how the products are used and information about the industry's efforts to market to youth.

i. E-cigarettes present many significant health risks to the public.

Not long after the introduction of e-cigarettes to the U.S. market, the FDA recognized their danger. Rather than allowing e-cigarettes to remain unregulated in an exponentially growing market, the FDA attempted to regulate e-cigarettes under the drug and drug delivery device provisions of the Food, Drug, and Cosmetic Act. This action was initiated after FDA analysis of commercially marketed e-cigarettes revealed that the nicotine content in many devices did not correspond with the advertised levels. Several products were advertised as not containing

nicotine while FDA tests revealed low levels of the drug.⁹⁴ The FDA analysis also found known toxicants and carcinogens including diethylene glycol and tobacco-specific nitrosamines. When the FDA's attempt at regulation was challenged by e-cigarette manufacturers, the U.S. Court of Appeals for the D.C. Circuit ruled in December 2010 that unless they are marketed as therapeutic devices (cessation aids), e-cigarettes containing tobacco-derived nicotine could only be regulated by the FDA under its authority to regulate tobacco products.⁹⁵ The FDA stated its intent to regulate e-cigarettes as tobacco products on April 25, 2011.⁹⁶

Since then, the FDA has taken a very cautious approach to e-cigarettes and the few public statements that it has made have emphasized the potential dangers of the product. The FDA's website explains:

As the safety and efficacy of e-cigarettes have not been fully studied, consumers of e-cigarette products currently have no way of knowing:

- whether e-cigarettes are safe for their intended use,
- how much nicotine or other potentially harmful chemicals are being inhaled during use, or
- if there are any benefits associated with using these products.

Additionally, it is not known if e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.⁹⁷

The very real possibility that e-cigarettes could become a popular youth initiation product has been a concern of numerous health organizations such as the American Cancer Society, American Legacy Foundation, and the American Academy of Pediatrics.⁹⁸ Several state attorneys general echo this apprehension.⁹⁹ In addition, members of both houses of Congress

⁹⁴ Memorandum from B.J. Westerberger, Deputy Dir., Center for Drug Evaluation and Research, to Michael Levy, Supervisor Regulatory Counsel, Center for Drug Evaluation and Research (May 4, 2009), *available at* <http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf>.

⁹⁵ *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891, 898 (D.C. Cir. 2010).

⁹⁶ Letter from Dr. Lawrence Deyton, Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Stakeholders (Apr. 25, 2011), *available at* <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>.

⁹⁷ U.S. Food & Drug Admin., *News & Events: Electronic Cigarettes (e-Cigarettes)*, FDA: U.S. FOOD & DRUG ADMIN. (Apr. 25, 2013), <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>.

⁹⁸ Am. Cancer Soc'y, *What about electronic cigarettes? Aren't they safe?*, AM. CANCER SOC'Y (July 8, 2013), <http://www.cancer.org/cancer/cancercauses/tobaccocancer/questionsaboutsmokingtobaccoandhealth/questions-about-smoking-tobacco-and-health-e-cigarettes>; AM. LEGACY FOUND., *TOBACCO FACT SHEET: ELECTRONIC CIGARETTES (E-CIGARETTES)* (2013), *available at*

<http://www.legacyforhealth.org/content/download/582/6926/file/LEG-FactSheet-eCigarettes-JUNE2013.pdf>. *See also* AM. ACAD. OF PEDIATRICS *E-CIGARETTES* (2014), *available at* http://www2.aap.org/richmondcenter/pdfs/ECigarette_handout.pdf.

⁹⁹ Letter from National Association of Attorneys General to Margaret Hamburg, Comm'r, U.S. Food & Drug Admin. (Sept. 24, 2013), *available at* [http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20\(5\)\(1\).pdf](http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20(5)(1).pdf).

have called on the FDA to take sweeping action to protect children from the potential harms of e-cigarettes.¹⁰⁰

The legitimacy of the concerns about youth initiation should not be in doubt. A 2013 CDC report found that between 2011 and 2012, e-cigarette experimentation among middle and high school students doubled, resulting in an estimated 1.78 million kids having tried e-cigarettes.¹⁰¹

In addition, data from the 2009 and 2010 national Consumer Styles surveys found that awareness of e-cigarettes by U.S. adults doubled from 16.4% in 2009 to 32.2% in 2010.¹⁰² Ever use of e-cigarettes increased over the same period, from 0.6% in 2009 to 2.7% in 2010.¹⁰³ National survey data also indicates an increase in awareness from 2010 to 2011 (40.9% to 57.9%), as well as ever use (3.3% to 6.2%).¹⁰⁴ In these studies, current smokers and former smokers reported higher use of e-cigarettes than non-smokers.¹⁰⁵ These may be early indications that e-cigarettes increase dual- and poly-use of tobacco products and could be reducing rates of cessation.

January 2012 data from the nationally representative Legacy Young Adult Cohort Study found that ever use of e-cigarettes among 18-34 year old men was reported by 16.4% of U.S.-born Hispanics, 4.8% of non-Hispanic Blacks, and 8.8% of non-Hispanic Whites; current use was

¹⁰⁰ Press Release, Senator Barbara Boxer, Senators Call on FTC and FDA to Protect Consumers from False Advertising Claims by E-Cigarette Makers (Apr. 7, 2014)(publishing full text of a letter to the FDA), *available at* <http://www.boxer.senate.gov/en/press/releases/040714a.cfm>; Letter From Senator Tom Harkin to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (Mar. 25, 2014), *available at* <http://www.help.senate.gov/newsroom/press/release/?id=4b79e9c0-3faa-4a2f-bfd6-4a6099e0db2d>; Letter from Senator Richard J. Durbin, et al. to Margaret Hamburg, Comm’r U.S. Food & Drug Admin. (Apr. 16, 2013), *available at* http://www.durbin.senate.gov/public/index.cfm/files/serve?File_id=90eae776-6b4f-471b-a2d2-fe1525d2ed74; STAFF OF SENATOR RICHARD J. DURBIN ET AL., GATEWAY TO ADDICTION (2014), *available at* http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f; Letter from Senator Richard J. Durbin to Sylvia Mathews Burwell, Dir., Office of Mgmt. & Budget (Dec. 20, 2013), *available at* <http://www.durbin.senate.gov/public/index.cfm/pressreleases?ID=1143c7a6-95ee-4d89-a67d-4078e1db75fc>; Letter from Senator Edward J. Markey, et al. to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (May 8, 2014), *available at* http://www.markey.senate.gov/imo/media/doc/2014-5-8_Hamburg_E-Cigs.pdf; Press Release, Senator Barbara Boxer, Members of Congress: More and More Children being Exposed to E-Cigarette Marketing are Picking Up Habit (Aug. 4, 2014), *available at* <http://www.boxer.senate.gov/en/press/releases/080414.cfm>.

¹⁰¹ Chatham-Stephens et al., *supra* note 82, at 292.

¹⁰² Annette K. Regan et al., *Electronic Nicotine Delivery Systems: Adult Use and Awareness of the ‘e-Cigarette’ in the USA*, 22 TOBACCO CONTROL 19, 20 (2013).

¹⁰³ *Id.*

¹⁰⁴ Brian A. King et al., *supra* note 35 at tbl.1. The 2010 data is echoed by the findings published in Pearson et al. Jennifer L. Pearson et al., *E-Cigarette Awareness, Use, and Harm Perceptions in US Adults*, 102 AM. J. PUB. HEALTH 1758, 1760-1762 tbl.2 (2012). Pearson et al. presents data from another national, web-based survey administered in 2010 which found 40.2% awareness of e-cigarettes and 3.4% ever use of cigarettes among surveyed adults. *Id.*

¹⁰⁵ Brian A. King et al., *supra* note 35 at tbl.1. (finding, in the 2011 web-based survey, that 21.2% of current smokers, 7.4% of former smokers, and 1.3% of never-smokers reported ever use of cigarettes); Pearson et al., *supra* note 102 at 1760, 1762 tbl.2 (finding that 11.4% of current smokers and 2.0% of former smokers had ever used an e-cigarette, in comparison to 0.8% of never smokers); Regan et al., *supra* note 102, at 21 (finding, in 2010, that 18.2% of current smokers and 6.2% of former smokers had ever tried an e-cigarette, in comparison to 3.8% of never-smokers).

5.3%, 3.5%, and 1.7%, respectively.¹⁰⁶ Ever use of e-cigarettes among 18-34 year old women was 5.1% for U.S.-born Hispanics, 5.3% for non-Hispanic Blacks, and 8.0% for non-Hispanic Whites; current use was 1.6%, 4.0%, and 1.8%, respectively.¹⁰⁷ The appeal of e-cigarettes to youth and young adults is clear from the data. The FDA must take swift and decisive action to regulate e-cigarettes so that future generations are not burdened by nicotine addiction.

Many have claimed that e-cigarettes, when used in isolation, are less harmful than cigarettes and could be a potentially successful cessation product.¹⁰⁸ E-cigarettes currently are not approved smoking cessation devices and may not be marketed as such without prior FDA approval, yet many consumers believe that e-cigarettes are effective for cessation and purchase the product with that purpose in mind.¹⁰⁹ Moreover, these consumers believe that e-cigarettes are a safer alternative than conventional cigarettes despite the lack of sound support for harm reduction.¹¹⁰ While there is some evidence that e-cigarette aerosol contains lower levels of cigarette-associated toxins than cigarette smoke,¹¹¹ the mixture of chemicals in e-cigarette aerosol has not been well studied and there is evidence that other toxic chemicals may be present in these products.¹¹² There is also not enough evidence to establish that e-cigarettes do not lead to dual-use, do not reduce cessation and do not increase initiation.

¹⁰⁶ Joseph T. Lariscy et al., *Race/Ethnicity, Nativity, and Tobacco Use Among U.S. Young Adults: Results From a Nationally Representative Survey*, 15(8) NICOTINE & TOBACCO RES. 1417, 1421 tbl.2 (2013).

¹⁰⁷ *Id.*

¹⁰⁸ See, e.g., Sabrina Tavernise, *Study Gives E-Cigarettes Edge in Helping Smokers Quit*, N.Y. TIMES, May 21, 2014, at A3, available at http://www.nytimes.com/2014/05/21/health/study-gives-e-cigarettes-edge-in-helping-smokers-quit.html?_r=0;

¹⁰⁹ Comments made in response to a petition filed by the American Association of Public Health Physicians (AAPHP) to the FDA make this clear. AMERICAN ASSOCIATION OF PUBLIC HEALTH PHYSICIANS, CITIZEN PETITION: RECLASSIFY NICOTINE VAPORIZERS (E-CIGARETTES) FROM “DRUG-DEVICE COMBINATION” TO “TOBACCO PRODUCT”, Docket No. FDA-2010-P-0095 (Feb. 23, 2010) [hereinafter AAPHP Citizen Petition], available at <http://www.regulations.gov#!docketDetail;D=FDA-2010-P-0095>. Examples of comments on the petition include: 1) “Electronic cigarettes have helped me to quit smoking. I have been tobacco free for over 6 weeks now after being a smoker of over 20yrs.” 2) “E-cigarettes have help me quit smoking real cigarettes.” 3) “I was able to quit smoking using the vaping method and have not smoked in over 2 months.” *Id.* These are just a few examples of many. Indeed, there are many websites on which e-cigarette users claim to have quit smoking by using e-cigarettes. See, e.g., *How to Quit Smoking in 30 Days Using Electronic Cigarettes*, PUFFWEB, <http://www.puffweb.com/how-to-quit-smoking-in-90-days-using-electronic-cigarettes/> (last visited Aug. 6, 2014, 4:23 PM) (“The following is an account of my (successful) attempt at quitting smoking using Electronic Cigarettes. I was able to become smoke free in 90 days...”).

¹¹⁰ Comments following the AAPHP Citizen Petition show this viewpoint: 1) “It took over a 100 years for someone to finally produce a nicotine delivery system that is much safer than burning cigarettes.” 2) “Some of these individuals have found e-cigarettes and in the process have decreased or eliminated their exposure to deadly smoke even if all risks are not eliminated with certainty.” 3) “[H]undreds of thousands of smokers already have significantly reduced their health risks by switching to e-cigarettes.” AAPHP Citizen Petition, *supra* note 109. There are many such claims by e-cigarette smokers online also. See, e.g., Yahoo News, *First Person: Electronic Cigarettes Key to My Quitting Smoking*, YAHOO! NEWS, <http://news.yahoo.com/first-person-electronic-cigarettes-key-quit-smoking-182000482.html> (Nov. 15, 2012). (“It was not until recently I found a way I could smoke without getting all of the extra stuff in cigarettes that makes is so much healthier. I started smoking an electronic cigarette.”).

¹¹¹ Maciej Lukasz Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes*, TOBACCO CONTROL 1, 3-6 (2013) (published online ahead of print), doi:10.1136/tobaccocontrol-2012-050859 (finding that e-cigarette aerosol contains small amounts of toxicants associated with tobacco smoke – including formaldehyde, acetaldehyde, acrolein, tobacco-specific nitrosamines, cadmium, nickel, and lead – but at lower levels than reported for cigarette smoke).

¹¹² Tests conducted by the FDA found small amounts of diethylene glycol in e-cigarette aerosol, along with small amounts of nitrosamines. Westenberger Memorandum, *supra* note 92.

Reports of adverse events related to e-cigarettes also raise concerns about the health effects of these unregulated products. Of the 102 adverse event reports on tobacco products that have been submitted to the FDA from the 1980s through the first quarter of 2012, 47 reports concern e-cigarettes starting in 2008.¹¹³ These reports have included eight adverse events that the FDA has characterized as serious, including:

Hospitalization for illnesses such as pneumonia, congestive heart failure, disorientation, seizure, hypotension, possible aspiration pneumonia, second-degree burns to the face (product exploded in consumer's mouth while driving and during routine use), chest pain and rapid heartbeat, possible infant death secondary to choking on e-cig cartridge, and loss of vision requiring surgery.¹¹⁴

The less serious events reported to the FDA included complaints of “headache/migraine, chest pain, cough/sputum, nausea/vomiting, dizziness, feeling sick, confusion/stupor, sore throat, shortness of breath, abdominal pain, pleurisy, blurry vision, and sleepy/tired.”¹¹⁵ These adverse events are not necessarily causally connected to e-cigarette use since they could be related to underlying conditions or other factors;¹¹⁶ however, the number and seriousness of the reports related to e-cigarettes emphasizes the need for regulation and further assessment of these products. The proposed regulation delays many of the important provisions that would allow the FDA to better understand what is in the products and how they are being used.

While the potential harm to users of e-cigarettes is worrisome, the potential poisoning risk for toddlers and young children is alarming. As mentioned above, a CDC study analyzing calls to poison control centers found a dramatic increase in e-cigarette-related calls each month and the proportion of calls related to e-cigarette exposure versus conventional cigarette exposure increased from 0.3% to 41.7%.¹¹⁷ The prevalence of poisonings and potential danger prompted the American Association of Poison Control Centers and its fifty-five member centers to issue a statement urging e-cigarette users to keep the devices and liquids away from children.¹¹⁸ While there is little record of the severity of the poisoning events, there is evidence that the liquid found in e-cigarettes contains amounts of nicotine that could be toxic or even lethal – especially to children - if ingested or absorbed transdermally.¹¹⁹ As mentioned above, the risk to children is particularly concerning given the fact that e-cigarettes are frequently sold in flavors attractive to

¹¹³ Ii-Lun Chen, *FDA Summary of Adverse Events on Electronic Cigarettes*, 15(2) NICOTINE & TOBACCO RES. 615, 615 (2013). The first adverse report related to e-cigarettes was submitted to the FDA in 2008. *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ Samira Asma, et al., *CDC Grand Rounds: Global Tobacco Control* 63(13) MORBIDITY AND MORTALITY WEEKLY REPORT 277 (2014), available at <http://www.cdc.gov/mmwr/pdf/wk/mm6313.pdf>.

¹¹⁸ News Release, *supra* note 84.

¹¹⁹ Jennifer M. Cameron et al., *Variable and Potentially Fatal Amounts of Nicotine in e-Cigarette Nicotine Solutions*, TOBACCO CONTROL 1, 1-2 (2012) (published online ahead of print), doi:10.1136/tobaccocontrol-2012-050604. Nicotine is estimated to be lethal at a dose of ten milligrams in a child and thirty to sixty milligrams in adults. *Id.* at 1. The e-cigarette solutions tested in this study were found to have nicotine concentrations ranging from about eight milligrams/milliliters to over twenty milligrams/milliliters. *Id.* at 1 tbl.1. At these concentrations, a commonly sold five milliliter vial would contain forty milligrams to one-hundred milligrams of nicotine—more than enough to potentially kill a child, or at least cause significant toxic effects. *Id.* at 1.

children.¹²⁰ The FDA is obligated to act to protect the public health by acting to protect users and non-users of tobacco products. The dangers posed by e-cigarettes warrants far more stringent action than the FDA has proposed.

ii. There are many known adverse health effects of nicotine.

While proponents of e-cigarettes portray nicotine as a harmless drug with effects on the body similar to that of caffeine, a growing body of scientific evidence paints a different picture. The most recent report of the U.S. Surgeon General, *The Health Consequences of Smoking – 50 Years of Progress*, devotes an entire chapter to the health effects of nicotine.¹²¹ In addition to the significant risk of addiction, the report warns of the potential risk of poisoning due to ingestion of nicotine, the effect on the rates of various types of cancer, the role in cardiovascular disease, the effect on the immune system, the various negative reproductive outcomes, the impact on lung development, as well as nicotine’s effect on cognitive development.

As explained above, the number of calls to poison control centers related to exposure to e-cigarettes and their refill liquid is growing at an alarming rate. The Surgeon General’s report notes that although the acute toxicity of nicotine is known, there are very few studies to determine the effects of poisoning or the threshold for lethality.¹²² What is known is that symptoms of poisoning include nausea, vomiting, diarrhea, increased salivation, increased respiratory secretions, bradycardia, seizures and respiratory depression.

Exposure to non-lethal doses of nicotine is also linked to several adverse health outcomes, some of them severe. The Surgeon General’s report concludes that while there is “insufficient data to conclude that nicotine causes or contributes to cancer in humans, but there is evidence showing possible oral, esophageal, or pancreatic cancer risks.”¹²³ Nicotine exposure is also linked to several reproductive health issues. Nicotine may play a role in fetal growth restriction.¹²⁴ There is also evidence that nicotine increases the risk of preterm delivery, stillbirth, and Sudden Infant Death Syndrome.¹²⁵ The report also concludes that nicotine may have significant adverse effects on fetal lung development.

There is a significant and worrisome risk of harm related to the exposure of nicotine during important and vulnerable stages of brain development, notably during fetal and adolescent growth.¹²⁶ The Surgeon General’s report finds that nicotine has an adverse impact on fetal development because nicotine is a developmental toxicant, vasoconstrictor and is “known to cross the placenta and concentrate in the fetus at levels slightly higher than those in the mother.”¹²⁷ In smokers, “the combination of exposure to nicotine and hypoxia could decrease the

¹²⁰ *Id.* at 2.

¹²¹ U.S. DEP’T OF HEALTH & HUMAN SERVS., *THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS A REPORT OF THE SURGEON GENERAL 107* (2014) [hereinafter *SGR 2014*]. *available at* <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

¹²² *Id.* at 111-112.

¹²³ *Id.* at 116.

¹²⁴ *Id.* at 118.

¹²⁵ *Id.* at 118-119.

¹²⁶ *Id.* at 120.

¹²⁷ *Id.* at 471.

supply of nutrients and oxygen to the embryonic tissues through a vasoconstrictive impact, resulting in congenital defects.”¹²⁸ Adolescents are also particularly “vulnerable to the adverse effects of nicotine on the central nervous system” including “long-term structural and functional changes in the brain.”¹²⁹ With the rising rates of use among youth and young adults, it is clear that the FDA must take action that will reduce the number of youth whose brains are being rewired for nicotine addiction by these unregulated products. The significant role that e-cigarettes are playing in youth initiation warrants significant action by the FDA.

iii. Given all of the unknowns regarding e-cigarettes, the FDA approach to regulation fails to sufficiently protect public health.

The proposed approach to the regulation of e-cigarettes seems to be based on the assumption that when the dangers of a product are not well understood, regulation ought to be less stringent than where the dangers of a products are well understood. The questions that the FDA asks the public in its proposal with regard to how it ought to regulate e-cigarettes focus on dual-use of e-cigarettes with combustible products or e-cigarettes as a vehicle to future combustible use.

The FDA can and must regulate e-cigarettes despite not having the level of scientific evidence that is available for most conventional tobacco products. The Tobacco Control Act instructs the FDA to protect the public health in its regulation of tobacco products. The regulatory flexibility of the public health standard was designed to allow the FDA to regulate in an environment where there is often a lack of adequate information and where the tobacco industry will propagate junk-science and deception. It is this reason that the public health standard speaks to the *likely* impact of a policy not the certain impact, and the risks and benefits to the population as a whole and not the risks and benefits to those current users of combustible products who may or may not switch to noncombustible products.

In addition, the proposed regulation almost entirely ignores the potential harm of widespread uptake of e-cigarettes by those who would never have used any tobacco product. If e-cigarettes pose any amount of harm to health and, given the mounting evidence of the health effects of nicotine, this is assured, and if they are being used by anyone who would not have used otherwise used a tobacco product, the public health standard justifies swift and significant action. It is impossible to reconcile the FDA’s hands-off approach to e-cigarettes with its congressional mandate to protect public health. There are several tools at the FDA’s disposal that would go far to reduce youth initiation into e-cigarette use that would have little to no negative effects for adult consumers. These policy options are discussed elsewhere in this comment.

It will take decades to understand the long-term public health effects of e-cigarettes but what is known at this point is that they contain nicotine, an addictive drug with serious adverse health effects. The devices represent technological “gadgets” that appeal to young people, and the advertising and marketing of the products preys on this appeal. The products are marketed in youth-attractive flavors that are prohibited for cigarettes. There is no question that unchecked, this exploited attractiveness will result in skyrocketing rates of use among youth and young adults. Those who try the products will eventually become addicted to nicotine and some will

¹²⁸ *Id.* at 472.

¹²⁹ *Id.* at 122.

likely experiment with other products to satisfy that addiction. Even if the rates of switching from e-cigarettes to highly toxic and carcinogenic combustible products are low, there is more than enough evidence for the FDA to do more than it has proposed to do. The FDA is tasked with protecting public health *now*, not with waiting to find the outer limits of the resulting harm and then attempting to remediate that harm.

b. The proposed regulation’s failure to regulate all of the different variations and types of e-cigarette devices would have dire consequences.

Given the vastly different outcomes of subjecting a given product and its manufacturer to: 1) only the statutory requirements of the Tobacco Control Act, 2) the Act and the FDA’s regulations promulgated under the Act, or 3) neither source of law, it is imperative that the FDA clearly outline what sources of law apply to which products. The proposed regulation falls short of that clarity.

This lack of clarity regarding which restrictions apply to which products results in several significant problems with the proposed regulation of e-cigarettes. One issue is the use of the terms “component,” “part,” and “accessory,” without clear, established definitions. A trip to any convenience store or e-cigarette specialty store across the country reveals the need for the FDA to set firm, clear boundaries for its regulatory reach and to develop infrastructure to ensure that the products that are outside of its authority are genuinely free of tobacco-derived nicotine. The proposed regulation also, perplexingly, does not address the issue of whether or not certain e-cigarette retail stores are tobacco product manufacturers according to the Food, Drug, and Cosmetic Act. Any establishment that is repackaging or relabeling tobacco products must register with the FDA and abide by the other requirements established for manufacturers.

i. The FDA must do more than the bare minimum in its regulation of “components,” “parts,” and “accessories.”

The proposed regulation would allow the FDA to begin regulating any product that meets the Tobacco Control Act’s broad definition of the term, “tobacco product.” That definition allows the FDA to regulate the components, parts, and accessories of tobacco products as well. However, in its proposal, the FDA has declined to assert its jurisdiction over all tobacco product accessories. Moreover, while it has proposed to subject all components and parts to the statutory provisions of the Tobacco Control Act, only those components and parts that contain nicotine will be subject to regulations promulgated by the FDA under its regulatory authority.

It is difficult to foresee the precise implications of these regulatory distinctions as the FDA has not provided definitions for the terms “component,” “part,” or “accessory.” However, it is clear that implementation of this regulation will be quite difficult due to this approach. Without clear, precise definitions, analysis of the regulatory impact is impossible.

E-cigarettes can be separated into two categories, those that are intended to be disposable and those that are intended to be reusable. So-called disposable e-cigarettes are typically sold individually or in very small packs which come with everything a user needs to begin using the device immediately. The device is sold with a charged battery and is prefilled with nicotine liquid. Once either the battery has died or the device has run out of nicotine liquid, a user

discards the entire device and must purchase another. These devices are marketed in many different flavors and are often sold with varying levels of nicotine, including some devices which are falsely advertised as not containing nicotine.

Reusable e-cigarettes come in endless varieties, most of which can be modified in various ways by the user. The battery inside the device can be recharged or replaced. The devices are either designed so that an empty cartridge containing the nicotine solution can be removed and replaced with a prefilled cartridge or the device includes a tank which a user may refill with nicotine liquid purchased from a retailer. These devices, refill cartridges and liquids come in many flavors and varying nicotine levels including some products that are falsely advertised as not containing nicotine.

Under the proposed deeming regulation, all of those products which contain nicotine will be subject to the statutory and regulatory requirements and restrictions. For those products that do not contain nicotine, the result is unclear. If a non-nicotine e-cigarette is not a tobacco product then the status quo remains; there is no regulation and children can purchase them. However, it is possible that the terms “component” and “part” could be defined in a way that makes these devices tobacco products. Some companies manufacture and sell both nicotine-containing and e-cigarettes advertised as non-nicotine, both of which contain interchangeable parts. Those products that are sold without nicotine could simply be regulated as components or parts of a tobacco product, that are sold without nicotine. They are still components or parts of a tobacco product that does contain nicotine.

The FDA’s Preliminary Regulatory Impact Assessment identifies many of the costs associated with complying with this proposed regulation. As can be expected, the transition from a truly free market to one that is regulated can create significant costs for regulated entities, although this is a sliding scale. Because of the potential costs associated with compliance with the Tobacco Control Act, a manufacturer that is looking to make a profit has a monetary incentive to ensure that as many of its products as possible are not tobacco products and thus outside of FDA regulation. Doing so preserves the status quo where manufacturers are essentially free to do as they please in the manufacturing, distribution, advertising and marketing of their products.

The FDA draws its regulatory distinctions in a way that will likely prove to be unwise, resulting in a change to the market such that the sale of nicotine liquid will be entirely separated from the sale of e-cigarette devices. This sales practice already exists to a degree but the regulation, as proposed, would likely drastically shift the market in this direction. This will create a regulatory scheme in which the FDA will be unable to collect adequate information on dosage and other aspects of how the devices are used in practice. This is particularly concerning given that some products that are advertised as not containing nicotine actually contain nicotine.

The problem is compounded by the fact that liquid nicotine can be purchased in very large quantities, much more than an individual user needs for a single device. If youth can easily acquire a device, they need only find a way to procure the liquid nicotine and given the fact that many users will have more than they can consume, black and gray markets will likely spring up.

Because there is such a fine line between a tobacco product component or part and a non-tobacco product, the FDA need not draw the lines in favor of the least amount of regulation, as it appears

to have done. It is well within the FDA's power to ensure that all e-cigarettes are subject to the statutory and regulatory schemes for tobacco products. The FDA also has a responsibility to the public to test all liquids that claim to be non-nicotine to confirm that manufacturers and retailers are making truthful claims. If they are not, the FDA also has a responsibility to take enforcement action against these products as misbranded tobacco products. With the tremendous public health impact that e-cigarettes will have, the FDA must do more than it has proposed to do. The agency ought to deem all e-cigarette-like devices as components or parts of a tobacco product subject to the statutory requirements and restrictions in the Tobacco Control Act. The FDA should also extend all of the regulatory provisions of the final rule resulting from this proposal to all deemed products, components and parts regardless of whether or not they contain nicotine. Such an action is justified under the broad reach of the public health standard.

ii. The FDA must more clearly define the terms “component,” “part,” and “accessory.”

If it does not establish firm definitions in its regulations, the FDA must issue a guidance document that more fully explains its interpretation of the terms “component,” “part,” and “accessory.” The language of the proposal leaves too many unanswered questions: Is an e-cigarette that does not contain nicotine simply not a tobacco product? Will the FDA regulate only the nicotine-containing cartridges in a line of products that includes varying degrees of nicotine including allegedly nicotine-free cartridges? How will retailers be able to determine which products are subject to minimum age requirements when there are so many variations in the product? Can an e-cigarette store offer free samples of a nicotine-free liquid and then sell the same liquid in a nicotine version to an adult customer? Can an e-cigarette store allow youth to sample non-nicotine e-cigarette liquid?

The most definitive statements made by the FDA in this proposal do not provide enough information to sort out the differences between the three terms.

FDA believes that components and parts of tobacco products are those items that are included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product. Components and parts that would be covered under this proposal include those items sold separately or as part of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product. Such examples would include air/smoke filters, tubes, papers, pouches, or flavorings used for any of the proposed deemed tobacco products (such as flavored hookah charcoals and hookah flavor enhancers) or cartridges for e-cigarettes. In addition, FDA considers accessories to be those items that are not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product, but may be used, for example, in the storage or personal possession of a proposed deemed product. Therefore, items such as hookah tongs, hookah bags and cases, hookah charcoal burners and holders, cigar foil cutters, humidors, or cigar carriers would be considered accessories and would not fall within the scope of this proposed rule.¹³⁰

¹³⁰ Deeming Regulation, 79 Fed. Reg. at 23,153.

The FDA never definitively states that the terms component and part have the same meaning although this seems to be the case. The distinction between components/parts and accessories seems to hinge on whether or not an item is “used by consumers in the consumption” of a tobacco product or not. Based on the proposed regulation, an item used during consumption is a component/part and one that is not is an accessory. This distinction seems to render lighters and matches to be components/parts of combustible tobacco products because they are “used by consumers in the consumption” of combustible products. However, the examples provided for components/parts and accessories would suggest that lighters and matches would more likely fit into the category of accessories if the definitions did not hinge on usage during consumption. This problem, illustrated by the example of lighters and matches is exacerbated in the context of e-cigarettes. For example, what are the regulatory consequences of marketing a device that is labelled for use with non-nicotine e-cigarette liquid, or for use with recreational or medicinal marijuana, or a flavoring additive that is marketed as being used only with non-tobacco products? There is too much at stake in the regulation of all products and e-cigarettes in particular, for the FDA to be so unclear about what products will be regulated in what way. For that reason, the FDA needs to define these terms.

iii. The FDA should clarify that the scope of the term “manufacturer,” covers many e-cigarette retail stores.

The issue of whether e-cigarette retail stores will be treated as tobacco product manufacturers is not explicitly addressed in the proposed deeming regulation. Whether the issue was never examined by the FDA or whether the discussion was merely left out of the proposal is unclear. What is clear, given the language of the Tobacco Control Act, is that many retail stores will either need to change their business practices or register with the FDA as tobacco product manufacturers and abide by all of the other requirements of the Tobacco Control Act.

Under the Act, a tobacco product manufacturer is “any person, including any repacker or relabeler, who—manufactures, fabricates, assembles, process, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States.”¹³¹ As e-cigarettes have risen in popularity, thousands of new or existing retail stores have begun to sell e-cigarette liquid that is mixed on-site to the customer’s specifications. Store employees mix various concentrations of nicotine with flavor additives and other chemicals and package the liquid for the consumer in the retail store. Even the most conservative reading of the Act would show that any store selling custom-made e-cigarette mixtures is a tobacco product manufacturer. A business that mixes custom nicotine liquid solutions is repackaging, assembling, and processing the nicotine solution. Furthermore, if the store puts its own labels on the products, this activity constitutes labeling or relabeling. In addition, many of these stores also sell items to modify devices and, thus, could be engaged in the manufacturing, fabricating, and assembling of tobacco products.

The growing number of these types of retailers, combined with the potential dangers of handling and mixing dangerous chemicals or modifying the devices, makes it necessary for the FDA to require that these establishments be treated as manufacturers under the Tobacco Control Act and

¹³¹ Tobacco Control Act, § 900(20), 123 Stat. at 1786 (codified at 21 USC § 387).

abide by all of the requirements of the Act. The FDA should be clear in its final regulation that it intends to treat them this way. This will help the FDA implement these provisions.

V. The proposed regulation prioritizes tobacco industry business interests at the expense of public health.

There are several proposed provisions that would protect business interests at the expense of public health, a disappointing and curious result from an agency tasked with protecting of public health. The only consideration that the FDA must take into account when making regulatory decisions about tobacco products is how and to what degree a given regulatory action will affect public health. The Notice of Proposed Rulemaking included a number of statements and questions that focus on weighing the costs and benefits to businesses, all of which manufacture and sell products known to cause addiction and are the leading cause of preventable disease and death.

There is no public health justification for any exemption in this regulatory scheme for so-called premium cigars. None of the differences between premium cigars and non-premium cigars warrant any kind of disparate treatment in terms of which products are to be within the scope of the FDA's regulatory authority. Both categories of products negatively affect public health. The FDA must also reevaluate its proposed timeline for implementing this regulation. The proposal unnecessarily defers enforcement of some of the most important provisions in the Tobacco Control Act. Particularly important is the FDA's proposed delay of requiring premarket review of new tobacco products, a process which has been rife with problems since the passage of the Act. The FDA's proposed enforcement timeline will cause substantial harm to public health and must be significantly shortened in order to uphold the public health standard.

a. To protect public health, the FDA must assert its jurisdiction over all cigars, without exception.

The proposed regulation includes two options for the regulation of cigars: Option 1 would have the FDA regulate all cigars while Option 2 carves out an exemption from all regulation for certain so-called premium cigars. When viewed through the lens of the public health standard, there is no legitimate justification for the FDA to fail to regulate any tobacco product, including premium cigars. The Tobacco Control Act creates a comprehensive regulatory scheme for tobacco products which would protect public health by restricting youth access to cigars and decreasing the harm caused by cigars for adult cigar users. There is also a significant risk that any exemption for a tobacco product, no matter how narrow, will be exploited by manufacturers who will develop products that will fall within the exemption although they were not intended to be covered by the exemption. This is a particularly dangerous and well-established risk for cigars which have been continually modified to avoid federal, state, and local taxation and regulation.

i. An exemption for premium cigars is not justified under the public health standard, the only criterion the FDA is to use for regulating tobacco products.

As discussed above, the public health standard requires the FDA to examine the risks and benefits to the population as a whole including users and nonusers as well as a particular action's

likely effect on initiation and cessation.¹³² However, the mere assertion of jurisdiction over tobacco products, does not require evidence that the action will protect public health. The FDA may deem any tobacco product to be subject to the Act as long as it does so through the formal rulemaking process. The Tobacco Control Act creates no other requirements for this action. For the imposition of any additional requirements or restrictions, the FDA must look to the public health standard. Given these considerations, there is no justification for exempting any tobacco products from the FDA's regulatory scheme.

Moreover, the evidence concerning cigars demonstrates that cigars of all types not only should be subject to the minimal requirements of the Tobacco Control Act but also should be regulated more rigorously by the FDA to protect the public's health. The dangers caused by cigar smoking are not in doubt. In 1998, the National Cancer Institute documented causal connections between regular cigar use and cancers of the lungs, larynx, oral cavity, and esophagus.¹³³ Cigar smokers who smoke regularly and those who inhale deeply are at increased risk of coronary heart disease and chronic obstructive pulmonary disease.¹³⁴ Cigar smoking increases cotinine levels and is associated with decreased lung function.¹³⁵ Cigars can be more harmful than cigarettes due to higher levels of tobacco-specific *N*-nitrosamines that are inhaled by users and bystanders.¹³⁶ The tar, carbon monoxide, and ammonia levels in cigars are higher than those found in cigarettes as well,¹³⁷ and the tar found in cigars contains a type of hydrocarbon linked to an increased capability of producing tumors.¹³⁸ The disease-free life-years lost due to cigar smoking have been estimated at 5.2 years.¹³⁹ One study found that cigar smokers experienced an increased risk of hospitalization and death due to chronic obstructive pulmonary disease, the fourth leading cause of death in the United States.¹⁴⁰ The bottom line is that cigar smoking contributes to the increased morbidity and mortality caused by smoking.

Moreover, data demonstrates the increasing prevalence of cigar use. Although cigars are certainly not as popular as cigarettes, there are disturbing trends in cigar smoking, as more young people begin to experiment and become regular users. This trend underscores the need for the FDA to strengthen this proposal and finalize it quickly. Cigars are becoming the product of choice for initiation of tobacco use, and the data shows that younger people are becoming cigar users. The statistics describing the trends of cigar use highlight this problem:

¹³² Tobacco Control Act, §907(a)(3)(B)(i)(I)-(III), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)-(III)); Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)).

¹³³ NAT'L CANCER INST., SMOKING AND TOBACCO CONTROL MONOGRAPH NO. 9: CIGARS: HEALTH EFFECTS AND TRENDS (1998), available at http://cancercontrol.cancer.gov/brp/tcrb/monographs/9/m9_complete.pdf.

¹³⁴ Gary A. Giovino, *The Tobacco Epidemic in the United States*, 33 AM J. PREV. MED. S318, S319 (2007).

¹³⁵ Josanna Rodriguez et al., *The Association of Pipe and Cigar Use with Cotinine Levels, Lung Function, and Airflow Obstruction*, 152 ANNALS INTERNAL MED. 201, 209 (2010).

¹³⁶ Michael B. Steinberg & Cristine D. Delnevo, *Tobacco Smoke by Any Other Name is Still as Deadly*, 152 ANNALS INTERNAL MED. 259, 259 (2010).

¹³⁷ Frank Baker et al., *Health Risks Associated with Cigar Smoking*, 284 JAMA 735, 737 (2000).

¹³⁸ *Id.*

¹³⁹ Michael B. Steinberg & Cristine D. Delnevo, *Tobacco Smoke by Any Other Name is Still as Deadly*, 152 ANNALS INTERNAL MED. 259, 259 (2010).

¹⁴⁰ Rodriguez et al., *supra* note 133, at 201.

- Between 2000 and 2011, cigar sales increased 123%, while cigarette sales decreased by 32.8%.¹⁴¹
- While cigar smoking in the United States was historically a behavior of older men,¹⁴² cigar smoking is now a behavior that skews younger, with young adults (age 18-24) smoking cigars at a significantly higher rate (15.9%) than adults age 25-44 (7.2%), age 45-64 (4.9%), and age 65 or older (1.8%).¹⁴³
- Experimentation with cigars is widespread in the U.S. among young adults, especially men. Among Hispanic, non-Hispanic Black, and non-Hispanic White men age 18-34, ever use of cigars ranges from 26.1% to 46.4%.¹⁴⁴ Among women age 18-34, ever use of cigars ranges from 20.7-25.8%.¹⁴⁵
- With the exception of foreign-born Hispanics, experimentation with little cigars is similarly widespread among young adults age 18-34, with 33.2-35.6% of men reporting ever use of little cigars¹⁴⁶ and 21.9-27.2% of women reporting ever use of little cigars.¹⁴⁷ Approximately 13.1% of high school students are current cigar smokers¹⁴⁸ while 6.6% of adults regularly use cigars.¹⁴⁹
- In some states, high school boys are more likely to smoke cigars than cigarettes. For example, in Montana, 22.1% of high school boys smoke cigars, while only 6.7% smoke cigarettes. In Massachusetts, 20.2% of high school boys smoke cigars versus 15.6% who smoke cigarettes.¹⁵⁰
- Rates of cigar use are likely even higher among high school-age cigarette users; in a study of students at sixteen Chicago area high schools, 76.7% of adolescents who reported smoking at least one cigarette in the 30 days prior to the beginning of the study reported ever using cigars, cigarillos, or little cigars 24 months later, while 40.7% reported past 30 day use of cigars, cigarillos, or little cigars.¹⁵¹
- One recent report found that nearly 60% or more of current cigar smokers are either current or former cigarette smokers; these persons are more likely to inhale cigar smoke more deeply, putting them at particularly high risk for tobacco-related diseases.¹⁵²

¹⁴¹ Ctrs. for Disease Control & Prevention, *Consumption of Cigarettes and Combustible Tobacco – United States, 2000-2011*, 61(30) MORBIDITY & MORTALITY WKLY. REP. 565, 565 (2012), available at <http://www.cdc.gov/mmwr/pdf/wk/mm6130.pdf>.

¹⁴² SGR 2012, *supra* note 63, at 203.

¹⁴³ These usage rates are for all respondents of the National Adult Tobacco Survey. Brian A. King et al., *Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009-2010 National Adult Tobacco Survey*, 15 NICOTINE & TOBACCO RES. 608, 610 (2012).

¹⁴⁴ Lariscy et al., *supra* note 104, at 1421 tbl.2.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ Ctrs. for Disease Control & Prevention, *Youth Risk Behavior Surveillance—United States, 2011*, 61(4) MORBIDITY & MORTALITY WKLY. REP. 1, 16 (2012) [hereinafter CDC YRBS], available at <http://www.cdc.gov/mmwr/pdf/ss/ss6104.pdf>.

¹⁴⁹ Brian A. King et al., *Current Tobacco Use Among Adults in the United States: Findings from the National Adult Tobacco Survey*, 102(11) AM. J. PUB. HEALTH e93, e95-e96 tbl.1 (2012).

¹⁵⁰ CDC YRBS, *supra* note 146, at 16; *see also* CAMPAIGN FOR TOBACCO-FREE KIDS, FACTSHEET: THE RISE OF CIGARS AND CIGAR-SMOKING HARMS (2013) [hereinafter TFK Cigar Factsheet], available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0333.pdf>.

¹⁵¹ Randi M. Schuster et al., *Cigar, Cigarillo, and Little Cigar Use Among Current Cigarette-Smoking Adolescents*, 15 NICOTINE & TOBACCO RES. 925, 927 (2013).

¹⁵² Sara E. Luckhaupt & Geoffrey M. Calvert, *Prevalence of Coronary Heart Disease or Stroke Among Workers*

These statistics may underestimate cigar use, particularly among youth. An analysis of data from the Virginia Youth Tobacco Survey observed differences in youth reporting of cigar use in response to general versus brand-specific questions; for example, 57.3% of high school students who reported use of Black & Mild cigarillos did not report current use of “cigars, cigarillos, or little cigars.”¹⁵³ Other studies have echoed this concern – particularly in regards to rates of cigar use among African-American adolescents.¹⁵⁴ Thus, the problem of youth use of cigars may be even more grave than shown by the existing data.

Federal regulation of cigars would have immediate and important public health benefits. The FDA’s vast retail enforcement resources alone would reduce the number of youth who are able to acquire cigars. In its proposal, the FDA has recognized that there is a growing body of evidence that young adults are using premium cigars at just as high of a rate as they are using filtered little cigars.¹⁵⁵ A federal law prohibiting the sale of cigars to anyone under eighteen, requiring age verification for anyone under twenty-six – enforced by the FDA – would reduce youth access to premium cigars and consequently reduce the rates of youth initiation into tobacco product use. If premium cigars are less of a threat to public health than other cigars, as some have asserted, this is not an argument to exempt them from FDA regulation. It may be an argument to treat the products differently in future regulations, but there is no question that the products should not be sold to youth and that consumers ought to know the health effects of the products that they are using. Exempting premium cigars from FDA regulation would not provide this obvious and simple public health benefit.

The comprehensive regulatory scheme that will take effect for all deemed products would also provide benefits for adult premium cigar users. Regulation will provide consumers with better information regarding the contents of the products and the health effects that they cause. This assertion of jurisdiction also allows the FDA to issue product standards in the future that could result in reductions in toxicants and carcinogens. Exempting premium cigars from this regulatory scheme will prevent the FDA from reducing youth initiation, from obtaining and sharing important information about the products, and from taking any appropriate future actions to reduce the harmfulness of premium cigars. The risk to the health of future generations is too great for the FDA to acquiesce. The FDA must protect public health and it must do so by regulating all cigars. There is no justification within the confines of the public health standard for the FDA to exempt any tobacco product from its regulation. All tobacco products are dangerous and addictive and the FDA must work to reduce initiation and increase cessation.

Aged <55 Years — United States, 2008–2012, 63(30) MORBIDITY & MORTALITY WKLY. REP. 645, 653 (2014).

¹⁵³ Aashir Nasim et al., *Cigar Use Misreporting Among Youth: Data from the 2009 Youth Tobacco Survey, Virginia*, 9 (110084) CDC: PREVENTING CHRONIC DISEASE 2-4 (2012), available at www.cdc.gov/pcd/issues/2012/pdf/11_0084.pdf.

¹⁵⁴ Joshua Terchek et al., *Measuring Cigar Use in Adolescents: Inclusion of a Brand-Specific Item*, 11 NICOTINE & TOBACCO RES. 842, 843-44 (2009) (finding that reported cigar use among high school students on a local Youth Risk Behavior Survey increased from 12.9% in 2002 to 20.7% in 2004 after inclusion of a “brand-specific example” in a question about cigar, little cigar, or cigarillo use, despite no significant changes in national cigar smoking rates over the same period); Valerie Yerger, et al., *When is a Cigar Not A Cigar? African American Youths’ Understanding of “Cigar” Use*, 91 AM. J. PUB. HEALTH 316, 316 (2001) (finding that African American youth who participated in focus groups “exploring patterns and understanding of cigar use” were more likely to report cigar use post-discussion than pre-discussion, suggesting that there had been confusion regarding what is meant by “cigar”; participants also tended to refer to thinner cigars, such as Black & Milds, by brand, rather than as “cigars”).

¹⁵⁵ Deeming Regulation, 79 Fed. Reg. at 23,151.

ii. An exemption from FDA regulation for any product will inevitably have unintended consequences.

In deciding whether to create an exemption for premium cigars, the FDA must consider all of the available evidence demonstrating cigar manufacturers' ability and propensity to manipulate their products to receive favorable taxation and favorable regulation. If the FDA establishes an exemption of any kind, it should expect some form of exploitation of that exemption. The cigar industry is well aware of what is at stake and will likely take action to ensure that as many of its products as possible will be eligible for a premium cigar exemption.

The most illustrative example of a cigar being engineered to exploit a loophole is the so-called little cigar,¹⁵⁶ also known as a brown cigarette. For all intents and purposes a little cigar is a cigarette. Little cigars are the same size as cigarettes, generally have an integrated cellulose or acetate filter like cigarettes and are typically offered in packages containing twenty little cigars.¹⁵⁷ However, because a little cigar is taxed as a cigar and not a cigarette, a 20-pack of little cigars sells for much less than a package of cigarettes,¹⁵⁸ making it easier for price-sensitive consumers, particularly youth, to purchase. In addition, little cigars may be sold singly, further decreasing their cost. Because they aren't considered cigarettes, little cigars are also available in youth-enticing flavors and bear no health warnings.

Despite the fact that they are likely to be offered or purchased as cigarettes and may satisfy the federal definition of cigarette, the little cigar is not considered a cigarette for regulatory and taxing purposes under federal law, despite the fact that the only difference between the two products is a small amount of tobacco used in the paper wrapping the little cigar.¹⁵⁹ While the FDA's proposed exemption for premium cigars would not exempt little cigars, the product serves as an example of the ability of the tobacco industry to adapt products for its own financial benefit at the expense of public health.

Product manufacturers are adept at exploiting differential treatment in existing laws between cigars and other products to undermine the positive public health impact of those laws. For

¹⁵⁶ Many jurisdictions make no regulatory distinction between small cigars and little cigars, including the federal tax scheme. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, TOBACCO TAXES: LARGE DISPARITIES IN RATES FOR SMOKING PRODUCTS TRIGGER SIGNIFICANT MARKET SHIFTS TO AVOID HIGHER TAXES, 19-20 (2012) [hereinafter GAO Tax], available at <http://www.gao.gov/assets/600/590192.pdf>. This comment refers to little cigars as those products that are offered or purchased as cigarettes and would be regulated as such but for a small amount of tobacco in their wrappers.

¹⁵⁷ The Tobacco Control Act adopts the definition of little cigar used in section 1332, subdivision 7 of the Federal Cigarette Labeling and Advertising Act (FCLAA): "any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco . . . and as to which one thousand units weigh not more than three pounds." Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §1332(7) (2013).

¹⁵⁸ Federal, state and local cigarette taxes far exceed taxes on cigars. *See, e.g.,* Cristine D. Delnevo et al., *Trading Tobacco: Are Youths Choosing Cigars Over Cigarettes?*, 95 AM. J. PUB. HEALTH 2123, 2123 (2005); *see also* TFK Cigar Factsheet, *supra* note 148.

¹⁵⁹ Most states define cigarette as a roll of tobacco made for smoking wrapped only in paper. *See, e.g.,* MD. BUSINESS REG. § 16-101(b). A few jurisdictions, however, have specifically included little cigars in their definition of cigarettes for various reasons, including to impose the cigarette tax on little cigars. *See, e.g.,* IOWA CODE § 453A.43(1)(d) (2013); VT. STAT. ANN., tit. 32, § 7771(c) (2013); MONT. ADMIN. R. 42.31.207 (2013); N.M. CODE R. § 3.9.1.7 (2013).

example, in 2009, Congress increased the excise tax on small cigars weighing less than three pounds per thousand but did not increase the tax on other cigars to address the tobacco companies' practice of making cigarette-like small cigars that would not be subject to the higher taxes imposed on cigarettes.¹⁶⁰ Manufacturers, in response, engineered their cigars that look just like cigarettes to be slightly heavier to pass over the weight threshold into the large cigar category and therefore be subject to a lower tax.¹⁶¹ After the passage of the tax increase on small cigars, the cigar market dramatically shifted toward larger cigars that now weighed slightly more than three pounds per thousand, with a 116% increase in the number of larger cigars sold from 2008 to 2011, and a concomitant 85% decline in the number of small cigars sold.¹⁶² This market trend was not a consumer shift towards more expensive premium cigars but a manipulation, by manufacturers, of the weight of cigars to change their product category for the purpose of favorable taxation.

No matter how narrow an exemption the FDA creates, cigar manufacturers will find a way to manipulate their products to qualify for it to avoid any regulatory oversight. The FDA must implement regulatory Option 1 and regulate all cigars without exception.

b. The proposed regulation would delay enforcing the Tobacco Control Act requirements for the newly-covered products, resulting in significant public health harm by exceeding what is necessary to allow tobacco product manufacturers to adapt to a new regulatory environment.

On the effective date of the final rule, all deemed products will become subject to the Food, Drug, and Cosmetic Act as modified by the Tobacco Control Act. Those products will, for the first time, be governed by all of the provisions in the Act that use the term “tobacco product” to describe regulated products. The swift and effective implementation of these important provisions can potentially be one of this regulation’s greatest successes. However, the proposed regulation would delay the enforcement of these provisions, preventing that success. Rather than compel manufacturers – who have had five years notice of the eventuality of regulation and the additional time between the initial notice of this proposal and the implementation of the final rule that results from this proposal – to submit to the regulatory framework that applies to all other tobacco product manufacturers, the proposed regulation would accommodate industry interests with unnecessary delays. There is no reason, especially in light of the Act’s public health standard, for lengthy delays of the enforcement of important sections of the Tobacco Control Act. Many of these provisions are necessary to protect public health and foundational to the greater implementation of the Act.

¹⁶⁰ GAO Tax, *supra* note 154, at 19-20; CAMPAIGN FOR TOBACCO-FREE KIDS, NOT YOUR GRANDFATHER’S CIGAR: A NEW GENERATION OF CHEAP & SWEET CIGARS THREATENS A NEW GENERATION OF KIDS, 15 (2013), available at http://www.tobaccofreekids.org/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf (noting that cigar companies add a clay substance often found in cat litter to increase the weight of a cigar to avoid higher taxes).

¹⁶¹ GAO Tax, *supra* note 154, at 20.

¹⁶² *Id.*

i. There is no legitimate justification for the FDA’s proposed delays in enforcing the Tobacco Control Act.

Rather than establishing an enforcement schedule tailored to this regulation, the FDA has merely taken the delayed implementation schedule from the Tobacco Control Act and mirrored it to the effective date of this proposed rule. For all provisions in the Act that were delayed until twenty-four months after the Act was passed, they will also be delayed twenty-four months from the effective date of this rule for all deemed products. Given the circumstances, this action is illogical and provides another example of the FDA prioritizing industry interests over the public’s health.

It is likely that Congress included delays for implementing the Tobacco Control Act to allow for the creation, staffing, and training of a previously non-existent FDA center. The FDA needed that time to build the Center for Tobacco Products. Now that the Center is staffed and trained, the proposed delays in implementation are solely for the benefit of the tobacco industry, and to the detriment of public health. There is no rationale that supports such a delay other than a clear deference to the industry’s interests. Notice of Proposed Rulemaking appears to justify the proposed delay in the enforcement of this regulation by raising issues of “consistency and fairness.” Setting aside for the time being that neither of these concepts are connected to the FDA’s statutory obligation of protecting public health, the delayed enforcement of these provisions promotes neither consistency nor fairness.

The Act is inherently inconsistent. The FDA began regulating cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco in 2009 and certain provisions in the Act related to those products took effect immediately while others were phased in over time. The FDA will not officially have jurisdiction over deemed products until this rule is finalized which, given the FDA’s track record, could still be at least a year away, even assuming that there are no delays resulting from tobacco industry litigation. Ensuring consistency in regulation would have required FDA to assert jurisdiction immediately or as soon as possible after the Act was passed to regulate all products in the same manner and at the same time or as close as possible to the same time. Because consistent FDA regulation is achieved through uniform FDA regulation, the only way that the FDA can promote consistency at this point is to put all products under the same regulatory scheme as quickly as possible. In order to do this, the FDA must significantly shorten the proposed delays in implementation and use the shortest possible timeline that will reasonably allow the industry time to comply with the law.

The proposed delays in enforcement also do not promote fairness for the very same reasons. Different regulation of different products for arbitrary reasons is inherently unfair, to manufacturers of those products, consumers of the products who suffer the health effects, and to public health more broadly. To promote fairness for everyone affected by tobacco product regulation, the FDA must regulate all products as quickly as it is able.

While consistency and fairness are important in any regulatory process, delayed implementation under the guise of these goals is counter to the protection of public health, which is the FDA’s touchstone in its regulation of tobacco products. To protect public health, the FDA must minimize the delay in compliance for the statutory and regulatory provisions that will apply to all products. While there may be difficulty imposing some requirements on manufacturers

immediately, without very short delays, and the FDA will need to prepare to enforce the Act, the FDA's established timelines for enforcement extend far beyond that which is needed for manufacturers to comply with the law and the FDA to enforce the law.

The FDA need not assume that the release of its proposal was the first time that newly-covered tobacco product manufacturers ever considered that their products could be the subject of federal regulation. Contrary to that assumption, manufacturers of newly-covered products have been on notice of the potential for the FDA to issue this regulation since at least as early as June 22, 2009, when the Act was passed, giving the FDA the authority to promulgate this regulation. Starting on that date, all manufacturers of tobacco products, including those that the FDA was not compelled to regulate when the Act was passed, should have been aware that at some point in the future, it was possible that they would be required to submit to all of the requirements and restrictions established in the Tobacco Control Act.

Tobacco product manufacturers most certainly should have been on notice that being subject to the existing federal requirements was no longer just a possibility, but indeed a near certainty once the FDA named this regulation a priority in the United Regulatory Agenda. The FDA used this process to formally state its intention to regulate cigars on April 26, 2010, and its intention to regulate all tobacco products on July 7, 2011. E-cigarette manufacturers in particular were aware of the potential for regulation because the FDA also issued a statement of intent to regulate e-cigarettes as a tobacco product on April 25, 2011, following the conclusion of the *Sottera* case. In fact, many e-cigarette manufacturers first entered the marketplace following that decision and have always been operating in an environment where the FDA could assert its jurisdiction over the products at any time.

Manufacturers have no legitimate justification for any claims that they are unprepared for this regulation and the FDA has no justification for accommodating such false concerns. In addition to years of forewarning, some manufacturers of newly-covered products also manufacture products that are already subject to FDA regulation and thus should be well prepared for the FDA to take this action. Delaying implementation of the provisions in the Act with respect to the newly-covered products by as much as 36 months goes far beyond what is necessary. The delayed enforcement in the Act allowed the manufacturers of regulated products to learn about FDA regulation of tobacco while Congress allowed the FDA time to create and begin staffing the Center for Tobacco Products and establish processes necessary for tobacco product regulation. Now that CTP is fully operational and the tobacco industry has been on notice of this potential, there is no need to delay enforcement as significantly as the FDA has proposed.

Rather than setting dates based on misperceptions of what constitutes "consistency and fairness," this regulation must be implemented in a manner that maximizes the protection of public health, as is required under the Tobacco Control Act. At the most basic level, that would require the FDA to implement this regulation as quickly as is feasibly possible. The known and unknown health effects of the newly-covered products, the youth attractiveness of cigars and e-cigarettes, the mounting evidence of experimentation and regular use of newly-covered products by youth and young adults, and the very real potential for these products to addict another generation into a lifetime of tobacco use requires the FDA to act swiftly to protect public health. Manufacturers have been on notice of this potential action for at least three years and the core requirements of the Act that apply to manufacturers by virtue of their products being deemed subject to the

FDA's authority have been public and static for that entire time. Any manufacturer truly interested in complying with this action will be well prepared to do what must be done as soon as a final rule is published. The FDA need not extend implementation deadlines to cater to business interests when its mission is to protect public health.

ii. A more balanced enforcement schedule will provide greater protection for public health while remaining feasible for the tobacco industry and the FDA.

The proposed enforcement timeline is far too accommodating to the tobacco industry and will not adequately protect public health as required by the Tobacco Control Act. A more balanced approach to the enforcement of the regulation will better protect public health and allow the tobacco industry ample time to comply with the new law. A balanced approach must defer not to industry desire to delay enforcement but to the importance of the regulation and the feasibility of enforcement. Those regulations that will provide the greatest protection to public health by preventing significant harm must be implemented as quickly as is feasibly possible, despite claims of the potential hardship to the industry. Any regulatory scheme will impose some burdens on those who are regulated. For those provisions that are particularly crucial to the protection of public health, this comment proposes short timelines that, while still reasonable, would compel the tobacco industry and the FDA to act quickly.

The proposed timeline below is based on the estimated burden hours from the FDA's regulatory impact assessment, using the FDA's estimates for the amount of time required for compliance to determine the shortest amount of time that would be feasible to implement the regulation. If it is determined that the burden estimates are too high, the proposed enforcement timeline should be shortened accordingly.

Of the dates suggested below, for any requirement that would require sixty or fewer days for the tobacco industry to comply, this comment proposes that the FDA begin enforcing the requirement sixty days following the date of publication of the final rule. Because this proposed regulation is a "major rule" according to the Office of Information and Regulatory Affairs,¹⁶³ the Congressional Review Act mandates that the rule cannot take effect until sixty days after the final rule is published in the Federal Register.¹⁶⁴ While the FDA proposed to begin enforcing parts 1100 and 1140 of the rule thirty days following the date of publication of the final rule,¹⁶⁵ in order to comply with the Congressional Review Act no part of the rule can be enforced until sixty days have passed after the final rule's publication in the Federal Register.

¹⁶³ 5 U.S.C. § 804(2) (1996); *OIRA Conclusion of EO 12866 Regulatory Review*, OFFICE OF INFORMATION AND REGULATORY AFFAIRS (Aug, 8, 2014, 9:46 AM), <http://www.reginfo.gov/public/do/eoDetails?rrid=123467> (designating the regulation as major).

¹⁶⁴ 5 U.S.C. § 801(a)(3) (1996).

¹⁶⁵ Deeming Regulation, 79 Fed. Reg. at 23,171.

Figure 1

FDCA citation	FDA Proposal	Consortium Proposal	Justification
903(a)(2)	24 months after the issuance of the final regulation	60 days after the issuance of the final regulation	Identification of manufacturer and contents of product is too important to defer
903(a)(3)	Effective date of part 1100 PLUS 1 year	60 days after the issuance of the final regulation	Allows enforcement of other substantive provisions
903(a)(4)	Effective date of part 1100 PLUS 1 year	60 days after the issuance of the final regulation	Use of a product's established name is too important to defer
903(a)(8)	Effective date of part 1100 PLUS 1 year	60 days after the issuance of the final regulation	Use of a product's established name, warnings and side effects are too important to defer
904(a)(1) and 904(c)(1)	Effective date of part 1100 PLUS 6 months (products on the market as of the effective date) or 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date)	60 days after the issuance of the final regulation	At 3 hours per submission and at most 33 submissions per manufacturer, the disclosure of ingredients and additives takes 99 hours – less than 13 days – for the largest manufacturers to comply
904(a)(3)	Effective date of part 1100 PLUS 3 years	6 months after the issuance of the final regulation, 9 months for small manufacturers	FDA draft guidance for industry on reporting harmful and potentially harmful constituents issued March 2012 ¹⁶⁶ with enforcement beginning 6 months later on September 22, 2012 for large manufacturers and 9 months later on December 22, 2012 for small manufacturers
904(a)(4)	Effective date of part 1100 PLUS 6 months (current manufacturers) or 90 days prior to delivery for introduction	60 days after the issuance of the final regulation	At 50 hours per submission and at most 4 submissions per manufacturer, submitting health documents takes

¹⁶⁶ FOOD AND DRUG ADMINISTRATION, REPORTING HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS IN TOBACCO PRODUCTS AND TOBACCO SMOKE UNDER SECTION 904(A)(3) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2012), *available at* <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297828.pdf>.

	into interstate commerce (new manufacturers)		200 hours – 25 days – for manufacturers to comply
905(b), (c), (d), and (h)	If the final rule publishes in the second half of the calendar year, FDA will designate a date for owners and operators to register that is no later than 6 months into the subsequent calendar year. (The registration date will be specified in a draft guidance for registration.) The timeframes for paragraphs (c) and (d) take effect after the date specified for (b) occurs	60 days after the issuance of the final regulation	At 3 hours per submission and at most 1 submission per manufacturer, registration of manufacturers takes 3 hours – less than one day – for manufacturers to comply
905(i)(1)	Must submit at the time of initial registration; see date specified for 905(b)	60 days after the issuance of the final regulation	At .75 hours per submission and at most 33 submissions per manufacturer, submitting a list of products takes 24.75 hours – less than 4 days – for manufacturers to comply
907(a)(1)(B)	Effective date of part 1100 PLUS 2 years	60 days after the issuance of the final regulation	This special rule requires manufacturers to comply with any established federal standards for pesticide chemical residue. According to the FDA, no such standards exist. ¹⁶⁷ For that reason, no extension beyond the 60 days is required.
911(b)(2)(A)(i) and (ii)	Use of “light,” “low,” and “mild” descriptors: Effective date of part 1100 PLUS 1 year (stop manufacture); Effective date of part 1100 PLUS	No manufacturing or distributing beginning 60 days after the issuance of the final regulation and no retail sale beginning 90 days after	Regulation of modified risk claims is too important to defer

¹⁶⁷ Letter from Lawrence R. Deyton, Dir., Ctr. for Tobacco Products, to James E. Swauger, Vice President, Regulatory Oversight, R.J. Reynolds Tobacco Company, (Dec. 6, 2011), *available at* <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM282742.pdf>; Letter from Lawrence R. Deyton, Dir., Ctr. for Tobacco Products, to Victor L. Moldovan, attorney for Universal Corporation, (Dec. 6, 2011), *available at* <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM282745.pdf>.

	13 months (stop distribution)	the issuance of the final regulation	
920(a)(1)	24 months after the issuance of the final regulation	60 days after the issuance of the final regulation	Identification of products for sale in the U.S. is too important to defer

c. The FDA’s proposed delay in enforcing the premarket review requirements for deemed tobacco products will create a loophole in the tobacco product regulation that will eviscerate the public health gains that this rule is intended to create.

The FDA’s proposal to delay the implementation of premarket review of new tobacco products for twenty-four months following the effective date of the final regulation is a shocking display of deference to the regulated industry at the expense of public health. Such a delay would be a monumental mistake for an agency that must regulate novel products with unknown public health effects, when that agency possesses a tool like premarket review with such potential to protect public health. The FDA must not open yet another loophole in the premarket review process and allow the tobacco industry to once again flood the market with deadly, addictive tobacco products.

With the passage of the Tobacco Control Act, Congress unambiguously delegated to the FDA the authority to approve the sale of new tobacco products before those products can be introduced to the market.¹⁶⁸ This premarket review authority for tobacco products is a first-of-its-kind regulatory power, not just for an American regulatory agency, but for the entire global tobacco control movement. At the height of a global tobacco pandemic, the success or failure of the FDA to carry out its mission will have repercussions for hundreds of millions of people throughout the world, for decades to come.

The FDA has been entrusted with a leadership position in tobacco control in the United States. State and local governments have fewer resources and look to the FDA to provide direction with respect to the development of a science base to support regulation and look to the FDA to develop policies that will complement state and local efforts to reduce the disease and death caused by tobacco use. It is particularly important for the FDA to provide strong leadership in those areas where state and local governments are preempted from taking action. Where state and local governments cannot act, they depend on the FDA to use its full authority to protect public health. The premarket review of tobacco products is one such area where the federal government has the sole authority to regulate.

For the first five years of its existence, the FDA’s Center for Tobacco Products has not adequately addressed the tobacco industry’s blatant manipulation of the premarket review process and, as a result, has failed to use its full authority to protect public health. The industry, found by the courts to perpetuate deception collaboratively and individually, earning the label

¹⁶⁸ Tobacco Control Act, § 905(j), 123 Stat. at 1974 (codified at 21 U.S.C. § 387e(j)); Tobacco Control Act, § 910, 123 Stat. at 1807 (codified at 21 U.S.C. § 387j).

“racketeers,”¹⁶⁹ has brazenly focused its resources on an unfortunate and obvious legal loophole in the premarket review process. This loophole allows the tobacco industry to exploit the premarket review process and maximize its profits at the expense of public health, potentially resulting in the introduction of thousands of new products to the market without the proper level of oversight foreseen by Congress. The FDA has proposed to establish a similar loophole with respect to newly-covered products that would allow the tobacco industry to introduce thousands of additional new products without the regulatory scrutiny that the Tobacco Control Act mandates.

i. The Tobacco Control Act creates three pathways for new tobacco products.

The regulatory scheme for premarket review envisioned by Congress, established in the Tobacco Control Act, is simple. The Act creates three categories of new products, each with a different set of requirements for a manufacturer to market a new product. The most stringent pathway for new products is the Premarket Tobacco Product Application (PMTA) process. The process was created for products that are the least similar to past products and thus have the greatest potential to do additional harm. The PMTA pathway is intended to be the primary pathway for new tobacco products.¹⁷⁰ A PMTA is to be denied by the FDA if: 1) the product does not appropriately protect public health,¹⁷¹ considering the product’s impact on initiation and cessation;¹⁷² 2) the manufacturing process for the product does not comply with established standards;¹⁷³ 3) the product contains false or misleading labeling;¹⁷⁴ or 4) the product does not comply with an FDA established product standard.¹⁷⁵

The Tobacco Control Act also establishes a pathway for those products that are “Substantially Equivalent” to products that were marketed in the past. The Substantial Equivalence (SE) pathway, a secondary pathway to bring products to the market, is intended to be used for products that have the same characteristics as past products,¹⁷⁶ or different characteristics that do not raise different questions of public health.¹⁷⁷ This process necessitates the comparison between a past product, called a predicate product, and a new product. To serve as a predicate, a product must be grandfathered and Congress established specific requirements for the certification of such products. Any product commercially marketed (not test marketed) in the

¹⁶⁹ United States v. Philip Morris USA, Inc., 449 F.Supp.2d 1 (D.D.C. 2006). For an overview of industry practices from the findings section of the case, see TOBACCO CONTROL LEGAL CONSORTIUM, THE VERDICT IS IN: FINDINGS FROM THE UNITED STATES V. PHILIP MORRIS (2006) *available at*

<http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>; *See also*, DESMOND JENSON, TOBACCO CONTROL LEGAL CONSORTIUM, RACKETEERS AT THE TABLE: HOW THE TOBACCO INDUSTRY IS SUBVERTING THE PUBLIC HEALTH PURPOSE OF TOBACCO Regulation (2013), *available at* <http://publichealthlawcenter.org/sites/default/files/resources/tclc-synopsis-racketeers-table-2013.pdf>.

¹⁷⁰ Webinar: 20 Years Later – Returning to FDA to Regulate Tobacco, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm368823.htm> (last visited Aug. 8, 2014).

¹⁷¹ Tobacco Control Act § 910(c), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(A)).

¹⁷² Tobacco Control Act § 910(c), 123 Stat. at 1810 (codified at 21 U.S.C. § 387j(c)(4)).

¹⁷³ Tobacco Control Act § 910(c), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(B)).

¹⁷⁴ Tobacco Control Act § 910(c), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(C)).

¹⁷⁵ Tobacco Control Act § 910(c), 123 Stat. 1809-1810 (codified at 21 U.S.C. § 387j(c)(2)(D)).

¹⁷⁶ Tobacco Control Act § 901(a), 123 Stat. at 1808 (codified at 21 U.S.C. § 387j(a)(3)(A)(i)).

¹⁷⁷ Tobacco Control Act § 901(a), 123 Stat. at 1808 (codified at 21 U.S.C. § 387j(a)(3)(A)(ii)).

United States on February 15, 2007, can be certified as a “grandfathered” tobacco product,¹⁷⁸ making it eligible to be used as a predicate product on an SE report so long as the product is compliant with any product standards established by the FDA. A product that is approved for sale under the SE pathway can also serve as a predicate product even though it is not a “grandfathered” tobacco product.¹⁷⁹

The final pathway established by the Act creates a narrow exemption from the requirement to submit an SE report. The SE Exemption pathway is intended for a product that is so similar to a predicate product that the difference between the two is considered minor and thus the submission of a full SE report is not necessary to protect public health.¹⁸⁰ The statutory example of a product eligible for this pathway is one where an additive is deleted or added or where the level of an existing additive is increased or decreased.¹⁸¹

While Congress intended the FDA to use its full premarket review authority over all tobacco products, it created a loophole in this process, presumably to attempt to create a smooth transition between an era when the industry had free reign to sell products without any oversight and an era when a newly-created center within the FDA would approve any changes to any products. This loophole allows manufacturers to market a new product through the SE pathway as long as an SE report was filed on or before March 22, 2011 (called a “Provisional SE Report”). The products for which a Provisional SE report was filed can remain on the market until the FDA denies the SE report. For SE reports submitted on or after March 23, 2011, called “Regular” SE reports, the products follow the SE process mentioned above – they cannot be introduced to the market until *after* the FDA has issued an SE order based on the report. In theory, as of March 23, 2011, no new tobacco product can be introduced into the market without the approval of the FDA regardless of the pathway chosen by the manufacturer.

ii. The tobacco industry has expended tremendous resources to manipulate the Substantial Equivalence process and the FDA has failed to adequately prevent and/or mitigate that manipulation.

The tobacco industry orchestrated a massive exploitation of the Provisional SE loophole. As of March 31, 2014, the tobacco industry has submitted 4 PMTAs and 59 SE Exemption requests.¹⁸² However, the industry flooded the FDA with SE reports just before the March 2011 deadline, bringing the total number of Provisional SE reports to 3,517.¹⁸³ This represents 78% of the 4,492 submissions that the FDA has received for all three pathways *combined* since it was granted

¹⁷⁸ Tobacco Control Act § 905(j), 123 Stat. at 1794 (codified at 21 U.S.C. § 387e(j)(1)(A)(i)).

¹⁷⁹ Tobacco Control Act § 905(j), 123 Stat. at 1794 (codified at 21 U.S.C. § 387e(j)(1)(A)(i)).

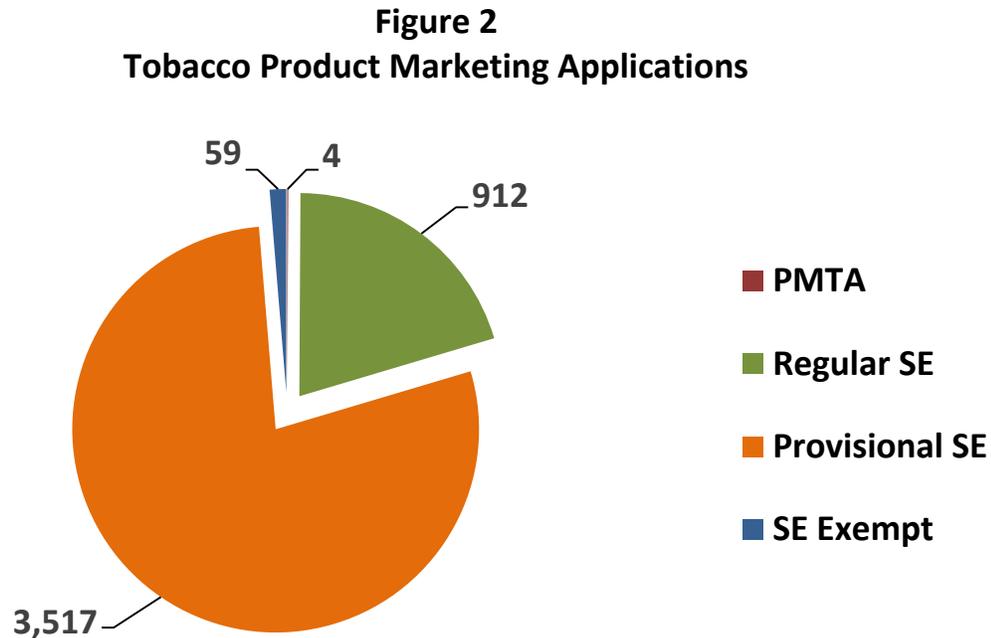
¹⁸⁰ Tobacco Control Act § 905(j), 123 Stat. at 1794 (codified at 21 U.S.C. § 387e(j)(3)).

¹⁸¹ Tobacco Control Act § 905(j), 123 Stat. at 1794 (codified at 21 U.S.C. § 387e(j)(3)).

¹⁸² *Total Number of Product Submission Received or Filed in the Month*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/FDA/Track/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all> (last visited Aug. 8, 2014). All application totals current through March 31, 2014. *Id.*

¹⁸³ *Total Number of Product Submission Received or Filed in the Month*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/FDA/Track/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all> (last visited Aug. 8, 2014).

authority over tobacco products.¹⁸⁴ Figure 2 attempts to put this tactic into perspective. The FDA has received far more Provisional SE reports than any other type of submission, more than triple all other submissions combined, almost all of which were submitted in one month.



It is clear that the tobacco industry has focused its efforts on the parts of the tobacco product application process that will maximize its ability to get new addictive and deadly products on the market with the least amount of scrutiny possible.

Mitch Zeller, Director of the Center for Tobacco Products, has repeatedly stated that the PMTA process was intended to be the primary pathway to bring new products to the market.¹⁸⁵ The amount of evidence and the level of scrutiny required under the PMTA process is appropriate for an industry that has spent decades manipulating its products to deliver the precise amount of nicotine to create and sustain addiction.¹⁸⁶ Understandably, the industry has submitted substantially more Regular SE reports than applications under the PMTA pathway in hopes of finding an easier way to get new products to the market. While the Tobacco Control Act tries to find a balance with the introduction of new products that do not pose new questions of public

¹⁸⁴ *Total Number of Product Submission Received or Filed in the Month*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all> (last visited Aug. 8, 2014).

¹⁸⁵ *See, Webinar: 20 Years Later – Returning to FDA to Regulate Tobacco*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm368823.htm> (last visited Aug. 8, 2014).

¹⁸⁶ *United States v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1 (D.D.C. 2006). For an overview of industry practices from the findings section of the case, see TOBACCO CONTROL LEGAL CONSORTIUM, *THE VERDICT IS IN: FINDINGS FROM THE UNITED STATES V. PHILIP MORRIS (2006)* available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>; *See also*, Desmond Jenson, TOBACCO CONTROL LEGAL CONSORTIUM, *RACKETEERS AT THE TABLE: HOW THE TOBACCO INDUSTRY IS SUBVERTING THE PUBLIC HEALTH PURPOSE OF TOBACCO Regulation (2013)* available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-synopsis-racketeers-table-2013.pdf>.

health by offering the SE pathway, the tobacco industry racketeers' use of the Provisional SE process represents a clear manipulation of the premarket review process.

Many, if not thousands, of Provisional SE reports pending before the FDA are being used as placeholders that will allow the tobacco industry to continue to introduce new products at will, rather than following the proper legal procedures established by the Tobacco Control Act. While the Tobacco Control Act requires that a Provisional SE report be filed on or before March 22, 2011, and requires the report to predate the initial marketing of the product by ninety days, there is no deadline for the initial marketing of the corresponding product. Thus, as long as a tobacco company filed a Provisional SE report for a new product before the March 22, 2011 deadline, it is free to market that product – without premarket review – at any point in the future, until the FDA issues an order to remove the product from the market, circumventing the Act's premarket review requirements.

The tobacco industry's own regulatory filings describe this tactic. Lorillard Inc. has indicated, in one of its filings to the docket for its citizen petition asking the FDA to convert all Regular SE reports to Provisional SE reports, that it believes that its “competitor (P.M. USA) continues to launch product after product having taken advantage of a loophole in the law.”¹⁸⁷ Using a Provisional SE report as a placeholder to market a future product without first seeking premarket review is the loophole to which Lorillard refers. While we do not know exactly how many of the 3,517 Provisional SE reports are being used as placeholders, tobacco retail outlets did not start selling a large influx of new tobacco products in late June 2011. Because there was no expansion of the number of tobacco products available that would correspond with the flood of Provisional SE reports, it is reasonable to conclude that most of these products were not ready to enter the market when the Provisional SE reports were filed.

There is one example of this tactic with clear documentation. As Lorillard alleges, Philip Morris USA (PM) is one of the manufacturers that has used Provisional SE reports as placeholders. PM launched a new cigarette sub-brand to its Marlboro line of products in 2012 and then expanded the marketing of the product in 2013. In its filings to the U.S. Securities and Exchange Commission, Altria Group, Inc., parent company of PM, explains that the new product, Marlboro NXT, was marketed in twenty-seven states at the end of September 2012.¹⁸⁸ In a subsequent filing, it explains that Marlboro NXT was expanded into an additional twenty-three states in July 2013.¹⁸⁹ Neither filing specifically labels a particular date as the date of initial marketing but clear dates are given for the marketing of the product in all fifty states, with the earliest date being a full year after the ninety day waiting period for the marketing of a product for which a Provisional SE report was filed. Given the sheer volume of Provisional SE reports, it is likely

¹⁸⁷ Letter from Murray S. Kessler, Chairman, President & CEO, Lorillard, Inc., to Lawrence Deyton, Dir., Ctr. for Tobacco Products, U.S. Food and Drug Admin. (June 26, 2012), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0695-0007>.

¹⁸⁸ Altria Grp., Inc., Quarterly Report (Form 10-Q) (Oct. 30, 2012), *available at* <http://www.sec.gov/Archives/edgar/data/764180/000076418012000030/form10-q.htm> (noting that Philip Morris USA, Inc. was “expanding Marlboro NXT into 27 states at the end of September 2012).

¹⁸⁹ Altria Grp., Inc., Quarterly Report (Form 10-Q) (July 24, 2013) *available at* <http://www.sec.gov/Archives/edgar/data/764180/000076418013000064/a2013form10-qq22013.htm> (noting that Philip Morris USA, Inc. had “expanded distribution of Marlboro NXT to an additional 23 states).

that PM and other manufacturers have used this tactic for other products as well, although it is unclear to what extent.

While it may have been difficult to predict the tobacco industry's manipulation of this loophole while leaving the PMTA process virtually unutilized, the FDA should not create a situation in which this can occur again with the newly-covered products.¹⁹⁰ The FDA has not fulfilled its mandate to protect public health by preventing harmful products from entering the market without oversight. The public health threat caused by the FDA's continued delay on Provisional SE reports will be multiplied if the proposed regulation is adopted and implemented as it is written.¹⁹¹

iii. The proposed delay in enforcing premarket review would seriously diminish the potential benefits to public health that would result from this regulation.

Upon the effective date of the final rule, all products that meet the statutory definition of "tobacco product," will be deemed to be subject to the requirements and restrictions established in the Food, Drug, and Cosmetic Act. On that date, the FDA will be compelled to exercise its premarket review authority for all of the newly-covered tobacco products. Starting on that date, no newly-covered tobacco product can be sold without prior approval from the FDA. However, manufacturers cannot submit, and FDA cannot accept, any marketing application until the FDA's formal authority is established by a final rule. This regulatory paradox creates potential problems for both the regulated industry and the FDA. The FDA has a few options to address these problems and the decision as to which options to utilize must be informed by the FDA's experience with the tobacco product marketing application process thus far.

As explained above, the passage of the Tobacco Control Act presented a similar problem for the FDA and the Act incorporated two tools to solve this problem. First, the Act allows the continued marketing of those products already on the market on February 15, 2007. Second, the Act established a provisional period for the submission of SE reports which has resulted in substantial tobacco industry manipulation. There is questionable merit to both of these approaches but they were not included solely for the benefit of the tobacco industry. The structure was at least partially intended to allow a fledgling FDA office to hire and train enough staff to prepare for the full implementation of the premarket review process. As is explained above, in the five years since the passage of the Act, the FDA has struggled to uphold the

¹⁹⁰ This potential problem would be compounded if, with the newly-covered products, the FDA continued its current practice of focusing on reviewing the regular SE reports before Provisional SE reports. With a mountain of untouched Provisional SE reports and a much smaller but growing pile of Regular SE reports, the FDA has focused its efforts on Regular SE reports. Because Regular SE reports represent products that are not yet on the market, delay on these reports poses no threat to public health, only a minor inconvenience to the tobacco industry. The FDA has not explained why allowing manufacturers to market new products takes priority over ensuring that harmful products never make it to the market. The FDA has a legal obligation to protect public health; it does not have a legal obligation to expedite the process of allowing the tobacco industry to market new products.

¹⁹¹ Deeming Regulation, 79 Fed. Reg. at 23,142; *see also*, TOBACCO CONTROL LEGAL CONSORTIUM, FDA TAKES SMALL STEPS TO EXPAND TOBACCO REGULATION (2014) *available at* <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-fda-takes-small-step-expand-tobacco-regulation-2014.pdf>.

statutory mandate. Now that the FDA is fully staffed and trained, there is no reason to allow this level of deference to the tobacco industry.

The FDA has proposed to delay the enforcement of premarket review for twenty-four months following the regulation's implementation. During that time, the FDA will accept marketing applications through all product pathways and allow tobacco product manufacturers to continue marketing products on the market and to introduce new products at any time. Following the conclusion of the twenty-four month period, the introduction of a new product will require premarket review.

The FDA's proposed twenty-four month delayed enforcement period will serve as a provisional period much like that used for SE reports after the passage of the Act, allowing those products for which a manufacturer has filed an application during the provisional period to stay on the market until the FDA issues an order mandating the removal of the product from the market. However, this provisional period will be significantly more problematic than before. For newly-covered products, the FDA will accept provisional applications from all three product pathways. According to the FDA's proposal, the agency expects to receive 1,402 SE Exemption requests, 54 PMTAs, and 4,208 SE reports in the twenty-four months after the regulation takes effect.¹⁹² These may be low estimates because the FDA expects that the regulation will result in over 13,000 new products being brought under its authority. By these estimates there will be at least 5,664 provisional submissions following the implementation of the final rule – 5,664 new products that will be able to enter the market without first being approved by the FDA. In the three years since the FDA received the 3,517 Provisional SE reports created by the Act, it has acted on only four. It is frightening that the FDA proposes to use this same regulatory scheme for an additional 5,664 newly-covered tobacco products.

This proposal would recreate the provisional application loophole, at the expense of public health. There is no need to repeat this mistake.

iv. Implementation of the premarket review process can allow enough time to submit and process marketing applications without establishing a provisional period that incentivizes deficient and incomplete submissions.

This comment suggests an entirely different timeline for the enforcement of premarket review. As was done with the delayed enforcement of other provisions of the Act, we propose a timeline that is based on the FDA's estimates of the burden of creating a new product submission found in the FDA's proposal. Should these estimates prove to be too high, the timeline can be shortened accordingly.

Below, we examine each new product pathway individually and suggests an enforcement timeline according to the time that it would take the manufacturer to generate a submission and the time that the FDA expects that it will take for the agency to review the submission. The proposal makes necessary assumptions that could result in timelines being lengthened or

¹⁹² Deeming Regulation, 79 Fed. Reg. at 23,142.

shortened,¹⁹³ but we believe that this proposal is reasonable and feasible to implement. Further, it is not unreasonable to expect a regulated industry to act quickly to comply with important, life-saving regulations and, most importantly, the proposed timelines below require no provisional period for enforcement. The proposal allows ample time for the tobacco industry to complete and submit applications and the FDA to review them before premarket review is implemented. The FDA must not repeat past mistakes in implementing the premarket review process, and instead must institute a process that will protect public health.

1. Products commercially marketed in the United States on or before February 15, 2007.

For tobacco products marketed on or before February 15, 2007, the FDA assumes that a manufacturer will spend 10 hours on each submission. The FDA also assumes that the two largest cigar manufacturers will have 25 submissions each and that the next highest number of submission for a manufacturer is 2.8. Given the relative difference in resources between the largest cigar manufacturers and other manufacturers, a reasonable baseline for the number of submission per manufacturer is 10. With 10 submissions requiring 10 hours of work, this process requires 100 staff hours. Because the FDA does no independent verification of information submitted through this process, FDA staff time spent reviewing submissions is minimal. Even if the estimate of industry time spent on submission and the FDA time spent on reviewing is significantly low, there is no legitimate reason to delay the enforcement of this portion of the premarket review process beyond the minimum required delay of 60 days, or 2 months.

2. Substantial Equivalence Exemption

For SE Exemption submissions (for products with minor changes to additive levels), the FDA estimates that a manufacturer will spend 12 hours on an exemption request under 21 C.F.R. § 1107.1(b), 3 hours preparing additional information under 21 C.F.R. § 1107.1(c), 12 hours preparing an environmental assessment under 21 C.F.R. § 25.40, and 3 hours submitting an optional report under 905(j)(1)(a)(ii), for a total of 30 hours. Using 2 submission per manufacturer as a baseline, the greatest amount of time expected for a manufacturer to complete all of its submissions is 60 hours. The FDA has stated that it plans to review and act on incoming SE Exemption submissions within 60 days and over the next few years will be approaching that goal. Allowing the industry 1 week to complete a submission and even providing the FDA with extra time for the review of SE Exemption submissions, there is no legitimate reason to delay the enforcement of this portion of the premarket review process beyond 90 days, or 3 months.

3. Substantial Equivalence Reports

For SE reports, the FDA estimates that a manufacturer will spend 180 per report under 905(j)(1)(A)(i) with an additional 12 hours for the preparation of an environmental assessment under 21 C.F.R. § 25.40. Using 5 reports per manufacturer as a baseline, the greatest amount of time expected for a manufacturer to complete its SE reports is 960 hours. The FDA has stated

¹⁹³ For example, the proposal assumes that all staff working on submissions only work on one submission at a time. The proposal also assumes that a manufacturer is devoting 100 hours of staff time (2.5 FTEs) to the creation of new product submissions per work week.

that it plans to review and act on incoming SE reports within 90 days and over the next few years will be approaching that goal. Allowing the industry 10 weeks to complete its submissions and even providing the FDA extra time for the review of SE reports, there is no legitimate reason to delay the enforcement of this portion of the premarket review process beyond 180 days, or 6 months.

4. Premarket Tobacco Product Applications

For PMTAs, the FDA estimates that a manufacturer will spend 5,000 hours per PMTA submitted under Section 910(c)(1)(A)(i), 4 hours requesting a meeting with the Office of Science and 12 hours submitting an environmental assessment under 21 C.F.R. § 25.40. Using 1 report per manufacturer as a baseline, the greatest amount of time expected for a manufacturer to complete a PMTA is 5,016 hours. Under the Tobacco Control Act, the FDA is required to act on a complete PTMA within 180 days. Allowing the industry 1 full year to complete a PMTA and providing the FDA the maximum amount of time to review a PMTA, there is no legitimate reason to delay the enforcement of this portion of the premarket review process beyond 18 months.

In addition, strengthening the proposed administration of the PMTA process, the FDA could use the PMTA process to significantly curtail the youth-focused marketing tactics that many tobacco product manufacturers are using to target new young consumers. Section 910(c)(1)(B) of the Tobacco Control Act grants the FDA the authority to restrict the sales, distribution, advertising and promotion of tobacco products that it approves for sale through the PMTA process. This could be a powerful tool for the FDA to restrict or eliminate the predatory marketing practices of e-cigarette manufacturers such as using youth-attractive flavors and selling their products over the internet without effective verification of the purchaser's age. We urge the FDA to use this authority to significantly limit youth access to addictive and deadly tobacco products.

v. Swift implementation of premarket review will compel compliance by the industry and the use of strategic enforcement discretion will allow the FDA to fulfill its mandate of protecting public health.

Because our proposed timelines are shorter than the FDA's proposal and do not allow for provisional submissions, the industry will have an incentive to generate high-quality, complete reports as quickly as it is able. Incentivizing complete reports will allow the FDA to begin its review immediately and allow the agency to act on the reports quickly. The swift execution of premarket review for the newly-covered products is the most effective way for the FDA to protect public health.

Some of the questions that the FDA has asked in its proposal seem to suggest that the FDA is seeking regulatory flexibility for newly-covered products for which the SE process is unavailable (because no version of them was on the market in the United States on February 15, 2007) and for newly-covered products, such as e-cigarettes, that may be less harmful on an individual level than conventional combustible tobacco products. This is the wrong approach, betraying public health for increased tobacco industry profits. The new product application processes laid out in the Tobacco Control Act are the only processes available for the tobacco industry to market new products which have no eligible predicate. The very reason that the PMTA process was created

was to provide a higher level of oversight to new products with unknown health consequences for the individual and for the public. The PMTA process is, rightly, the only process available for e-cigarettes. The burden of showing that these products meet the standards established in the Tobacco Control Act is on the manufacturers of these products, not on the FDA.

However, the FDA has also asked about other circumstances where it may allow for more favorable compliance policies related to the enforcement of premarket review, presumably due in part to its need to prioritize its efforts. The FDA has asked specifically about affording more favorable compliance, “[w]hen the marketing of the new tobacco product is limited to existing adult users of the product,” and “[w]hen the marketing of the new tobacco product is unlikely to be seen or received by youth.”¹⁹⁴ These are the only circumstances that the FDA ought to consider if it decides to grant “favorable” enforcement of premarket review. Because 80% of all tobacco users became addicted when they were children or young adults,¹⁹⁵ the FDA should use its broad authority and enforcement discretion to stop the youth-focused marketing tactics of newly-covered products.

As is mentioned above, the FDA has premarket review authority over all newly-covered tobacco products as soon as the deeming regulation is implemented, 60 days after the final rule is published. The power over when and how to implement premarket review could be a powerful tool for the FDA that could benefit public health. As an alternative to the enforcement timelines established above, the FDA could begin swift enforcement of premarket review for those products that are using youth-focused marketing tactics while granting longer delays in compliance and even granting provisional status to only those products where, “the marketing of the new tobacco product is unlikely to be seen or received by youth.”¹⁹⁶ Using product marketing as a guide, the FDA could remove youth-attractive products from the market and incentivize marketing only to adults.

Address predatory practices that target youth in this way would be a short-term tool to deal with these marketing practices. The FDA must still work to promulgate a rule prohibiting all flavors in all tobacco products as well as working to combat all of the marketing tactics that are targeted towards youth. The FDA must implement this regulation as quickly as is feasible and use the processes that are established in the Tobacco Control Act to protect public health rather than tobacco industry interests.

VI. Conclusion

After five years, the FDA has finally taken a small step in the long journey to bring all tobacco products under its regulatory authority. The power to take this action, provided by Congress in its grant of authority to the FDA, has been dormant far too long. Despite the FDA’s broad authority and congressional mandate, the proposed deeming regulation falls far short of the public health community’s expectations, short of the full extent of the FDA’s authority, and short of what the agency can do given the information that it has at its disposal. This proposal leaves glaring regulatory gaps that can be filled by the legally-sound, evidence-based policies discussed

¹⁹⁴ Deeming Regulation, 79 Fed. Reg. at 23,176.

¹⁹⁵ SGR 2014, *supra* note 119, at 708.

¹⁹⁶ Deeming Regulation, 79 Fed. Reg. at 23,176.

in this comment. The nation has waited too long for the FDA to act, the deeming regulation must be strengthened before the final rule is adopted.

The FDA has been granted the authority – and the responsibility – to regulate all tobacco products, including obtaining information about those products and how they are actually used, and establishing standards for their manufacture, sale, distribution, advertising and promotion. Most importantly, FDA tobacco product regulation must ensure that our nation’s children are protected from the addiction, disease, and death caused by tobacco use. By this criteria, the proposed regulation fails to measure up. There is ample evidence for the FDA to prohibit characterizing flavors in all tobacco products, to restrict the advertising and marketing of tobacco products, to require much stronger warning labels, to prohibit self-service access to tobacco products, to establish minimum pack sizes for tobacco products and to mandate child resistant packaging for all products that contain liquid nicotine.

The proposed deeming regulation fails to effectively address one of the most contentious and fastest growing tobacco products: e-cigarettes. The deeming regulation should be crafted to prevent a potential public health epidemic, rather than waiting for further evidence of harm. If future evidence shows that e-cigarettes are an effective tool to reduce the health harms of tobacco addiction, the FDA can always adjust its regulatory approach accordingly. Until then, the agency must act decisively to regulate this new tobacco product. Evidence suggests that as the popularity and prevalence of e-cigarettes increase, so too will experimentation and regular use by youth. This fear is heightened by the public’s knowledge of past tobacco industry behavior as we collectively experience *déjà vu* as we witness e-cigarette companies using marketing tactics that are known to appeal to youth and are now forbidden for cigarettes. The proposed deeming regulation must do more to protect public health from the potential harms of e-cigarettes.

Finally, the FDA’s proposal prioritizes tobacco industry business interests at the expense of public health. The FDA has proposed to unnecessarily delay the enforcement of many important provisions of the Tobacco Control Act years longer than is necessary. Rather than expect manufacturers of addictive and dangerous products to work quickly to comply with federal law, the proposed regulation would allow those manufacturers to continue to peddle their products to children and profit from addiction. The proposal would also delay enforcement of premarket review for newly-covered products and allow manufacturers to continue selling products indefinitely while the FDA reviews applications, which to date, has happened at a glacial pace.

FDA regulation of tobacco products should be anticipatory not reactionary. The FDA must strengthen its proposal in the ways suggested by this comment and it must also act quickly to issue a final rule. The public has waited too long already and every day that passes without FDA regulation is a day that thousands of children try new products many of whom will become addicted to products that will eventually cost them their lives. The FDA has the authority and the evidence, it must act now.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Douglas Blanke". The signature is fluid and cursive, with the first name "Douglas" and last name "Blanke" clearly distinguishable.

D. Douglas Blanke, JD
Director, Tobacco Control Legal Consortium
William Mitchell College of Law
875 Summit Avenue
Saint Paul, MN

Tobacco Technical Assistance Consortium
Emory Centers for Training and Technical Assistance
Rollings School of Public Health, Emory University
848 Green Bay Road
Highland Park, IL 60035

Boston Public Health Commission
1010 Massachusetts Ave. 6th Floor
Boston, MN 02118