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HEALTHY
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Tobacco Control
Legal Consortium

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

CITIZEN PETITION

The undersigned submit this petition pursuant to Title 21, Chapter 9, Subchapter V, Part A of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 10.30 to request that the Commissioner of the U.S. Food and Drug Administration (FDA) assert jurisdiction over and regulate the manufacturing, marketing, sale, and distribution of certain non-cigarette tobacco products, also known as “other tobacco products” (OTPs).¹ The authority to take the requested action is found in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).²

I. PRELIMINARY STATEMENT

¹ The term, “other tobacco products,” generally refers to all non-cigarette tobacco products. The text of this petition will use the term to refer to products not yet regulated by the FDA although some of the supporting materials may not use the term in the same way.

² Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387) [hereinafter Tobacco Control Act].

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Under the Tobacco Control Act, Congress gave the FDA broad regulatory authority over all tobacco products.³ In the Act, which amends the Food, Drug and Cosmetic Act (FDCA), 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.”⁴ However, the FDA currently is regulating only the products that it is required to by the Tobacco Control Act – cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. In order for the FDA to regulate other tobacco products, it must take an affirmative step and deem those products to be subject to regulation.⁵ Thus far, more than four years since the passage of the Tobacco Control Act, the FDA has failed to enact a single regulation that addresses the public health hazards posed by other tobacco products such as cigars, dissolvables, e-cigarettes and hookah. The authority to subject these other products to FDA regulation is made explicitly clear in the Tobacco Control Act and is limited only by the very broad definition of “tobacco product.” Under the FDCA, 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. . . .”⁶ All of the specific products described in this petition fall within this definition. The FDA should fulfill its mandate of protecting the public health by asserting jurisdiction over and regulating all tobacco products.

Congress’ mandate to the FDA is clear: the FDA must promulgate regulations that protect the public health.⁷ The Tobacco Control Act establishes a public health standard of review that is entirely different from the “safe and effective” standard that the FDA has traditionally used to evaluate drugs and medical devices, “because tobacco products are inherently not ‘safe’ or ‘safe and effective.’”⁸ 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.”⁹

The tobacco industry and its allies have attempted to assert that the FDA needs to show strict causation of the harm of tobacco products at the individual level in order to make regulatory decisions. This argument ignores the nature of the public health standard as well as the standard of proof envisioned by Congress in the Tobacco Control Act. In order to implement a tobacco product regulation, Congress directs the FDA to determine that this tobacco product regulation is “appropriate for the protection of public health” 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.¹⁰ The tobacco industry has misrepresented the weight of the evidence needed for FDA to act. It also has ignored, in its communications, the fact that an assessment of what is “appropriate for the public health,” as defined by the Tobacco Control Act,

³ Tobacco Control Act, § 901, 123 Stat. at 1786-87 (codified at 21 U.S.C. § 387a).

⁴ Tobacco Control Act, § 901(b), 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)).

⁵ *Id.*

⁶ Tobacco Control Act, § 101(a), 123 Stat. at 1783 (codified at 21 U.S.C. § 321(rr)(1)).

⁷ Tobacco Control Act, §906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)).

⁸ H.R. REP. NO. 111-58, pt. 1, at 39 (2009), reprinted in 2009 U.S.C.C.A.N. 468, 488.

⁹ *Id.*

¹⁰ Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)).

necessarily involves broader and different considerations,¹¹ 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.¹²

Although it is clear that regulating all tobacco products would benefit public health, it is not surprising that Congress imposed immediate requirements on and gave the FDA immediate regulatory authority over cigarettes and other historically popular tobacco products. Cigarettes have been the best-selling type of tobacco product for generations. As a result of their widespread use and the resulting catastrophic public health consequences, including causing 443,000 deaths annually, cigarettes have been the main focus of public health regulation and community education efforts designed to prevent tobacco initiation and encourage cessation. Cigarette regulation and education began in earnest after the 1964 Surgeon General's Report on Smoking and Health,¹³ and became more prevalent after several Attorneys General brought suit against cigarette and smokeless tobacco manufacturers in the late 1990s. The resulting Master Settlement Agreement (MSA), Smokeless Master Settlement Agreement (SMSA) and four individual state settlements drove up cigarette prices, imposed restrictions on marketing to youth and sent a strong public message about the hazards of smoking. It also raised awareness about the cigarette manufacturers' manipulation of scientific data and tobacco products. Decades of deception by the tobacco industry prompted this action by the Attorneys General, who alleged that the industry manipulated data and successfully pressured scientists to hide the true risks associated with smoking,¹⁴ including controlling what information was made available to the public;¹⁵ manipulating the tobacco plant itself in order to increase the level of nicotine and make tobacco more addictive;¹⁶ and manipulating the design and manufacture of cigarettes to assure the most effective delivery of this addictive component.¹⁷ These allegations were proven by the federal government in *U.S. v. Philip Morris*, when a federal court found that the major cigarette manufacturers violated the Racketeer Influenced and Corrupt Organizations Act (RICO).¹⁸

¹¹ *Id.* For example, the 2004 Surgeon General Report separated causal conclusions from public health recommendations, “a 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 ch. 1, at 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.* ch. 1, at 18.

¹² Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1))(emphasis added).

¹³ U.S. DEP’T OF HEALTH, EDUC., & WELFARE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE OF THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE (1964), available at <http://profiles.nlm.nih.gov/ps/access/NNBBMQ.pdf>.

¹⁴ United States v. Philip Morris USA Inc., 449 F.Supp. 2d 1, 801 (D.D.C. 2006).

¹⁵ *Id.* at 208.

¹⁶ *Id.* at 339-49.

¹⁷ *Id.* at 349-74.

¹⁸ *Id.* at 903-06.

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.¹⁹ Proving their business savvy, however, cigarette manufacturers have been adding to their product lines with novel tobacco products designed to escape the more effective regulations applicable to cigarettes and smokeless tobacco. Other businesses have also entered the market with their new, non-cigarette tobacco products. As sales of these products increase and the public continues to be exposed to the harm that they cause, the need for regulation and public health education becomes critical. The FDA must take steps to regulate the manufacturing, marketing and sale of OTPs that have already secured a place in the market and must prevent new products from eroding gains achieved by existing tobacco product regulation. These steps would 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.²⁰

Current trends in tobacco product development underscore the need for FDA 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.²¹

Emerging tobacco products, such as dissolvable tobacco products, electronic cigarettes, and hookah, enter the market unencumbered by restrictions designed to limit the enticement of youth, reduce youth access or deter adult consumption. Yet all of these products present the threat of addiction and negative health consequences that requires federal regulators to take action. While state and local jurisdictions have been examining and adopting some restrictions to address the threat created by OTPs,²² the FDA has the power and ability to adopt comprehensive regulations that would have a positive impact on public health throughout the U.S. and the agency should take action now. The FDA understands the need to regulate these products and since 2011 has indicated its intention to assert jurisdiction over all tobacco products.²³ Despite the fact that this intent is expressed through the agency's unified agenda²⁴ and has been expressed to the industry in various letters,²⁵ the FDA has not taken the necessary steps to assert jurisdiction over all tobacco products. Continuing to delay action provides the tobacco industry with wide reign in designing, marketing and selling tobacco products that entice and addict young people through

¹⁹ 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>.

²⁰ Tobacco Control Act, Pub. L. No. 111-31, § 906(d)(1), 123 Stat. 1776, 1796 (2009) (codified at 21 U.S.C. § 387f(d)(1)).

²¹ Connolly *supra* note 19; see also, FED. TRADE COMM'N, *supra* note 19; 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>.

²² 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 to -718 (2013); PROVIDENCE, R.I., CODE OF ORDINANCES, § 14-309.

²³ Unified Agenda, 78 Fed. Reg. 44,252, 44,257 (July 23, 2013); Unified Agenda, 78 Fed. Reg. 1,574, 1,579 (Jan. 8, 2013); Unified Agenda, 77 Fed. Reg. 7,946, 7,952 (Feb. 13, 2012); Unified Agenda, 76 Fed. Reg. 40,052, 40,062 (July 7, 2011).

²⁴ Unified Agenda, 78 Fed. Reg. at 44,257 (July 23, 2013) available at <http://www.gpo.gov/fdsys/pkg/FR-2013-07-23/pdf/2013-17060.pdf>.

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

many of the tactics long-forbidden with respect to cigarettes. The public health community is unwilling to tolerate continued delay in protecting public health,²⁶ a sentiment that is shared by members of both houses of Congress.²⁷

II. ACTION REQUESTED

Petitioners request that the Food and Drug Administration adopt regulations in accordance with the substance of the petition. Specifically, the petitioners request that the FDA:

- A. Assert jurisdiction over all products that meet the Tobacco Control Act's definition of "tobacco products."²⁸ In doing so, the FDA must recognize that all references to "tobacco products" in the Tobacco Control Act apply not just to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, but also to all products that currently meet or that will meet the definition of "tobacco product." Consequently, the FDA must exercise all of the regulatory authority granted to it by the Tobacco Control Act with respect to all tobacco products, including the products over which it will assert jurisdiction. This authority includes but is not limited to:
 - a. The authority to regulate adulterated tobacco products;
 - b. The authority to regulate misbranded tobacco products;
 - c. The authority to compel the disclosure of health information;
 - d. The authority to compel registration of tobacco product manufacturers, disclosure of product lists and review of substantially equivalent products;
 - e. The authority over premarket review of new product applications which must be exercised with respect to dissolvable tobacco products, such as sticks, strips and orbs, electronic cigarettes, and any other products that were not marketed in the U.S. prior to February 15, 2007; and
 - f. The authority to regulate "Modified Risk Tobacco Products."
- B. Extend many of the existing restrictions and requirements for cigarettes and smokeless tobacco to all tobacco products, including those requirements related to:
 - a. Sales and Distribution
 - i. Establish a minimum age of 18 to purchase tobacco products,²⁹ and mandate age verification of all persons not over the age of 26.³⁰

²⁶ 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.

²⁷ Letter from Richard J. Durbin, Frank R. Lautenberg, Richard Blumenthal, Sherrod Brown & Jack Reed, 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, *supra* note 21.

²⁸ Tobacco Control Act, Pub. L. No. 111-31, § 101(a), 123 Stat. 1776, 1783 (2009) (codified at 21 U.S.C. § 321(rr)(1)).

²⁹ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.14(a) (2013).

³⁰ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.16(c) (2013).

- ii. Prohibit all non-face-to-face sales of tobacco products including the use of vending machines and self-service displays except in adult-only facilities.³¹
- iii. Establish a minimum package size for all tobacco products,³² prohibit breaking or opening of packages to sell individual tobacco products,³³ and where necessary, engage in a study to determine an appropriate pack size for a particular product.
- iv. Prohibit sampling of all tobacco products including smokeless tobacco that is currently exempt from this regulation if the sample is distributed in a qualified adult-only facility.³⁴
- b. Product Regulation
 - i. Prohibit characterizing flavors in all tobacco products.³⁵
 - ii. Establish warning labels for all tobacco products.³⁶
- c. Advertising and Marketing
 - i. Prohibit tobacco product brand and trade names of non-tobacco products.³⁷
 - ii. Prohibit brand and trade name sponsorship of sporting and cultural events.³⁸
 - iii. Require notice of all advertising in any non-traditional medium.³⁹

III. STATEMENT OF GROUNDS

A variety of non-cigarette tobacco products are currently marketed and sold throughout the country. Some products present known risks of disease and death, while other products are known to contain carcinogens, toxicants and other dangerous chemicals. Some of the newest products have not been subject to sufficient testing to determine their long-term effect on individual and public health. When assessing these novel products, the FDA is required to use the public health standard in determining whether to allow such products on the market and under what restrictions. In addition to posing risks on their own, many of these products undermine public health efforts to encourage smokers to quit, either by allowing smokers to use non-combustible products to sustain their nicotine addiction when in smoke-free venues or by offering lower cost combustible products that reduce incentives to quit. In many jurisdictions,

³¹ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.14(c) (2013) and 21 C.F.R. § 1140.16(c) (2013).

³² Equivalent regulations related to cigarettes can be found at 21 C.F.R. § 1140.16(b) (2013).

³³ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.14(d) (2013).

³⁴ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.16(d) (2013).

³⁵ Equivalent regulations related to cigarettes can be found at Tobacco Control Act, § 907(a)(1)(A), 123 Stat. at 1799-1800 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)).

³⁶ The authority to require warning labels on other tobacco products can be found at Tobacco Control Act, Pub. L. No. 111-31, § 906(d)(1), 123 Stat. 1776, 1796 (2009) (codified at 21 U.S.C. § 387f(d)(1)); *See also*, Tobacco Control Act, Pub. L. No. 111-31, § 907(a)(3), 123 Stat. 1776, 1800 (2009) (codified at 21 U.S.C. § 387g(a)(3)).

³⁷ 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. *Renegade Tobacco Co. v. U.S. Food and Drug Admin.*, No. 3:10-CV-00265 (E.D. Va. May 19, 2010) (stipulation).

³⁸ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.34(c) (2013).

³⁹ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.30(a) (2013).

these products are attractive to youth because of their sweet and sassy flavors, low price and lack of age restrictions for their sale. Although there are many products that contribute to this dynamic, we discuss below the categories of greatest interest, presenting information about prevalence of use and health effects where available.

Because some of these products are very new, at least to the U.S. market, there are gaps in the information regarding the full risk of disease posed by each of these products. This lack of information cannot be interpreted as an indicator of safety. Over half a century's worth of research into the health effects of cigarettes has shown that many tobacco-caused diseases, particularly cancers, have a long latency period which makes it difficult to assess the true scope of disease risk in the short-term.⁴⁰ For example, there is little immediate difference in the mortality risk of young smokers versus young nonsmokers, but differences in morbidity and mortality are readily detectable after decades of smoking.⁴¹ As has been noted by the Institute of Medicine,

The latent period between beginning exposure to tobacco and the development of most adverse consequences is so long that empirical, direct evidence (assessment of immediate and long-term toxicity of individual tobacco products in humans) that one tobacco product is less harmful than another will rarely be available in time to be a basis for informing users.⁴²

While tobacco researchers have attempted to facilitate early risk assessment by searching for biomarkers that are predictive of later disease development, few of these have been validated. The scientific community has not yet been able to determine the extent of reduction in biomarkers that is required to reduce disease risk or the threshold of change that is required for reduced risk.⁴³ However, “it is recognized that today, biomarkers of exposure are better validated compared to biomarkers of potential harm.”⁴⁴ In short, the relative lack of data addressing the direct health effects of OTPs should not be interpreted as indicative of safety, especially when it is known that exposure to these products encourages youth initiation of smoking and reduces the likelihood of quitting smoking.

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, promotion, and distribution. Within this context, any existing tobacco product ought to be subject to regulatory oversight by the FDA and

⁴⁰ INST. OF MED., CLEARING THE SMOKE: ASSESSING THE SCIENCE BASE FOR TOBACCO HARM REDUCTION 140 (2001), available at <http://iom.edu/Reports/2001/Clearing-the-Smoke-The-Science-Base-for-Tobacco-Harm-Reduction.aspx> (noting that, “[f]inally, the responses are most often diseases with long periods of disease progression until diagnosis and from time point of dose estimation.”).

⁴¹ Benjamin J. Apelberg & Jonathan M. Samet, *Estimating the Impact of Tobacco Control Policies on Future Mortality Patterns in the U.S.*, in AFTER TOBACCO: WHAT WOULD HAPPEN IF AMERICANS STOPPED SMOKING 233, 233 (Peter Bearman, Kathryn M. Neckerman & Leslie Wright eds., 2011).

⁴² INST. OF MED., *supra* note 40, at 145.

⁴³ Dorothy Hatsukami et al., *Developing the Science Base for Reducing Tobacco Harm*, 9(supp. 4) NICOTINE & TOBACCO RESEARCH S537, S540 (2007).

⁴⁴ INST. OF MED., *supra* note 40, at 145.

should be subject to restrictions to prevent youth initiation and to help adult consumers quit. In addition, new products must be rigorously scrutinized and kept out of the marketplace unless the agency has determined, pursuant to the public health standard,⁴⁵ that the product has met all of the requirements established in the Tobacco Control Act⁴⁶.

1. Non-cigarette tobacco products raise public health concerns

A. Cigars—cheap flavored singles and little cigars⁴⁷

The term cigar includes a variety of products that differ in size, price, type of fill tobacco, and flavor. So-called small cigars are increasingly the tobacco product of choice for young people.⁴⁸ These cigars are wrapped in paper-tobacco mulch or in something other than 100% whole leaf tobacco, often contain pipe or other cheap types of tobacco, and may have a plastic or wooden filter tip.⁴⁹ Popular brands include Black and Mild, Swisher Sweet, and Phillies Blunt and these cigars come in a variety of flavors, such as grape, apple, peach, wine, chocolate, and cream.⁵⁰ Just as no federal law prohibits flavored small cigars from being sold, no federal law prohibits them – unlike cigarettes – from being sold individually. As a result, these products are available at a low price. Beyond the increased accessibility to youth and other price-sensitive consumers of products with a low price point, permitting the sale of individual cigars is also problematic

⁴⁵ Tobacco Control Act, Pub. L. No 111-31, § 910(c)(4), 123 Stat. 1776, 1810 (2009) (codified at 21 U.S.C. § 387j(c)(4)).

⁴⁶ Tobacco Control Act, § 910(c)(2), 123 Stat. at 1809-10 (codified at 21 U.S.C. § 387j(c)(2)).

⁴⁷ This petition does not repeat the request made in the petition filed by the Maryland Department of Health and Mental Hygiene and others that the FDA assert jurisdiction over cigars and subject cigars to the sales and distribution regulations currently imposed on cigarettes and smokeless tobacco products. 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) [hereinafter Maryland Citizen Petition]. We support that request and build upon it here with a more specific proposal concerning the regulation of cigars.

⁴⁸ For example, in Maryland, cigar use among young people increased from 6.5% in 2006 to 10.6% in 2008. See MD. DEP'T OF HEALTH & MENTAL HYGIENE, MONITORING CHANGING TOBACCO USE BEHAVIORS (2000–08)—LEGISLATIVE REPORT, Gen. Assemb. 426, Appendix A, at 30 (Md. 2008) available at http://crf.maryland.gov/pdf/2009crf_bienial_tobacco_legis_rpt_AppendixA.pdf; see also Substance Abuse and Mental Health Services Administration (SAMHSA), National Survey on Drug Use and Health Report, Cigar Use Among Young Adults Age 18 to 25, NSDUH REPORT, Jan. 15, 2009, available at <http://www.oas.samhsa.gov/2k8/cigars/cigars.htm>.

⁴⁹ NAT'L CANCER INST., FACTSHEET ON CIGAR SMOKING AND CANCER, <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cigars> (last visited July 12, 2013); see also MD. DEP'T OF HEALTH & MENTAL HYGIENE, WHAT IS A CIGAR?, available at http://dhmh.maryland.gov/thecigartrap/PDF/WhatIsACigar_1.pdf.

⁵⁰ See, e.g., Our Products and Brands, JOHN MIDDLETON, http://www.johnmiddletonco.com/en/cms/Products/Our_Products_and_Brands/default.aspx (last visited July 12, 2013) (offering for sale Black and Mild flavors that include: Wine, Cream and Apple); *Phillies Blunts Cigars*, ALTADIS U.S.A., <http://altadisusdomesticcigars.com/cigar/phillies-blunts.asp> (offering for sale Phillies Blunt Cigar flavors that include: Chocolate, Grape, Strawberry, and Sour Apple); *Products*, SWISHER SWEETS, <http://www.swisher.com/web/main/map#/store/products/americasFavCigars> (offering for sale Swisher Sweets flavors that include: Grape, Peach, Strawberry, Wine, and Chocolate). The FDA has acknowledged that flavored cigars entice children to smoke. See 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; 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>.

because manufacturers are not required to affix health warnings to single cigars. Because retailers may break packages and sell a single cigar from a pack, any package warnings may not be seen by consumers.⁵¹

Also becoming more popular are so-called little cigars,⁵² also known as brown cigarettes. 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.⁵³ A 20-pack of little cigars sells for much less than a package of cigarettes,⁵⁴ making it easier for price-sensitive consumers to purchase and increases youth appeal. In addition, little cigars are available in youth-enticing flavors and may be sold as singles, again at a low cost and bearing no health warning. 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, because a small amount of tobacco is used in the paper wrapping the product.⁵⁵

The arbitrary regulatory distinction between small or little cigars and cigarettes is troubling because it is not related to any distinction in the health hazards inflicted upon users or bystanders. In addition, product manufacturers are adept at exploiting the differential treatment to promote small or little cigars as a cigarette replacement when cigarette taxes increase, undermining the positive public health impact of the tax increase. For example, in 2009, Congress passed an increase in the excise tax on small and little cigars, but not large cigars, in effort to address the issue of tobacco companies making cigarette-like small and little cigars to avoid the higher taxation of cigarettes.⁵⁶ There is evidence that manufacturers, in response,

⁵¹ In 2000, the seven largest cigar manufacturers, importers and marketers agreed to comply with several Federal Trade Commission-issued consent agreements requiring them to list health warning statements on all cigar packaging and advertising; however, this federal mandate, unfortunately, does not apply to single cigars or to all manufacturers. See Press Release, Federal Trade Commission Press Release, FTC Announces Settlements Requiring Disclosure of Cigar Health Risks (June 26, 2000), available at <http://www.ftc.gov/opa/2000/06/cigars.shtm>.

⁵² 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 petition 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.

⁵³ 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).

⁵⁴ 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 50.

⁵⁵ 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).

⁵⁶ GAO TAX, *supra* note 52, 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

engineered their cigars that look just like cigarettes to be slightly heavier in order to pass over the weight threshold into the large cigar category and therefore be subject to a lower tax scheme.⁵⁷ After the passage of the tax increase on small and little cigars, the cigar market dramatically shifted toward large cigars, with a 116% increase in the number of large cigars sold from 2008 to 2011, and a concomitant 85% decline in the number of small cigars sold.⁵⁸ This market trend is 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. Consumers are merely choosing the least expensive cigar that is consumed in a manner similar to that of cigarettes. Allowing little cigars to be sold without the restrictions placed on cigarettes contributes to consumer confusion about the relative risk of use of cigars as well.

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.⁵⁹ Cigar smokers who smoke regularly and those who inhale deeply – both of which are more likely with small and little cigars – are at increased risk of coronary heart disease and chronic obstructive pulmonary disease.⁶⁰ Cigar smoking increases cotinine levels and is associated with decreased lung function.⁶¹ Cigars can be more harmful than cigarettes because of higher levels of tobacco-specific *N*-nitrosamines inhaled by users and bystanders.⁶² The tar, carbon monoxide, and ammonia levels in cigars are higher than those found in cigarettes as well,⁶³ and the tar found in cigars contains a type of hydrocarbon linked to an increased capability of producing tumors.⁶⁴ The disease-free life-years lost due to cigar smoking have been estimated at 5.2 years.⁶⁵ Meanwhile, cigar smokers in one study experienced an increased risk of hospitalization and death due to chronic obstructive pulmonary disease, the fourth leading cause of death in the United States.⁶⁶ 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 federal action. Initiation of tobacco use is one of the three factors the FDA must consider as part of the public health standard. Cigars are becoming the product of choice for initiation of tobacco

(noting that cigar companies add a clay substance often found in cat litter to increase the weight of a cigar to avoid higher taxes).

⁵⁷ GAO TAX, *supra* note 52, at 20.

⁵⁸ *Id.*

⁵⁹ 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.

⁶⁰ Gary A. Giovino, *The Tobacco Epidemic in the United States*, 33 AM J. PREV. MED. S318, S319 (2007).

⁶¹ 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).

⁶² Michael B. Steinberg & Cristine D. Delnevo, *Tobacco Smoke by Any Other Name is Still as Deadly*, 152 ANNALS INTERNAL MED. 259, 259 (2010).

⁶³ Frank Baker et al., *Health Risks Associated with Cigar Smoking*, 284 JAMA 735, 737 (2000).

⁶⁴ *Id.*

⁶⁵ Steinberg & Delnevo, *supra* note 62, at 259.

⁶⁶ Rodriguez et al., *supra* note 61, at 201.

use, and the data shows that younger people are becoming cigar users. The statistics describing the trends of cigar use highlight this problem:

- Between 2000 and 2011, cigar sales increased 123%, while cigarette sales decreased by 32.8%.⁶⁷
- While cigar smoking in the United States was historically a behavior of older men,⁶⁸ 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%).⁶⁹
- 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%.⁷⁰ Among women age 18-34, ever use of cigars ranges from 20.7-25.8%.⁷¹
- 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 cigars⁷² and 21.9-27.2% of women reporting ever use of little cigars.⁷³ Approximately 13.1% of high school students are current cigar smokers⁷⁴ and 6.6% of adults regularly use cigars.⁷⁵
- 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.⁷⁶
- 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

⁶⁷ 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>.

⁶⁸ U.S. DEP’T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 203 (2012) [hereinafter SGR 2012], available at <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>.

⁶⁹ These usage rates are for all respondents of the National Adult Tobacco Survey. Brian A. King, Shanta R. Dube & Michael A. Tynan, *Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009-2010 National Adult Tobacco Survey*, 15 NICOTINE & TOBACCO RES. 608, 610 (2012).

⁷⁰ Joseph T. Lariscy et al., *Race/Ethnicity, Nativity, and Tobacco Use Among U.S. Young Adults: Results From a Nationally Representative Survey*, NICOTINE & TOBACCO RES. 1, 5 tbl.2 (2013) (published online ahead of print), doi:10.1093/ntr/nts344.

⁷¹ *Id.* at 4 tbl.1.

⁷² *Id.* at 5 tbl.2.

⁷³ *Id.* at 4 tbl.1.

⁷⁴ 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>.

⁷⁵ Brian 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).

⁷⁶ CDC YRBS, *supra* note 74; see also TFK Cigar Factsheet, *supra* note 50.

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.⁷⁷

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.”⁷⁸ Other studies have echoed this concern – particularly in regards to rates of cigar use among African-American adolescents.⁷⁹ Thus, the problem of youth use of cigars may be even more grave than shown by the existing data.

These trends in cigar use do not come as a surprise to those who monitor the industry. Tobacco product manufacturers are marketing cigars, with a particular aim at youth, and exploiting the lack of regulation to further entrench these products in the market.

B. Smokeless tobacco products: From conventional to dissolvables

Smokeless tobacco is defined in the Tobacco Control Act as “any tobacco product that consists of cut, ground, powdered or leaf tobacco and that is intended to be placed in the oral or nasal cavity.”⁸⁰ Emerging products like snus, sticks, strips, and orbs — which are made of ground tobacco and are intended to be placed in the oral cavity — fall squarely within this definition.⁸¹ While Petitioners believe that dissolvable products are smokeless products already subject to the FDA’s regulation, the agency’s position with regard to these products is unclear. The FDA has stated that smokeless tobacco “can” include dissolvable tobacco products,⁸² suggesting that some dissolvable products are regulated, while others are not. Clearly, the agency believes some dissolvables are not within its current authority, because it has rejected two Modified Risk Tobacco Product applications based on the agency’s determination that the particular dissolvable

⁷⁷ Randi M. Schuster, Andrew W. Hertel & Robin Mermelstein, *Cigar, Cigarillo, and Little Cigar Use Among Current Cigarette-Smoking Adolescents*, 15 NICOTINE & TOBACCO RES. 925, 927 (2013).

⁷⁸ Aashir Nasim, Melissa D. Blank, Brittany M. Berry & Thomas Eissenberg, *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.

⁷⁹ Joshua Terchek, Elizabeth M. G. Larkin, Margaret L. Male & Scott H. Frank, *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, Charles Pearson & Ruth E. Malone, *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”).

⁸⁰ Tobacco Control Act, Pub. L. No. 111-31, § 900(18), 123 Stat. 1776, 1785 (2009) (codified at 21 U.S.C. § 387(18)).

⁸¹ Snus is a moist ground oral tobacco product. J. Foulds et al., *infra* note 86. Dissolvable tobacco products including sticks, strips, and orbs are finely milled, ground or pressed tobacco. McMillen, Maduka & Winickoff, *infra* note 104; Blank & Eissenberg, *infra* note 121; Rainey, *infra* note 121; Stepanov et al., *infra* note 121.

⁸² *Clarification About Dissolvable Tobacco Products*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm248801.htm>.

products involved were not subject to the Food, Drug and Cosmetic Act.⁸³ Whether the agency believes other dissolvable products are regulated today remains unclear, because, to petitioners' knowledge, the agency has given no public indication which, if any, of these products are regulated.

This petition asks the FDA to clarify its understanding as to which products are smokeless tobacco products currently subject to its regulation, to assert jurisdiction over any tobacco products not currently regulated, and to promulgate the regulations requested in this petition so that there is clear and uniform regulation of all smokeless tobacco products.

We group smokeless products into two categories: conventional smokeless tobacco products, which include snus, and dissolvable tobacco products. In the time that the FDA has been regulating smokeless tobacco, there has been an increase in the prevalence of the use of smokeless tobacco across most demographic groups. This is in part because the regulation of smokeless tobacco is still much weaker than that of cigarettes. We present data regarding new conventional smokeless tobacco products, like snus, not because they are unregulated by the FDA but because the FDA must regulate them more stringently. Where cigars have become a go-to product when cigarettes become expensive and less appealing, smokeless tobacco has become a go-to product when the use of cigarettes is prohibited or inconvenient. It is also clear that smokeless tobacco is appealing to youth and in many cases is becoming the product that leads to initiation into the use of other tobacco products, such as cigarettes. The tobacco industry is deliberately making these products more appealing and many users are not aware that smokeless tobacco can lead to a lifetime of disease and addiction. We request that the FDA promulgate the regulations requested in this petition so that all smokeless tobacco products are regulated at least as stringently as cigarettes.

i. Conventional smokeless tobacco products

Conventional smokeless tobacco products are those that are comprised of cut tobacco that is placed in the mouth either in a wad or in a pouch.⁸⁴ When using the oldest form of conventional smokeless products, the user must spit out tobacco juice and saliva as they build up in the mouth. Newer smokeless products are spitless and designed to allow the user to swallow any juices drawn from the tobacco during use. This type of smokeless tobacco is usually sold in small pouches; the user sucks on the pouch and discards it after a period of use (typically 20 to 30 minutes) without the unpleasant side effect of having to spit or having pieces of tobacco stuck between teeth and along the gums. Skoal, Copenhagen, Grizzly, Red Man, and Kodiak are among the popular brands of conventional smokeless tobacco. Many products are available in sweet or minty flavors, such as apple, cherry, citrus, berry, peach, wintergreen, and spearmint.⁸⁵

⁸³ Letter from Lawrence R. Deyton, Dir., Ctr. for Tobacco Prod., to Paul L. Perito, Chairman, Star Scientific Inc. (Mar. 17, 2011); Letter from Lawrence R. Deyton, Dir., Ctr for Tobacco Prod., to Paul L. Perito, Chairman, Star Scientific Inc. (Mar. 17, 2011).

⁸⁴ CAMPAIGN FOR TOBACCO-FREE KIDS, FACTSHEET: SMOKELESS TOBACCO IN THE UNITED STATES (2012), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0231.pdf>. Snuff is dry tobacco that is inhaled through the nose; it is prohibited in some states and is generally not a particularly popular product. We do not discuss snuff in detail in this petition, however, regulation of smokeless tobacco products would include snuff.

⁸⁵ See *Facts and Figures: Brands and Flavors of Smokeless Tobacco, Dip, Snuff, and Chewing Tobacco*, KILL THE CAN, <http://www.killthecan.org/facts/brands.asp> (last visited July 12, 2013).

The newest form of this spitless tobacco in pouch form is snus, which originated in Sweden. The tobacco used in snus is processed in a manner that is different than that used for the pouches of spitless tobacco that have been sold in the U.S. for the last several years.⁸⁶ Although relatively new to the U.S. market, snus is sold under some of the most popular cigarette brand names from the leading cigarette manufacturers—Camel (R.J. Reynolds) and Marlboro (Altria/Philip Morris). Now available in 27 states, Camel Snus comes in mint flavor.⁸⁷ Marlboro Snus is still only available in a modest number of test markets but is marketed in peppermint and spearmint.⁸⁸ The vast majority (79.6%) of snus sold in convenience stores in 2011 was flavored.⁸⁹

Use of smokeless tobacco is linked to periodontal disease and tooth decay.⁹⁰ Chewing tobacco users, for example, are nearly four times more likely than non-users to have decayed dental root surfaces.⁹¹ Of course, smokeless tobacco also creates nicotine addiction.⁹² In addition, smokeless tobacco use is harmful to health in other ways. There are at least 28 chemicals found in smokeless tobacco that are known to cause cancer.⁹³ Use of smokeless tobacco is linked to the development of leukoplakia, white spots that form on tobacco users' cheeks, gums, or tongue; leukoplakia is a precursor to oral cancer.⁹⁴ The Surgeon General, the Centers for Disease Control and Prevention, and the National Institutes for Health agree: smokeless tobacco use causes cancer.

⁸⁶ J. Foulds et al., *Effect of Smokeless Tobacco (Snus) on Smoking and Public Health in Sweden*, 12 TOBACCO CONTROL 349 (2003). Interestingly, "tobacco for oral use," including snus, is prohibited throughout the European Union, with some exemptions that permit manufacturing and use in Sweden, but prevent export into other EU countries from Sweden. See Council Directive 2001/37, of the European Parliament and Council of 5 June 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco Products, 2001 O.J. (L 194) 26, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:194:0026:0034:EN:PDF>. There is continuing debate on this issue in the EU as Sweden has lobbied strongly for a lifting of the prohibition and for permission to export to EU countries. See A. Molin, *Swedish Hopes Rise on Snus Ban*, WALL ST. J. (U.S. EDITION), Oct. 21, 2012, at B3, available at <http://online.wsj.com/article/SB10001424052970203406404578070431989335300.html>.

⁸⁷ See CSP Daily News, *RJR Launches Camel Snus Campaign*, CSP DAILY NEWS (Dec. 30, 2010), <http://www.cspnet.com/news/tobacco/articles/rjr-launches-camel-snus-campaign>.

⁸⁸ See J. Foulds & H. Furberg, *Is Low-Nicotine Marlboro Snus Really Snus?*, 5:9 HARM REDUCTION J. (2008). The authors argue that Marlboro snus differs significantly from Swedish snus such that the health impact of use of Marlboro Snus cannot be compared to the use of Swedish snus; they argue that, for this reason, Philip Morris ought not be permitted to use the term snus for such a product. This debate only strengthens the argument made in this petition for more stringent regulation of smokeless tobacco products, particularly new products.

⁸⁹ Cristine D. Delnevo et al., *Examining Market Trends in the United States Smokeless Tobacco Use: 2005-2011*, TOBACCO CONTROL 1, 2 (2012) (published online ahead of print), doi: 10.1136/tobaccocontrol-2012-050739.

⁹⁰ See SGR 2012, *supra* note 68; U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF USING SMOKELESS TOBACCO: A REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL (1986) [hereinafter SGR 1986], available at <http://profiles.nlm.nih.gov/ps/access/NNBBFC.pdf>.

⁹¹ Scott L. Tomar & Deborah M. Winn, *Chewing Tobacco Use and Dental Caries Among U.S. Men*, 130 J. AM. DENTAL ASS'N 1601, 1604 (1999).

⁹² NAT'L CANCER INST., SMOKING AND TOBACCO CONTROL MONOGRAPH NO. 2: SMOKELESS TOBACCO OR HEALTH: AN INTERNATIONAL PERSPECTIVE (1992), available at http://cancercontrol.cancer.gov/brp/tcrb/monographs/2/m2_complete.pdf.

⁹³ NAT'L CANCER INST., FACTSHEET ON SMOKELESS TOBACCO AND CANCER (2010), available at <http://www.cancer.gov/cancertopics/factsheet/Tobacco/smokeless>.

⁹⁴ *Id.*; see also SGR 2012, *supra* note 68; SGR 1986, *supra* note 90.

There is an ongoing discussion about where on the spectrum of harm various smokeless tobacco products should be placed, with many advocates for smokeless tobacco noting that smokeless products, while harmful, are less harmful than cigarettes. We need not venture into that debate in this petition as there is no doubt that use of smokeless tobacco is harmful to health, far more harmful than not using smokeless tobacco. That is the appropriate standard for the FDA to consider when deciding whether and how to further regulate smokeless tobacco. The public health standard, established by Congress, mandates FDA action on this issue.

Although not as popular as cigarettes or cigars, smokeless tobacco use is dangerously high. The most recent Youth Risk Behavior Surveillance Report reveals that 7.7% of high school students currently use smokeless tobacco, with rates particularly high among 11th and 12th grade males—about 15% of all 11th and 12th grade males use smokeless tobacco.⁹⁵ The prevalence of use of smokeless tobacco has remained steady in some youth demographics (females 9th through 12th grade) since 2003 and has increased sharply in other youth demographics (white males 9th through 12th grade).⁹⁶ Current use among all adults was reported at 3.4%, with use among males at 6.5%.⁹⁷ Use decreases with increasing age.⁹⁸

Moist snuff is emerging as an increasingly important segment of the tobacco market. From 2005 to 2011, total consumption of cigarettes declined 23%,⁹⁹ while convenience store unit sales of smokeless tobacco increased by 56.8% over the same time period.¹⁰⁰ This increase was driven in large part by the increasing popularity of moist snuff products, which comprised at least 90% of the smokeless tobacco market each year and increased in sales by 65.6% from 2005 to 2011.¹⁰¹ Sales of pouched moist stuff increased an incredible 333.8% while flavored moist snuff sales increased 72.1%, in convenience store sales between 2005 and 2011.¹⁰² The trends in moist snuff sales appear to also be driven by the emergence of “value brands.” A recent study highlighted the rise of the value brand Grizzly to the position of number one selling brand of moist snuff in a market that was historically dominated by “premium” brands, like Skoal or Copenhagen.¹⁰³ This trend towards low-cost products is particularly concerning given the fact that low-cost products are more attractive to youth.

⁹⁵ CDC YRBS, *supra* note 74.

⁹⁶ *Id.*; SGR 2012, *supra* note 68, at 144.

⁹⁷ King et al., *supra* note 75, at e95, e96 tbl.1.

⁹⁸ See Lariscy et al., *supra* note 70, at 4 tbl.1, 5 tbl.2 for a breakdown of use of smokeless tobacco among young adults (age eighteen to thirty four) by race/ethnicity, gender, and sub-type of smokeless tobacco. Current and ever use was particularly high among eighteen- to thirty-four-year-old men. For example, among U.S.-born Hispanic and non-Hispanic black and white young men, current use of dip/snuff ranged from 2.6-4.7%; current use of chewing tobacco ranged from 1.2-3.5%, and current use of snus ranged from 1.9-3.6%. Ever use ranged from 10.3-21.5% for dip/snuff, 4.9-18.1% for chewing tobacco, and 5.4-14.0% for snus. Among young women, estimates of current use were unreliable for all products due to small cell sizes; ever use ranged from 2.6-6.7% for dip/snuff, 0.8-4.2% for chewing tobacco, and 0.7-3.9% for snus.

⁹⁹ Ctrs. for Disease Control & Prevention, *supra* note 67, at 567 tbl.1 (2012) (reporting a total consumption of 381.098 billion cigarettes in 2005, which decreased to 292.769 billion in 2011 – a decrease of approximately 23%).

¹⁰⁰ Cristine D. Delnevo et al., *supra* note 89, at 2. It should be noted that convenience store sales of smokeless tobacco represent ninety-three% of all smokeless tobacco sales. *Id.* at 1.

¹⁰¹ *Id.* at 2. The 65.6% growth includes snus within the category of “moist snuff.” “Conventional” moist snuff sales increased 59.3% from 2005 to 2011. *Id.*

¹⁰² *Id.* at 2.

¹⁰³ *Id.* at 2-3. The growth in sales of this “value” brand contributed to 44% of the overall sales growth in the moist snuff category from 2005 to 2011. *Id.* at 2.

The subcategory of snus has also emerged as a notable player in the smokeless tobacco market. As recently as 2007 snus comprised only 0.1% of the smokeless tobacco market; by 2011, snus comprised 3.7% of the market. Reinforcing this data are the rates of reported snus experimentation by adults. Two nationally representative cross-sectional surveys, the 2010 Social Climate Survey of Tobacco Control and the 2009 Consumer Styles Survey, both found that over 5% of surveyed adults reported trying snus.¹⁰⁴ Reported use of snus is even higher among surveyed daily smokers (12.9%) and all younger adults (8.0% of 18- to 24-year-olds).¹⁰⁵ The trends in this product category reflect the same concerns as moist snuff: more young people and smokers are experimenting with these new products.

In regulating these products, the FDA is mandated to consider their effects on initiation and it is clear that these products, often having characterizing flavors and available at a low cost, are designed to be enticing to youth and the data shows that youth are experimenting with them. The FDA must also examine a product's effect on cessation. The fact that smokers are experimenting with these products is troubling. As was noted above, there is an ongoing debate as to the relative harm of tobacco products and whether or not tobacco users are switching to or from various smokeless products. Once again, this petition will not speculate about relative harm nor will it speculate about product switching. However, what must be clear is the tobacco industry's role in dual use¹⁰⁶ and product switching. It goes without saying that the tobacco industry's goal is to sell as many tobacco products as possible. Now that the largest smokeless tobacco companies are owned by cigarette companies,¹⁰⁷ it is unlikely that the tobacco industry will be encouraging tobacco users to move away from one product and towards another when it would be more profitable to encourage dual or poly-use of tobacco products. In fact, the tobacco industry's own marketing campaigns reveal that this is absolutely the case. It is noteworthy that the industry markets its most popular brands across product categories. For example, R.J. Reynolds now markets Camel Snus to complement its line of Camel cigarettes. It has used the slogan, "Before, during and after boldly go everywhere,"¹⁰⁸ to inform smokers that snus can be used in places

¹⁰⁴ Robert McMillen, Jeomi Maduka & Jonathan Winickoff, *Use of Emerging Tobacco Products in the United States*, 2012 J. OF ENVTL. & PUB. HEALTH, Article ID 989474 at 5 tbl.2 (2012) (presenting data from the Social Climate Survey of Tobacco Control); Annette K. Regan, Shanta R. Dube, Rene Arrazola, *Smokeless and Flavored Tobacco Products in the U.S.: 2009 Styles Survey Results*, 42(1) AM. J. OF PREV. MED. 29-30, 30 fig.1 (2012) (presenting data from the 2009 Consumer Styles survey).

¹⁰⁵ McMillen, Maduka & Winickoff, *supra* note 104104, at 5 tbl.2.

¹⁰⁶ Dual use refers to the use of two different types of tobacco products to sustain the user's nicotine addiction. The most common form of dual use is the smoking of combustible products whenever possible in conjunction with the use of smokeless products that can be used legally in smoke-free environments when the use of combustible products is prohibited. Poly-use is the use of three or more tobacco products.

¹⁰⁷ Reynolds American Inc. purchased Conwood Sales Co. (now American Snuff Co.). See Chris Burritt, *Reynolds American Agrees to Buy Conwood for \$3.5 Bln*, BLOOMBERG, Apr. 25, 2006, available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aLBPJrVZ4WE>. Altria Group Inc. (formerly Philip Morris Companies Inc.) purchased U.S. Smokeless Tobacco Co. See Chris Burritt, *Altria to Buy UST for \$10.3 Billion, Gaining Skoal*, BLOOMBERG, Sept. 8, 2008, available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=ab6rmcKnryK8>. Lorillard entered into a joint venture with Swedish Match AB which was later terminated when Lorillard announced it would develop its own brand of smokeless tobacco. See Anjali Cordeiro, *Lorillard to Enter Market for Moist Smokeless Tobacco*, WALL ST. J., Feb. 9, 2010, available at <http://online.wsj.com/article/SB10001424052748703630404575053013703202080.html>.

¹⁰⁸ Visual Exhibits: *Camel Snus*, 2010, TRINKETS & TRASH: ARTIFACTS OF THE TOBACCO EPIDEMIC, <http://www.trinketsandtrash.org/detail.php?artifactid=6256&page=1> (last visited July 12, 2013).

where smoking is prohibited. Philip Morris USA has been even more blatant in its promoting dual use of Marlboro Snus. It has designed the product packaging to mimic the shape of a cigarette package so that it can easily be carried with a package of cigarettes. It has used the slogan, "Fits alongside your smokes,"¹⁰⁹ to entice smokers to use both products. Philip Morris has also used the slogan, "When the work won't wait,"¹¹⁰ and both of these slogans end with the tagline, "When smoking *isn't an option*, reach for Marlboro Snus."¹¹¹ By its own admission, the tobacco industry continues to focus up to 90% of its resources on cigarettes.¹¹² It uses its other products, like smokeless tobacco, to create and maintain nicotine addiction with the ultimate goal of selling more cigarettes. The tobacco industry's intention is to keep people from quitting smoking. The FDA must be aware of the potential impact on cessation in its regulation of these products.

ii. Dissolvable tobacco products

Dissolvable tobacco products are among the newest smokeless tobacco products. These products are unlike any other that has been on the market before. Dr. Lawrence Deyton, former Director of the FDA's Center for Tobacco Products, has described dissolvables as "flavored, smokeless products that resemble candy products and dissolve in the mouth of the user."¹¹³ R.J. Reynolds has taken the most significant step into the market with Camel Sticks, Strips and Orbs.¹¹⁴ Camel Sticks are comprised of pulverized, flavored tobacco formed into breakable sticks (about the size of a toothpick); Strips are thin patches of flavored tobacco, much like breath strips; and Orbs are compressed, flavored tobacco formed into a pellet, similar in shape but slightly larger than a Tic-Tac candy. Dissolvables do just as their name implies—they dissolve in the user's mouth, with no requirement for spitting and no residual packaging to be discarded.

Because dissolvables are relatively new, there is little information available on prevalence of use or demographics of users. National, cross-sectional surveys from 2009 and 2010 indicated that 0.5-0.6% of adults had tried dissolvables,¹¹⁵ and convenience store retail sales indicate that, as of 2011, dissolvables held only a negligible share of the smokeless tobacco market.¹¹⁶ About 1% of a nationally representative sample of young adults (age 18-34) reported ever use of dissolvables,

¹⁰⁹ Visual Exhibits: *Marlboro Snus*, 2009, TRINKETS & TRASH: ARTIFACTS OF THE TOBACCO EPIDEMIC, <http://www.trinketsandtrash.org/detail.php?artifactid=6155&page=1> (last visited July 12, 2013).

¹¹⁰ Visual Exhibits: *Marlboro Snus*, 2010, TRINKETS & TRASH: ARTIFACTS OF THE TOBACCO EPIDEMIC, <http://www.trinketsandtrash.org/detail.php?artifactid=6199&page=1> (last visited July 12, 2013).

¹¹¹ Both of the Marlboro mailers referenced also included a coupon for a free package of snus with the purchase of Marlboro cigarettes. (emphasis in original).

¹¹² Transcript RAI Investor Day Presentation (Nov. 12, 2012), available at <http://seekingalpha.com/article/1001691-reynolds-american-s-ceo-hosts-investor-day-transcript?part=single>.

¹¹³ Letter from Dr. Lawrence R. Deyton M.D., Dir., Ctr. for Tobacco Prods., to Daniel M. Delan, Chairman, President, & Chief Exec. Officer, R.J. Reynolds Tobacco Co. (Feb. 2, 2010), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM284149.pdf>.

¹¹⁴ Products at a Glance: *Camel Orbs, Sticks and Strips*, R.J. REYNOLDS, <http://rjrt.com/uploadedFiles/RJRT%20Camel%20Dissolvables%20At%20A%20Glance.pdf> (last visited July 12, 2013).

¹¹⁵ McMillen, Maduka & Winickoff, *supra* note 104, at 5 tbl.2; Regan et al., *supra* note 104, at 30, 30 fig.1.

¹¹⁶ Delnevo et al., *supra* note 89, at 2.

while 3% of adult dual users of tobacco products reported dissolvable use.¹¹⁷ However, although use rates appear low, dissolvable tobacco products were introduced in 2009 and were available only in limited locations until 2011 – the time period during which this data was gathered.¹¹⁸ Despite this limited initial availability, a 2009 national cross-sectional survey indicated that 10.4% of all responding adults, and 19.8% of 18-24-year olds, had heard of dissolvables.¹¹⁹ Given the public awareness of dissolvables and the positive perception of these products by young people,¹²⁰ the use of dissolvables may increase as these products become more widely available and established in the market.

Regardless of whether this prediction of increased use of dissolvables proves to be true, it is in the public health's interest for dissolvables to be regulated like other tobacco products. Due to the fact that these are newer products, there is little information available about the health risks associated with dissolvables. Most of the publicly available research to date consists of chemical analyses or biomarker studies of dissolvable products.¹²¹ Initial studies suggest that the nicotine or tobacco-specific *N*-nitrosamine (TSNA) content may be lower for at least some dissolvable products relative to cigarettes and other smokeless tobacco products.¹²² However, there is variation in these products,¹²³ and it is not clear whether or to what degree the reduction in concentration of nicotine or TSNA translates to meaningful reductions in addictiveness and disease risk.¹²⁴ The initial data does indicate that FDA regulation of these tobacco products is warranted.

The FDA's Tobacco Products Scientific Advisory Committee (TPSAC) held hearings on dissolvables in early 2012. TPSAC issued a report summarizing the information provided by tobacco manufacturers, harm reduction advocates, researchers, and public health professionals at these meetings.¹²⁵ The report does not contain the results of any direct research by the FDA regarding the health effects of dissolvables or regarding prevalence of use or demographics of

¹¹⁷ Jessica M. Rath, Andrea C. Villanti, David B. Abrams & Donna M. Vallone, *Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link Between Youth Prevention and Adult Cessation*, 2012 J. OF ENVTL. & PUB. HEALTH, Article ID 679134, at 4 tbl.1 (2012) (published online ahead of print), doi: 10.1155/2012/679134.

¹¹⁸ Regan, et al., *supra* note 104, at 34.

¹¹⁹ *Id.* at 30, 32 tbl.1.

¹²⁰ In focus group discussions, young adult college students/college graduates expressed positive perceptions of dissolvable and other novel tobacco products, noting their accessibility, concealability, convenience, modern image, and amenability to recreational use. Kelvin Choi et al., *Young Adults' Favorable Perceptions of Snus, Dissolvable Tobacco Products, and Electronic Cigarettes: Findings from a Focus Group Study*, 102(11) AM. J. PUB. HEALTH 2088, 2089 (2012).

¹²¹ See Melissa D. Blank & Thomas Eissenberg, *Evaluating Oral Noncombustible Potential-Reduced Exposure Products for Smokers*, 12(4) NICOTINE & TOBACCO RES. 336 (2010); Christina L. Rainey, *Chemical Characterization of Dissolvable Tobacco Products Promoted to Reduce Harm*, 5 J. AGRIC. & FOOD CHEMISTRY 2745 (2011); Irina Stepanov et al., *Monitoring Tobacco-Specific N-Nitrosamines and Nicotine in Novel Marlboro and Camel Smokeless Tobacco Products: Findings from Round I of the New Product Watch*, 14(3) NICOTINE & TOBACCO RES. 274 (2012).

¹²² Stepanov, *supra* note 121, at 276 tbl.1, 277 tbl.2.

¹²³ *Id.*

¹²⁴ Hatsukami et al., *supra* note 43.

¹²⁵ TOBACCO PRODS. SCIENTIFIC ADVISORY COMM., SUMMARY: TPSAC REPORT ON DISSOLVABLE TOBACCO PRODUCTS (2012) [hereinafter TPSAC Dissolvable Rep.], available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM295842.pdf>.

users. Based on the information provided to TPSAC, it concluded that *exclusive* use of dissolvables presents a reduced risk of harm to users from *smoking-caused disease* as compared to regular use of cigarettes.¹²⁶ The report does not make conclusive statements about the risk of disease due to dual use of dissolvable and combustible products nor does it speak to the risk of diseases that are not considered to be smoking-caused.

Indeed, TPSAC acknowledges that the effects of dissolvables on the health of the U.S. population are uncertain and that key questions have yet to be addressed by researchers.¹²⁷ Outstanding issues include the risk of children confusing dissolvables with candy and ingesting dangerous levels of nicotine; negative health effects, particularly cancers of the mouth, throat and stomach, from use of dissolvables; and the health effects associated with dual use of dissolvables and combustible tobacco products including the effects of sustained addiction rather than successful quit attempts. The question of dual use is particularly important, given that dissolvable tobacco products do not appear to be a complete substitute for cigarettes in regular smokers,¹²⁸ suggesting that smokers are more likely to engage in dual use of cigarettes and dissolvables – maintaining their addiction to nicotine and exposure to the carcinogens in cigarettes – than to replace their cigarette habit with dissolvables. Additionally, TPSAC itself concluded that dissolvables are being marketed as an accessory or dual use product for smokers that provides nicotine in circumstances when smoking is not permitted or acceptable.¹²⁹ This conclusion underscores the need for FDA action. Not only is more information needed about the harms associated with the use of dissolvables, but also if these products hinder smoking cessation, they clearly pose a threat to public health.

In conclusion, snus and dissolvable tobacco products are smokeless tobacco products under the Tobacco Control Act and the FDA's regulations issued pursuant to the Act. The FDA should either clarify that it considers these products to be subject to all provisions of the Act and existing regulations applicable to other smokeless tobacco products, or should assert jurisdiction over any products that it has determined do not meet the definition and promulgate the regulations requested in this petition.

C. Waterpipes: Hookah or shisha

Hookah – or shisha – originated in the Middle East, where tobacco is consumed using a waterpipe. The tobacco in the pipe is heated, typically by lit charcoal briquettes, and when the user draws on the mouthpiece, the tobacco smoke bubbles through the water and is drawn up a

¹²⁶ *Id.* (emphasis added).

¹²⁷ *Id.* at 6. TPSAC determined that it did not have sufficient information to “reach a conclusion as to the potential point of balance between potential risks and benefits of [dissolvables] on public health,” given the uncertainty regarding the population health effects of dissolvables. *Id.*

¹²⁸ Blank & Eissenberg, *supra* note 121, at 341; TPSAC Dissolvable Rep., *supra* note 125, at 4.

¹²⁹ TPSAC Dissolvable Rep., *supra* note 125, at 6.

thin tube to the user.¹³⁰ Hookah use typically occurs with more than one person sharing a pipe over the course of an hour or more.¹³¹

The use of water pipes as tobacco delivery mechanisms has been described as “a virulent strain in the tobacco epidemic.”¹³² Although not as much research has been conducted on the health consequences of hookah as compared to cigarette smoking, there is evidence of several significant health risks associated with hookah smoking.¹³³ These risks include cardiovascular disease, clogged arteries and lung, oral, lip and bladder cancer.¹³⁴ Hookah smoking may also lead to nicotine addiction.¹³⁵ While an average cigarette is smoked for 5 to 10 minutes, an average hookah session lasts 40 to 45 minutes.¹³⁶ Studies comparing the effect of a single cigarette to 45 minutes of hookah use suggest that a hookah smoker doubles his carbon monoxide exposure and triples his nicotine exposure, thereby intensifying the negative health effects of the smoke.¹³⁷ Additionally, the heat sources used to burn the tobacco create additional dangers because carbon monoxide, heavy metals and other chemicals are released when charcoal or cinder is burned.¹³⁸

In addition to the health effects caused by smoking hookah or being exposed to secondhand hookah smoke, sharing a hookah pipe can spread infectious disease.¹³⁹ Shared mouthpieces and the moist smoke associated with hookah smoking allow not only for the spread of common viruses like the cold, flu, or herpes simplex but also deadly diseases including tuberculosis and hepatitis. The World Health Organization issued an advisory on hookah smoking in 2005 recommending that hookah smoking be regulated in the same way as cigarettes and other tobacco products.¹⁴⁰

¹³⁰ For the purpose of this petition, we discuss only the use of hookah or shisha tobacco in waterpipe smoking. Some hookah or shisha may be comprised of non-tobacco herbs and plants. Because this petition draws on the FDA’s power to regulate tobacco products, the proposals in this petition related to hookah apply only to hookah or shisha containing tobacco.

¹³¹ CTRS. FOR DISEASE CONTROL & PREVENTION, SMOKING & TOBACCO USE: HOOKAHS [hereinafter CDC Hookah], available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs.

¹³² W. Maziak et al., *Tobacco Smoking Using a Waterpipe: A Re-emerging Strain in a Global Epidemic*, 13 TOBACCO CONTROL 327, 330 (2004).

¹³³ CDC Hookah, *supra* note 131; AM. LUNG ASS’N, AN EMERGING DEADLY TREND: WATERPIPE TOBACCO USE 2 (2007) [hereinafter ALA Hookah Report], available at http://www.lungusa2.org/embargo/slatti/Trendalert_Waterpipes.pdf.

¹³⁴ CDC Hookah, *supra* note 131; ALA Hookah Report, *supra* note 133, Maziak et al., *supra* note 132; B. Knishkowy & Y. Amitia, *Waterpipe (Narghile) Smoking: An Emerging Health Risk Behavior*, 116 PEDIATRICS e113, e116 (2005).

¹³⁵ WORLD HEALTH ORG., WHO ADVISORY NOTE: WATERPIPE TOBACCO SMOKING: HEALTH EFFECTS, RESEARCH NEEDS AND RECOMMENDED ACTIONS BY REGULATORS 3 (2005) [hereinafter WHO Hookah], available at http://www.who.int/tobacco/global_interaction/tobreg/Waterpipe%20recommendation_Final.pdf; CDC Hookah, *supra* note 131.

¹³⁶ ALA Hookah Report, *supra* note 133, at 2.

¹³⁷ Maziak et al., *supra* note 134, at 329.

¹³⁸ ALA Hookah Report, *supra* note 133, at 2-3; WHO Hookah, *supra* note 135, at 5; Maziak et al., *supra* note 132, at 329.

¹³⁹ E. Akl et al., *The Effects of Waterpipe Tobacco Smoking on Health Outcomes: A Systematic Review*, 39 INT’L J. EPIDEMIOLOGY 834 (2010); CDC Hookah, *supra* note 131.

¹⁴⁰ WHO Hookah, *supra* note 135.

Currently, hookah smoking is particularly popular among college students. Results obtained by the 2008-2009 National College Health Assessment survey indicate that 8.4% of college students (10%, if limited to 18-24 year olds) reported current use of hookah while 30.5% of college students reported ever use.¹⁴¹ Similarly, only 1.5% of adults reported ever using hookah in a 2009-2010 national survey, while 7.8% of 18 to 24 year olds reported current use.¹⁴² Reinforcing the popularity of hookah use among young adults, nationally representative survey data collected in January 2012 by the Legacy Young Adult Cohort Study found that ever use of hookah by men age 18-34 was 19.2% among U.S. born Hispanics, 13.7% among non-Hispanic Blacks, and 21.5% among non-Hispanic Whites; current use was 4.8%, 4.0%, and 3.0%, respectively.¹⁴³ Ever use by women age 18-34 was 26.5% among U.S.-born Hispanics, 10.7% among non-Hispanic Blacks, and 18.4% among non-Hispanic Whites; current use was 2.0%, 4.9%, and 1.8%, respectively.¹⁴⁴

While national data regarding hookah use among youth is limited, local studies of hookah use among high school students suggest that the popularity of hookah is not solely a college student phenomenon. For example, a cross-sectional study of students from three San Diego high schools found that 26.1% of surveyed students reported ever using hookah, including 23% of participants under 18; 10.9% of surveyed students had used hookah in previous month, and 10.3% were current users. A study of Chicago area high schools students suggest that hookah use is especially high among youth who have already tried cigarette smoking: 58.5% reported ever use of hookah and 30.2% reported past-month use.¹⁴⁵ Youth likely are attracted to the sweet aroma and taste—and the exotic experience—of hookah. As hookah becomes more popular it likely will play a larger role in the young adult and youth tobacco experience and pose more opportunities for exposure to risk.

D. Electronic cigarettes as tobacco products

Electronic cigarettes, also known as e-cigarettes or electronic nicotine delivery systems (ENDS),¹⁴⁶ are battery-powered devices that are designed to look like conventional cigarettes and hold liquid containing nicotine and other chemicals. The heating unit of the e-cigarette vaporizes the nicotine chemical mixture and that vapor is inhaled by the user. For most models, users replace the nicotine liquid cartridge when it is empty; those cartridges are available in many flavors, including fruit, dessert and candy-like flavors.¹⁴⁷ Disposable e-cigarettes also are

¹⁴¹ B.A. Primack et al., *Waterpipe Smoking Among U.S. University Students*, 15(1) NICOTINE & TOBACCO RES. 29, 31 (2013) (excluding from analysis only those college students over age 60, resulting in current use of 8.4% among college students, and ever use of 30.4%). Current use, however, increases to 10%, if the analysis is limited to college students age eighteen to twenty-four. Traci Jarrett et al., *Hookah Use Among U.S. College Students: Results from the National College Health Assessment II*, 14(10) NICOTINE & TOBACCO RES. 1145, 1147 tbl.1 (2012).

¹⁴² King et al., *supra* note 75, at e96 tbl.1.

¹⁴³ Lariscy et al., *supra* note 70, at 5 tbl. 2.

¹⁴⁴ *Id.* at 4 tbl.2.

¹⁴⁵ Kymberle L. Sterling & Robin Mermelstein, *Examining Hookah Smoking Among a Cohort of Adolescent Ever Smokers*, 13(12) NICOTINE & TOBACCO RES. 1202, 1204 (2011).

¹⁴⁶ Jennifer L. Pearson et al., *E-Cigarette Awareness, Use, and Harm Perceptions in US Adults*, 102 AM. J. PUB. HEALTH 1758, 1758 (2012). We use the term “e-cigarette” throughout the petition with the intention to include all electronic nicotine delivery systems, including products marketed as e-cigars, e-pipes, and e-hookah.

¹⁴⁷ Pearson, *supra* note 146, at 1763; see also E-LIQUID NICOTINE, <http://eliquidnicotine.net/> (last visited July 15, 2013); LIQUID NICOTINE, <http://www.liquidnicotine.com/> (last visited July 15, 2013).

available, many of which are offered in a variety of flavors. Although e-cigarettes were expensive when first marketed, more recent e-cigarettes are more affordable, including available disposable products, which are sold at convenience stores and elsewhere for as little as five dollars.

Although the FDA initially determined that e-cigarettes ought to be regulated under the drug and drug delivery device provisions of the FDCA, a federal court ruling concluded that unless they are marketed as therapeutic devices (cessation aids), e-cigarettes containing tobacco should be considered tobacco products that may be regulated by the FDA under the Tobacco Control Act.¹⁴⁸ The agency did not appeal that decision and issued a statement of intent to regulate e-cigarettes as tobacco products as long as no therapeutic claims are made.¹⁴⁹ The final ruling in this case came on December 7, 2010 and the FDA stated its intent to regulate e-cigarettes as tobacco products on April 25, 2011, yet as of this filing, the FDA has not asserted jurisdiction over, nor has it proposed regulations related to, e-cigarettes.

The long-term health effects of e-cigarettes are unknown because they have only been sold in the United States for a few years and have not yet been subject to rigorous, reliable testing. Although e-cigarettes may have been available from China through online purchasing in 2007, these products were not offered for sale in the U.S. until after 2007.¹⁵⁰ As the FDA explains on its website:

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.¹⁵¹

Similarly, health organizations such as the American Cancer Society and the American Legacy Foundation have expressed concern that e-cigarettes could increase nicotine addiction and tobacco use in young people.¹⁵² Prominent tobacco researchers echo this concern.¹⁵³ Additional

¹⁴⁸ Sottera, Inc. v. Food & Drug Admin., 627 F.3d 891, 898 (D.C. Cir. 2010).

¹⁴⁹ 2011 Letter from Deyton to Stakeholders, *supra* note 25.

¹⁵⁰ Pearson, *supra* note 146, at 1758; see also Mike Freiberg, *Federal Approaches to the Regulation of Noncigarette Tobacco Products*, 43(5 Supp. 3) AM. J. PREV. MED. S249, S252 (2012).

¹⁵¹ 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>.

¹⁵² 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/version/5/file/LEG-FactSheet-eCigarettes->

research indicates that e-cigarettes may be used as a long-term or permanent substitute to smoking cigarettes, with people replacing cigarettes with e-cigarettes, even though there is virtually no data regarding the ingredients in or the potential harm caused by these new products.¹⁵⁴

The World Health Organization has also recently announced its growing concerns regarding e-cigarettes, noting that, “The safety of ENDS has *not* been scientifically demonstrated,” and “The efficacy of ENDS for helping people to quit smoking has not been scientifically demonstrated.”¹⁵⁵ The statement concludes by stating that, “[u]ntil such time as a given ENDS is deemed safe and effective and of acceptable quality by a competent national regulatory body, consumers should be strongly advised not to use any of these products, including electronic cigarettes.”¹⁵⁶

The concerns of the public health and research community are reinforced by the growing awareness and prevalence of e-cigarette use. 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 2010.¹⁵⁷ Ever use of e-cigarettes increased over the same period, from 0.6% in 2009 to 2.7% in 2010.¹⁵⁸ 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%).¹⁵⁹ In these studies, current smokers and former smokers reported higher use of e-cigarettes than non-smokers.¹⁶⁰

Recently published data suggests that e-cigarette use is even more prevalent among young adults. 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

JUNE2013.pdf. The American Academy of Pediatrics has also expressed this concern and references the Legacy document in support. See AM. ACAD. OF PEDIATRICS, http://www2.aap.org/richmondcenter/pdfs/ecigarette_factsheet.pdf (providing link to the aforementioned Legacy document).

¹⁵³ J.E. Henningfield & G.S. Zaatari, *Electronic Nicotine Delivery Systems: Emerging Science Foundation for Policy*, 19 TOBACCO CONTROL, 89, 89-90 (2010).

¹⁵⁴ Nathan K. Cobb et al., *Novel Nicotine Delivery Systems and Public Health: The Rise of the ‘E-cigarette’*, 100 AM. J. PUB. HEALTH 2340, 2340-41 (2010).

¹⁵⁵ World Health Organization, Tobacco Free Initiative, Questions and answers on electronic cigarettes or electronic nicotine delivery systems (ENDS) (July 9, 2013), http://www.who.int/tobacco/communications/statements/electronic_cigarettes/en/index.html (emphasis in original).

¹⁵⁶ *Id.*

¹⁵⁷ 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).

¹⁵⁸ *Id.*

¹⁵⁹ Brian A. King et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, NICOTINE & TOBACCO RES., 1, 3 tbl.1 (Feb. 28, 2013) (published online ahead of print), doi:10.1093/ntr/ntt013. The 2010 data is echoed by the findings published in Pearson et al., *supra* note 146, at 1760, 1762 tbl.2. 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.*

¹⁶⁰ King et al., *supra* note 159, at 3 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 146 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 157, 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).

Hispanics, 4.8% of non-Hispanic Blacks, and 8.8% of non-Hispanic Whites; current use was 5.3%, 3.5%, and 1.7%, respectively.¹⁶¹ 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.¹⁶²

Particularly troubling is the fact that e-cigarettes are not approved as smoking cessation devices and may not be marketed as such without prior FDA approval, yet consumers overwhelmingly believe that e-cigarettes are effective for cessation and consumers purchase the product with that purpose in mind.¹⁶³ Moreover, these consumers believe that e-cigarettes are a safer alternative than conventional cigarettes despite the lack of sound support for harm reduction.¹⁶⁴ While there is some evidence that e-cigarette vapor contains lower levels of cigarette-associated toxins than cigarette smoke,¹⁶⁵ the mixture of chemicals in e-cigarette vapor has not been well studied and there is evidence that other toxic chemicals may be present in these products.¹⁶⁶

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-

¹⁶¹ Lariscy et al., *supra* note 70, at 5 tbl.2.

¹⁶² *Id.* at 4 tbl. 1.

¹⁶³ Comments made in response to a petition filed by the American Association of Public Health Physicians to the FDA make this clear. Citizen Petition: Reclassify Nicotine Vaporizers (E-cigarettes) from "Drug-Device Combination" to "Tobacco Product," Docket No. FDA-2010-P-0095 (Feb. 23, 2010) [hereinafter AAHP 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 July 17, 2013) ("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 . . .).

¹⁶⁴ Comments following the AAPHP Citizen Petition support this: 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 163. 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-quitting-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 unhealthier. I started smoking an electronic cigarette.").

¹⁶⁵ 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 vapor 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).

¹⁶⁶ Tests conducted by the FDA found small amounts of diethylene glycol in e-cigarette vapor, along with small amounts of nitrosamines. Letter from B.J. Westenberger, Deputy Dir., Div. of Pharmaceutical Analysis, Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Michael Levy, Supervisor Regulatory Counsel, Div. of New Drugs & Labeling Compliance, Ctr. for Drug Evaluation and Research, U.S. Food & Drug Admin. (May 4, 2009), available at <http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf>.

cigarettes starting in 2008.¹⁶⁷ These reports have included eight adverse events that CTP 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.¹⁶⁸

The less serious events reported to CTP 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."¹⁶⁹ As CTP notes, these adverse events are not necessarily causally connected to e-cigarette use since they could be related to underlying conditions or other factors,¹⁷⁰ however, the number and seriousness of the reports related to e-cigarettes emphasizes the need for regulation and further assessment of these products.

There is also 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, yet no warning labels are required on these products.¹⁷¹ The risk to children is particularly concerning because e-cigarettes are frequently sold in flavors attractive to kids.¹⁷² Further, there is no federal age requirement to purchase these products and most state and local governments have not amended their minimum age requirements for the purchase of tobacco products to include e-cigarettes. With such significant concerns about the safety and youth access to e-cigarettes, regulatory action must be taken.

2. The FDA should assert jurisdiction over and regulate OTPs

The provisions of the Tobacco Control Act currently, apply to cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. The Act may apply to "any other tobacco products that the Secretary by regulation deems to be subject to [the Act]."¹⁷³ Once the FDA asserts jurisdiction over every tobacco product for the protection of public health, many

¹⁶⁷ Li-Lun Chen, *FDA Summary of Adverse Events on Electronic Cigarettes*, 15 NICOTINE & TOBACCO RES. 615, 615 (2013). The first adverse report related to e-cigarettes was submitted to the FDA Center for Tobacco Products (CTP) in 2008. *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ 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.

¹⁷² *Id.* at 2.

¹⁷³ Tobacco Control Act, §901(b), Pub. L. No. 111-31, 123 Stat. 1776, 1786-87 (2009) (codified at 21 U.S.C. § 387a(b)).

provisions of the Act would automatically apply to these products. This petition also asks that the FDA extend many of the existing restrictions and requirements for cigarettes and smokeless tobacco to all tobacco products.

A. Upon asserting jurisdiction over all tobacco products, the FDA must exercise all of its existing regulatory authority over all tobacco products

Many provisions of the Tobacco Control Act refer to “tobacco products,” generally but these provisions currently only relate to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. Once the FDA asserts jurisdiction over any other tobacco products, they will also fall within this category of “tobacco products” for the purpose of regulation. When this happens, all references in the Act to “tobacco products” will also refer to these products. We urge the FDA to not grant any kind of exemptions to any class of products. It is understandable that a phase-in period might be necessary to ensure compliance but these products must be regulated in the same way as cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. This petition will not attempt to describe all of the FDA’s existing regulatory authority with respect to “tobacco products” generally that would automatically apply to additional products over which the FDA asserts jurisdiction but the authority is broad and comprehensive.¹⁷⁴ However, there are two provisions that are worth examining in more detail in the context of OTP regulation: premarket review of new products and products that are marketed as posing less risk.

i. Premarket review of new product applications

An important component of the Tobacco Control Act is the provision requiring that any new tobacco products be subject to pre-market review by the FDA before they can enter the market. This section of the Act requires that for any product not commercially marketed in the U.S. on February 15, 2007, the manufacturer must file an application for approval of the product at least 180 days prior to marketing the product. Products that are shown to be the substantial equivalent of a product that was on the market on February 15, 2007 are excepted from the application process. The FDA must deny an application to market a new tobacco product if the applicant fails to demonstrate that permitting marketing of the product would be appropriate for the protection of the public health. In deciding whether to approve an application, the FDA will consider:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products¹⁷⁵

¹⁷⁴ See *supra* Part II.A. Action Requested in this petition.

¹⁷⁵ Tobacco Control Act, §910(c)(4), 123 Stat. at 1810 (codified at 21 U.S.C. § 387j(c)(4)); see also U.S. Food & Drug Admin., *Tobacco Products: Protecting the Public Health through Tobacco Regulation*, U.S. FOOD & DRUG ADMIN. (Aug. 7, 2012), <http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm313854.htm>.

Two of the product varieties discussed above are new products that should be subject to the pre-market approval process. Although e-cigarettes may have been on the market in China prior to 2007, it appears that e-cigarettes were not marketed in the U.S. until after February 15, 2007.¹⁷⁶ Little is known about e-cigarettes beyond that they do contain some toxins, have allegedly caused adverse events, and that the FDA has authority to regulate e-cigarettes as tobacco products.¹⁷⁷ In light of these facts, the FDA should require that e-cigarette manufacturers submit an application and the required documentation about the health impact of e-cigarettes—and prohibit marketing and sale of those products until the agency has rendered a decision on the application.

The same is true for dissolvables. Although certain types of smokeless tobacco and snuff have been on the market for decades, dissolvable sticks, strips and orbs are unlike any other smokeless tobacco product marketed before 2007. As discussed above, there is little evidence concerning the health effects of using these products or how the use of these products affects the use of other tobacco products. These products must be subject to premarket review and the burden should be on the tobacco manufacturer to either demonstrate that dissolvables are the substantial equivalent to a tobacco product marketed before 2007 or to file new product application.

ii. Modified Risk Tobacco Products

Congress made explicit in the Tobacco Control Act that use of misleading descriptors, such as light, mild, and low tar, is prohibited in the marketing of tobacco products. For too long consumers have been unfairly manipulated into thinking that such products offer reduced risk when there is no sound evidence to support such a conclusion. More broadly, Congress included the modified risk tobacco product (MRTP) provisions, requiring pre-market approval by the FDA for any tobacco product marketed as presenting less risk of harm.¹⁷⁸ It is imperative that the FDA enforce these provisions with respect to all tobacco products.

Although it is clear from the Tobacco Control Act and the FDA's guidance documents related to the MRTP provisions that the provisions apply to all tobacco products and not just cigarettes, the FDA has mainly focused on cigarettes and the removal of terms such as light and low tar from cigarette packaging. The FDA should make clear to manufacturers and retailers that pre-market approval is required for any tobacco product for which reduced risk claims are made.

B. In order to fully protect public health, the FDA must also extend many of the existing restrictions and requirements for cigarettes and smokeless tobacco to all tobacco products

i. Sales and Distribution

¹⁷⁶ Freiberg, *supra* note 150, at S252.

¹⁷⁷ Sottera, Inc. v. Food & Drug Admin., 627 F.3d 891 (D.C. Cir. 2010).

¹⁷⁸ Tobacco Control Act §911, 123 Stat. at 1812 (codified at 21 U.S.C. § 387k).

It is understandable that the initial sales and distribution regulations issued by the FDA in March of 2010¹⁷⁹ applied only to cigarettes and smokeless tobacco with the exception of a provision related to product sampling;¹⁸⁰ cigarettes and smokeless tobacco were the only products subject to the agency's 1996 regulations that Congress ordered revived in the Tobacco Control Act. But there is no justification for the continued narrow scope of those regulations, particularly the basic retail sales restrictions. Due to the sales regulations only covering certain tobacco products but not others, the message sent to the public about the dangers of tobacco products may be blunted. Further, it might hinder compliance by retailers with regard to state and local laws that go further to protect public health by prohibiting sales to minors, restricting product placement, and imposing identification requirements with respect to all tobacco products.¹⁸¹ Retailers who are focused only on the federal requirements may not abide state and local laws designed to reduce youth tobacco sales, increasing the likelihood of youth access and reducing the public health impact of those state and local laws. At a time when state and local health agencies are experiencing severe budget cuts, enforcement of the federal restrictions may be the only youth access enforcement in place. Expanding the coverage of these sales and distribution regulations to all tobacco products should not greatly increase expenses of enforcement under the contracts that the FDA has with the states and should result in reduced youth access to all tobacco products. We urge the FDA to extend the following sales and distribution restrictions that currently only apply to cigarettes and smokeless tobacco to all tobacco products:

- Establish a minimum age of 18 to purchase tobacco products,¹⁸² and mandate age verification of all persons not over the age of 26.¹⁸³
- Prohibit all non-face-to-face sales of tobacco products including the use of vending machines and self-service displays except in adult-only facilities.¹⁸⁴
- Prohibit sampling of all tobacco products and remove the current limited exemption for sampling of smokeless tobacco.¹⁸⁵

¹⁷⁹ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 60 Fed. Reg. 13225 (Mar. 19, 2010) (codified in 21 C.F.R. pt. 1140).

¹⁸⁰ 21 C.F.R. § 1140.16(d)(1) (2013).

¹⁸¹ Comments made during some retailer training events suggest that confusion may exist among retailers about the applicability of state and local laws in light of federal regulation. See U.S. Food & Drug Admin., *Tobacco Retailer Compliance Training—Archived Webinars*, U.S. FOOD & DRUG ADMIN. (May 15, 2013), <http://www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm220111.htm> (providing archived live training sessions for retailers on federal tobacco regulations).

¹⁸² Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.14(a) (2013).

¹⁸³ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.16(c) (2013).

¹⁸⁴ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.14(c) and 21 C.F.R. § 1140.16(c) (2013).

¹⁸⁵ The regulations also state that "no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act)." 21 C.F.R. § 1140.16(d)(1) (2013) (emphasis added). There is an exception allowing limited distribution of smokeless tobacco in adult-only facilities under certain circumstances. The FDA has chosen to not apply the prohibition beyond cigarettes and smokeless tobacco, despite the clear language including other tobacco products. Petitioners encourage the FDA to apply the prohibition on free samples to all tobacco products and to eliminate the exception for smokeless products in adult-only facilities.

These are best practices for tobacco sales that are supported by research and recommended by public health agencies and advocates. Many of these practices are even recognized by the tobacco industry as basic measures to reduce youth access to tobacco.¹⁸⁶ For all of the same reasons that these measures are imposed on the sale of cigarettes and smokeless tobacco, they should be applied to all OTPs, including cigars, dissolvables, hookah and e-cigarettes.

Because application of these regulations to cigars is set out fully in a previous petition,¹⁸⁷ we address here specifically hookah and e-cigarettes. As was noted above, young people do not comprehend the health risks associated with smoking hookah. The product is marketed in a manner that suggests it is more natural and therefore less harmful than cigarettes. Although many state and local laws restricting the sale of all tobacco products to minors apply to hookah, the lack of federal regulation of hookah contributes to the dangerous misunderstanding of the risks presented by its use. This concern is perhaps even more pronounced with respect to e-cigarettes. Under the *Sottera* decision, e-cigarettes are a tobacco product for purposes of FDA regulation; yet many state and local youth access laws – including their self-service provisions – have not yet been amended to include these products as products that cannot be sold to youth.¹⁸⁸ The public health community agrees that these products should not be sold to minors and that the FDA should take regulatory action to protect young people.¹⁸⁹ Indeed, many e-cigarette manufacturers must agree as their product packaging notes that the product should not be sold to minors. There is simply no justification for failing to extend the federal sales restrictions to hookah and e-cigarettes.

Few issues are simple and concise in the federal regulatory arena; this is the exception to the rule. Presenting a risk of harm to young people, all tobacco products should be subject to federal regulations prohibiting sales to minors, mandating identification check by retailers, eliminating self-service displays, and prohibiting free samples. To fulfill Congress's intent that the FDA act to protect the public health—especially the health of children—this modest step should be taken immediately.

The regulations discussed above are small step towards reducing youth access; in addition the FDA must also extend its mandatory minimum pack size requirement to all tobacco products.

¹⁸⁶ See L. Stead & T. Lancaster, *A Systematic Review of Interventions for Preventing Tobacco Sales to Minors*, 9 TOBACCO CONTROL 169 (2000); CTRS. FOR DISEASE CONTROL & PREVENTION, BEST PRACTICES FOR COMPREHENSIVE TOBACCO CONTROL PROGRAMS (2007), available at http://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2007/bestpractices_complete.pdf. Even the tobacco industry's We Card program, which purports to decrease youth access to tobacco products, adopts many of these basic principles. See THE WE CARD WEB CENTER, www.wecard.org (last visited July 15, 2013).

¹⁸⁷ Maryland Citizen Petition, *supra* note 47.

¹⁸⁸ See, e.g., CAL. CODE ANN., HEALTH & SAFETY § 119405 (West 2011); COLO. REV. STAT. § 18-13-121 (2011); IDAHO CODE ANN. § 39-5705 (West 2012); MD. CODE ANN., HEALTH GEN. § 24-305 (West 2012); MINN. STAT. ANN. § 609.6855 (West 2010).

¹⁸⁹ According to the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, and the Campaign for Tobacco-Free Kids, more regulation and clarification is needed from the FDA in determining how to treat these new electronic products. These groups believe e-cigarettes should be carefully regulated with regard to access for minors because it is indisputable that nicotine is a highly addictive substance for humans. AM. CANCER SOC'Y ACTION NETWORK, AM. HEART ASS'N, AM. LUNG ASS'N & CAMPAIGN FOR TOBACCO-FREE KIDS, POLICY GUIDANCE DOCUMENT REGARDING E-CIGARETTES (2010), available at http://www.ttac.org/tcn/tfp/2010/may-2010/pdfs/Policy_Guidance_E-Cigarettes.pdf.

Current sales and distribution regulations prohibit the sale of cigarettes in packages of less than twenty and prohibit a retailer from breaking a package of cigarettes or smokeless tobacco and selling the product in a package that is “smaller than the smallest package distributed by the manufacturer for individual consumer use.”¹⁹⁰ The minimum pack size for cigarettes is designed to keep the price of access for cigarettes high to discourage youth purchasing.¹⁹¹ The provision prohibiting the breaking of packages also accomplishes this goal to some extent. Moreover, both provisions ensure that the products sold will contain the required health warnings, as single cigarettes or smokeless pouches do not contain such warnings. The petitioners request that the FDA establish a minimum package size for all tobacco products, and prohibit breaking or opening of packages to sell individual tobacco products.

The minimum pack size for cigarettes serves as a model for what the FDA should impose with respect to all tobacco products and the provision prohibiting the breaking of packages should also apply to all tobacco products.

Minimum pack size is easily addressed with respect to small cigars and little cigars.¹⁹² Because they are virtually identical to cigarettes and are already marketed most often in a package of twenty, little cigars should be subject to the same restriction imposed on cigarettes. With respect to small cigars, which are often cheap, flavored and offered for sale as a single cigar, a four cigar minimum pack size is recommended. Those jurisdictions that have imposed a minimum pack size have typically opted for the minimum of four or five to keep the prices up and consumption down. In addition, there is little burden on manufacturers because many of the products, when offered by the pack, are in a pack of four or five.¹⁹³ Even this modest minimum drives up the

¹⁹⁰ 21 C.F.R. § 1140.14(d) (2013).

¹⁹¹ The pack size requirement originated in the Master Settlement Agreement. This MSA term expired in 2003, five years after execution of the MSA. See Master Settlement Agreement, § III(k), available at http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/MSA%20with%20Sig%20Pages%20and%20Exhibits.pdf/file_view (last visited Nov. 24, 2012). The goal was to impose the restriction for five years, allowing state and local authorities to impose restrictions by statute, ordinance or regulation. Many jurisdictions did adopt such provisions during and after that five year period. See, e.g., MD. CODE ANN., COM. LAW §§11-5A-02. This now includes the federal government since the passage of the Tobacco Control Act. 21 C.F.R. § 1140.15(b) (2013)

¹⁹² We do not intend for the minimum pack size provisions to apply to premium cigars. Premium cigars may be defined as cigars that sell at wholesale for more than \$2 per stick or at retail for more than \$2.50 per stick; this has been used in local legislation. See Stead & Lancaster *supra* note 186. The FDA would reserve authority to revisit the price point as needed to adjust to the Consumer Price Index or similar measures. See, e.g., WESTPORT, MASS., SALE & USE OF TOBACCO PRODS. & NICOTINE DELIVERY PRODS REGULATION, § F, available at http://aldenhill.com/Community_Event_Text/2012_Events/Westport_Tobacco_Regulation_october_1_2012.pdf (“The Westport Board of Health may adjust from time to time the amounts specified in this Section to reflect changes in the applicable Consumer Price Index by amendment of this regulation.”) New York City is currently considering an ordinance that limits little cigar pack-size to twenty. N.Y.C., N.Y., Sensible Tobacco Enforcement Bill (Int. No. 1021) (2013). For an explanation of the bill, see Campaign for Tobacco-Free Kids, *What Does the “Sensible Tobacco Enforcement Bill” Do?*, CAMPAIGN FOR TOBACCO-FREE KIDS, available at <http://savenyckids.org/content/wp-content/uploads/2013/06/N-Price-Proposal-Provisions-group-logos-4-24-13.pdf> (2103).

¹⁹³ See, e.g., BOSTON, MASS., PUB. HEALTH COMM’N REGULATIONS, YOUTH ACCESS REGULATION, § III(4), available at <http://www.bphc.org/boardofhealth/regulations/Forms%20%20Documents/Tobacco%20Control%20Regulation%20FINAL%20Adopted%20December%202011%20Corrected%20Version%20-%20Update%203.pdf> (4-pack)

price of access such that youth purchasing—and impulse purchasing by adults—will decrease. For example, a single small cigar may cost \$1, an accessible price for young people; a five cigar pack will be priced at about \$4.50, a level that reduces youth access, particularly by young teens.

Pack size regulation for other tobacco products, such as dissolvables, hookah, and e-cigarettes, is less obvious. While we do not have sufficient information to propose minimum packaging for these products, we encourage the agency to conduct research on whether there are appropriate minimum pack sizes for other products such that youth access and impulse purchasing decrease.

ii. Product Regulation

a. Prohibit characterizing flavors in all tobacco products

The Tobacco Control Act explicitly prohibits flavored cigarettes, with the exception of those that are menthol—or tobacco—flavored.¹⁹⁴ While Congress focused its attention on a wide range of flavored cigarettes, it did not expressly mention other tobacco products.¹⁹⁵ This is an obvious gap that could be closed by agency regulation. Moreover, the prohibition on flavored OTPs can and should include all flavored products; there is no limitation in the Act that would prevent the FDA from including mint and menthol flavored products and there is no rational basis for excluding them from the prohibition.¹⁹⁶

minimum) (amended Dec. 1, 2011). At least seven additional local jurisdictions in Massachusetts have adopted provisions similar to the Boston regulation (Bedford, Buckland, Middleton, Montague, Salem, Suagus, Westport).

¹⁹⁴ Tobacco Control Act §907(a)(1)(A), Pub. L. No. 111-31, 123 Stat. 1776, 1799 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)).

¹⁹⁵ 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.*

¹⁹⁶ 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 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 this agency's power, any flavored prohibition for OTPs ought to include menthol and mint flavorings. Hence, throughout this petition, 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. 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]. 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 petition.

The same reasons that undergird the prohibition on the sale of sweetly flavored cigarettes apply to flavored OTPs. As this agency's *Parental Advisory on Flavored Tobacco Products* states, flavored tobacco products:¹⁹⁷

- 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 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 is absolutely correct about the appeal and harm of flavored tobacco products.¹⁹⁸ While adults use flavored products as well, it is clear that these products are designed to appeal to youth. Even adult smokers and non-smokers understand that flavored tobacco products are designed to entice and addict youth because the marketing entices young people to try the product and the flavors make it easier for youth to smoke or chew successfully.¹⁹⁹ Flavorings clearly form the basis of youth-enticing marketing campaigns. For example, Apple Blend Skoal Chew promotions assert that it will "combine rich, premium tobacco with the crisp flavor of juicy apples,"²⁰⁰ available in a pouch similar to a tea bag. One manufacturer's little cigar is

¹⁹⁷ FDA, *supra* note 50.

¹⁹⁸ 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.").

¹⁹⁹ Stacy M. Carter & Simon Chapman, *Smokers and Non-smokers Talk About Regulatory Options in Tobacco Control*, 15 TOBACCO CONTROL 398 (2006).

²⁰⁰ Press Release, U.S. Smokeless Tobacco Co., Skoal Pouches Line Expands with Apple Blend Pouches (May 23, 2005), available at http://phx.corporate-ir.net/phoenix.zhtml?c=75256&p=irol-newsArticle_Print&ID=719395&highlight=.

marketed as containing “a nice punch of ‘wild raspberry’ to tantalize the taste buds.”²⁰¹ Advertisements and packaging employ stylish designs and bright colors that further emphasize the flavor and entice youth.²⁰² 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 gradually go up the ladder.”²⁰³ “Cherry is like the kindergarten for Copenhagen,” said another high school boy.²⁰⁴

In addition to their use by youth, it is troubling that 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 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 65.²⁰⁵ 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 LGBT than heterosexual/straight cigar smokers (67.0% vs. 41.8%).²⁰⁶

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 products (57.7%).²⁰⁷ 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.²⁰⁸ 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

²⁰¹ *Pipe Tobacco: Dean's Wild Berry Wide Cigars*, PIPE TOBACCO PLACE, <http://www.pipetobacco.com/deans-wild-berry-wide-cigars-100mm.html> (last visited July 15, 2013).

²⁰² 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.

²⁰³ Alex M. Freedman, *Juiced Up: How a Tobacco Giant Doctors Snuff Brands to Boost Their “Kick”*, WALL ST. J., Oct. 26, 1994, at A1.

²⁰⁴ *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>.

²⁰⁵ King et al., *supra* note 159 at 3 tbl.1.

²⁰⁶ *Id.* at 3 tbl 1, 4-5.

²⁰⁷ 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).

²⁰⁸ *Id.* at 90 fig.1.

2011, but also contributed to about 60% of growth in sales in the moist snuff category overall.²⁰⁹ Each year from 2005 to 2011, flavored products comprised at least 54% of the overall moist snuff market share.²¹⁰ The market share of flavored products is even higher for the subcategory of snus – 79.6% in 2011.²¹¹

Some state and local governments have taken action to prohibit the sale of flavored OTPs. 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.²¹² The City of New York passed an even more expansive bill restricting the sale of *all* flavored non-cigarette tobacco products, including flavored cigars and smokeless tobacco products, excepting menthol, mint and wintergreen but exempting sales in adult-only facilities.²¹³ The City Council had been alarmed by the wide array of cigar flavors, like cookie dough, chocolate chip and pink berry, which appeared to target minors.²¹⁴ Other jurisdictions, including Santa Clara County, California, and Providence, Rhode Island, have followed suit in enacting their own flavored OTP sales restrictions to protect youth.²¹⁵ Providence and New York City are currently defending those provisions against legal challenges.²¹⁶ Although New York City and Providence have prevailed in the first round, both cases continue on appeal. The threat of litigation deters many local jurisdictions, with limited legal resources, from taking action. As a result, state and local

²⁰⁹ Delnevo et al., *supra* note 89, at 2.

²¹⁰ *Id.*

²¹¹ *Id.* at 4.

²¹² H.P. 1086, 2010 Leg., 124th Sess. (Me. 2010). 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 ILL. COMP. STAT. 685/4 (emphasis added).

²¹³ N.Y.C., N.Y., ADMIN. CODE, tit. 17, 17-713 TO -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).

²¹⁴ 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/testi20090521.pdf>.

²¹⁵ 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).

²¹⁶ Nat'l Ass'n of Tobacco Outlets v. City of Providence, Rhode Island, No. 12-96-ML, 2012 WL 6128707 (D.R.I. Dec. 10, 2012); see also PUB. HEALTH LAW CENTER, <http://www.publichealthlawcenter.org/sites/default/files/resources/amicus-NATO-providence-2012.pdf> (last visited July 15, 2013) (Amicus Curiae brief); 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://www.center4tobaccopolicy.org/CTPO/_files/_file/The%20National%20Association%20of%20Tobacco%20Outlets%20and%20Ordinances%20Related%20to%20Tobacco%20Retailers%20July%202012\(1\).pdf](http://www.center4tobaccopolicy.org/CTPO/_files/_file/The%20National%20Association%20of%20Tobacco%20Outlets%20and%20Ordinances%20Related%20to%20Tobacco%20Retailers%20July%202012(1).pdf) (describing this and similar challenges).

legislative efforts may fail²¹⁷ and the effect of the flavored OTP sales restrictions that do pass does not measure up to the impact that a nationwide restriction on flavored tobacco products would have both with respect to decreasing youth initiation and reducing adult tobacco use.

Each of the products discussed in Section 1, above, is 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 should prohibit the sale of all flavored tobacco products. The petitioners propose the following language, that 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 menthol²¹⁸) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.²¹⁹

b. Establish warning labels for all tobacco products

Warning labels are one of the oldest and most basic public health measures to attempt to mitigate the negative health effects of smoking.²²⁰ Since the first warning labels appeared on cigarette packages in 1965, warning labels have been an important source of information for tobacco users.²²¹ While there is evidence that the current warning labels may have gone stale,²²² and the need for large graphic warning labels is clear,²²³ the products mentioned in this petition are

²¹⁷ See, e.g., S.B. 632, 2012 Gen. Assemb., Reg. Sess. (Md. 2012) (would have prohibited the sale of flavored cigars but failed in committee).

²¹⁸ As explained above, we request 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 separate petition to remove the menthol exception from the flavored restriction for cigarettes which is discussed earlier in this petition. See Menthol Citizen Petition, *supra* note 196.

²¹⁹ Tobacco Control Act §907(a)(1)(A), Publ L. No. 111-31, 123 Stat. 1776, 1799 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)) (strike through shown to demonstrate removal of those words).

²²⁰ Ctrs. For Disease Control & Prevention, *Cigarette Package Health Warnings and Interest in Quitting Smoking—14 Countries, 2008–2010*, 60(20) MORBIDITY & MORTALITY WKLY. REP. (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*, TOBACCO CONTROL 1 (Oct. 23, 2012) (published online ahead of print), doi:10.1136/tobaccocontrol-2012-050541.

²²¹ SGR 2000, *supra* note 220, at 163.

²²² 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.

²²³ SGR 2012, *supra* note 68, at 718-19; 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) (published exclusively online);

typically marketed with no warning labels whatsoever. This contributes to the state of confusion surrounding the health effects of these new products.²²⁴ The FDA must step in and establish warning labels for cigars, hookah, and e-cigarettes and recognize that dissolvable tobacco products are smokeless tobacco products for the purpose of warning label regulation. 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.

iii. Advertising and Marketing

Consistent with the FDA's existing sales and distribution regulations, the FDA's advertising and marketing regulations, currently only apply to cigarettes and smokeless tobacco. These regulations should apply to all tobacco products; especially cigars,²²⁵ hookah and electronic cigarettes. As noted above, the definition of smokeless tobacco product in the Act includes snus and dissolvables; and thus, the FDA must clarify that these products are smokeless tobacco products for the purposes of regulation. With respect to advertising and marketing restrictions, the petitioners specifically request that the FDA extend the following advertising and marketing restrictions that currently only apply to cigarettes and smokeless tobacco to all tobacco products:

- Prohibit tobacco product brand and trade names of non-tobacco products.²²⁶
- Prohibit brand and trade name sponsorship of sporting and cultural events.²²⁷
- Require notice of all advertising in any non-traditional medium.²²⁸

The justification underlying the application of these restrictions to cigarette and smokeless tobacco advertising apply to all tobacco products. The tobacco industry has a long history of marketing its products to young adults and children with the goal of getting them addicted to nicotine at a young age.²²⁹ 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 interest of these products to youth and young adults and the amount of experimentation that is already present, there is clearly a need to implement these restrictions to curb youth initiation of tobacco use. These restrictions represent the first, small step in the right direction.

A.A. Strasser et al., *Graphic Warning Labels in Cigarette Advertisements: Recall and Viewing Patterns*, 43(1) AM. J. PREV. MED. 1 (2102) (published online ahead of print), doi: 10.106/j.ameprev.2012.02.026 (2012).

²²⁴ See, e.g., comments to AAPHP petitions cited *supra* notes 163-64.

²²⁵ A previous 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 Maryland Citizen Petition, *supra* note 47.

²²⁶ 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 *Renegade Tobacco Co. v. U.S. Food & Drug Admin.*, No. 3:10-cv-00265-HEH.

²²⁷ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.34(c) (2013).

²²⁸ Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.30(a) (2013).

²²⁹ U.S. v. Philip Morris USA Inc., 449 F.Supp.2d 1, 561-692 (D.D.C. 2006).

IV. CONCLUSION

The use of tobacco products is a scourge on public health and has been for many decades. The passage of the Family Smoking Prevention and Tobacco Control Act was heralded as a vigorous and aggressive step toward eliminating this plague on public health, finally taking a step towards stemming the tide of illness and death caused by tobacco products. The Act and the FDA have already had an impact, pushing toward the goal of eradicating morbidity and mortality associated with tobacco use. Yet there is much more to be done. The FDA must complement state and local activity by promulgating regulations designed to impact the products most attractive to young people, most likely to encourage adults to continue to use and most aggressively promoted by the tobacco industry to initiate youth. This is precisely what the public health standard requires: regulation that will increase cessation, decrease initiation and protect users and non-users from these dangerous products. The tobacco industry has always been one step ahead of the regulatory curve, with tactics such as marketing light cigarettes just as health warnings were required,²³⁰ or by creating more palatable and socially acceptable smokeless tobacco products as comprehensive smoke-free laws were enacted. The reality is that as one form of tobacco product is subject to regulation, the industry develops new products or strategies that expose regulatory gaps, illustrated by the explosion in sweetly flavored cigars in response to the Tobacco Control Act's prohibition of flavored cigarettes. The FDA has the power to bring all tobacco products under its jurisdiction and regulate all of these products for the protection of public health. A modest, evidence-based step in that direction is the assertion of jurisdiction over all tobacco products and the imposition of existing restrictions for cigarettes and smokeless tobacco on all tobacco products. The petitioners urge the FDA to take that step.

V. ENVIRONMENTAL IMPACT

The action requested in this petition will not have any significant effect on the quality of the human environment.

VI. ECONOMIC IMPACT

No statement of economic impact of the requested action is presented as none has been requested by the Commissioner.²³¹

VII. CERTIFICATION

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners and which are unfavorable to the petition.²³²

²³⁰ See Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 283 (1964).

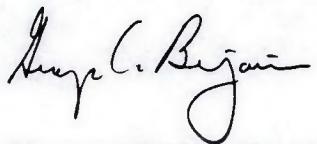
²³¹ 21 C.F.R. § 10.30 (b) (2013).

²³² *Id.*

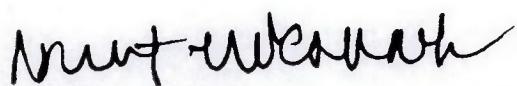
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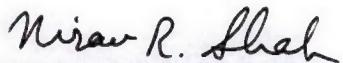
²³³ The Consortium's affiliated legal centers include: ChangeLab Solutions in Oakland, California; the Legal Resource Center for Tobacco Regulation, Litigation & Advocacy at the University of Maryland School of Law in Baltimore, Maryland; the Tobacco Control Resource Center, a project of the Public Health 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 state of New York and Vermont. All of the Consortium's affiliated legal centers join this petition.



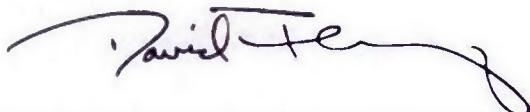
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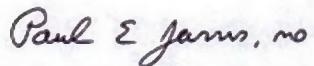
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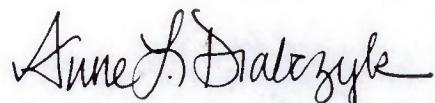
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