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

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG38, Proposed Rule on Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

The undersigned organizations submit these comments in response to the Proposed Rule of the Food and Drug Administration (FDA) deeming various tobacco products subject to the Federal Food, Drug and Cosmetic Act as amended by the Family Smoking Prevention and

Tobacco Control Act (Tobacco Control Act or TCA).<sup>1</sup> A description of each organization is provided in the Appendix to these comments. In the aggregate, the organizations joining these comments represent over 500,000 healthcare and public health professionals. Some of these organizations also have filed separate comments in this Docket.

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<sup>1</sup> Throughout these comments, the terms “Tobacco Control Act” or “TCA” will refer to the Food, Drug and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act.

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### **Executive Summary**

The deeming of all tobacco products as subject to FDA’s regulatory authority is critical to protecting the public health against the risks posed by an increasingly dynamic and diverse marketplace in tobacco products and ensuring continued, and accelerated, progress toward eliminating tobacco-related disease and death. However, the proposed rule must be strengthened,<sup>2</sup> and made comprehensive in scope, to prevent the manufacturers of tobacco products from designing and marketing their products in ways that undercut the full potential of the Tobacco Control Act to achieve its lifesaving objectives.

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<sup>2</sup> Each of the changes needed to strengthen FDA’s Proposed Rule is discussed in greater detail below and may be enacted as part of the Final Rule without further notice and comment procedures because each of the changes is a logical outgrowth of, and reasonably foreseeable from, the proposed FDA rule. *Agape Church, Inc. v. FCC*, 738 F.3d 397, 411-412 (D.C. 2013) (holding that final rule that differed from proposed rule did not require additional comment period and that “[t]he final rule need not be the one proposed in the [Notice of Proposed Rulemaking]. Rather, ‘[a]n agency’s final rule need only be a logical outgrowth of its notice.’”) (citation omitted)); *id.* (noting that a final rule fails the logical outgrowth test if it was “surprisingly distant” from the proposed rule (citation omitted)); *Arizona Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000) (holding that final rule that differed from proposed rule did not require additional notice and comment procedures under the “logical outgrowth” rule where “the final rule was not wholly unrelated or surprisingly distant from the what EPA initially suggested.”)

The serious adverse public health consequences of the current unregulated market for cigars, e-cigarettes, and other products demand that FDA exhibit a sense of urgency in its rulemaking process on deeming. FDA should commit itself to issuing a final deeming rule within one year of publication of the proposed rule, i.e., on or before April 25, 2015. It must also commence proceedings immediately to close various regulatory gaps left by its proposal, such that additional final rules closing those gaps are published coincident with the final deeming rule, i.e., no later than April 25, 2015.

### ***Scope of the Deeming Rule: A Possible Exemption for “Premium Cigars”***

FDA has raised the possibility of a regulatory option that would exempt so-called “premium cigars.” There is no justification for exempting any cigars from FDA regulation. All cigars are harmful and potentially addictive to users. The industry’s arguments for an exemption are based on the premises that premium cigars are not hazardous because their users do not inhale and that young people do not use premium cigars. These premises are not consistent with the scientific evidence. Moreover, all cigars threaten the health of non-users by giving off significant amounts of harmful secondhand smoke.

Even if the science were to show that “premium cigars,” as defined by the FDA’s eight criteria, pose risks of a different nature and degree than other kinds of cigars, the proper response would be for FDA to assert its regulatory authority over all cigars and to then apply its authority in a manner appropriate to the risk. But exempting any tobacco product from the deeming rule would create a dangerous precedent with the potential to lay the groundwork for additional dangerous exemptions and loopholes.

Should FDA nevertheless decide to define a category of “premium cigars” that is subject to a lesser degree of regulation than other cigars, it must be careful to define the category of “premium cigars” with sufficient care to prevent the industry from manipulating the definition to the detriment of public health. In no event should the eight-factor definition of “premium cigars” proposed by FDA be broadened. If anything, the FDA’s proposed definition should be narrowed to ensure against continued youth usage of addictive and dangerous cigars.

### ***Importance of Applying to Newly-Deemed Products the Full Scope of Statutory Provisions Applicable to “Tobacco Products”***

As FDA notes in its Notice of Proposed Rulemaking (NPRM), certain provisions of the TCA apply automatically to any product deemed by FDA subject to its jurisdiction. Each one of these provisions is important in ensuring that FDA effectively regulate the newly-deemed products in the interest of public health.

- The adulteration and misbranding provisions are important because they trigger various key enforcement provisions of the statute. TCA Sec. 903 and 904.

- Ingredient disclosure, including listing of harmful and potentially harmful constituents, is important to furnish the factual basis for appropriate regulation of the deemed products. TCA Sec. 904.
- Manufacturer registration, inspection authority and required product listing are necessary to furnish FDA with necessary foundational information for appropriate regulation. TCA Sec. 905. In addition, Sec. 905(j) must be applied to properly enforce the premarket notification requirements for new tobacco products.
- FDA authority to impose restrictions on the sale and distribution of tobacco products, including their advertising and promotion, is necessary to prevent irresponsible industry marketing practices that are directed at young people. TCA Sec. 906 (d).
- FDA authority to prescribe good manufacturing practices is important to ensure the manufacture of products according to consistent specifications, particularly for e-cigarette products for which the absence of rigorous quality control creates great uncertainty about the level of nicotine and other constituents actually being consumed. TCA Sec. 906(e).
- FDA authority to issue product standards can be used to limit the substances in the deemed products that increase the risk of harm and youth initiation and use. TCA Sec. 907.
- FDA authority to require manufacturers to provide information regarding adverse medical reactions to tobacco products is a fundamental safety protection. TCA Sec. 909.
- Premarket review of new products, including products alleged to be substantially equivalent products, is critical to reducing the risk that the industry will introduce new products that are more attractive, more addictive and more dangerous. TCA Sec. 910.
- FDA authority to require testing and reporting of tobacco product constituents by brand and subbrand is necessary to ensure accurate, reliable data on which to make, and enforce, regulatory decisions.

There is no reason to exempt manufacturers of deemed products from these provisions based on the size of the manufacturer. Small manufacturers can make tobacco products that cause significant harm. Given the necessity of these requirements to adequate regulation of any tobacco product, the cost of compliance is far outweighed by the public health benefits.

### ***Sales and Marketing Restrictions***

There now is overwhelming evidence that manufacturers of cigars and e-cigarettes are using many of the marketing strategies and techniques long used by cigarette companies to attract young people to their addictive products. Therefore, FDA must not only implement the sales and marketing restrictions it has proposed for the deemed products, but it must go further to impose on cigars, e-cigarettes and other deemed products the restrictions in the cigarette and smokeless regulations promulgated by FDA in 2010 pursuant to the mandate in the TCA. FDA should also prohibit on-line sales of the deemed products as a step toward prohibiting on-line sales of all tobacco products, including cigarettes and smokeless.

Thus, FDA should implement its proposed minimum age requirement of 18 and age verification for retailer sales of the deemed products. Because of the ready availability of the deemed products to young people through the internet, and the inherent difficulty of enforcing effective age verification for on-line sales, FDA should prohibit internet sales of the deemed products. If the agency decides to permit internet sales, it should at least impose age verification procedures on internet sellers of the deemed products analogous to the procedures mandated for internet cigarette sales by the Prevent All-Cigarette Trafficking Act of 2009.

FDA should make final its proposals to prohibit vending machine sales (except in adult-only facilities) and prohibit free samples. However, it should go further to impose all the restrictions in the 2010 rule, including prohibiting self-service displays, the use of deemed product brand names on non-tobacco merchandise and deemed product brand name sponsorship of events. FDA also should require 30-day prior notification to FDA of intent to advertise on the internet, through social media and in other non-traditional media.

FDA should not wait to make the deeming rule final before moving forward with additional proceedings to impose these marketing restrictions, but should begin those proceedings immediately to enable all the marketing restrictions to be final either as part of this rule or coincident with the final deeming rule.

### ***Flavorings***

FDA's failure in the proposed deeming rule to address the growing use of characterizing flavors in deemed products creates a serious regulatory gap that is adverse to public health. FDA should immediately develop rules prohibiting characterizing flavors (other than tobacco) in the deemed products, including cigars and e-cigarettes, as well as in currently regulated tobacco products. Such action is consistent with the TCA's strong policy against characterizing flavors in cigarettes and is justified in light of the commonplace use of candy and fruit flavors in cigars and e-cigarette products, the appeal of such flavored products to young people and the marketing of those products in ways that enhance their appeal to young people. FDA also should vigorously enforce the current prohibition on flavors in cigarettes against all products that meet

the statutory definition of “cigarette,” including those marketed as cigars in an effort to evade the current prohibition of flavored cigarettes.

FDA should require, as to each non-tobacco flavor that the manufacturer wants to market that the manufacturer first submit valid scientific evidence prior to the addition of the flavor that the flavor (1) enhances the efficacy of the product in increasing the number of smokers who quit smoking, (2) does not contribute to initiation of tobacco product use, including e-cigarette use, particularly among youth, or relapse into tobacco product use, and (3) does not result in continued use of tobacco products by those who otherwise would have quit.

FDA should commence proceedings to issue a final rule governing flavors either as part of, or to be issued coincident with, the final deeming rule.

### ***Child-resistant Packaging of Nicotine Liquid Products***

There has been a dramatic increase in calls to poison control centers involving nicotine poisoning of children arising from the indiscriminate availability of liquid nicotine for e-cigarette products in containers without child-resistant packaging. The unregulated market for these products is a direct and immediate threat to the health and safety of our children. Because of the special urgency of this threat, FDA should issue a proposed rule mandating child-resistant containers for liquid nicotine products by September 2014 and issue a final rule coincident with the final deeming rule no later than April 25, 2015.

### ***Health Warnings***

Because of the addictiveness of nicotine, the vulnerability of youth to nicotine addiction and the misperception, particularly among young people, that nicotine poses little risk of addiction, FDA should make final its proposed health warning regarding the addictiveness of nicotine in the deemed products.

In addition, FDA should mandate health warnings on cigars. However, it should go beyond its proposal to require four of the five current FTC cigar warnings to also require the FTC warning about the reproductive effects of tobacco use. All the FTC warnings communicate messages about the harmfulness of cigars that are supported by the scientific evidence, including the warning about reproductive effects. Mandating these warnings is consistent with the policy of the Tobacco Control Act and the scientific evidence about the impact of large, text-based warning labels on increased perception of risk and consumer health knowledge.

The final rule also should provide for regular FDA review of the effectiveness of the warnings and revision of their content as necessary to ensure their freshness and informative power.



### *Premarket Review of New Products*

FDA's proposed rule recognizes the importance of applying the premarket review provisions of the TCA to the deemed products and the need for FDA to use its enforcement discretion to adapt those provisions to the special circumstances of tobacco products that become subject to the TCA by virtue of deeming. FDA, however, should revise its premarket review proposal in two important ways.

First, the agency should shorten the period of non-enforcement from 24 months to 12 months from the date of the final deeming rule for all deemed products. Because the impact of FDA's enforcement forbearance is to allow new tobacco products to remain on the market even though FDA has made no determination that marketing of the products either meets the statute's public health standard, or that the product is substantially equivalent to a product on the market as of February 15, 2007, this "compliance" or "grace" period should be as short as possible and still afford manufacturers a reasonable opportunity to prepare and file an application for a marketing order. A compliance period of twelve months is sufficient.

Second, significant conditions should be imposed on manufacturers of deemed products seeking marketing orders and taking advantage of FDA's enforcement forbearance. Because the newly-deemed new products will not be in compliance with the TCA, and would be illegal but for FDA's exercise of its enforcement discretion, the agency has discretion to impose conditions on the manufacturers to minimize the harm to public health from the presence of these products on the market. FDA should use that discretion to impose conditions to prevent the marketing of the deemed products to children. Thus, FDA should require manufacturers of those products to abide by the 2010 advertising restrictions as a condition of receiving the benefit of the FDA compliance period for premarket review of new products. Companies should also be required to agree not to target youth or engage in marketing that has broad appeal to youth. Given the evidence that deemed products like cigars and e-cigarettes are being successfully marketed in ways that appeal to children, at a minimum FDA should not permit any company's product marketed in these ways to receive the benefits of remaining on the market prior to receiving a marketing order. FDA also should impose conditions requiring ingredient disclosure and consistent delivery of nicotine and other components according to specifications.

In addition to these revisions of the proposed deeming rule, FDA must develop and implement a system to ensure against delay in processing and resolving applications for marketing orders of products already on the market to avoid continuation of the chronic problems in processing applications for currently-regulated products. In considering substantial equivalence and new product applications for the deemed products, FDA should apply the same standards it has developed for currently-regulated products, but should recognize that the evidence relevant to the public health standard is likely to be different for e-cigarette products.

### ***Modified Risk Claims***

In light of numerous instances of e-cigarette manufacturers making claims that their products are a healthier alternative to cigarettes, and that their products may help smokers to quit or reduce their use of cigarettes, it is important that FDA make it clear that the modified risk provisions of the TCA apply to the deemed products. The statute requires that such claims be evaluated not only for their accuracy as to the consumer, but also as to their effect on the population as a whole, including users and nonusers of the products. The TCA protects consumers from false or misleading health claims, while permitting claims as to which the manufacturer can demonstrate the likelihood of a measurable reduction in morbidity and mortality.

### ***FDA's Regulatory Impact Assessment***

FDA's Regulatory Impact Assessment (RIA) accompanying the proposed rule significantly underestimates the net welfare gain from the rule, both because it underestimates the benefits and because its application of the concept of lost consumer surplus is flawed. The RIA appropriately recognizes the increased health and longevity from smoking cessation or non-initiation, but then erroneously excludes 70 percent of that welfare gain to take account of "lost consumer surplus," i.e., the "pleasure" that individuals give up by not smoking.

The concept of lost consumer surplus is designed for contexts where consumer buying decisions are fully informed and rational. Both the application of the consumer surplus concept to all smokers who quit and the calculation of the quantitative value of the lost pleasure are flawed. The vast majority of smokers begin smoking and become addicted when they are underage, have imperfect information, and insufficiently understand the power of addiction to nicotine when they start smoking. In addition, the large majority of smokers regret having begun smoking and wish they could quit; in fact, each year a large percentage attempts to quit. Such smokers do not derive pleasure from smoking; they smoke primarily to avoid the effects of withdrawal. Unwelcome addiction is not a "pleasure"; rather, it is a severe burden. Thus, FDA's application of "consumer surplus" to discount 70 percent of the benefits of not smoking is unjustified and results in a large underestimate of the benefits of the proposed deeming rule.

## Specific Comments on Proposed Rule

### I. THERE IS NO JUSTIFICATION FOR EXEMPTING ANY CIGARS FROM FDA REGULATION

Despite FDA’s statement in its letter to stakeholders of April 25, 2011 that the agency intended to apply “appropriate regulatory mechanisms” to all products that meet the statutory definition of “tobacco product,” the proposed deeming rule contemplates the possible exemption from regulation of so-called “premium cigars.” FDA thus solicits comments on two options for the regulation of cigars. Option 1 would apply the deeming rule to all categories of cigars. Option 2 would restrict the deeming rule to “covered cigars” and would exclude “premium cigars” from the definition of “covered cigars.”<sup>3</sup> The possibility of a deeming exemption for “premium cigars” was added to the proposed rule after it was referred for review by OMB’s Office of Information and Regulatory Affairs (OIRA). Our organizations are strongly opposed to Option 2.

All cigars pose an increased risk of disease. No cigar has been scientifically shown to be safe. Because there is no public health justification for exempting any cigars from FDA regulation, Option 2 should be rejected and FDA should adopt a final deeming rule subjecting all cigars to its regulatory authority. To the extent that different kinds of cigars have different implications for public health, FDA has the flexibility under the Tobacco Control Act to adapt its regulatory approach to take those differences into account. To apply this flexible approach, FDA must first deem all cigars subject to the TCA, including those FDA has labeled “premium cigars.”

Recently released data from the 2013 Youth Risk Behavior Survey (YRBS) underscores the importance of FDA regulation of cigars. Increasingly, young smokers are turning to cigars instead of cigarettes. Whereas the high school cigarette smoking rate was 15.7 percent in 2013, a significant decline from 18.1 percent in 2011, the cigar smoking rate for high school students was 12.6 percent, essentially unchanged from 13.1 percent in 2011 and only slightly down from 14 percent in 2005.<sup>4</sup> Indeed, high school boys now smoke cigars at the same rate as cigarettes. In 2013, 16.5 percent of high school boys smoked cigars, compared to 16.4 percent who smoked cigarettes.<sup>5</sup> In fully 21 states high school boys smoke cigars at the same or at a higher level than smoke cigarettes.<sup>6</sup> In 2011, 17.8 percent of high school boys smoked cigars, while 19.9 percent

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<sup>3</sup> 79 Fed. Reg. at 23150-52.

<sup>4</sup> U.S. Centers for Disease Control and Prevention (CDC), “Youth Risk Behavior Surveillance – United States, 2013,” *Morbidity and Mortality Weekly Report (MMWR)* 63(4), June 13, 2014 (2013 YRBS) <http://www.cdc.gov/mmwr/pdf/ss/ss6304.pdf>.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

smoked cigarettes.<sup>7</sup> An alarming 23 percent of male high school seniors smoke cigars (compared to 19.6 percent who smoke cigarettes).<sup>8</sup> It is apparent that our tobacco control policies are having less effect in curbing cigar use among kids than in curbing cigarette use, due in part to FDA’s delay in extending its regulatory authority to include cigars.

It is essential that FDA deem cigars within its regulatory authority and ensure that its regulation of cigars is comprehensive and appropriate to the public health.

A. All Cigars Present a Significant Risk of Disease and Addiction to Users

As FDA’s NPRM on deeming itself acknowledges, “all cigars are harmful and potentially addictive.”<sup>9</sup> In the National Cancer Institute’s Monograph 9, *Cigars: Health Effects and Trends*, it is noted that “[t]he smoke from both cigars and cigarettes is formed largely from the incomplete combustion of tobacco, and therefore it comes as no surprise that cigar smoke is composed of the same toxic and carcinogenic constituents found in cigarette smoke.”<sup>10</sup> Indeed, Monograph 9 concludes that “cigar smoke is as, or more, toxic and carcinogenic than cigarette smoke . . . .”<sup>11</sup> In all cigars, regardless of size, the higher nitrate content of cigar tobacco results in higher concentrations of nitrogen oxides, carcinogenic N-nitrosamines and ammonia than cigarette smoke; the lower porosity of cigar wrappers results in more of carbon monoxide per gram of tobacco burned.<sup>12</sup> When bioassayed in animals, the tar of cigar smoke is more carcinogenic than cigarette smoke tar.<sup>13</sup> Although there are differences in disease risk between smoking cigars and smoking cigarettes, NCI Monograph 9 concludes those differences “relate more to differences in patterns of use, and differences in inhalation, deposition and retention of cigarette and cigar smoke than the differences in smoke composition.”<sup>14</sup>

In discussing its Option 2 to exempt premium cigars from regulation, FDA notes the claim of the International Premium Cigar and Pipe Retailers Association (IPCRA) that the vast majority of premium cigar smokers do not inhale the smoke.<sup>15</sup> But cigar smokers, regardless of whether they inhale, expose the mouth and throat to the carcinogens in tobacco smoke that collect on the surface of the mouth and are swallowed with saliva, thus causing an increased risk of cancer of the esophagus.<sup>16</sup> Regular cigar smokers who have never smoked cigarettes, even those who do not inhale, are still at substantially increased risk of cancers of the larynx, oral

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<sup>7</sup> CDC, “Youth Risk Behavior Surveillance – United States, 2011,” *MMWR* 61(4), June 8, 2012 <http://www.cdc.gov/mmwr/pdf/ss/ss6104.pdf>.

<sup>8</sup> 2013 YRBS.

<sup>9</sup> 79 Fed. Reg. at 23150.

<sup>10</sup> National Cancer Institute, *Cigars: Health Effects and Trends*, NCI Smoking and Tobacco Control Monograph 9, 1998, at 3 (NCI Monograph 9), <http://cancercontrol.cancer.gov/brp/tcrb/monographs/9/index.html>.

<sup>11</sup> *Id.* at 3.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> 79 Fed. Reg. at 23152.

<sup>16</sup> NCI Monograph 9, at 130.

cavity (including pharynx), and esophagus.<sup>17</sup> The overall risk of oral and pharyngeal cancers is similar for cigar smokers and cigarette smokers, with an overall risk seven to ten times higher than for never-smokers.<sup>18</sup> Moreover, a long-term study of more than 130,000 men found that even cigar smokers who reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked.<sup>19</sup>

Thus, although the degree of risk presented by cigars may vary according to use, it is clear that use of the cigars meeting the FDA’s proposed criteria for “premium cigars” present an elevated risk of disease. As observed in NCI Monograph 9, “[t]here is little evidence from what is known about the tobacco content and manufacture of premium cigars to suggest that they are not hazardous.”<sup>20</sup> The NCI Monograph also stated that “the risks of tobacco smoke exposure are similar for all sources of tobacco smoke, and the magnitude of the risks experienced by cigar smokers is proportionate to the nature and intensity of their exposure.”<sup>21</sup>

Moreover, all cigars deliver nicotine, an addictive substance with known adverse health consequences. One full-size cigar may contain as much tobacco as a whole pack of cigarettes and thus contains more nicotine than a cigarette. Cigarettes contain an average of about 8 mg of nicotine; many popular brands of larger cigars contain between 100 and 200 mg.<sup>22</sup> NCI Monograph 9 found that nicotine levels in the smoke of premium cigars can be as much as eight times higher than in cigarette smoke.<sup>23</sup> Although the amount of nicotine taken in by the cigar smoker depends on various factors like how long the person smokes the cigar, the number of puffs taken and the degree of inhalation, a leading review of the science of cigar smoking concluded that “[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled.”<sup>24</sup>

The evidence shows that many cigar smokers do inhale the smoke, particularly if they are current or former cigarette smokers. Studies indicate that two thirds of those who smoke both cigars and cigarettes (which is over 40 percent of cigar smokers) inhale cigar smoke, compared with less than 15 percent of cigar smokers who never smoked cigarettes.<sup>25</sup> Further, analysis of data from the 2012 National Survey on Drug Use and Health (NSDUH) show that 27 percent to

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<sup>17</sup> *Id.* at ii.

<sup>18</sup> *Id.* at 125.

<sup>19</sup> Shapiro, JA, et al., “Cigar Smoking in Men and Risk of Death from Tobacco-Related Disease,” *Journal of the National Cancer Institute*, 92(4):333-337, 2000, at 334, <http://jnci.oxfordjournals.org/content/92/4/333.full.pdf>.

<sup>20</sup> NCI Monograph 9, at 3.

<sup>21</sup> *Id.* at ii.

<sup>22</sup> American Cancer Society, “Cigar Smoking” (2010) <http://www.cancer.org/acs/groups/cid/documents/webcontent/002965-pdf.pdf>.

<sup>23</sup> NCI Monograph 9, at 67.

<sup>24</sup> Baker, F, et al., “Health Risks Associated With Cigar Smoking,” *Journal of the American Medical Association* 284(6):735-740, 2000, at 737.

<sup>25</sup> *Id.*

40 percent of smokers of premium cigar brands have, at one time, smoked cigarettes daily.<sup>26</sup> Cigar smokers who are current or former cigarette smokers are at higher risk of disease than cigar smokers who never smoked cigarettes.<sup>27</sup> In addition, according to the 2012-2013 National Adult Tobacco Survey, 35.1 percent of cigar smokers who usually smoked premium cigars currently smoked cigarettes and 23 percent previously smoked cigarettes. Among all adult cigar smokers, nearly 60 percent were current or former cigarette smokers.<sup>28</sup> Thus, not only does cigar smoke increase the risk of disease even if the smoker does not inhale; it also is apparent that many cigar smokers do inhale and increase their risk of disease by doing so.

There is substantial evidence that consumption of premium cigars is not limited to older smokers. Findings from the 2012-2013 National Adult Tobacco Survey indicate that the percentage of young adult cigar smokers aged 18 to 29 reporting current premium cigar use (15.1 percent) is higher than the percent reporting current use of little filtered cigars (12.8 percent). Overall, 19.9 percent of adult cigar smokers identified premium cigars as their usual type of cigar smoked.<sup>29</sup>

The 2012 NSDUH data also show that youth cigar smokers age 12-17 name premium cigar brands – some of which can sell for more than \$10 per cigar – as products they smoked in the previous 30 days.<sup>30</sup>

#### B. All Cigars Give Off Significant Amounts of Harmful Secondhand Smoke

Because cigars contain more tobacco than cigarettes, and because they often burn for much longer, they give off greater amounts of secondhand smoke. This smoke includes both the smoke from the end of the burning cigar and the smoke exhaled by the smoker. “Compared with a single cigarette (0.55 g) smoked to 70 percent of its mass, a large cigar smoked 70 percent emits about 20 times the carbon monoxide, five times the respirable particles, and twice the amount of polycyclic aromatic hydrocarbon.”<sup>31</sup> Moreover, smoke from a single cigar burned in a home can take five hours to dissipate, adding to the risk incurred by members of the household.<sup>32</sup> Thus, as found in NCI Monograph 9, “cigar smokers pollute enclosed environments to a significantly higher degree than cigarette smokers.”<sup>33</sup>

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<sup>26</sup> Substance Abuse and Mental Health Administration (SAMHSA), Analysis of 2012 National Survey on Drug Use and Health data.

<sup>27</sup> NCI Monograph 9, at 155.

<sup>28</sup> Corey, CG, et al., “Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012-2013,” *MMWR* 63(30):650-654, August 1, 2014, at 652, 653. The study authors defined premium cigar smokers as “those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper.”

<sup>29</sup> *Id.* at 651.

<sup>30</sup> SAMHSA, Analysis of 2012 National Survey on Drug Use and Health data.

<sup>31</sup> Baker at 738.

<sup>32</sup> NCI Monograph 9, at iii.

<sup>33</sup> *Id.* at 79.

The causal connection between secondhand cigarette smoke and lung cancer and heart disease is now beyond dispute.<sup>34</sup> Given that the overall amount of toxicants and pollutants emitted by cigar smoking typically exceeds the amount emitted by cigarettes, it is reasonable for FDA to assume that secondhand cigar smoke creates similar, if not greater, risks of disease than cigarette smoke.

### C. FDA Should Deem All Cigars Subject to the Statute

As presented in the NPRM, FDA's proposed Option 2 contemplates exempting from regulation a category of cigars – called “premium cigars” by FDA – defined by eight proposed criteria, each of which must be met to qualify for the exemption. Generally speaking, this proposed category of premium cigars would include cigars hand-wrapped (not machine wrapped) in whole tobacco leaf, with 100 percent leaf tobacco binder, without filters or tips, with no characterizing flavors other than tobacco, weighing more than 6 pounds per 1,000, with a retail price of at least \$10 per cigar. According to the NPRM, FDA is considering the option of exempting such cigars because the argument is made (primarily by cigar interests) that such “premium cigars” differ from other cigars in usage patterns to such a degree, with such fundamentally different implications for public health than other cigars, that they should be entirely exempt from FDA's regulatory authority.<sup>35</sup>

Whatever distinction in usage patterns there may be between “premium cigars” as defined in the NPRM, and other cigars, there is no justification for a complete exemption of such cigars from FDA regulatory authority. As described above, all cigars, including those falling within FDA's proposed definition of “premium cigars,” create a significant risk of disease and addiction to smokers, as well as having adverse health effects on non-smokers. If FDA were to exempt such cigars from regulation entirely, they would not be subject to the agency's proposed minimum age and age verification provisions, health warning labels, ingredient disclosure requirements, harmful and potentially harmful constituent disclosure requirements, health impact document disclosure requirements, good manufacturing practices, the requirement that a company's claim of lower risk from its products be substantiated, and other key provisions FDA proposes to apply to all newly-deemed tobacco products.

Even if it were shown that cigars meeting the proposed definition in Option 2 pose risk of a different nature and degree than other cigars, the proper response would be for FDA to assert jurisdiction and then to apply its authority in a way that fits the risk posed by these products, given the nature of the products, who uses them, and how they are used. By taking this action, FDA would be able to move swiftly to address changes in the products or their use. Of equal importance, such action would be consistent with the fundamental principle that decisions about

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<sup>34</sup> See generally, U.S. Department of Health and Human Services (HHS), *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*, 2006 [http://www.cdc.gov/tobacco/data\\_statistics/sgr/2006/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/2006/index.htm).

<sup>35</sup> 79 Fed. Reg. at 23150.

what products should be regulated, and how they should be regulated, should be within the purview of FDA and be based on science and what is appropriate for the protection of the public health. That result can only be achieved if FDA has authority over all tobacco products. Exempting any category of product would create a dangerous precedent and would be inconsistent with the overarching intent of the TCA.

D. Should FDA Determine it is Appropriate to Regulate “Premium Cigars” Differently than Other Cigars, It Should Adopt a Narrow Definition of “Premium Cigars” to Ensure that the “Premium” Category Applies Only to a Small Portion of the Cigar Market with Little Appeal to Youth

For the reasons given above, FDA should deem all cigars subject to its regulatory authority. However, if FDA determines that some regulations that should apply to other cigars should not be applied to “premium cigars,” the agency must be careful to define the category of “premium cigars” so as to minimize the risk that the tobacco industry will exploit these distinctions to the detriment of public health.

Tobacco companies have a long history of skillfully modifying their products to circumvent regulation and minimize the effectiveness of policies designed to reduce consumption of their lethal products and protect the public health. In the 1960s and 1970s, “little cigars” that look like cigarettes were developed to avoid the ban on broadcast advertising of cigarettes and higher cigarette taxes.<sup>36</sup> More recently, manufacturers have modified their products to be classified as cigars rather than cigarettes to evade the TCA’s prohibition of characterizing flavors in cigarettes and the use of misleading cigarette descriptors such as “light” and “low.”<sup>37</sup> They have also added weight to filters to allow for reclassification of their cigarettes or “little cigars” as “large cigars” subject to lower federal excise taxes.<sup>38</sup>

FDA must ensure that any differential regulatory treatment of a “premium cigar” product category cannot similarly be exploited by the industry. Toward this end, FDA should make changes in its proposed definitional criteria for “premium cigars” only to narrow the definition, not to broaden it. FDA should, for example, reject any arguments to allow the category of “premium cigars” to include:

- cigars that are not wrapped entirely in whole tobacco leaf, or
- involve any machines in the production process, or

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<sup>36</sup> Delnevo, CD & Hrywna, M, “A Whole ‘Nother Smoke’ or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars,” *American Journal of Public Health* 97(8):1368-75, August 2007 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1931466/pdf/0971368.pdf>.

<sup>37</sup> See generally, Campaign for Tobacco-Free Kids, *Not Your Grandfather’s Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids*, March 13, 2013, at 14-15 (*Not Your Grandfather’s Cigar*), [http://www.tobaccofreekids.org/content/what\\_we\\_do/industry\\_watch/cigar\\_report/2013CigarReport\\_Full.pdf](http://www.tobaccofreekids.org/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf).

<sup>38</sup> *Id.* at 15.



- allow the use of homogenized tobacco leaf or reconstituted tobacco, or
- weigh less than the minimum weight requirement, or
- have any characterizing flavor other than tobacco.

Perhaps of greatest importance, FDA should not decrease, and should consider increasing, the \$10 minimum price per cigar and should continue to make clear that this minimum price is after any discounts or coupons. It also should make clear that the \$10 minimum price will be indexed for inflation. Of all FDA’s proposed criteria for defining “premium cigars,” a high price minimum likely is subject to the lowest risk of industry manipulation and evasion, and may be most important in ensuring that no “premium cigars” are likely to be purchased by youth. It should be noted that the cigar industry itself has defined “premium cigars” by reference to a similar price-point. For example, in comments filed in FDA Docket No. 2011-N-0467 concerning regulation of non-face-to-face sales and distribution of tobacco products, Cigar International, Inc. and other cigar interests told FDA “[t]here is no reason to believe, and no support for, the contention that minors are purchasing – anywhere – premium cigars that often sell for \$10 or more.”<sup>39</sup> Actually, this statement is inaccurate. In its focus group study, *Youth Use of Cigars: Patterns of Use and Perceptions of Risk*, the HHS Office of Inspector General found that 20 teens out of 167 participants, or 12 percent, said they had spent \$10 or more for a cigar.<sup>40</sup> If anything, FDA’s proposed price point should be increased.

Our organizations reiterate, however, that FDA should reject any exemption for “premium cigars,” regardless of how that category is defined.

## II. IT IS CRITICAL TO PUBLIC HEALTH FOR FDA TO APPLY TO THE DEEMED PRODUCTS ALL PROVISIONS OF THE TOBACCO CONTROL ACT APPLICABLE TO “TOBACCO PRODUCTS”

Numerous provisions of the Tobacco Control Act apply automatically to “tobacco products.” By their terms, such provisions would apply not only to cigarettes and smokeless tobacco products, but also to other tobacco products deemed by regulation to be subject to the Act pursuant to section 901(b). It is critical that these provisions apply to any newly deemed tobacco products.

Sections 902 and 903, respectively, prescribe when a tobacco product would be considered “adulterated” or misbranded” within the meaning of those terms in the Food, Drug

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<sup>39</sup> Comments of Cigars International, Inc. et al., filed in Docket No. FDA-2011-N-0467, January 19, 2012, at 3.

<sup>40</sup> HHS, Office of the Inspector General, *Youth Use of Cigars: Patterns of Use and Perceptions of Risk*, February 1999, at 8, <http://oig.hhs.gov/oei/reports/oei-06-98-00030.pdf>.

and Cosmetic Act (“FDCA”). Numerous enforcement provisions of the FDCA are triggered by a finding that a product is “adulterated” or “misbranded.” Application of these provisions is necessary for FDA to exercise effective authority over the deemed products.

Section 904 requires the submission of a broad range of health information, including ingredient listing and a listing of harmful and potentially harmful constituents. Submission of this information provides a factual basis for FDA’s formulation of regulatory policy. The section also gives FDA the authority to obtain from manufacturers additional information concerning research findings on the health, toxicological, behavioral or physiologic effects of tobacco products. Such information would facilitate the issuance of product standards pursuant to Section 907 of the statute or for the evaluation of manufacturer applications for the marketing of products.

FDA has sought comments on whether application of this section to small manufacturers should be deferred.<sup>41</sup> No such deferral is justified. The public health benefits of prompt disclosure far outweigh the modest costs of compliance. Little is known about the impact of different components of e-cigarettes, including nicotine yield of different products. In light of FDA’s proposal to allow products to remain on the market that would otherwise be illegal except for FDA’s decision to exercise enforcement discretion, prompt disclosure is especially important without delay even if FDA gives small manufacturers of some deemed products more time to comply with other provisions of the TCA as contemplated by the Act. The introduction of products that deliver nicotine as do e-cigarettes raises a number of health related questions. Until the *Sottera* decision<sup>42</sup> the delivery of nicotine in any form other than a traditional tobacco product required extensive testing because of concerns about nicotine. Testing and disclosure are minimum requirements that should be enforced if these products are to be allowed on the market before a more complete review by FDA. The size of a manufacturer does not alter the health concerns raised by their products, especially because e-cigarettes can be made in large quantities and delivered through the internet and in retail outlets to large numbers of consumers.

Section 905 requires manufacturers to register the ownership of manufacturing facilities with FDA. It also provides FDA with authority to conduct inspections at such facilities. In addition, it requires registrants to provide FDA with a list of their products and labeling. Application of section 905 to the deemed products is necessary for FDA to obtain relevant information for the exercise of its regulatory authority. FDA has sought comments on whether application of this section to small manufacturers should be deferred.<sup>43</sup> As with disclosure of ingredients and harmful constituents, the public health benefits of promptly applying these requirements far outweigh the cost of compliance and no such deferral is justified.

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<sup>41</sup> 79 Fed. Reg. at 23148.

<sup>42</sup> *Sottera, Inc. (dba NJOY) v. FDA*, 627 F.3d 891 (2010).

<sup>43</sup> 79 Fed. Reg. at 23148.

It is critical that Section 905(j) be applied. Section 905(j) provides requirements for demonstrating that new tobacco products are substantially equivalent to products that were marketed on February 15, 2007. Products that meet these standards can be marketed under criteria different from and less stringent in some ways than criteria for other new tobacco products. This section applies to the newly deemed products. Detailed comments on FDA's approach to the application of this section are included in Section VII of these comments.

Section 906 provides several important regulatory authorities, including authority to impose restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product. FDA cannot effectively protect the public, especially but not only children, unless FDA can exercise its authority under these provisions over all deemed products. Section 906(d)(4) also requires FDA to promulgate regulations regarding the sale, distribution, promotion and marketing of tobacco products in remote sales. This section provides the authority for FDA to promulgate regulations applying the provisions of the 2010 rule to the deemed products as well as any other additional sales restrictions that FDA might impose in the future. *The evidence is now clear: in the absence of FDA regulation of the advertising and marketing of products, such as e-cigarettes, the manufacturers have launched aggressive national advertising campaigns and engaged in extensive marketing activities that have significant and disproportionate appeal to youth and that make claims that their tobacco products are safer than others.*

Section 906(e) gives FDA authority to prescribe good manufacturing practice requirements for tobacco products. While important for all tobacco products, such requirements are particularly important for e-cigarettes, where substantial questions exist concerning the ability of manufacturers to produce products consistently to specifications. As major manufacturers of nicotine for the e-cigarette market have noted, the difference between nicotine produced to pharmaceutical standards and nicotine mixed by unqualified or inexperienced manufacturers could have profound health consequences and "the quality requirements for the ingredients of e-cigs have to be defined."<sup>44</sup> FDA should use its authority under this section to require e-cigarette manufacturers to demonstrate that they can produce products with rigorous ingredient quality controls, attain consistent levels of nicotine and other constituents and ensure that products are being produced consistently in accordance with product specifications.

Section 907 gives FDA authority to issue product standards establishing maximum levels for nicotine yield, reduction or elimination of other constituents, testing, and measurement. Such authority is necessary for FDA to carry out its regulatory functions. It may be especially important for FDA to exercise this authority with respect to e-cigarettes. The e-cigarette category includes products that allow the uncontrolled delivery of nicotine in various quantities, mixed with other substances. FDA must have the authority to limit the use of substances in e-

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<sup>44</sup> "Nicotine Branded in Switzerland Gets E-cig Boost," *Bloomberg News*, March 7, 2014, quoting representatives of pharmaceutical-grade nicotine manufacturers, <http://www.bloomberg.com/news/2014-03-06/nicotine-branded-made-in-switzerland-gets-e-cig-boost.html>.

cigarettes that increase the risk of harm and to set parameters for nicotine delivery to reduce toxicity, to minimize the potential for certain products to serve as starter products for kids or to sustain cigarette use.

Section 909 gives FDA authority to require manufacturers to provide information regarding adverse medical reactions to tobacco products and to order corrective action. It is essential for FDA to have this authority over newly deemed products.

Section 910 provides the requirements for the marketing of new tobacco products (i.e., tobacco products that were not marketed on February 15, 2007). FDA has issued draft guidelines for compliance with Section 910. Section 910 applies to the newly deemed products. Detailed comments on FDA's approach to the application of section 910 to the newly deemed products are contained in Section VII of these comments.

Section 915 gives FDA authority to require testing and reporting of tobacco product constituents by brand and subbrand. It is critical for FDA to have and exercise this authority over newly deemed products.

All these provisions are elements of FDA's basic regulatory authority. Extension of the authority provided by these sections to the deemed products appears to and should follow automatically from the assertion of authority by FDA. Explicit mention of these provisions in the text accompanying the rule is appropriate, however, to clarify FDA's intention to extend all such provisions to the deemed products.

### III. THE PROVISIONS OF FDA'S 2010 REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS SHOULD BE APPLIED TO THE DEEMED PRODUCTS

#### A. A Purpose of the Tobacco Control Act is to Prevent Minors from Using Tobacco Products

The stated purpose of FDA's 2010 Regulations is "to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use."<sup>45</sup> The 2010 rules are substantially identical to the rules for cigarettes and smokeless tobacco products originally proposed by FDA in 1995<sup>46</sup> and promulgated as a final rule in 1996.<sup>47</sup> These rules were the product of the longest rulemaking

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<sup>45</sup> 75 Fed. Reg. at 13230. 21 CFR § 1140.2.

<sup>46</sup> 60 Fed. Reg. at 41314, August 11, 1995.

<sup>47</sup> 61 Fed. Reg. at 44396, August 28, 1996.

process in FDA history, with more than 700,000 comments received.<sup>48</sup> When Congress enacted the Tobacco Control Act, it relied on this extensive record and directed FDA to reissue these rules and the promulgation of the 2010 rules was responsive to this directive. Congress explained the reasons for directing the promulgation of these regulations by explicitly finding that advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and that those efforts have resulted in increased usage of those products by youth.<sup>49</sup> As FDA had noted when it originally proposed the regulations, “[t]he use of tobacco products is a pediatric disease and an effective program to address this disease must include restrictions on youth access and advertising.”<sup>50</sup> When FDA promulgated the 2010 rules, it relied not only on the extensive record compiled in 1995 and 1996, but also on scientific data that had become available since the publication of the 1996 rule.<sup>51</sup>

The reasons that underlay the promulgation of the 2010 rules also support application of these rules to the deemed products. Like cigarettes and smokeless tobacco, the deemed products are all addictive and there is a broad consensus that they should not be consumed by anyone under the age of 18. Combusted deemed products all expose users to large numbers of carcinogens and toxicants and non-combusted products also contain toxicants and carcinogens. Moreover, the public health standard in the Tobacco Control Act explicitly directs FDA to consider “the increased or decreased likelihood that those who do not use tobacco products” in determining what policies are “appropriate for the protection of the public health.” As the large majority of new users of tobacco products are under 18 years of age, this directive requires FDA to consider the effect of its policies on youth usage of any tobacco products. In order to carry out the purposes of the Tobacco Control Act, FDA should adopt policies intended to reduce the number of children and adolescents who use the deemed products.

#### B. The Deemed Products Are Being Marketed to Children

An examination of the marketing and advertising of e-cigarettes and cigars clearly reveals a strategy to market these products to children.

No company has more egregiously pursued this strategy than Lorillard, the manufacturer of blu, the largest-selling brand of e-cigarettes. The elements of this strategy are strikingly similar to the well-documented efforts Lorillard and the other major cigarette manufacturers so successfully pursued over many decades to addict children to cigarettes.

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<sup>48</sup> 60 Fed. Reg. 41314-15, August 11, 1995, *quoted with approval*, 75 Fed. Reg. 13226, March 19, 2010; Tobacco Control Act, Sec. 2(1).

<sup>49</sup> Tobacco Control Act, Sec. 2(15).

<sup>50</sup> 60 Fed. Reg. 41314-15, August 11, 1995, *quoted with approval*, 75 Fed. Reg. 13226, March 19, 2010; Tobacco Control Act, Sec. 2(1).

<sup>51</sup> 75 Fed. Reg. at 13227-29.

The compilation at Tab A demonstrates how this strategy is being executed by comparing actual advertisements for blu to advertisements for cigarettes.

Like cigarette advertisements targeting youth, advertisements for blu use celebrities popular with young people such as actor Stephen Dorff and former Playboy model and MTV host Jenny McCarthy to endorse the product and build the product's image.

Like cigarette advertisements targeting youth, advertisements for blu feature muscular men and glamorous women to associate the product with virility and sex appeal.

Like cigarette advertisements, advertisements for blu blatantly trade on the depiction of sex, implicitly associating the product with an adolescent's idealized life style.<sup>52</sup>

Like now-banned cigarette promotions, blu sponsors automobile races and rock concerts, events popular with youth.

Like now-banned cigarette marketing campaigns, blu features sweet and fruity flavors popular with youth.

Like now-banned cigarette redeemable points programs for branded items such as "Camel Cash," blu offers t-shirts, water bottles, and other items branded with the blu logo.

Like now-banned cigarette marketing campaigns such as the infamous Joe Camel campaign, blu features cartoon characters.

Like the successful cigarette marketing campaign of the 1980s to persuade smokers to use light cigarettes instead of quitting, blu discourages smokers from quitting.

Tab B shows additional examples of advertisements and marketing strategies by blu in ways that are attractive to youth. These images speak for themselves. Many of them would be illegal if the product being promoted were cigarettes. Moreover, taken as a whole, the strategy would clearly constitute targeting of youth within the meaning of Section III.a. of the tobacco Master Settlement Agreement if the product being promoted were cigarettes.

In addition, e-cigarette manufacturers have an enormous advantage over cigarette manufacturers in the marketing of their product because they can market the product on television and radio. A recently published study in the journal *Pediatrics* documents the results. According to the study 24 million children have been exposed to television advertisements for e-cigarettes. Of this total, more than 80 percent of the television advertisements that youth and

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<sup>52</sup> The U.S. District Court for the District of Columbia concluded that the tobacco companies' marketing of cigarettes was intended to "burnish. . .the image of their youth brands to convey rugged independence, rebelliousness, love of life, adventurousness, confidence, self-assurance and belonging to the 'in' crowd. *U.S. v. Philip Morris USA, Inc.*, 449 F.Supp.2d at 616.

young adults were exposed to were for blu.<sup>53</sup> The advertising budget for blu increased sevenfold between 2011 and 2012.<sup>54</sup> Youth exposure to e-cigarette television advertising increased by 256 percent between 2011 and 2013 and young adult exposure increased by 321 percent during the same period.<sup>55</sup> The *Pediatrics* study notes that some ads present e-cigarette use as an adult activity (“We’re all adults here,” one ad proclaims), echoing a theme long used to make regular cigarettes appealing to kids. The researchers point out that U.S. District Court Judge Gladys Kessler, in her 2006 verdict that the major cigarette manufacturers had violated civil racketeering laws, wrote, “Emphasizing that smoking is an adult activity underscores the desirability of engaging in adult behavior for adolescents who are particularly motivated to appear mature.”<sup>56</sup>

Although blu is by far the most egregious (and successful) youth marketer, it is not alone. As just a few examples: NJOY has featured rebellious rock musician Courtney Love in advertisements for its product; Vapor Shark featured a billboard with an image of a smiling Santa on Interstate 95 in Miami, Florida; Mystic’s website features a video of cartoon characters being drawn to demonstrate the benefits of e-cigarettes; displays, advertisements, and signs at retail locations are placed near candy or other places that are readily visible by children; and Apollo Electronic Cigarettes offer rewards programs, as do other companies. Additional examples of such marketing are attached at Tab C. These examples demonstrate that e-cigarettes are widely marketed to children.

As the recent study in *Pediatrics* points out, advertising for e-cigarettes may be even more effective in influencing youth behavior than cigarette advertising because, in contrast to cigarettes, there are no government-sponsored counter-marketing advertising messages. Thus, the only advertising messages being delivered to young people are those delivered by the product manufacturers. This fact, combined with their unique ability to employ television advertising, has made the delivery of their message doubly effective. The impact of television ads is magnified by such youth-friendly websites as YouTube. The fact that e-cigarette makers have widely disseminated advertisements that are highly appealing to youth is profoundly disturbing and a threat to public health.

Marketing messages for cigars have also targeted youth, although the types of promotion and the mode of delivery differ from that for e-cigarettes. One such method is through the distribution of non-tobacco merchandise. Typically such items will be articles popular with youth, such as coasters designed to look like records, ear buds, drink shakers, and ash trays, all of

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<sup>53</sup> Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics* 134:1-8, 2014, <http://pediatrics.aappublications.org/content/early/2014/05/27/peds.2014-0269.full.pdf>.

<sup>54</sup> Kim, AE, Arnold, KY, & Makarenko, O, “E-cigarette Advertising Expenditures in the U.S., 2011–2012,” *American Journal of Preventive Medicine* 46(4):409-412, 2014.

<sup>55</sup> Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics* 134:1-8, 2014.

<sup>56</sup> *U.S. v. Philip Morris, USA, Inc.*, 449 F.Supp.2d at 669.

which are shown on Tab D. Cigar manufacturers have also sponsored athletic and other events that draw significant youth interest and attendance (see Tab E).

Cigars are also made attractive to youth through the extensive use of flavors, including many that are obviously directed to children, such as grape, peach, fruit punch, and cherry. Typically, these products are packaged in brightly colored wrapping designed to appeal to youth. Moreover, they are placed in self-service store displays next to candy, where youth are most likely to notice them and pick them up.<sup>57</sup> By contrast, under the 2010 FDA regulations, cigarettes and smokeless tobacco products cannot be placed in self-service displays.<sup>58</sup>

As FDA notes in its NPRM, consumers—and particularly adolescents—often mistakenly think non-cigarette tobacco products have been proven to be a safer alternatives to cigarettes. Even more, that belief can lead to increased use of those other tobacco products.<sup>59</sup> Adolescents are particularly vulnerable to the appeal of novel tobacco products and non-cigarette tobacco products that can introduce youth into a lifetime of addicted tobacco product use and related harms.<sup>60</sup> Moreover, the adolescent brain, particularly at younger ages, is differentially sensitive to both the acute and repeated effects of nicotine and alterations in the brain caused by nicotine may have a lasting effect on the brain.<sup>61</sup> In addition, because the brain processes that lead to rational decision-making are still in the formative process during adolescence, young people may not have the ability to rationally consider the long-term effects of tobacco use.<sup>62</sup> Exposure of adolescents to products containing nicotine—regardless of whether such products are combusted or non-combusted—has serious, negative long-term consequences and there is a strong

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<sup>57</sup> *Not Your Grandfather's Cigar*, at 11.

<sup>58</sup> 75 Fed. Reg. at 13231.

<sup>59</sup> In addition to the references cited in 79 Fed. Reg. at 23158-59, see also: *Cigars*: Jolly, DH, “Exploring the use of little cigars by students at a historically black university,” *Preventing Chronic Disease* 5(3):1-9, July 2008, [http://www.cdc.gov/pcd/issues/2008/jul/07\\_0157.htm](http://www.cdc.gov/pcd/issues/2008/jul/07_0157.htm). Sterling, K, et al., “Factors Associated With Small Cigar Use Among College Students,” *American Journal of Health Behavior* 37(3):325-333, May 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3757522/pdf/nihms450226.pdf>. U.S. Department of Health and Human Services, *Youth use of cigars: patterns of use and perceptions of risk*, Washington, DC: HHS, Office of the Inspector General, OEU 06-98-00030, 1999. Soldz, S & Dorsey, E, “Youth Attitudes and Beliefs Toward Alternative Tobacco Products: Cigars, Bidis, and Kreteks,” *Health Education & Behavior* 32(4):549-266, August 2005. *E-Cigarettes*: Tan, ASL & Bigman, CA, “E-Cigarette Awareness and Perceived Harmfulness: Prevalence and Associations with Smoking-Cessation Outcomes,” *American Journal of Preventive Medicine* [epub ahead of print], April 28, 2014. Zhu, S-H, et al., “The Use and Perception of Electronic Cigarettes and Snus among the U.S. Population,” *PLoS ONE* 8(10):e79332, 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3824062/pdf/pone.0079332.pdf>.

Peters, RJ, et al., “The Social Norms and Beliefs of Teenage Male Electronic Cigarette Use,” *Journal of Ethnicity in Substance Abuse* 12(4):300-307, 2013. Choi, K & Forster, JL, “Beliefs and Experimentation with Electronic Cigarettes: A Prospective Analysis Among Young Adults,” *American Journal of Preventive Medicine* 46(2):175-178, 2014. Pepper, JK & Brewer, NT, “Electronic nicotine delivery system (electronic cigarette) awareness, use, reactions and beliefs: a systematic review,” *Tobacco Control* [epub ahead of print], doi: 10.1136/tobaccocontrol-2013-051122, November 20, 2013. Choi, K & Forster, J, “Characteristics Associated With Awareness, Perceptions, and Use of Electronic Nicotine Delivery Systems Among Young US Midwestern Adults,” *American Journal of Public Health* 103:556-561, 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3567225/pdf/nihms430822.pdf>.

<sup>60</sup> 79 Fed. Reg. at 23158-59.

<sup>61</sup> *Id.* at 23159.

<sup>62</sup> *Id.*



governmental interest in establishing policies that avoid or minimize these consequences.<sup>63</sup> In recent years, the need to extend these policies to all tobacco products has grown.

Thus, use of these non-cigarette tobacco products by youth is dangerous even if such use does not lead to or increase cigarette smoking. However, as FDA noted, a non-cigarette tobacco product can be a starter product for new tobacco users before they migrate to cigarettes or other tobacco products or for existing users to become dual users. Some non-cigarette tobacco users may go on to become addicted cigarette smokers.<sup>64</sup> Of the estimated 7.3 million adolescent cigarette smokers in 2002 and 2004, almost half used more than one tobacco product.<sup>65</sup> One study showed that among high school students who tried cigars before trying cigarettes, almost 44 percent used both cigarettes and cigars.<sup>66</sup>

The decline in cigarette consumption between 2000 and 2011 has been accompanied by a sharp increase in consumption of e-cigarettes and no decline in the use of cigars and pipe tobacco.<sup>67</sup> Moreover, between 2011 and 2012 the percentage of high school students who had used e-cigarettes more than doubled.<sup>68</sup> As noted previously, nationally, 12.6 percent of high school students currently smoke cigars (16.5 percent among boys, 8.7 percent among girls).<sup>69</sup> Each day, more than 2,700 children under age 18 try cigar smoking for the first time.<sup>70</sup> In many states, cigar smoking equals or surpasses cigarette smoking among high school boys.<sup>71</sup>

The fact that the manufacturers of the proposed deemed products are marketing their products in ways that appeal to children should come as no surprise; all the major cigarette manufacturers—the same companies that were adjudicated to have marketed cigarettes to children for decades—now have wholly-owned subsidiaries that are manufacturing e-cigarettes—including blu, the leading seller of e-cigarettes nationally.<sup>72</sup> After one of the most

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<sup>63</sup> U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, Centers for Disease Control and Prevention (CDC), Office on Smoking and Health, 2010, [http://www.cdc.gov/tobacco/data\\_statistics/sgr/2010/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/2010/index.htm). HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, Office on Smoking and Health, 2012 (2012 Surgeon General's Report), [http://www.cdc.gov/tobacco/data\\_statistics/sgr/2012/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/2012/index.htm). HHS, *The Health Consequences of Smoking: 50 Years of Progress: A Report of the Surgeon General*, CDC, Office on Smoking and Health, 2014, [http://www.cdc.gov/tobacco/data\\_statistics/sgr/50th-anniversary/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm).

<sup>64</sup> 79 Fed. Reg. at 23159.

<sup>65</sup> 79 Fed. Reg. at 23159.

<sup>66</sup> 79 Fed. Reg. at 23160.

<sup>67</sup> 79 Fed. Reg. at 23147.

<sup>68</sup> Carey, C, et al., "Notes from the field: electronic cigarette use among middle and high school students: United States, 2011-2012," *MMWR* 62(35):729-30, 2013, <http://www.cdc.gov/mmwr/pdf/wk/mm6235.pdf>.

<sup>69</sup> 2013 YRBS. Cigars are defined as cigars, cigarillos or little cigars.

<sup>70</sup> SAMHSA, *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*, 2013. Cigars are defined as cigars, cigarillos or little cigars, <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDefTables/DefTabs/NSDUH-DefTabsSect4peTabs1to16-2012.htm#Tab4.10A>.

<sup>71</sup> 2013 YRBS. Cigars are defined as cigars, cigarillos or little cigars.

<sup>72</sup> In addition to Lorillard's blu, RJ Reynolds recently commenced nationwide sales of its Vuse e-cigarette and Altria is planning introduction of its MarkTen e-cigarette.

extensive trials in history, the United States District Court for the District of Columbia concluded:

“The evidence is clear and convincing—and beyond any reasonable doubt—that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely denying they do so. . . . Defendants knew that youth were highly susceptible to marketing and advertising appeals, would underestimate the health risks and effects of smoking, would overestimate their ability to stop smoking, and were price sensitive. Defendants used their knowledge of young people to create highly sophisticated and appealing marketing campaigns targeted to lure them into starting smoking and later becoming nicotine addicts. . . . [c]igarette marketing is a substantial contributing factor to youth smoking initiation and continuation.”<sup>73</sup>

The marketing departments of the major tobacco companies have simply applied these tactics quite successfully to the marketing of the deemed products. Other manufacturers, recognizing the effectiveness of this strategy, have tried to emulate them. These facts should be clearly recognized in the formulation of policies to protect young people against such practices.

These findings compel the extension of all the regulations contained in the 2010 rule to the deemed products. Inexplicably, FDA has extended only some of these regulations to the deemed products. The undersigned organizations strongly support FDA’s proposal to extend to all deemed products the provisions of the 2010 rule prohibiting sales to minors, vending machine sales, and free sampling of all deemed products. However, taking such an action is not sufficient to protect the public health. We support the application of the other provisions of the 2010 rule to all the deemed products, including the prohibition of self-service displays of deemed products, the prohibition of tobacco brand names on non-tobacco merchandise, and the brand name sponsorship of musical and athletic events. Strong provisions to prevent on-line sales of the proposed deemed products to underage buyers are a logical outgrowth of FDA’s proposal to prohibit retail sales to such buyers and to require age verification to implement that prohibition.

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<sup>73</sup> *U.S. v. Philip Morris, Inc.*, 449 F. Supp. 2d 1, 691-92 (D.D.C. 2006), *aff’d in relevant part*, 566 F.2d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct.3501 (2010).

C. In Order to Fulfill the Purposes of the Tobacco Control Act, FDA Should Adopt, and, Where Necessary, Strengthen the Provisions of the 2010 Rule that It Proposes to Apply to the Deemed Products

1. Application of prohibition on sales to minors to deemed products
  - a. FDA correctly proposes to prohibit sales of the deemed products to minors.

The 2010 regulations already prohibit retailers from selling cigarettes and smokeless tobacco products to any person younger than 18 and require age verification for such sales.<sup>74</sup> FDA correctly proposes to extend this prohibition to all the deemed products. As FDA’s discussion of this regulation demonstrates, enforcement of minimum age and identification provisions is effective to limit youth usage of tobacco products.<sup>75</sup> We believe FDA is correct in concluding that the proposed minimum age requirements would reduce underage tobacco use and serve the stated purpose of the regulation.

The prohibition applies to all persons who sell the deemed products to individuals for personal consumption, including internet sellers. Given the large and growing number of young people who purchase tobacco products on the internet, it is important to extend the prohibition to such sales, as FDA has done in this proposed rule.

- b. FDA should prohibit internet sales of the deemed tobacco products in its final rule.

The prohibition on sales of deemed tobacco products to minors applies to all retailers of cigarettes, including internet sellers. Such requirements provide meaningful constraints, however, only if there are strong age verification requirements. With regard to face-to-face sales, the proposed rule provides for the same age verification requirements as those applicable to cigarettes and smokeless tobacco products. Strong policies to prevent internet sales to underage buyers are a logical outgrowth of, and a necessary element to make effective, FDA’s proposal to bar generally sales of the proposed deemed products to such buyers.

The rule originally proposed in 1995 would have prohibited the use of “mail-order sales and mail-order redemption of cigarettes.”<sup>76</sup> It did so on the ground that such sales do not involve face-to-face transactions hence do not enable verification of consumer’s age. After receiving comments, however, FDA concluded that in 1996 there was “inadequate evidence demonstrating that young people use mail-order sales to any significant degree” and deleted the prohibition.<sup>77</sup> In the text accompanying the rule, FDA “strongly advise[d] mail-order firms to take appropriate

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<sup>74</sup> 75 Fed. Reg. at 13230. 21 CFR §1140.14.

<sup>75</sup> 79 Fed. Reg. at 25160-62.

<sup>76</sup> 60 Fed. Reg. at 41326.

<sup>77</sup> 61 Fed. Reg. at 44459.

steps to prevent the sale of cigarettes and smokeless tobacco to anyone under age 18” and stated that FDA would monitor the situation and take appropriate action if it determined that young people were obtaining such products by mail order.<sup>78</sup>

The situation changed drastically, however, with the introduction of internet marketing shortly after the FDA’s 1996 rulemaking. The 1996 rulemaking did not, and could not have, anticipated the revolution in marketing brought about by the internet. Significantly, the rule did not even refer to the internet but rather to “mail-order sales.” With the advent of the internet, the issue of non-face-to-face sales and the absence of age verification provisions became a very serious one. As discussed below, underage purchasers obtain tobacco products in large numbers through internet purchases and the problem of age verification in such sales is a major one.

When FDA re-promulgated the rules in 2010 it left in place both the 1996 rules regarding age verification in face-to-face sales and the continued authorization for internet sales of cigarettes and smokeless tobacco products. It did not supplement the provisions for age verification with regard to internet sales, but circumstances had changed because the Prevent All Cigarette Trafficking Act of 2009 (the “PACT Act”)<sup>79</sup> had been enacted before the regulations were issued. The PACT Act provided a detailed set of rules for age verification for internet sales of cigarettes and smokeless tobacco products. The PACT Act also banned the use of the mail to transport cigarettes for commercial purposes and state attorneys general had obtained an agreement from the major common carriers not to deliver cigarettes. The PACT Act, however, does not cover the newly deemed products.

At the time the 2010 rule was promulgated, it was hoped that enactment and enforcement of the PACT Act would provide an effective age verification regime sufficient to prevent sales of cigarettes and smokeless tobacco products to minors. In enacting the Tobacco Control Act, Congress directed FDA specifically to consider both the effect of internet sales on the availability of such products to minors and the internet promotion and advertising of such products and to promulgate regulations addressing these subjects.<sup>80</sup> FDA responded to this requirement in 2011 by initiating an Advance Notice of Proposed Rulemaking setting forth a series of questions regarding the non-face-to-face sale of tobacco products and the advertising and promotion of tobacco products on the internet.<sup>81</sup>

In 2011, in response to FDA’s Advance Notice of Proposed Rulemaking concerning non-face-to-face sales of tobacco products, some of the undersigned organizations submitted comments that noted that non-face-to-face sale and distribution of tobacco product may undermine effective tobacco control policies by facilitating evasion of age verification requirements and facilitating evasion of state and federal excise taxes. The comments noted that the rapid development of

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<sup>78</sup>

*Id.*

<sup>79</sup>

P.L. 111-154, 124 Stat. 1087.

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Tobacco Control Act, Sec. 906(d)(4)(A)(ii).

<sup>81</sup>

Docket No. FDA-2011-0467.

internet sales had greatly increased the difficulty of implementing an effective program of age verification and concluded that “unless FDA can develop and implement regulations that ensure in practice that remote sales undermine neither the age verification requirements nor the enforcement of state tax law, such sales should be prohibited.”<sup>82</sup> These comments and others submitted in the same docket by the University of North Carolina and the National Association of Attorneys General provided substantial detail about the ineffectiveness of age verification measures then in use and noted that minors can and do purchase cigarettes on the internet with little difficulty.<sup>83</sup> Our comments urged FDA to undertake its own efforts to determine the efficacy of age verification procedures in non-face-to-face sales and “if these investigations reveal that such programs do not effectively eliminate a large share of purchases by underage users, FDA should give serious consideration to banning non-face-to-face sales of tobacco products.”<sup>84</sup>

Comments filed in the same docket by National Association of Attorneys General Tobacco Committee detailed the problems of age verification for non-face-to-face tobacco sales and concluded that “the only way to remedy the adverse public health consequences of such sales is to . . . ban them.”<sup>85</sup> The most detailed comments in that docket regarding internet sales of tobacco products were submitted by Professors Rebecca Williams, Kurt Ribisl and Catherine Jo of the University of North Carolina Center for Health Promotion and Disease Prevention.<sup>86</sup> Citing extensive research, that submission concluded that minors can and do buy tobacco products online and that age verification procedures were inadequate in preventing such purchases. The comment concluded that “unless FDA can develop, implement, and effectively enforce regulations to ensure that (1) minors are unable to obtain tobacco products through non-face-to-face sales and (2) state and federal taxes are collected on all non-face-to-face sales, such sales should be banned.”<sup>87</sup>

Since those comments were filed nearly two and one-half years ago, we are unaware of any action taken by FDA to ensure that minors do not obtain tobacco products through purchases made on the internet. Since the issuance of the Advance Notice of Proposed Rulemaking in that docket, FDA has taken no public action to address this problem. All the same issues that arise with regard to non-face-to-face sales of cigarettes and smokeless tobacco products apply with equal validity to the sale of the deemed products.

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<sup>82</sup> Comments of American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society—Cancer Action Network, American Heart Association, American Lung Association, Association of State and Territorial Health Officials, Campaign for Tobacco-Free Kids and Legacy, January 19, 2012, at 5.

<sup>83</sup> *Id.* at 7.

<sup>84</sup> *Id.* at 8.

<sup>85</sup> Comments of the National Association of Attorneys General Tobacco Committee in Docket No. FDA-2011-N-0467, January 19, 2012.

<sup>86</sup> Williams, R, Ribisl, K, Jo, C, “Response to Advance Notice of Proposed Rulemaking on Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products,” in Docket No. FDA-2011-N-0467, January 19, 2012.

<sup>87</sup> *Id.*

In light of the absence of evidence that any age verification process can effectively accomplish this goal and since prevention of such sales to minors remains a paramount objective of tobacco control policy, we believe that it would be appropriate for FDA to prohibit the sale of all tobacco products—including the deemed products—in any non-face-to-face situation, including over the internet. We therefore urge FDA to include a prohibition on the sale of deemed products over the internet when it promulgates a final rule.

- c. If FDA does not prohibit internet sales of deemed products, FDA should strengthen the age verification requirements for internet sales of deemed products.

The PACT Act applies only to cigarettes and smokeless tobacco and whatever support it provides for age verification would not extend to the deemed products. Therefore, if internet sales of the deemed products are permitted, it is necessary for the deeming rule to provide adequate age verification provisions with regard to internet sales of the deemed products. The proposed rule's language is not as clear as necessary on this point and any ambiguity needs to be clarified.

Effective provisions for age verification are indispensable for the enforcement of minimum age requirements for the sale of tobacco products; such provisions are a logical outgrowth, and integral element, of such requirements. If FDA does not prohibit internet sales of the deemed products, then it should adopt as regulations applicable to internet sales of such products the age verification provisions of the PACT Act that currently apply to cigarettes and smokeless tobacco products. These rules were fashioned by the Congress over the course of several years and were the subject of considerable scrutiny. Adoption of these provisions would mean that the age-verification provisions applicable to the deemed products would be the same as the provisions applicable to cigarettes and smokeless tobacco products. If FDA permits the sale of deemed products on the internet, it should, at a minimum, adopt regulations applying the requirements of the PACT Act to the internet sale of the deemed products.

2. FDA correctly proposes to restrict sales through vending machines

The undersigned organizations support FDA's proposal to extend the restrictions on vending machine sales of tobacco products that currently apply to cigarettes and smokeless tobacco products pursuant to 21 CFR § 1140.16 to all the deemed products. Vending machine sales present the potential for evasion of age verification requirements and accordingly should not be permitted in any area to which persons under 18 have access. The text accompanying FDA's proposed rule enumerates persuasively the reasons why such restrictions on vending machine sales are necessary. As FDA recognizes, all the arguments presented in the 1995, 1996, and 2010 proposed and final regulations with regard to cigarettes and smokeless tobacco

products apply equally to sales of the deemed products. FDA’s discussion of this issue demonstrates that this prohibition would serve the stated purpose of the regulation.<sup>88</sup>

FDA’s conclusion that it is important to restrict vending machine sales is premised on a recognition that prohibitions on sales to minors are meaningless without effective provisions for age verification. FDA’s recognition of the importance of effective procedures for age verification highlights the absence of detailed provisions for age verification in the proposed rule for internet sales of the deemed products.

### 3. FDA correctly proposes to prohibit free samples

The undersigned organizations support FDA’s proposal to prohibit distribution of free samples of the deemed products. The reasons for this prohibition are fully documented in the text accompanying the proposed regulation. Free samples of tobacco products increase the availability of such products to minors. As noted by FDA in its NPRM, the Institute of Medicine found that free samples of cigarettes “encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity.”<sup>89</sup>

The FDA’s 2010 Regulation prohibited the distribution of free samples of cigarettes.<sup>90</sup> Tobacco product manufacturers challenged the constitutionality of the prohibition, but both the United States District Court for the Western District of Kentucky and the United States Court of Appeals for the Sixth Circuit upheld the prohibition.<sup>91</sup> The court found that the government had presented “extensive documentation that free samples of tobacco products are an easily accessible source of these products to young people. . . and [are] freely obtainable.”<sup>92</sup> The court found

Providing an opportunity for an underage nonsmoker to actually try a tobacco product, at no cost, may serve as the best advertisement of all for a product that is physiologically addictive, and socially attractive to youth. But placing cigarettes and other tobacco products into the hands of minors clearly undermines the purposes and interests undergirding the Act. Banning such practices embodies a narrow fit between the harm articulated and the restriction employed.<sup>93</sup>

As FDA concluded, the same rationale for prohibiting free sampling of cigarettes is applicable to the deemed products.<sup>94</sup> The major sellers of e-cigarettes have engaged in extensive

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<sup>88</sup> 79 Fed. Reg. at 23162.

<sup>89</sup> 79 Fed. Reg. at 23149, quoting Institute of Medicine, “Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths (1994).

<sup>90</sup> 75 Fed. Reg. at 13231. 21 CFR 1140.16(d)(1).

<sup>91</sup> *Discount Tobacco City & Lottery, Inc. v. US*, 674 F. 3d 509, 541 (6<sup>th</sup> Cir. 2012), *cert. denied*, 133 S.Ct. 1996 (2013).

<sup>92</sup> *Id.*, citing 61 Fed. Reg. at 44460.

<sup>93</sup> 674 F. 3d at 541.

<sup>94</sup> 23 Fed. Reg. at 23149.

distribution of free samples, particularly in venues such as sporting events and concerts that are likely to attract large youth audiences.<sup>95</sup> Moreover, as FDA noted, the National Youth Tobacco Survey found that ever use of e-cigarettes among youth more than doubled between 2011 and 2012, including a doubling of concurrent e-cigarette and cigarette use.<sup>96</sup>

D. In Order to Fulfill the Purposes of the Tobacco Control Act, FDA Should Apply Other Provisions of the 2010 Regulations Not Included in FDA's Proposed Deeming Rule

As noted above, the undersigned organizations believe FDA should include in the final deeming rule all the following provisions of the 2010 rule.

1. FDA should prohibit self-service displays

FDA's Regulations Restricting the Sale of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents prohibit the use of self-service displays at retail establishments.<sup>97</sup> Self-service displays are product displays where a customer can take an item without requiring the assistance of a retail employee. This provision was designed, in part, to facilitate the requirement for age verification by the retailer, contained in the same regulation. This provision is substantially identical to a section 897.14(b)(1) of the 1996 rule. The text accompanying that rule stated:

[R]emoving self-service displays should increase interaction between retailers and potential consumers. . . . [B]y restricting self-service displays, the rule eliminates a young person's ability to take a package of cigarettes or smokeless tobacco, leave money on the counter, and leave the retailer's premises without having to provide proof of age. . . . An important component of these regulations is to eliminate those modes of sale used by young people that do not require them to show proof of age or otherwise do not challenge a young person to show that he or she is legally entitled to purchase the product.<sup>98</sup>

The text further explained that the prohibition on self-service displays was also designed to make it more difficult for young people to shoplift tobacco products. FDA stated that the purpose of the rule was to eliminate self-service displays as an avenue that young people use to obtain [tobacco] products and that "self-service displays must be eliminated from places that are accessible to young people as part of the general restriction against impersonal modes of sale."<sup>99</sup>

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<sup>95</sup> *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Marketing to Youth*, April 14, 2014, [http://www.durbin.senate.gov/public/index.cfm/files/serve?File\\_id=a85bb717-ac5d-4835-a584-206dbdb1f856](http://www.durbin.senate.gov/public/index.cfm/files/serve?File_id=a85bb717-ac5d-4835-a584-206dbdb1f856).

<sup>96</sup> 79 Fed. Reg. at 23152.

<sup>97</sup> 75 Fed. Reg. at 13231. 21 CFR §1140.16(c)(1).

<sup>98</sup> 61 Fed. Reg. at 44456 (August 28, 1996).

<sup>99</sup> *Id.* at 44457.



Numerous studies have reached the conclusion that prohibition of self-service displays has a considerable impact on the acquisition of cigarettes by minors.<sup>100</sup> One study found that stores that allow customers access to tobacco through self-service displays were more than twice as likely to sell tobacco to minors than stores that did not (30.6 percent vs. 12.8 percent).<sup>101</sup> The same study found that almost one in ten students surveyed (9.3 percent) reported stealing from stores as their primary means of obtaining cigarettes.<sup>102</sup> In addition, the court in *U.S. v. Philip Morris USA, Inc.* specifically found that “self-service of cigarettes in retail locations (as opposed to behind-the counter-service) allows ease of access to cigarettes, particularly for youth.”<sup>103</sup>

The proposed deeming rule contains the same minimum age requirements as the 2010 and 1996 rule and the same age verification requirements for face-to-face sales. A prohibition of self-service displays is a logical outgrowth of the proposal to prohibit face-to-face sales to minors and is necessary to make that proposal effective. All the same reasons that underlay the prohibition on self-service displays for cigarettes and smokeless tobacco apply equally to such displays of the proposed deemed products.

FDA advances no reason why the prohibition on self-service displays was not included in the proposal and in fact does not mention it at all.

The evidence indicates that many deemed products are sold at retail from self-service displays. Moreover, many such self-service displays are deliberately designed to place tobacco products in close proximity to candy and similar items that are attractive to children. The pictures attached at Tab F vividly illustrate the problem.

2. FDA should prohibit use of tobacco brand names on non-tobacco merchandise

Pursuant to Section 102 of the Tobacco Control Act, on March 19, 2010, FDA promulgated a rule now codified as 21 CFR § 1140.34(a) that prohibits manufacturers of cigarettes or smokeless tobacco from “market[ing], licens[ing], distribut[ing] or sell[ing] any item (other than cigarettes or smokeless tobacco products) which bears the brand name, . . . logo,

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<sup>100</sup> Wildey, MB, et al., “Self-service sale of tobacco: how it contributes to youth access,” *Tobacco Control* 4:355-61, 1995, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1759458/pdf/v004p00355.pdf>; Forster, JL, et al., “Perceived and measured availability of tobacco to youths in 14 Minnesota communities,” *American Journal of Preventive Medicine* 13(3):167-74, 1997; Caldwell, MC, et al., “Self-service tobacco displays and consumer theft,” *Tobacco Control* 5:160-61, 1996, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1759506/pdf/v005p00160b.pdf>; Bidell, MP, et al., “Case study of attempts to enact self-service tobacco display ordinances: a tale of three communities,” *Tobacco Control* 9(1):71-77, 2000, <http://tobaccocontrol.bmj.com/content/9/1/71.full.pdf+html>; Kropp, R, “A position paper on reducing tobacco sales to minors by prohibiting the sale of tobacco products by means of self-service merchandising and requiring only vendor-assisted tobacco sales,” North Bay Health Resources Center, 1994; Teall, AM, et al., “Youth access to tobacco in two communities,” *Journal of Nursing Scholarship*, 33(2):175-78, 2001.

<sup>101</sup> Wildey, MB, et al.

<sup>102</sup> *Id.*

<sup>103</sup> *U.S. v. Philip Morris, USA, Inc.*, 449 F.Supp. 2d at 662.

symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.”<sup>104</sup> (This prohibition will be referred to as a prohibition on “brand name merchandise.”) This prohibition was identical to a prohibition originally proposed by FDA in 1995<sup>105</sup> and promulgated in 1996.<sup>106</sup> The 1996 rule was invalidated by the Supreme Court’s decision in *Brown & Williamson Tobacco Corp. v. FDA*, 529 U.S. 120 (2000) holding that FDA lacked statutory authority to regulate tobacco products. When Congress granted FDA such regulatory authority in 2009 it expressly directed FDA to promulgate the provisions of the 1996 rule, including the prohibition on brand name marketing.

FDA should, as part of the deeming rule, extend the prohibition on brand name marketing to all deemed products. All the same arguments that underlay the prohibition on brand name marketing for cigarettes and smokeless tobacco are equally applicable to the deemed products.

When FDA originally proposed this regulation, it stated that its purpose was “reducing the appeal of ...cigarettes and smokeless tobacco by persons under 18 years of age.”<sup>107</sup> Similarly, the purpose of extending the prohibition on brand name merchandise to deemed products would be to reduce the appeal of these products to minors. In promulgating the 2010 rule, FDA, quoting NCI Monograph 19, found that “tobacco advertising forms part of an integrated marketing communications strategy combining sponsorship, brand merchandising, brand stretching, packaging, point-of-sale promotions, and product placement” and that such marketing had targeted youth, which was disproportionately vulnerable to tobacco advertising.<sup>108</sup> Quoting the findings by the Institute of Medicine, FDA found that “the evidence clearly shows that youth exposure to images that create a positive association with smoking is associated with a higher likelihood of smoking” and “prevailing scientific opinion regards the relationship between promotional exposures and smoking to be a causal one.”<sup>109</sup> In the notice accompanying the promulgation of the 1996 final rule FDA concluded:

...[T]he evidence establishes that [brand name merchandise is] readily available to young people and . . . [is] attractive and appealing to them with as many as 40 to 50 percent of young smokers having at least one item. The imagery and the item itself create a badge product for the young person and permit him/her the means to portray identification.<sup>110</sup>

Tobacco product manufacturers challenged the constitutionality of the prohibition on brand name merchandise but both the United States District Court for the Western District of Kentucky and the United States Court of Appeals for the Sixth Circuit, applying the rigorous

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<sup>104</sup> 75 Fed. Reg. at 13232.

<sup>105</sup> 60 Fed. Reg. at 41314 (August 11, 1995).

<sup>106</sup> 61 Fed. Reg. at 44396 (August 28, 1996).

<sup>107</sup> 60 Fed. Reg. at 41322.

<sup>108</sup> 75 Fed. Reg. at 13228 (March 19, 2010).

<sup>109</sup> *Id.* at 13229.

<sup>110</sup> 61 Fed. Reg. at 44524 (August 28, 1996).

*Central Hudson* standard,<sup>111</sup> upheld the regulation.<sup>112</sup> The court cited evidence that nearly half of adolescent smokers—and more than a quarter of non-smokers—owned at least one tobacco-related promotional item, as well as a 2001 study by the National Cancer Institute demonstrating that obtaining branded non-tobacco products “precedes, and reliably predicts, smoking initiation, even when controlling for other factors that have been shown to influence smoking uptake.”<sup>113</sup> Moreover, it cited with approval a 1998 study finding that “tobacco promotional items are causally related to the onset of smoking.”<sup>114</sup>

The use of brand-name merchandise as part of a coordinated strategy to market tobacco products to children has been well documented. As early as 1994, an Institute of Medicine report found that the distribution of items, such as hats, t-shirts, and sporting goods are capable of conveying to children the idea that tobacco use is the norm.<sup>115</sup> Several longitudinal studies have concluded that the use of such items is predictive of adolescent tobacco use. In 2000, a longitudinal study published in the *American Journal of Public Health* found that adolescents who had a tobacco promotional item with a brand logo and who named a cigarette brand were twice as likely to become regular tobacco users.<sup>116</sup> A 2007 longitudinal study concluded that a teenager’s having or being prepared to use a tobacco promotional item increased the odds of his initiating tobacco use.<sup>117</sup> A study of adolescents in Vermont found that owning or willing to own a tobacco promotional item was correlated with a greater likelihood of tobacco use and the likelihood of initiating smoking decreased when a youth smoker no longer owned a branded promotional item or was not using one.<sup>118</sup> Another study of Vermont adolescents found that the more cigarette promotional items a non-user possessed the more likely he was to be a smoker.<sup>119</sup> The 2012 Report of the Surgeon General on *Preventing Tobacco Use Among Use and Young Adults* cites numerous studies finding a relationship among adolescents of ownership of a promotional tobacco item and actual tobacco use.<sup>120</sup> In addition, in *U.S. v. Philip Morris, USA*,

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<sup>111</sup> *Central Hudson Gas & Electric Corp. v. Public Serv. Commission of N.Y.*, 447 U.S. 557 (1980).

<sup>112</sup> *Discount Tobacco City & Lottery, Inc. v. US*, 674 F. 3d 509 at 540-43.

<sup>113</sup> *Id.* at 542.

<sup>114</sup> *Id.*, citing Pierce, JP, et al., “Tobacco Industry Promotion of Cigarettes and Adolescent Smoking,” *Journal of the American Medical Association* 279(7):511-15, 1998, <http://jama.jamanetwork.com/article.aspx?articleid=187258>

<sup>115</sup> Lynch, BS, & Bonnie, RJ, eds., *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths*, Washington, DC: The National Academies Press, 1994, at 80.

<sup>116</sup> Biener, L & Siegel, M, “Tobacco marketing and adolescent smoking: more support for a causal inference,” *American Journal of Public Health* 90(3):407-11, 2000, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446173/pdf/10705860.pdf>.

<sup>117</sup> Gilpin, EA, et al., “Receptivity to tobacco advertising and promotions among young adolescents as a predictor of established smoking in young adulthood,” *American Journal of Public Health* 97(8):1489-95, 2007, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1931446/pdf/0971489.pdf>.

<sup>118</sup> Sargent, JD, et al., “Effect of cigarette promotions on smoking uptake among adolescents,” *Preventive Medicine* 30(4):320-7, 2000.

<sup>119</sup> Sargent, JD, et al., “Exposure to cigarette promotions and smoking update in adolescents: evidence of a dose-response relation,” *Tobacco Control* 9:163-168, 2000, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1748336/pdf/v009p00163.pdf>.

<sup>120</sup> 2012 Surgeon General’s Report, at 515, and sources cited therein.

*Inc.*, the court specifically found that the major tobacco companies had used the distribution of merchandise carrying their brand names and logos to target young people.<sup>121</sup>

Brand-name merchandise serves the same function with regard to the deemed products. By agreeing to the tobacco Master Settlement Agreement of 1998 and the Smokeless Tobacco Master Settlement of 1998, the major manufacturers of these products agreed to a prohibition on brand name merchandise for cigarettes and smokeless tobacco products.<sup>122</sup> There have been no such restrictions, however, on brand name merchandise for other tobacco products and there has been a large proliferation of such merchandise. A sampling of such brand name merchandise advertising cigars and e-cigarettes is attached at Tab G. The products include lighters, t-shirts, coolers, iPad covers and shot glasses. As with other tobacco products, the evidence demonstrates that adolescent boys who own a tobacco promotional item are more likely to smoke cigars, even after controlling for cigarette use.<sup>123</sup>

This result is hardly surprising. Major tobacco companies, having used brand name merchandise for decades in successfully marketing cigarettes and smokeless tobacco products to adolescents, simply applied the same marketing principles to other tobacco products.

### 3. FDA should prohibit tobacco brand name sponsorship of events

The 2010 Regulations Restricting the Sale of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents also prohibited manufacturers, distributors or retailers of these products from sponsoring any athletic, musical, artistic, or other social or cultural event or any entry or team in any event in the brand name.<sup>124</sup> In adopting a similar regulation in 1996, FDA had concluded that “the effect of sponsored events [such as automobile races, rodeos, and concerts] on the young people who attend or see these events is enormous...by creating attractive and exciting images that can serve as a badge or identification, . . .by utilizing multiple and prolonged exposure<sup>125</sup> in a variety of media, thereby creating an impression of prevalence and normalcy about tobacco use, and . . .by associating the product with varied positive events and images. The sponsorship of events by tobacco companies uniquely achieves all three objectives.”<sup>126</sup> And in its 1995 proposed rule, FDA noted that sponsorship “provides an opportunity for what sponsorship experts call “embedded advertising” that actively creates a “friendly familiarity” between tobacco and sports enthusiasts, many of whom are children and adolescents. Those watching a sponsored event, including children and adolescents, repeatedly

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<sup>121</sup> *U.S. v. Philip Morris USA, Inc.*, 449 F.Supp.2d at 635, 667.

<sup>122</sup> Tobacco Master Settlement Agreement, [www.naag.org/backpages/naag/tobacco/msa](http://www.naag.org/backpages/naag/tobacco/msa); Smokeless Tobacco Master Settlement Agreement, [www.naag.org/backpages/naag/tobacco/msa](http://www.naag.org/backpages/naag/tobacco/msa).

<sup>123</sup> Frazier, AL, et al., “Association of adolescent cigar use with other high-risk behaviors,” *Pediatrics* 106(2):E26, 2000, <http://pediatrics.aappublications.org/content/106/2/e26.full.pdf+html>.

<sup>124</sup> 75 Fed. Reg. at 13232. 21 CFR § 1140.34(c).

<sup>125</sup> At a Marlboro Grand Prix event, for example, the Marlboro logo was visible for more than 46 of the total of 94 minutes of the telecast. Blum, A, “The Marlboro Grand Prix: Circumvention of the Television Ban on Tobacco Advertising,” *New England Journal of Medicine* 324(13): 913-17, March 28, 1991.

<sup>126</sup> 61 Fed. Reg. at 44528-29.

see the sponsor's brand or corporate name linked with an event they enjoy.”<sup>127</sup> Tobacco brand name sponsorships in sports include sponsorships in automobile racing, billiards, golf, tennis, and rodeo.<sup>128</sup> FDA cited extensive evidence that sponsored events of all types are attended and seen on television by a substantial number of young people.<sup>129</sup> The 1994 Surgeon General's Report, *Preventing Tobacco Use Among Young People*, noted that sponsorship is a way to deliver a brand message without including a government-mandated warning.<sup>130</sup>

As noted above, research supports a causal relationship between tobacco promotion generally, including sponsorships, and initiation of tobacco use by children.<sup>131</sup> Under marketing theories of brand equity, researchers have hypothesized that cigarettes “are a likely product group to benefit from the kinds of brand image associations and awareness benefits that can be derived from sport sponsorship, particularly among youth.<sup>132</sup> Although data are limited, research suggests that associations between exposure to tobacco sponsorships and children adopting attitudes favorable to smoking or initiating smoking itself.”<sup>133</sup>

Tobacco product manufacturers challenged the constitutionality of the 2010 regulation but the validity of the regulation was upheld both by the U.S. District Court for the Western District of Kentucky and by the United States Court of Appeals for the Sixth Circuit. Citing numerous academic sources, the Court found that “tobacco advertising through event sponsorship has an effect on juvenile tobacco consumption. . . . Just as branded non-tobacco merchandise reaches a wide audience of juveniles and contributes to their decisions to use tobacco products, so too does branded event sponsorship.”<sup>134</sup>

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<sup>127</sup> 60 Fed. Reg. at 41335-36.

<sup>128</sup> Rosenberg, NJ & Siegel, M, “Use of corporate sponsorship as a tobacco marketing tool: a review of tobacco industry sponsorship in the USA, 1995-99,” *Tobacco Control* 10(3):239-46, 2001. See also, *U.S. v. Philip Morris USA, Inc.*, 449 F.Supp.2d at 664 (“Defendants sponsor televised racing events which have great appeal to youth. As a result, millions of youth watching these events are exposed to Defendants’ cigarette marketing imagery.”).

<sup>129</sup> *Id.* at 22536.

<sup>130</sup> HHS, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*, CDC, Office on Smoking and Health, 1994 at 185, [http://www.cdc.gov/tobacco/data\\_statistics/sgr/1994/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/1994/index.htm).

<sup>131</sup> DiFranza, JR, et al., “Tobacco promotion and the initiation of tobacco use: assessing the evidence for causality,” *Pediatrics* 117(6):e1237, 2006.

<sup>132</sup> Sparks, R, “Youth awareness of tobacco sponsorship as a dimension of brand equity,” *Young Consumers: Insight and Ideas for Responsible Marketers* 1(3):193-218, 1999.

<sup>133</sup> Vaidya, SG, Naik, UD, & Vaidya, JS, “Effect of sports sponsorship by tobacco companies on children’s experimentation with tobacco,” *British Medical Journal* 313(7054):400, 1996, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2351807/pdf/bmj00555-0032.pdf>. Vaidya, SG, Vaidya, JS, & Naik, UD, “Sports sponsorship by cigarette companies influences the adolescent children’s mind and helps initiate smoking: results of a national study in India,” *Journal of the Indian Medical Association* 97(9):354-356, 1999; Charlton, A, While, D, & Kelly, S, “Boys’ smoking and cigarette-brand-sponsored motor racing,” *The Lancet* 350(9089):1474, 1997; Kelly, B, et al., “Tobacco and alcohol sponsorship of sporting events provide insights about how food and beverage sponsorship may affect children’s health,” *Health Promotion Journal of Australia* 22(2):91-96, 2011.

<sup>134</sup> *Discount Tobacco City & Lottery, Inc. v. US*, 674 F.3d at 543.

The tobacco Master Settlement Agreement of 1998 and the Smokeless Tobacco Master Settlement Agreement of 1998 restricted the sponsorship of events and teams by manufacturers of cigarettes and smokeless tobacco products.<sup>135</sup> However, there has been no restriction on the ability of manufacturers of the deemed products to sponsor such events and in fact such sponsorships have been ubiquitous. At least eight e-cigarette companies promote their products through sponsored or sampling events, many of which appear to be youth-oriented, and in 2012 and 2013 alone, six e-cigarette companies sponsored or provided free samples at 348 events.<sup>136</sup> For example, FIN Electronic Cigarettes sponsors multi-state bus tours; Swisher sponsors a ten-city “Vapor Tour;” V-2 electronic cigarettes sponsored events in Venice, California and Las Vegas; blu, Green Smoke (owned by Altria), Swisher, and Mystic e-cigarettes all sponsor cars in NASCAR events (long a favorite venue for tobacco sponsorships), where the corporate logo is prominently displayed on the cars (and, of course, in television coverage of the races);<sup>137</sup> Swisher also sponsors sailing races and the World Series of Poker; blu sponsors numerous concerts with youth-oriented music all over the country (including Las Vegas, New York City, Miami, Austin, New Orleans, Gulf Shores, Alabama, Manchester, Tennessee, and Kingston Downs, Georgia are shown) as well as the Freedom Project, a nationwide tour starring several bands and musicians; and Twenty-First Century sponsors concerts in Chicago. See images at Tab H.

#### 4. FDA should require notification regarding advertising

The 2010 regulation requires manufacturers, distributors, or retailers intending to disseminate advertising for cigarettes or smokeless tobacco in a medium other than newspapers, magazines or periodicals, billboards, posters or placards, non-point-of-sale promotional material (including direct mail); point-of-sale promotional material; and audio and video formats delivered at the point of sale to notify FDA prior to the use of such medium. The notice is to describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age.<sup>138</sup>

This provision would, among other things, apply to television advertising and advertising on the internet and social networks. In evaluating whether deemed tobacco products meet the public health standard, FDA will have to consider the risks and benefits of the products to the population as a whole, including both users and nonusers. The likelihood that the marketing of such products will lead young people to initiate tobacco use is an important consideration in performing this analysis. The way the product is advertised—and particularly the exposure of adolescents to advertising and marketing messages—is relevant to this analysis and it would be

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<sup>135</sup> Tobacco Master Settlement Agreement, [www.naag.org/backpages/naag/tobacco/msa](http://www.naag.org/backpages/naag/tobacco/msa); Smokeless Tobacco Master Settlement Agreement, [www.naag.org/backpages/naag/tobacco/msa](http://www.naag.org/backpages/naag/tobacco/msa).

<sup>136</sup> *Gateway to Addiction?*, at 1.

<sup>137</sup> See Dewhirst, T & Hunter, A, “Tobacco sponsorship of Formula One and CART auto racing: tobacco brand exposure and enhanced symbolic imagery through co-sponsors’ third party advertising,” *Tobacco Control* 11(2):146, 2002, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1763846/pdf/v011p00146.pdf>.

<sup>138</sup> 75 Fed. Reg. at 13232. 21 CFR §1140.30 (a)(2).

helpful for FDA to have this material before it. FDA should therefore apply this requirement to advertising of the newly deemed products.

E. FDA Should Apply Restrictions on the Marketing of Deemed Products that Would Otherwise Be Illegal but for FDA's Exercise of Its Enforcement Discretion

Under the terms of the Tobacco Control Act, any deemed products that were introduced or modified after February 15, 2007 are new tobacco products and cannot be marketed in the absence of an order under Section 910 finding that the marketing of the product is appropriate for the protection of the public health or an order under Section 905(j) finding that the product is substantially equivalent to a product that was marketed on February 15, 2007. FDA has proposed to permit the marketing of deemed products for a period of two years following the promulgation of a final rule by adopting a policy of not enforcing the requirements of those sections during such period. These products would otherwise be illegal. This policy affords manufacturers of the deemed products opportunities to market their products that would not be possible under the terms of the statute in the absence of the exercise of FDA's proposed discretionary policy of non-enforcement. We provide detailed comments on this approach in Part VII of these comments.

As noted in this section of our comments, we strongly urge FDA to modify its proposed rule to make applicable to the deemed products all of the provisions of the 2010 marketing rule and other restrictions on the marketing of these products that were agreed to by the major cigarette manufacturers in the 1998 tobacco Master Settlement Agreement. If FDA does not apply all such provisions to the deemed products, however, it is important for FDA, at a minimum, to make compliance with all such provisions a condition of FDA's exercise of its enforcement discretion to permit the continued marketing of products that would otherwise not be allowed to be marketed under the terms of the statute.

Part III.B. of these comments has demonstrated that the deemed products are being marketed extensively to children. The proposed "compliance period" would in essence permit manufacturers of the deemed products to market them without the application of new product or substantial equivalence requirements contained in the statute. Moreover, the proposed rule would permit such products marketed during the period to remain on the market after the end of the compliance period unless and until FDA denies a marketing application. Whatever the justification for these provisions, they create a threat to the public health by permitting tobacco products that are already being marketed to children to continue to be marketed during the compliance period and beyond. If FDA plans to adopt a proposal that would implement a policy of non-enforcement of the new product requirements during the compliance period, it should, at a minimum, require that such products are not marketed in ways that appeal to children during the compliance period. Accordingly, FDA should, at a minimum, require as a condition of its exercise of its discretionary authority that any new deemed product marketed during the

compliance period must meet all such requirements as a condition of qualifying for marketing during that period.

F. The Recommended Restrictions are Narrowly Tailored and Leave Ample Room for Manufacturers to Communicate with Their Customers

The restrictions recommended in these comments are all narrowly tailored to prevent marketing of addictive products to youth while still permitting manufacturers ample opportunity to communicate with their adult customers. All of them involve channels of communications that have been used to promote tobacco products to youth. Given the importance of discouraging initiation of tobacco usage by underage customers, the restrictions proposed here are appropriate. Numerous channels remain open for communications by tobacco product manufacturers to their adult customers, including advertising in newspapers and magazines, through direct mail, a wide range of electronic media, and at the point of sale. In addition, the restrictions recommended do not limit the content of advertising.

IV. FDA SHOULD IMMEDIATELY DEVELOP RULES PROHIBITING CHARACTERIZING FLAVORS IN THE DEEMED PRODUCTS

Section 907 of the Tobacco Control Act prohibits the use of characterizing flavorings in cigarettes, reflecting the Congressional understanding that the tobacco industry long manufactured and sold cigarettes with sweet and fruity flavors as a key part of its strategy to addict young people to its lethal products. As early as 1972, advisors to Brown & Williamson reviewed new concepts for a “youth cigarette,” including cola and apple flavors, and a “sweet flavor cigarette,” noting, “It’s a well-known fact that teenagers like sweet products. Honey might be considered.”<sup>139</sup> An R.J. Reynolds (RJR) interoffice memo in 1974 suggested, “Make a cigarette which is obviously youth oriented. This could involve cigarette name, blend, flavor and marketing technique . . .for example, a flavor which would be candy-like but give the satisfaction of a cigarette.”<sup>140</sup> A Lorillard report, summarizing the test results from new cigarette flavors, included smokers’ description of ‘Tutti Frutti’ flavored cigarettes as “for younger people, beginner cigarette smokers, teenagers . . . when you feel like a light smoke, want to be reminded of bubblegum.”<sup>141</sup>

When it implemented the statute’s prohibition of characterizing flavors in cigarettes, FDA cited studies showing that 17-year-old smokers are three times as likely to use flavored

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<sup>139</sup> Marketing Innovations, “Youth Cigarette – New Concepts,” Memo to Brown & Williamson, September 1972, Bates No. 170042014, <http://legacy.library.ucsf.edu/tid/wwq54a99>.

<sup>140</sup> R.J. Reynolds Inter-office Memorandum, May 9, 1974, Bates No. 511244297-4298, <http://legacy.library.ucsf.edu/tid/jtd53d00>.

<sup>141</sup> R.M. Manko Associates report for Lorillard, Summary Report: New Flavors Focus Group Sessions, August 1978, Bates No. 85093450, <http://legacy.library.ucsf.edu/tid/blx31e00>.



cigarettes as are smokers over the age of 25.<sup>142</sup> FDA noted that “[i]n addition to being more attractive to young people, flavored products make it easier for new smokers to start smoking by masking the unpleasant flavor of tobacco” as well as leading young people to believe that flavored tobacco products are safer than unflavored ones.<sup>143</sup>

Since the TCA was enacted in 2009 many tobacco companies have pursued a strategy of producing flavored non-cigarette products, as well as selling small, flavored “cigar” products virtually indistinguishable from cigarettes. A recent chemical analysis of flavorings used in various sized cigars and smokeless tobacco products shows that they are chemically identical to flavorings used in such products as Jolly Rancher candies, Life Savers and Kool-Aid.<sup>144</sup> Indeed, the analysis found that “[s]ome tobacco products contained flavor chemicals at much higher levels per serving than the non-tobacco products.” “What we are seeing,” the authors observed, “is truly candy-flavored tobacco.”<sup>145</sup>

In its NPRM, FDA noted that “many of the products proposed to be covered by this rule are offered in fruit and candy flavors, such as chocolate and grape flavors, making them especially attractive to children and young adults.”<sup>146</sup> See Tab I for additional examples of flavored cigars and e-cigarettes. The agency has requested comments on what actions it should take “to address the sale of candy and/or fruit-flavored tobacco products to children and young adults.”<sup>147</sup> FDA should promulgate a final rule prohibiting characterizing flavors in deemed products, as well as in currently regulated tobacco products, either as part of its final deeming rule, or as a separate final rule to be issued coincident with the final deeming rule. FDA should also undertake immediate enforcement actions against any flavored products that, although marketed as cigars, nevertheless meet the definition of “cigarette” under the TCA.

Some e-cigarette manufacturers claim that non-tobacco flavors, by making e-cigarettes more appealing to adult smokers, increase the number of smokers who switch from cigarettes to e-cigarettes. It is important to note that these assertions have not been subjected to scientific review. The proper regulatory response to such an assertion is for FDA to require, as to each non-tobacco flavor, that the manufacturer submit valid scientific evidence prior to addition of the flavor pursuant to Sections 910 or 911 of the TCA, that the flavor (1) enhances the efficacy of the product in increasing the number of smokers who quit smoking, (2) does not contribute to initiation of tobacco product use, including e-cigarette use, particularly among youth, or relapse into tobacco product use, and (3) does not result in continued use of tobacco products by those who otherwise would have quit. Thus, the burden would be on the manufacturer to establish that

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<sup>142</sup> FDA Guidance for Industry and FDA Staff, “General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) (“FDA Guidance on Characterizing Flavors”), at 2.

<sup>143</sup> *Id.*

<sup>144</sup> Brown, JE, et al., “Candy Flavorings in Tobacco,” *New England Journal of Medicine*, DOI:10.1056/NEJMc143015, May 7, 2014, <http://www.nejm.org/doi/pdf/10.1056/NEJMc1403015>.

<sup>145</sup> *Id.* at 2.

<sup>146</sup> 79 Fed. Reg. at 23146.

<sup>147</sup> 79 Fed. Reg. at 23147.

marketing of the particular flavored product would meet the statutory public health standard, which necessarily involves an assessment of the risks and benefits to the population as a whole, including users and nonusers of tobacco products, the likelihood that existing users of cigarettes will stop using those products, and the likelihood that non-users will start using those products.

A. The Sale of Flavored Cigars is Commonplace and Increasing

Although cigarette smoking has been declining in the United States, total U.S. cigar consumption has increased dramatically in recent years. Between 2000 and 2013, cigar consumption increased by 114 percent as cigarette consumption declined by 37 percent.<sup>148</sup> Flavored products are driving much of this increase. A recent study based on Nielsen convenience store scanner data indicates that cigar dollar and unit sales in convenience stores increased by 30 percent and 21 percent respectively, between 2008 and 2011, with flavored cigars responsible for 75 percent of this increase in sales.<sup>149</sup> According to the Nielsen data, flavored cigars rose from 41.9 percent of the convenience store market in 2008 to 49.5 percent in 2011.<sup>150</sup> A recent survey of licensed tobacco retailers in Washington, D.C. found that 95 percent of stores that sold little cigars and cigarillos sold them in flavors like fruit, candy and wine.<sup>151</sup> A 2013 survey of internet tobacco retailers found that more than 40 percent of cigarette-sized cigars, machine-made cigars, moist snuff, and dry snuff tobacco products were flavored, including fruit, sweet, and mint/menthol.<sup>152</sup>

In recent years, there has been an explosion in flavoring options available in cigars, including candy, fruit, chocolate and other kid-appealing tastes. These flavors often are described in youthful jargon, with names like “Purple Haze,” “Hush Honey” and “Banana Split.”<sup>153</sup> The vice president of one distributor commented that “[f]or a while it felt as if they were operating a Baskin-Robins ice cream store,” in reference to the variety of cigar flavors available.<sup>154</sup> They also typically are sold in shiny, colorful packages that reinforce the appeal of fruit and candy flavors that appeal to kids, particularly when placed in strategically prominent locations within retail stores.<sup>155</sup> With their colorful packaging and sweet flavors, flavored cigar products are often hard to distinguish from the candy displays in retail outlets.<sup>156</sup>

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<sup>148</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics.

<sup>149</sup> Delnevo, C, et al., “Preference for flavoured cigar brands among youth, young adults and adults in the USA,” *Tobacco Control*, 2014, at 2.

<sup>150</sup> *Id.* at 3.

<sup>151</sup> Cantrell, J, et al., “Marketing Little Cigars and Cigarillos: Advertising, Price and Associations with Neighborhood Demographics,” *American Journal of Public Health* 103(10):1902-9, October 2013.

<sup>152</sup> Morris, DS & Fiala, SC, “Flavoured, non-cigarette tobacco for sale in the USA: an inventory analysis of Internet retailers,” *Tobacco Control*, doi:10.1136/tobaccocontrol-2013-051059, August 8, 2013.

<sup>153</sup> *Not Your Grandfather’s Cigar*, at 19, listing examples of cigar flavors and flavor names.

<sup>154</sup> Niksic, M, “Flavored Smokes: Mmmmm...More Profits?,” *Tobacco Retailer*, April 2007.

<sup>155</sup> *Not Your Grandfather’s Cigar*, at 10.

<sup>156</sup> *Not Your Grandfather’s Cigar*, at 11.

## B. Flavored Cigars are Particularly Appealing to Young People

As noted above, 2,700 children under age 18 try cigar smoking for the first time every day and one in six high school boys currently smoke cigars. Teens and young adults are much more likely than adults 25 years and older to report smoking cigars.<sup>157</sup> The research indicates that flavored cigars are driving much of this usage. A national study found that youth and young adults prefer cigar brands that come in a variety of flavors, and that preference declines significantly with age – 95 percent of 12-17 year old cigar smokers reported a usual brand that makes flavored cigars compared with 63 percent of cigar smokers aged 35 and older.<sup>158</sup>

Surveys indicate that high percentages of young people, and young cigar smokers, are using flavored cigars. Nationally, more than one-third (35.9 percent) of middle and high school cigar smokers have reported using flavored cigars.<sup>159</sup> The 2013 Maryland Tobacco and Risk Behavior Survey showed that nearly three-quarters (71.9 percent) of high school cigar smokers use flavored cigars.<sup>160</sup> Similarly, the 2013 Florida Youth Tobacco Survey found that a strong majority of high school cigar smokers in Florida (68.8 percent) uses flavored cigars and that one in seven high school student in that state has tried a flavored cigar.<sup>161</sup> In Minnesota, more than one-fourth of high school students (28.6 percent) have tried smoking flavored cigars, cigarillos, or little cigars; the rate is even higher among high school males (35.9 percent).<sup>162</sup> Among adults, in the 2012-2013 National Adult Tobacco Survey, young adult current cigar smokers aged 18-29 years old reported the highest prevalence of any flavored cigar use (47.1 percent).<sup>163</sup>

The cigar industry acknowledges that flavors attract new users. The vice president of marketing for the international division of Swedish Match, which sells White Owl cigars and Game cigars in the U.S., stated, “It is mainly new recruits to cigar smoking who take to the new flavors, while long-time consumers still prefer the more traditional cigars.”<sup>164</sup> Industry insiders

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<sup>157</sup> 2013 YRBS. King, BA, Dube, SR, & Tynan, MA, “Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009–2010 National Adult Tobacco Survey,” *Nicotine & Tobacco Research* 15(2):608-14, 2013, at 610, <http://ntr.oxfordjournals.org/content/15/2/608.full.pdf+html>.

<sup>158</sup> Delnevo, C, et al., “Preference for flavoured cigar brands among youth, young adults and adults in the USA,” *Tobacco Control*, epub ahead of print, April 10, 2014.

<sup>159</sup> King, BA, et al., “Flavored-Little-Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students,” *Journal of Adolescent Health* 54(1):40-6, January 2014, <http://download.journals.elsevierhealth.com/pdfs/journals/1054-139X/PIIS1054139X13004151.pdf>.

<sup>160</sup> 2013 Maryland Tobacco and Risk Behavior Survey, in Moncrief, D, Maryland Statewide Youth Tobacco Initiatives, MDQuit 8<sup>th</sup> Best Practices Conference, January 23, 2014, [http://mdquit.org/sites/default/files/pdf\\_files/Moncrief.pdf](http://mdquit.org/sites/default/files/pdf_files/Moncrief.pdf).

<sup>161</sup> 2013 Florida Youth Tobacco Survey, <http://www.floridahealth.gov/reports-and-data/survey-data/fl-youth-tobacco-survey/reports/2013-state/index.html>.

<sup>162</sup> Minnesota Department of Health, *Teens and Tobacco in Minnesota, 2011 Update: Results from the Minnesota Youth Tobacco and Asthma Survey*, December 2011, at 12, <http://www.health.state.mn.us/divs/chs/tobacco/FullReport2011.pdf>.

<sup>163</sup> Coleman, B, et al., “Use of Flavored Cigars, Cigarillos and Little Filtered Cigars: Findings from the 2012-2013 National Adult Tobacco Survey,” Presented at SRNT Conference, 2014.

<sup>164</sup> Swedish Match, “No. 2 worldwide in cigars,” March 7, 2007, <http://www.swedishmatch.com/en/Media/Articles/No-2-worldwide-in-cigars/>.

also recognize the use of flavors for the uninitiated. The luxury lifestyle magazine, *Cigar Aficionado*, stated in an article, “More likely, flavored cigars serve as a bridge to premium cigars for the uninitiated, something to be smoked as an entryway into the world of cigar smoking. For the novice, a simple, sweet and easily identifiable flavor (honey or cherry, for example) is an easier step than moving into a box marked Cuban-seed Corojo.”<sup>165</sup>

There is no question that the considerable progress the nation has made to curb cigarette smoking, particularly among our youth, is being undercut by the high incidence of youth cigar use driven by the availability of flavored cigars. The same policy imperatives that led Congress to prohibit characterizing flavors in cigarettes now justify an FDA product standard prohibiting the use of such flavors in cigars.

### C. FDA Should Enforce the Law Against Manufacturers of Flavored Cigarettes Being Marketed as Cigars

In its NPRM, FDA expresses concern that manufacturers may be labeling or representing products that are, in fact, cigarettes, as “little cigars,” or “cigarillos” or similar products in an effort to evade the statutory prohibition against characterizing flavors in cigarettes.<sup>166</sup> FDA requests comments on the factors it should consider in determining whether a particular tobacco product is a “cigarette” as defined in section 900(3) of the TCA, despite being labeled as a little cigar or other non-cigarette product.<sup>167</sup>

Although cigars typically contain tobacco in the wrapper and cigarettes do not, the TCA makes it clear that companies cannot evade cigarette regulations simply by labeling a product as something other than a cigarette or by adding tobacco to the wrapper of a product otherwise indistinguishable from a cigarette. The TCA defines a “cigarette” as a tobacco product which meets the definition of “cigarette” in section 3(1) of the Federal Cigarette Labeling and Advertising Act (FCLAA) and “includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or a roll-your-own tobacco.”<sup>168</sup> In turn, the FCLAA defines “cigarette” as “(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).”<sup>169</sup> Under the TCA, therefore, whether a product is a cigarette turns on a functional evaluation of the way it is marketed, and its perception by the

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<sup>165</sup> Savona, D, “Cigars of a Different Flavor,” *Cigar Aficionado*, July/August 2005.

<sup>166</sup> 79 Fed. Reg. at 23147.

<sup>167</sup> *Id.*

<sup>168</sup> 21 U.S.C. 387(3).

<sup>169</sup> 15 U.S.C. 1332(1).

consumer, not on whether it has tobacco in the wrapper or on the words the manufacturer has chosen to put on the package.

When FDA implemented the prohibition on characterizing flavors in cigarettes, it issued a Guidance document announcing an aggressive enforcement policy toward evasion of the flavor ban: “If a product is labeled as a cigar or as some other tobacco product and the agency determines that the product meets the definition of a cigarette in section 900(3), then consistent with its enforcement policy, a warning letter will be issued to the firm to provide it with notice of its violation of the FSPTCA.”<sup>170</sup> FDA should aggressively enforce the law, consistent with this Guidance.

There is little doubt that, following the elimination of characterizing flavors in cigarettes, some of the flavored little “cigars” put on the market were introduced to evade the prohibition, were indistinguishable from cigarettes and should have been the subject of FDA enforcement actions. As noted in the Surgeon General’s 2012 Report, *Preventing Tobacco Use Among Youth and Young Adults*, Djarum clove cigarettes reappeared after the TCA as clove-flavored cigars, and Sweet Dreams cherry-flavored cigarettes reappeared as Sweet Dreams cherry-flavored cigars.<sup>171</sup> Cigarette manufacturers have simply mixed tobacco remnants into the cigarette’s paper wrapper to market the identical product as a flavored “little cigar” or “cigar” in packaging virtually identical to a cigarette brand. After the TCA took effect, the manufacturer of Cheyenne flavored cigarettes began selling Cheyenne flavored “little cigars” in 20-packs like cigarettes in the same packaging as the company’s cigarettes.<sup>172</sup> Tab J shows examples of cigarettes that have become “little cigars” and cigars.

As noted, the TCA makes consumer perception an element in determining whether a product labeled a “cigar” actually meets the definition of “cigarette,” for which characterizing flavors are prohibited. Research demonstrates that many consumers appear to be purchasing products labeled “cigars” believing them to be cigarettes. Data from the 2012 National Survey on Drug Use and Health show that when youth aged 12-17 were asked to name their usual cigarette brand, some responded with brands of little cigars or cigarillos.<sup>173</sup> In its NPRM, FDA itself notes data from several surveys “indicating consumer confusion between little cigars and

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<sup>170</sup> FDA Guidance on Characterizing Flavors, at 3.

<sup>171</sup> 2012 Surgeon General’s Report, at 205. See also, Delnevo, CD & Hrywna, M., “Clove cigar sales following the US flavoured cigarette ban,” *Tobacco Control* [pub ahead of print], March 20, 2014, doi: 10.1136/tobaccocontrol-2013-051415.

<sup>172</sup> A “little cigar” is defined in Section 900(11) of the TCA as “any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1) and as to which one thousand units weigh not more than three pounds.” 21 U.S.C. 387 (11) referencing 15 U.S.C. 1332(7). See *Not Your Grandfather’s Cigar*, at 13 (showing the transformation of Cheyenne cigarettes to Cheyenne “little cigars,” by adding tobacco to the paper wrapper, and then to Cheyenne “cigars” by adding weight to the filter to achieve a lower rate of federal excise taxation).

<sup>173</sup> SAMHSA, Analysis of data from the 2012 National Survey on Drug Use and Health.

cigarillos on one hand, and cigarettes on the other, as well as indicating consumer substitution of little cigars and cigarillos for cigarettes.”<sup>174</sup>

The marketing of flavored tobacco products labeled “cigars,” which appear to be functionally identical to cigarettes, and the data indicating persistent consumer confusion, suggest that there may be widespread illegal marketing of flavored cigarettes masquerading as cigars. FDA should be aggressively monitoring the market to find violations and should be bringing enforcement actions against violators. FDA already has the authority, and obligation, to bring such actions now; it need not wait for the deeming of cigars as regulated products because the illegal flavored products that would be the subject of those enforcement actions are not cigars. At the same time, FDA’s existing authority to bring enforcement actions against these illegal flavored products in no way diminishes the need to deem cigars subject to FDA regulatory authority and to issue a product standard prohibiting characterizing flavors in cigars.

#### D. The Use of Characterizing Flavors in Electronic Cigarettes is Commonplace, Making These Addictive Products Appealing to Youth

Although electronic cigarettes are viewed by some as having promise in offering smokers a less harmful alternative to cigarettes and cigars, there also is a legitimate concern that these new nicotine-delivery devices expose youth to nicotine, result in the initiation and addiction of young people and/or function as a gateway to smoking or other tobacco use for kids who otherwise would not have used any tobacco product. This concern has been intensified by the marketing of these products, which employs many of the same strategies and images to target young people long perfected by the tobacco industry in the sale of cigarettes and other tobacco products. One such strategy has been the widespread marketing of e-cigarettes and nicotine-laced “e-juice” with the same candy and fruit flavors used in cigarettes to make them more appealing to kids.

FDA’s NPRM observes that “e-cigarettes are available in numerous flavors including vanilla, chocolate, peach schnapps, bubblegum and cola.”<sup>175</sup> A recent survey of leading e-cigarette manufacturers by staff for 11 members of Congress found that marketing of products with kid-friendly flavors was common, with one manufacturer featuring as many as 42 different flavors.<sup>176</sup> Lorillard, with more than 45 percent of the market for its blu e-cigarette,<sup>177</sup> features such flavors as Cherry Crush, Vivid Vanilla and Pina Colada.<sup>178</sup> Lorillard itself recognizes that its e-cigarette flavors appeal to kids. Dr. Michael Popkin, who the company identifies as the

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<sup>174</sup> 79 Fed. Reg. at 23167.

<sup>175</sup> 79 Fed. Reg. at 23157

<sup>176</sup> *Gateway to Addiction?*, at 12.

<sup>177</sup> Lorillard, Inc., *Lorillard, Inc. Reports Fourth Quarter And Full Year 2013 Results*, February 12, 2014, <http://investors.lorillard.com/investor-relations/news/news-details/2014/Lorillard-Inc-Reports-Fourth-Quarter-And-Full-Year-2013-Results/default.aspx>.

<sup>178</sup> blu cigs, Flavor Cartridges, accessed June 10, 2014 from <http://www.blucigs.com/product/flavor-cartridges/>.

“longtime spokesperson” for Lorillard’s Youth Smoking Prevention Program, Real Parents Real Answers, states on the program’s website that “[k]ids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, pina-colada and berry.”<sup>179</sup>

The use of flavors in e-cigarette products is of even greater concern because e-cigarettes are the subject of extensive advertising campaigns and there is evidence that young people are exposed to significant amounts of e-cigarette advertising. In 2012, e-cigarette companies began airing media campaigns on television. A recent study shows that exposure of youth aged 12-17 to television e-cigarette advertising increased 256 percent from 2011 to 2013 and that e-cigarette companies advertise their products to a broad audience that includes 24 million youth.<sup>180</sup> Lorillard’s ads for its blu brand accounted for 81 percent of the youth exposure.<sup>181</sup>

The survey of leading e-cigarette manufacturers by staff for 11 members of Congress, noted previously, found that the surveyed e-cigarette manufacturers have significantly increased their marketing expenditures in recent years. Specifically, six of the surveyed companies spent a total of \$59.3 million on advertising and promotion in 2013. Between 2012 and 2013, one company’s marketing expenses increased by 300 percent and another company’s marketing expenses increased by 352 percent.<sup>182</sup> A study for Legacy found that, during the period June-November 2013, the e-cigarette industry spent \$39 million on advertising, with the majority spent on magazines and TV ads. Reinforcing the findings from the previously mentioned television study, this study found that Lorillard’s blu brand accounted for more advertising dollars than all other brands combined.<sup>183</sup> The study found that e-cigarette TV ads reached 14.1 million or 58 percent of teens age 12-17 during the June-November period.<sup>184</sup> Print ads for e-cigarettes reached 9.5 million or 39 percent of teens age 12-17 during that period.<sup>185</sup> Despite the industry’s assurances that e-cigarettes are not being marketed to kids, there is no question that ads for these products are reaching young people.

It should not be surprising that use of e-cigarettes by youth is increasing. As noted, CDC has found that ever-use of e-cigarettes by high school students doubled in one year from 2011-2012 from 4.7 percent to 10 percent. Almost 10 percent of students who have used e-cigarettes have never used traditional cigarettes.<sup>186</sup> Legacy’s study, involving surveys done in February,

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<sup>179</sup> Real Parents Real Answers, *What you need to know about e-cigarettes – infographic*, accessed June 10, 2014 from <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/>.

<sup>180</sup> Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics*, June 2, 2014.

<sup>181</sup> *Id.*

<sup>182</sup> *Gateway to Addiction?*, at 15.

<sup>183</sup> Legacy, *Vaporized: E-Cigarettes, Advertising and Youth*, May 2014, at 16, [http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig\\_Report-May2014.pdf](http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf).

<sup>184</sup> *Id.* at 16-17.

<sup>185</sup> *Id.* at 17.

<sup>186</sup> Carey at 729. The apparent appeal of e-cigarettes to a segment of non-smokers also is suggested by a study by McMillen, et al. submitted to this Docket. The study of e-cigarette use among adults found that, although smokers surveyed were the most likely to have tried e-cigarettes, almost a third of current e-cigarette users either

2014, found that 14 percent of those aged 13-17 had ever used e-cigarettes, as had 39 percent of those aged 18-21.<sup>187</sup>

Thus, there is every reason to believe that the use of sweet and fruity flavors in e-cigarettes, bolstered by advertising reaching kids, is having the same effect it has had for cigarettes and cigars – making a highly addictive product more appealing to youth. Although some have argued that certain flavors in e-cigarettes may enhance their appeal and effectiveness as devices to aid smoking cessation by adults, this is as yet an unproven assertion. For example, a 2013 survey that examined the impact of flavorings on the e-cigarette experience of dedicated e-cigarette users used a convenience sample of participants recruited from popular e-cigarette user forums and e-cigarette advocate websites.<sup>188</sup> Any number of biases can result from using a convenience sample because respondents are not representative of the population. Further self-selection bias is another major limitation of online survey research. In short, there is a tendency of some individuals to respond to an invitation to participate in an online survey, while others ignore it, leading to a systematic bias. In this study, the authors acknowledge that participants were primarily dedicated e-cigarette users who had a positive experience with e-cigarettes. In addition, this internet-based survey just asked participants to rate the importance of flavor variability in reducing or quitting smoking but did not actually assess if having access to a variety of flavors leads to reduced consumption or quitting or if those who said they had quit stayed quit over time. For these reasons, this study contributes very little to our knowledge of the impact of flavors on cessation.

Another recent study that was reported on in *The New York Times*<sup>189</sup> examined interest in using flavored e-cigarettes among non-smoking teens compared to current smokers, many of whom also use e-cigarettes. The study found that non-smoking teens' interest in using flavored e-cigarettes was very low compared to that of an adult smoker. It is not surprising that the adult smokers in the study, many of whom had already used e-cigarettes, reported higher interest in e-cigarettes as compared to teen never-smokers—what is being measured is interest in flavors in a group predisposed to use of a product versus interest in flavors in a group not predisposed to use the product at all. Further, there is a difference between teens who are committed non-smokers and those teens who display some susceptibility to smoking or who use or have tried e-cigarettes or had used tobacco products more recently. To fully explore the potential impact of flavors, independent studies must also examine this broader group of teens. Finally, the data do not address the question of whether flavors themselves enhance the potential effectiveness of the e-

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never smoked or are former smokers, “suggesting these products contribute to primary nicotine addiction and to renormalization of tobacco use.” McMillen, R, et al., “Trends in Electronic Cigarette Use Among U.S. Adults: Use is Increasing in Both Smokers and Nonsmokers,” at 11.

<sup>187</sup> Legacy at 11.

<sup>188</sup> Farsalinos, K, et al., “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey,” *International Journal of Environmental Research and Public Health* 10:7272-7282, 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/pdf/ijerph-10-07272.pdf>.

<sup>189</sup> Richtel, M, “E-Cigarette Makers Are in an Arms Race for Exotic Vapor Flavors,” *New York Times*, July 15, 2014.



cigarettes as a cessation device. The study does not provide the evidence to support their claims that flavors (beyond tobacco) are necessary to promote full conversion among smokers and does not address to what extent a prohibition on flavors would discourage smokers who otherwise would use e-cigarettes as a means of quitting smoking from doing so.

The burden should be on the industry to demonstrate this effect and to advance evidence that flavors in e-cigarettes do not enhance their appeal to youth and have been tested for toxicity and teratogenicity. If scientific evidence emerges supporting a claim of a therapeutic value of flavors in e-cigarettes, the proper forum for presentation of this evidence is the FDA’s Center for Drug Evaluation and Research (CDER) pursuant to CDER’s authority to regulate e-cigarettes as drugs and devices marketed with therapeutic claims.

The current state of the science, and the experience with other flavored tobacco products, supports a product standard prohibiting characterizing flavors (other than tobacco) in e-cigarettes and all the deemed products.

#### V. FDA SHOULD ISSUE A PRODUCT STANDARD REQUIRING CHILD-RESISTANT CONTAINERS FOR NICOTINE LIQUID PRODUCTS

The unregulated sale of electronic cigarettes and related nicotine liquids is proving to be a direct and immediate threat to the health of our children. As the American Academy of Pediatrics stated in its April 11, 2014 letter to President Obama, immediate action is required to prevent the continued dramatic rise in child poisonings involving e-cigarettes and accompanying liquid nicotine products.<sup>190</sup>

CDC recently reported that the number of calls to poison control centers involving these products increased from one per month in September 2010 to 215 per month in February 2014.<sup>191</sup> In its NPRM on the deeming rule, FDA itself noted that in February 2014, 41.7 percent of the combined calls to poison control centers for conventional cigarettes and e-cigarettes were for e-cigarette exposures.<sup>192</sup> Over 51 percent of those exposures involved children 5 years old and younger.<sup>193</sup> The fact that e-cigarettes are sold with candy flavors makes the threat even more acute.

In addition to being highly addictive, nicotine is a powerful neurotoxin and even tiny amounts absorbed through the skin can cause vomiting and seizures. The label on Altria’s MarkTen e-cigarette product warns, “Nicotine is addictive and habit forming and is very toxic by

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<sup>190</sup> Letter from James M. Perrin, President, American Academy of Pediatrics, to President Barack Obama, April 11, 2014.

<sup>191</sup> CDC, “Calls to Poison Centers for Exposures to Electronic Cigarettes – United States, September 2010-February 2014,” *MMWR* 63(13):292-293, April 4, 2014, at 292, <http://www.cdc.gov/mmwr/pdf/wk/mm6313.pdf>.

<sup>192</sup> 79 Fed. Reg. at 23157.

<sup>193</sup> *Id.* at 23158.

inhalation, in contact with the skin, or if swallowed.” Product packaging for at least three other e-cigarettes (NJOY, MarkTen, and Mystic) have included warnings that state nicotine is “very toxic by inhalation.” A recent letter to the *New England Journal of Medicine* reports the case of a 10-month-old boy who developed “vomiting, tachycardia, grunting respirations, and truncal ataxia” after ingesting a small amount of e-liquid with a nicotine concentration of 1.8 percent.<sup>194</sup> The letter correctly argues that “[l]ack of regulatory oversight has resulted in inconsistent labeling, insufficient or nonexistent child protective packaging and product design and flavoring that may encourage children to explore and ingest these products.”<sup>195</sup>

The unregulated market for e-cigarettes is allowing indiscriminate sale and availability of a dangerous poison, with fruit and candy flavors, in containers that allow easy access to young children. As the Director of a poison control center in California put it, “It’s not a matter if a child will be seriously poisoned or killed. It’s a matter of when.”<sup>196</sup> Because of the special urgency of this threat to our children, FDA should issue a proposed rule adopting a product standard mandating child-resistant containers for liquid nicotine products<sup>197</sup> by September 2014 and issue a final rule establishing such a standard immediately following issuance of a final deeming rule, which should occur no later than April 2015.

## VI. FDA SHOULD ADOPT STRONG HEALTH WARNINGS INFORMING CONSUMERS OF THE ADDICTIVENESS OF NICOTINE AND THE DANGERS OF CIGAR SMOKING

In its NPRM, FDA proposes to require cigar packages and advertising<sup>198</sup> to carry certain health warnings and to require all tobacco products containing nicotine to carry a nicotine health warning. FDA also proposes to apply the nicotine warning to cigarette tobacco and roll-your-own tobacco, which are currently regulated by FDA. These proposed health warnings would promote public health and should be adopted in the final rule. The final rule also should provide for regular FDA review of the effectiveness of the warnings and revision of their content as necessary to ensure their freshness and informative power.

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<sup>194</sup> Bassett, R, et al., “Nicotine Poisoning in an Infant,” *New England Journal of Medicine*, May 8, 2014, <http://www.nejm.org/doi/pdf/10.1056/NEJMc1403843>.

<sup>195</sup> *Id.*

<sup>196</sup> Richtel, M, “Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes,” *New York Times*, March 23, 2014.

<sup>197</sup> To foreclose any argument that some e-liquid containers are “accessories” not covered by the proposed deeming rule, FDA should deem “accessories” to be within its jurisdiction if they have intended or foreseeable effects on public health. This was the approach proposed by FDA before the deeming proposal was reviewed by OMB. The proposed rule as published exempts accessories entirely from the deeming regulation, 79 Fed. Reg. at 23143, which creates the risk that the industry could exploit this loophole to the detriment of public health.

<sup>198</sup> As noted above, however, FDA is considering the option of exempting “premium cigars” from regulation, including the requirement of health warning labels. For the reasons advanced above, we oppose exempting premium cigars and thus urge FDA to require the cigar warnings for all cigars.

A. Strong, Prominent Health Warning Labels on Tobacco Products Are Consistent with the Tobacco Control Act and Are an Effective Tool to Inform Consumers About the Risks of Disease and Addiction

Section 906(d) of the Food, Drug and Cosmetic Act, as amended by the Tobacco Control Act (TCA), gives FDA broad authority to issue regulations requiring “restrictions on the sale and distribution of a tobacco product” if appropriate for the protection of the public health.<sup>199</sup> The requirement of warning labels for cigars and nicotine-containing tobacco products is a reasonable exercise of this authority, in light of the strong policy supporting health warnings reflected in the TCA and the empirical support for their effectiveness in informing consumers about the dangers of tobacco products that may have profoundly adverse effects on their health.

FDA’s proposal for health warnings on the addictiveness of nicotine and the dangers of cigar smoking simply extends, to additional tobacco products, the preexisting strong policy of the TCA supporting health warnings. The TCA amended the Federal Cigarette Labeling and Advertising Act to require larger textual and graphic warning labels conveying to consumers the dangers of cigarettes and amended the Comprehensive Smokeless Tobacco Health Education Act to require larger textual health warnings on smokeless tobacco products. Indeed FDA’s proposal that the warning statements comprise 30 percent of the two principal display panels of the product packages is consistent with the determination Congress made with respect to smokeless products that such placement of the warnings would be effective in informing consumers. FDA’s proposal also is consistent with the international consensus on the effectiveness of health warnings, as reflected in Article 11 of the Framework Convention on Tobacco Control (FCTC), which requires ratifying nations to implement health warnings on cigarette packages that cover at least 30 percent of the surface and are “large, clear, visible, and legible.”<sup>200</sup> According to the World Health Organization’s 2011 report on the Global Tobacco Epidemic, effective warning labels increase smokers’ awareness of health risks and increase the likelihood they will think about reducing tobacco consumption and quitting. Warning labels that meet the FCTC requirements provide the most direct messages to smokers.<sup>201</sup> See Tab K for a summary of warning label status globally.

Studies demonstrate that large text-based warnings lead to increased perceptions of risk and health knowledge. For example, a cohort study in the United Kingdom before and after textual warnings were enhanced in 2003 to meet the minimum FCTC standard found that, after the enhanced warnings were implemented, UK smokers were more likely to think about quitting, to think about the health risks of smoking, and to be deterred from having a cigarette compared to smokers in Australia and the U.S. where smaller warnings did not conform to FCTC

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<sup>199</sup> 21 U.S.C. 387f(d)

<sup>200</sup> WHO Framework Convention on Tobacco Control, Article 11 (2005).

<sup>201</sup> WHO Report on the Global Tobacco Epidemic, 2011, [http://whqlibdoc.who.int/publications/2011/9789240687813\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789240687813_eng.pdf).

standards.<sup>202</sup> Other studies of enhanced textual warnings in EU nations “indicate that smokers’ awareness of the warnings increased following implementation of the new warnings and a considerable proportion of smokers reported measures consistent with increased perception of health risks as a result of more comprehensive text warnings.”<sup>203</sup> In contrast, more obscure warnings that appear on the sides of packages, such as the health warnings implemented in the U.S. in 1984, show low levels of salience.<sup>204</sup> A 2014 study published in *Health Psychology* found that health warnings are effective in changing behavior by making smokers’ think about the risks of smoking. Researchers examined warning labels that differed in size, content and nature (graphic vs. text) and concluded that even text-only warnings that prompt people to think about the health risks of smoking are effective if they are noticed.<sup>205</sup> Thus, the data on the impact of textual warnings supports the effectiveness of warnings similar to those proposed by FDA to apply to the newly-deemed products.<sup>206</sup> We agree with FDA’s view that the existing research on warnings labels on cigarettes and smokeless products supports the effectiveness of the warnings FDA has proposed for the newly-deemed tobacco products.<sup>207</sup>

#### B. A Proposed Warning on the Addictiveness of Nicotine is Appropriate to the Protection of Public Health

FDA proposes to mandate this warning on nicotine-containing tobacco products: “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.” The requirement of a health warning on the addictiveness of nicotine is appropriate for the protection of public health.<sup>208</sup>

A series of reports from the U.S. Surgeon General has established that nicotine is the chemical that makes tobacco products highly addictive. Indeed, the Surgeon General has

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<sup>202</sup> Hammond, D, et al., “Text and Graphic Warnings on Cigarette Packages, Findings from the International Tobacco Control Four Country Study,” *American Journal of Preventive Medicine* 32(3):210-217, 2007, at 215.

<sup>203</sup> Hammond, D, “Health warning messages on tobacco products: a review,” *Tobacco Control* 20(5):327-37, 2011, <http://bmj-tobacco.highwire.org/content/20/5/327.full.pdf+html>.

<sup>204</sup> *Id.* at 329.

<sup>205</sup> Yong, H-H, et al., “Mediational Pathways of the Impact of Cigarette Warning Labels on Quit Attempts,” *Health Psychology*, 2014.

<sup>206</sup> A wealth of evidence indicates that, although large, prominent textual warnings are effective in conveying health information to consumers, their effectiveness may be further enhanced by graphic warnings accompanying the text. *See generally*, Hammond, D. *supra*. FDA has indicated that it will develop a new set of graphic cigarette warnings in response to the Court’s ruling in *R.J. Reynolds Tobacco Co. v. FDA*, (D.C. Cir. 2012) striking down the graphic warnings developed by FDA pursuant to the mandate of the TCA. Graphic warnings may also prove appropriate to the public health as applied to certain deemed products as well. Moreover, the graphic warnings developed by FDA in response to the TCA mandate should be enforced against cigarettes masquerading as small cigars. *See* discussion at Sec. IV.C. *supra*.

<sup>207</sup> 79 Fed. Reg. at 23165.

<sup>208</sup> FDA should consider rewording this warning to make it easier to understand for all consumers, including those less educated and less skilled in reading comprehension. For example, the concept of nicotine “derived” from tobacco may introduce unnecessary complexity. A simpler alternative would be “WARNING: This tobacco product contains nicotine. Nicotine is an addictive chemical.”

compared the addictiveness of nicotine to that of heroin and cocaine.<sup>209</sup> The impact of nicotine on adolescents is of particular concern. Research suggests that the adolescent brain is more vulnerable to nicotine addiction than the adult brain. The Surgeon General has noted that key symptoms of nicotine dependence – such as withdrawal and tolerance – develop in adolescents following even minimal exposure to nicotine. The Surgeon General’s 2012 report cites one study following occasional adolescent smokers and finding that a large proportion experienced at least one symptom of nicotine dependence upon quitting, even in the first four weeks after initiating monthly smoking (at least two cigarettes within a 2-month period).<sup>210</sup> As FDA notes, research shows that more than 80 percent of established adult smokers began smoking before the age of 18.<sup>211</sup> The vulnerability of adolescents to nicotine is the reason they continue smoking. As a result of nicotine addiction, about three out of four teen smokers end up smoking into adulthood, even if they intend to quit after a few years.<sup>212</sup> Indeed, research has shown that adolescents have little understanding of the grip of nicotine. One study found that 60 percent of adolescents believed that they could smoke for a few years and then quit.<sup>213</sup>

As FDA notes, the misperception among youth that they can overcome nicotine and quit using tobacco products when they choose to do so is reinforced by the absence of nicotine warnings on certain tobacco products.<sup>214</sup> Although the TCA requires addiction warnings for cigarettes and smokeless tobacco, the absence of such warnings on products like cigars and electronic cigarettes may suggest to young people that such products pose little or no risk of addiction.

This prospect is particularly troubling because there is no question that significant numbers of young people are using these products. The 2013 Youth Risk Behavior Survey shows that one in six (16.5 percent) high school boys currently smoke cigars.<sup>215</sup> Each day more than 2,700 kids under 18 years old try cigar smoking for the first time, approaching the 3,200 who try cigarettes for the first time every day.<sup>216</sup> Adolescent use of electronic cigarettes also is becoming significant. According to results from the National Youth Tobacco Survey, the percentage of high school students who reported ever using e-cigarettes jumped from 4.7 percent in 2011 to 10 percent in 2012, while the percentage using e-cigarettes in the past 30 days rose from 1.5 percent to 2.8 percent. Use also doubled among middle school students. The CDC

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<sup>209</sup> HHS, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*, 1988, at vi, <http://profiles.nlm.nih.gov/ps/access/NNBBZD.pdf>.

<sup>210</sup> HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Attorney General*, 2012, at 24, (citing DiFranza, et al.)

<sup>211</sup> 79 Fed. Reg. at 23155.

<sup>212</sup> 2012 Surgeon General’s Report.

<sup>213</sup> Institute of Medicine of the National Academies, *Ending the Tobacco Problem: A Blueprint for the Nation*, 2007, at 91.

<sup>214</sup> 79 Fed. Reg. at 23166.

<sup>215</sup> 2013 YRBS.

<sup>216</sup> SAMHSA, *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*, 2013.

estimated that 1.78 million U.S. youth had used e-cigarettes as of 2012.<sup>217</sup> It is critical to public health that young people, and the general public, be adequately informed about the danger of nicotine addiction.<sup>218</sup>

It is noteworthy that the need to inform consumers about the addictiveness of nicotine has been implicitly recognized by a number of manufacturers of electronic cigarette products. A recent investigation by the staffs of eleven U.S. Senators and Representatives of the practices of nine of the largest electronic cigarette manufacturers revealed that, although their product warning labels “lack uniformity and may confuse consumers,” six of the nine companies had some form of nicotine warning as part of their packaging or instructions for use in addition to the nicotine warning mandated by the State of California.<sup>219</sup> These voluntary warnings fall far short of the FDA’s proposed requirement (or international standards) in terms of size and prominence, but they reflect the companies’ own recognition that their products are addictive and that consumers should be informed of their addictive properties.

C. The Proposed Warnings on the Dangers of Cigars Are Appropriate to the Protection of Public Health

FDA proposes the following warning labels for cigars:<sup>220</sup>

WARNING: Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even If You Do Not Inhale.

WARNING: Cigar Smoking Can Cause Lung Cancer and Heart Disease.

WARNING: Cigars Are Not a Safe Alternative to Cigarettes

WARNING: Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers

As FDA notes, each of these warnings is already required under the 2000 FTC consent orders involving the seven largest cigar manufacturers.<sup>221</sup> The proposed rule would enhance public health by extending the health labeling requirement beyond the seven manufacturers currently required to apply them, by providing for random display on cigar packages and

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<sup>217</sup> CDC, “Tobacco Product Use Among Middle and High School Students—United States, 2011 and 2012,” *MMWR* 62, November 15, 2013 <http://www.cdc.gov/mmwr/pdf/wk/mm6245.pdf>.

<sup>218</sup> The undersigned organizations also support FDA’s proposal to require this alternative statement on any tobacco product that does not contain nicotine: “This product is derived from tobacco.” Consumers have the right to know that a product is derived from tobacco regardless of whether it contains nicotine. In addition, FDA should be vigilant in monitoring the market for products that contain nicotine, even though their manufacturers and sellers represent them as nicotine-free, and should be aggressive in bringing enforcement actions against such companies.

<sup>219</sup> Durbin, R, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*,” April 14, 2014.

<sup>220</sup> 79 Fed. Reg. at 23163.

<sup>221</sup> *Id.* at 23163.

rotation in advertisements, and by requiring point-of-sale warnings for cigars sold individually that are not packaged.

The substance of each warning is strongly supported by the available scientific evidence.

1. Cigar smoking and cancers of the mouth and throat

As noted above, the overall risk of oral and pharyngeal cancers is similar for cigar smokers and cigarette smokers, with an overall risk 7 to 10 times higher than for never-smokers.<sup>222</sup> This is probably due to the similar doses of tobacco smoke delivered directly to these areas by cigars and cigarettes.<sup>223</sup> NCI Monograph 9 established that “regular cigar smokers who have never smoked cigarettes, even those who do not inhale, experience significantly elevated risks for cancers of the larynx, oral cavity (including pharynx), and esophagus.”<sup>224</sup>

2. Cigar smoking and lung cancer and heart disease

NCI Monograph 9 concluded that “the data clearly establish cigar smoking as a cause of lung cancer.”<sup>225</sup> It found that “[o]verall, lung cancer risks for cigar smokers may be similar to those seen in cigarette smokers once they are adjusted for differences in level of inhalation and quantity of tobacco smoked per day.”<sup>226</sup> As noted above, even cigar smokers who do not inhale are at increased risk of lung cancer.

NCI Monograph 9 also drew on data from the Cancer Prevention Study I, which studied nearly 1 million men and women in 25 states, to find a pattern of increasing rates of coronary events with increasing numbers of cigars smoked per day. Based on this and other studies, Monograph 9 concluded that “cigar smokers who smoke several cigars per day or who inhale are at increased risk for coronary heart disease.”<sup>227</sup> An analysis of data in Cancer Prevention Study II showed that among men younger than 75 years, current cigar smokers experienced a death rate from coronary heart disease about one third higher than those who had never smoked, a relationship not limited to men who reported inhaling cigar smoke.<sup>228</sup>

As noted previously, since the NCI Monograph was published in 1998, there has been considerable change in the cigar products on the market.<sup>229</sup> As a result, more cigar smokers could be inhaling from their products, which means more of them are at a higher risk of developing lung cancer or heart disease.

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<sup>222</sup> NCI Monograph 9, at 125.

<sup>223</sup> Baker, et al., at 738.

<sup>224</sup> NCI Monograph 9, at ii.

<sup>225</sup> *Id.* at 120.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.* at 144-45.

<sup>228</sup> Baker et al., at 739.

<sup>229</sup> *Not Your Grandfather's Cigar*, at 3-4.

### 3. Cigars are not a safe alternative to cigarettes

The evidence indicates that there is a widespread perception, particularly among young people, that cigars are less hazardous than cigarettes and this perception may be contributing to the incidence of cigar smoking.

One study found that adult cigar smokers in general are three times more likely to believe cigars are a safer alternative to cigarettes compared to those who do not smoke cigars.<sup>230</sup> This perception is especially evident in young people. An online survey of college students at six colleges in the southeastern U.S. found that smokers of little cigars and cigarillos “were more likely to report perceiving the harm of little cigars, cigarillos, and cigars to be less than that of cigarettes” compared to nonusers.<sup>231</sup> A study of middle and high school students in Massachusetts found that 34.9 percent of current youth cigar users agreed that “cigars are not as bad for you as cigarettes,” where only 12.2 percent of the total study population of students agreed with the statement.<sup>232</sup> Similarly, a focus group study of 230 middle school, high school and college students by the HHS Inspector General’s (IG) office found that 30 percent of teen cigar users made the statement that compared to cigarettes, cigars are less risky, whereas only 10 percent of teens with no cigar experience made that statement.<sup>233</sup> Cigar smoking teens expressed a comparable view when comparing the risk of cigars to spit tobacco products. The IG concluded: “What seems clear about teens’ assessment of the disease risks of cigar smoking is that they are not receiving sufficiently explicit information to clearly articulate the true health hazards of cigars.”<sup>234</sup>

Given the substantial risk of disease from cigar smoking, it is imperative that consumers, and particularly the young, be informed that cigars are not safe alternatives to cigarettes.

### 4. Lung cancer and heart disease in nonsmokers

According to the Surgeon General, a causal relationship exists between secondhand smoke exposure and lung cancer among lifetime nonsmokers; indeed, individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from secondhand

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<sup>230</sup> Nyman, AL, et al., “Trends in cigar smoking and perceptions of health risks among Massachusetts adults,” *Tobacco Control* 11(Suppl II):ii25-ii29, 2002,

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1766069/pdf/v011p0ii25.pdf>.

<sup>231</sup> Sterling, K, et al., “Factors Associated With Small Cigar Use Among College Students,” *American Journal of Health Behavior* 37(3):325-333, May 2013,

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3757522/pdf/nihms450226.pdf>.

<sup>232</sup> Soldz, S & Dorsey, E, “Youth Attitudes and Beliefs Toward Alternative Tobacco Products: Cigars, Bidis, and Kreteks,” *Health Education & Behavior* 32(4):549-266, August 2005.

<sup>233</sup> HHS, *Youth use of cigars: patterns of use and perceptions of risk*, Washington, D.C.: Office of the Inspector General, OEU 06-98-00030, 1999, at 22.

<sup>234</sup> *Id.* at 20.



exposure.<sup>235</sup> The Surgeon General also has found that exposure of adults to secondhand smoke has immediate adverse effects on the cardiovascular system and causes coronary heart disease, finding a 20 to 30 percent increase in the risk of coronary heart disease above that of persons not exposed to secondhand smoke.<sup>236</sup> Given that all cigars produce higher levels of toxicants than cigarette smoke, as noted previously, the science clearly supports the proposed warning of the risk of lung cancer and heart disease to nonsmokers.

D. In Addition to the Four Proposed Cigar Warnings, FDA Should Require the Existing FTC Warning on the Reproductive Effects of Tobacco Use

FDA proposes not to mandate the fifth FTC cigar warning concerning the reproductive effects of cigar smoking (WARNING: Tobacco Use Increases the Risk if Infertility, Stillbirth and Low Birth Weight) because “the Agency is not aware of studies specifically linking cigars to these reproductive effects.”<sup>237</sup> It makes this proposal to omit the fifth warning despite acknowledging that “cigarette smoking has been shown to cause these health effects and cigar smoke is similar. . . .”<sup>238</sup>

That cigarette smoking has been shown to cause these reproductive effects, along with the similarity between the toxicity of cigarette smoke and cigar smoke, should be sufficient to support an inference that cigar smoking causes these effects as well. Therefore, the fifth FTC warning should be mandated by FDA.

The Surgeon General’s 2010 Report, *How Tobacco Smoke Causes Disease*, finds causal links between cigarette smoking and a heightened risk of impaired fertilization, miscarriage and preterm delivery, lowered birth weight and other adverse reproductive effects.<sup>239</sup> Moreover, NCI Monograph 9 finds that “cigar smoke is as, or more, toxic and carcinogenic than cigarette smoke. . . .”<sup>240</sup> Monograph 9 does find a difference in risk between cigarette smokers and cigar smokers. This risk differential results from two primary factors affecting exposure to tobacco smoke: (1) the fact that, unlike cigarette smokers, a majority of cigar smokers do not inhale, and (2) cigars are generally smoked less frequently than cigarettes.<sup>241</sup> However, as depth of inhalation and frequency of use increases, the disease risk from cigars approaches that of cigarettes.<sup>242</sup> Monograph 9 also finds that the risks are more similar for the “sizeable fraction” of cigar smokers who are current or past cigarette smokers.<sup>243</sup> Monograph 9 finds that “[t]hese individuals are much more likely to continue to inhale when they switch to smoking cigars, and may therefore remain at much higher risk for all the major smoking related diseases than are

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<sup>235</sup> 2006 SG Report, at 445.

<sup>236</sup> *Id.* at 15.

<sup>237</sup> 79 Fed. Reg. at 23168.

<sup>238</sup> *Id.*

<sup>239</sup> 2010 SG Report, at 612.

<sup>240</sup> NCI Monograph 9, at 3.

<sup>241</sup> *Id.* at ii-iii.

<sup>242</sup> *Id.* at 112; Baker et al, at 739.

<sup>243</sup> *Id.* at iii.

cigar smokers who have never smoked cigarettes.”<sup>244</sup> Thus, the exposure of many cigar smokers to the toxins in tobacco smoke is similar to the exposure of cigarette smokers.

On the issue of reproductive effects of cigars, Monograph 9 observes that “[d]ata on the risks of cigar smoking during pregnancy are not sufficient to define the risks, *but there is no reason to expect that cigar smoke would be any less toxic for the mother or fetus. Regular cigar smoking, particularly with inhalation, should be presumed to have risks similar to that of cigarette smoking for the pregnant smoker.*”<sup>245</sup> For these same reasons, FDA should conclude that the evidence is sufficient to justify a warning that cigar smoking has adverse reproductive effects.

E. FDA Should Ensure that the Warning Labels Remain Fresh and Effective, and are Updated to Reflect New Scientific Evidence of Health Effects

Science demonstrates that the effectiveness of specific health warnings is likely to deteriorate over time. To ensure that the warning labels remain as effective as possible, FDA should establish a target schedule for review of the warnings to evaluate their effectiveness. Such a schedule should call for ongoing consumer research and re-examination of the adequacy of existing warning labels at no more than a one-year interval. There should be a presumption that new labels will be required at no more than a two-year interval. Introduction of new labels may also be required to convey newly available information about the dangers of a tobacco product or additional research indicating that certain warnings are particularly effective.

VII. FDA SHOULD TIGHTEN THE PREMARKET REVIEW PROVISIONS FOR NEW PRODUCTS, INCLUDING SUBSTANTIALLY EQUIVALENT PRODUCTS

A. The Existing Statutory Structure for New Products

The proposed rule would apply the basic principles of the premarket review sections of the Tobacco Control Act (Sections 905j and 910) to the deemed products. Premarket review is an essential authority under the Tobacco Control Act. Prior to the Act, there was no limitation on the introduction of new products or the modification of existing tobacco products. As a result, in the absence of regulation manufacturers continually introduced new products that were more addictive, more lethal, and more appealing to kids. The Tobacco Control Act requires premarket review of new and modified tobacco products in order to prevent the marketing of new and modified products unless the manufacturer has submitted scientific information demonstrating the effects of the new product on public health and FDA has issued an order permitting its marketing. The newly deemed products are changing rapidly and FDA cannot protect the public health unless manufacturers are required to comply with these provisions.

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<sup>244</sup> NCI Monograph 9, at 3.

<sup>245</sup> *Id.* at 10 (emphasis added).

Under the statute any product introduced into commerce after February 15, 2007 or modified after that date is a “new tobacco product” and may be marketed only if it meets the requirements of those sections. The statute creates three alternative pathways to market for new tobacco products: (1) through the grant by FDA of a new product application under Section 910; (2) through the provisions of Section 905(j) and 910 for new tobacco products that are “substantially equivalent” to a product that was marketed on February 15, 2007; or (3) through an exemption for “minor modifications” granted by FDA from the substantial equivalence requirements of Section 905(j)(3).

Section 910 directs FDA not to grant a new product application unless the manufacturer has demonstrated that introduction of the product would be “appropriate for the protection of the public health,” taking account of the risks and benefits to the population as a whole. FDA has issued draft guidelines for the submission of new product applications. No manufacturer has yet submitted a new product application. The exemption process under Section 905(j)(3) for “minor modifications” is available only to products that were commercially marketed on February 15, 2007 and that were modified only by the addition or deletion of an additive. Although 61 applications for “minor modification” exemptions have been filed, none have been granted and no tobacco product is currently marketed pursuant to this provision.<sup>246</sup> Thus, the only pathway to marketing for any “new” cigarette, smokeless tobacco product, or roll-your-own product (i.e., any such product not marketed on February 15, 2007 or modified after that date) has been through applications for “substantial equivalence.”

Section 910 of the statute creates two different categories for products as to which substantial equivalence applications are filed. Although the statute was enacted on June 22, 2009, manufacturers were permitted to continue to sell tobacco products they had introduced or modified subsequent to February 15, 2007 and to continue to introduce new or modified tobacco products into commerce until March 22, 2011, provided they filed a substantial equivalence application for any such products by that date. Pursuant to the statute, products for which a substantial equivalence application had been filed by that date can continue to be sold unless and until FDA denies the substantial equivalence application. In essence, the statute created a “compliance or grace period” lasting until March 22, 2011 in which manufacturers were allowed to continue to market new products provided they filed a substantial equivalence application by that date. After March 22, 2011, manufacturers were still permitted to file substantial equivalence applications but they could not market their product unless and until FDA granted the application.

In contrast, the statute did not create a compliance or grace period for new products that were not alleged to be substantially equivalent to a predicate product (i.e., a product that was

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<sup>246</sup> As of March 31, 2014, 36 such applications had been denied and 25 remained pending. Government Accountability Office, *Tobacco Product Regulation: Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities*, Report No. 14-561, June 20, 2014, at 24, Table 4 (GAO report).

marketed on February 15, 2007). Thus, a manufacturer wishing to market a new product pursuant to Section 910 for which a substantial equivalence application had not been filed could not do so after March 22, 2011 unless and until FDA granted a new product application.

#### B. New Products under FDA's Proposed Deeming Rule

Application of the statute to the deemed products would require that no such products introduced or modified subsequent to February 15, 2007 could continue to be marketed unless and until FDA granted a new product application, a substantial equivalence application, or an exemption. These products could not continue to be marketed legally pending action on their substantial equivalence applications because such applications would have been submitted after March 22, 2011.

The proposed deeming rule acknowledges that the statutory definition of a “new tobacco product” contains a specific date, February 15, 2007, and provides that any product introduced or modified subsequent to that date is a “new tobacco product.” In our view, FDA correctly concludes that it does not have discretion to alter that date. If the language of these sections of the statute were to be applied to newly deemed products introduced or modified after February 15, 2007, they would be illegal and would be required to be withdrawn from the market pending FDA's completion of its review process.

Thus, the only way such deemed products can remain on the market is for FDA in its enforcement discretion to permit them to remain on the market. FDA has proposed to exercise its enforcement discretion by not enforcing the prohibition against newly deemed products for 24 months from the date a Final Rule is issued, provided that the manufacturer files an application for a marketing order within that 24-month period. Moreover, if the manufacturer files such an application within that period, FDA proposes that the newly deemed product can remain on the market unless and until FDA denies such an application.

This general approach has similarities to the statutory structure applied to substantial equivalence filings for cigarettes and smokeless tobacco but differs in two respects. First, the grace period given for compliance for cigarettes and smokeless products was created by statute; the grace period provided for newly deemed products is entirely an exercise of FDA's enforcement discretion. Second, FDA's proposal for newly deemed products differs from the compliance period created by the statute for cigarettes and smokeless tobacco products in that it would apply not only to products for which substantial equivalence applications are filed but also to products for which new product applications are filed.

### C. Evaluation of the Proposed Compliance Period

1. FDA's exercise of its enforcement discretion to allow the continued marketing of newly deemed products that would otherwise be illegal can be made consistent with FDA's public health mandate if certain conditions are required.

The policy of the statute is to require premarket authorization for the marketing of new tobacco products. This policy was established in recognition of the fact that over the course of many decades the introduction of new tobacco products has been detrimental to public health.<sup>247</sup> Exceptions to this policy should therefore be justified by substantial reasons and should be drawn no more broadly than necessary to serve such reasons. This is even more true for products, such as e-cigarettes, for which little is known about the product, its contents, and the actual public health impact of the product.

In the absence of a compliance period similar to that created by statute for substantial equivalence applications for cigarettes and smokeless tobacco products, all deemed products would have to be removed from the market on the effective date of the final order because no substantial equivalence application had been filed by March 22, 2011. FDA has proposed to exercise its enforcement discretion to create a grace period in order to permit manufacturers who may be able to establish that their products are either substantially equivalent to a product marketed on February 15, 2007, or that their products meet the requirements for the marketing of a product under Section 910, to have a reasonable opportunity to present their applications to the FDA without having to remove their products from the market during the pendency of their applications.

FDA proposes to do this by not initiating enforcement actions against such products, provided that manufacturers file either a substantial equivalence application, an application for exemption from substantial equivalence requirements, or a new product application by the date on which the compliance period ends. A manufacturer taking advantage of this opportunity would be permitted to continue marketing the product during the compliance period and would also be permitted to continue marketing the product after the expiration of the compliance period unless and until FDA denied its application.

Such a proposal has the disadvantage of prolonging the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order. Some cigars and other combusted products may qualify as existing products if they were on the market on February 15, 2007 and if they have not been modified since that date. Some such products may be found to be substantially equivalent to a predicate

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<sup>247</sup> See Comments of the Campaign for Tobacco-Free Kids in Docket Nos. FDA-2010-D-0635, FDA-2011-D0-0147, and FDA-2010-N-0646, January 28, 2013, at 11-23.

product. It is unclear how many e-cigarette products will be found to be existing products (i.e., products marketed on February 15, 2007) or substantially equivalent to predicate products.

FDA proposes to permit deemed products that would otherwise be illegal under the statute to continue to be marketed for a specific period of time under FDA's enforcement discretion. Such action should not be considered unless proper precautions are taken to limit the time period these products are allowed to remain on the market without being reviewed by FDA and further provided that satisfactory conditions are established for these products during the interim period to adequately protect the public health, such as ensuring that these products are not marketed to youth.

If no conditions are placed on the marketing of these products during this period, manufacturers will be free to continue to market these products in ways that appeal to youth and to manipulate the content of these products in wholly uncontrolled ways for an indefinite period. In light of the irresponsible marketing of these products and the growth in their sales between the time FDA announced its intent to assert jurisdiction over these products and the date on which FDA announced its proposed rule, it would be inconsistent with FDA's public health mandate to allow these otherwise illegal products to continue to be marketed without any constraints on their marketing and with no controls over their content.

Therefore, FDA's exercise of its enforcement discretion should be conditioned on the following:

- The compliance period should be no longer than the 12 months originally proposed by FDA to permit manufacturers to prepare and submit appropriate applications for marketing orders;
  - The right to market deemed products during the compliance period should be conditioned on compliance with requirements designed to ensure that the product is not being manufactured or marketed in ways that appeal to minors; and
  - There are appropriate provisions to ensure that such products are not permitted to remain on the market for unreasonably long periods of time pending FDA review of the applications.
2. Conditions that should apply in order for products to qualify for the compliance period.
    - a. The compliance period in the proposed regulation should be limited to 12 months after the date the final regulation is promulgated, as FDA originally proposed.

The purpose of affording an interval for manufacturers of the deemed products to file a substantial equivalence or a new product application is to permit them to gather the information

necessary for the filing of the application and to prepare the application. However, because the public is thereby exposed during the compliance period to some products whose dangers are unknown and all of which contain nicotine, an addictive substance, in uncontrolled and unmonitored levels and that have not been subject to any review by the FDA, the compliance period should be no longer than necessary to permit such applications to be prepared and filed. The dangers are particularly acute for youth who, exposed to the unconstrained marketing of such products, may experiment with and become addicted to such unreviewed products during the compliance period.

The proposed deeming rule FDA originally submitted to OIRA included a compliance or grace period of 12 months from the date a final rule is promulgated. OIRA doubled the length of the compliance period to twenty-four months from the date a final rule is promulgated. The 12-month period following the date a final rule is promulgated originally proposed by FDA is long enough to permit manufacturers to prepare and submit their applications. Manufacturers are already on notice that such applications would be required. Provision of a year, beginning the date of such a final rule, provides ample time for the preparation and submission of such an application.

Extending the compliance period by an additional year, as OIRA apparently has proposed, would unnecessarily prolong the period during which manufacturers would be free to market and introduce new products without FDA review or the grant of a marketing order. As noted above, creation of such a compliance period is an exception to the statutory policy prohibiting the introduction of new products unless FDA has granted a marketing order. The compliance period in the final rule should be no longer than twelve months following promulgation of the final rule.

- b. Eligibility for the compliance period should be conditioned on a manufacturer's adherence to marketing practices that avoid marketing that appeals to youth.

The marketing of any newly deemed tobacco product that was not marketed on February 15, 2007 or that was modified since that date would be illegal as of the date of a final deeming rule in the absence of an FDA order finding that the marketing of the new product is appropriate for the protection of the public health or that the product is substantially equivalent to a product marketed on that date. The statute requires the issuance of a premarket order for new products because the tobacco industry had used the introduction of new products to addict new users and to prevent existing users from quitting by providing alternatives that would prolong their addiction. Despite this requirement and the strong policy reasons underlying it, FDA has proposed to permit manufacturers to keep products on the market for a period of time after the issuance of a final deeming rule and to permit the introduction of new products after that date without FDA's grant of a marketing application. This policy represents an extraordinary departure from the statutory requirements applicable to cigarettes and smokeless tobacco

products. FDA's proposal would be implemented through an administrative policy of (1) refraining from taking enforcement actions against such products during the compliance period and (2) permitting such products to stay on the market after the expiration of the compliance period unless and until FDA denies such applications.

One of the factors that weighs against such a policy is the fact that many of the newly deemed products are being actively marketed to children. All tobacco products—including cigars, e-cigarettes, and hookah—contain nicotine and are highly addictive. Moreover, the extensive findings in the announcement of the rule regarding the harmful and permanent effects of nicotine on the brain make it imperative for FDA to avoid policies that would facilitate the continued marketing of deemed tobacco products to minors.

It is appropriate to require that no tobacco product that is being marketed in a way that appeals to children should be eligible for the compliance period provided by the proposed rule. These comments have discussed in detail the importance of extending the provisions of the 2010 rule against marketing cigarettes to children to the deemed products. Accordingly, FDA should require that manufacturers who market newly-deemed products during the compliance period must comply strictly with such requirements. These include a prohibition on non-face-to-face sales of such products, including a prohibition on internet sales; a prohibition on the use of free samples; a prohibition on the sale of any such products in self-service displays; a prohibition on the use of tobacco brand names on non-tobacco merchandise; a prohibition on brand name sponsorship of events; and a requirement for manufacturers to notify FDA of advertising as provided in the 2010 regulations.

The reasons why these provisions are necessary to prevent the marketing of these products to children are set out in detail in Section III of these comments. No manufacturer should be permitted to take advantage of the compliance period for the marketing of new products unless it demonstrates that it is in compliance with all such provisions. It is critical that FDA address the need to regulate the marketing of these products to protect public health promptly. It should do so by incorporating such regulations in the final version of the proposed rule, but whether it does so or not in the final rule, newly deemed products that would otherwise be illegal should be allowed to be marketed during the grace period only if rules are in place to prevent them from being marketed in ways that appeal to youth.

In addition to applying the specific requirements of the 2010 youth marketing rule, FDA should also require manufacturers that would be permitted during the compliance period to market products that would otherwise be illegal to agree formally not to target youth in the advertising, marketing, and promotion of such products. This provision, which already applies to cigarettes and smokeless tobacco products marketed by manufacturers who are parties to the tobacco Master Settlement Agreement of 1998 and the Smokeless Tobacco Master Settlement Agreement of 1998, should be required of manufacturers who are permitted to market products during the compliance period that would otherwise be illegal but for FDA's decision not to



enforce the premarket review requirements of the Tobacco Control Act during the compliance period. As documented above (see Section III.B.), tobacco product manufacturers are currently appealing to youth in the advertising, marketing and promotion of these products in much the same way that they successfully targeted youth in the marketing of cigarettes. Moreover, this strategy is succeeding as the number of children experimenting with and becoming addicted to these products increases rapidly.

The marketing tactics being used include but are not limited to practices specifically prohibited by the 2010 youth marketing restrictions promulgated with regard to cigarettes and smokeless tobacco products. They include advertisements featuring performers popular with adolescents, crude and blatant appeals to adolescent preoccupation with sex, and the association of tobacco products with images designed to appeal to adolescents. Tobacco companies that piously disclaim an intention to market to young people continue the same marketing practices with respect to the newly deemed tobacco products that have created and sustained the youth tobacco epidemic with respect to cigarettes.

FDA should not grant special exemptions from the enforcement of important legal requirements to companies that continue to engage in such practices. Nor is it required to do so. Permitting a compliance period for newly deemed tobacco products is discretionary with FDA and FDA should exercise its discretion in accordance with the fundamental purposes of the Tobacco Control Act. No purpose is more fundamental than protecting young people from tobacco products. No tobacco company has a right to sell such products to children and no tobacco company has a right to market its products in a manner designed to appeal to children. FDA should not accord what amounts to an exemption from enforcement authority to any company that engages in such practices.

Accordingly, if FDA chooses to establish a compliance period during which tobacco companies will be permitted to sell new deemed products that otherwise would be illegal, it should require any manufacturer, as a condition of taking advantage of such a policy, to identify all products marketed under such provisions within 30 days of the issuance of a final rule, to agree to comply with the above noted marketing restrictions that apply to cigarettes and to agree not to otherwise advertise, market, or promote such products in ways that appeal to underage users, to provide documentation demonstrating compliance with this undertaking, and to make compliance with this undertaking an explicit condition of its being granted a substantial equivalence application or a new product application for any such product. FDA should not exercise its discretion to grant an exemption from the enforcement of legal requirements to any manufacturer that fails to meet these requirements.

- c. Eligibility for the compliance period should also be conditioned on requirements regarding ingredient disclosure and consistent delivery of nicotine and other components.

FDA should not exercise its discretion to withhold enforcement of premarket review provisions unless manufacturers meet other requirements as well. All ingredient information about products on the market as of the date the final rule is promulgated should be submitted to FDA no later than 90 days after promulgation of the final rule, including the nicotine content and nicotine yield, and test data demonstrating precisely what a consumer is receiving. Any product on the market as of such date for which such information has not been timely provided should be deemed an adulterated product. Manufacturers of products not on the market as of the date the final rule is promulgated should submit such information to FDA 90 days prior to marketing their product.<sup>248</sup>

As a condition of eligibility for the compliance period, FDA should require manufacturers to demonstrate the ability to produce consistently a product that meets specifications with regard to nicotine content and the content of all other components of the product. Such requirements should become effective as early as possible following the date a final rule is promulgated and should not be delayed until after the close of the compliance period. No manufacturer of e-cigarettes should be eligible for the compliance period unless it can demonstrate that its manufacturing process meets such requirements.<sup>249</sup> Previous analysis of two leading electronic cigarette products by FDA’s Center for Drug Evaluation showed that “quality control processes used to manufacture these products are inconsistent or non-existent” and that there was a high degree of variability in different samples of the same product.<sup>250</sup>

- d. FDA must ensure timely review of applications for products submitted during the compliance period.

Experience with the nearly 3,600 “provisional” substantial equivalence applications submitted by March 22, 2011 demonstrates the importance of insuring that priority be given for the process for reviewing such applications regarding the deemed products so that they do not remain on the market indefinitely without having been subjected to review.<sup>251</sup> More than three years after the applications were submitted, nearly all these 3,431 products remain on the market

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<sup>248</sup> This requirement is analogous to the requirement imposed by Section 904(c)(1) for manufacturers of cigarettes and smokeless tobacco products not on the market prior to the date of enactment of the Tobacco Control Act to provide such information 90 days prior to the introduction of the product into commerce.

<sup>249</sup> FDA has authority to establish standards for good manufacturing practices under Section 906. It has proposed to establish such standards for cigarettes (Docket No. FDA-2013-N-0227) but has not issued such standards. The undersigned organizations filed comments in that docket urging FDA to act promptly to establish such standards and continue to believe that it is important for FDA to do so. Regardless of when FDA establishes such standards for cigarettes, however, FDA should insist, as a condition of establishing a compliance period for deemed products, that manufacturers of these products can consistently produce products to specifications.

<sup>250</sup> <http://www.fda.gov/newsevents/publichealthfocus/ucm173146.htm>, accessed July 30, 2014.

<sup>251</sup> See GAO report, *supra*, at 42-43.

pending a FDA’s ruling even though FDA has not found that any of them meet the statutory standard.

The possibility that this unfortunate pattern would be repeated for newly deemed products is a legitimate concern that FDA should address. Manufacturers, knowing that submission of an application—however incomplete or deficient—will permit them to market products for years, have every incentive to file as many applications as possible. FDA should not create a compliance period for newly deemed products unless it can ensure that it will promptly reject applications that do not meet the statutory requirements.

If FDA creates a process similar to that in existence for products already covered by the statute it should adopt several policies designed to avoid a repetition of the unsatisfactory experience that has resulted to date. First, FDA should devote sufficient resources to the processing of these applications to permit an early evaluation of their merit. There must be a process that permits FDA to identify unmeritorious or incomplete applications promptly. When FDA identifies such applications, it should deny them, or give manufacturers a one-time opportunity to supplement them, rather than permitting manufacturers repeated opportunities to correct flaws in the application while continuing to sell the products. Products for which incomplete or defective applications are filed should be required to be withdrawn from the market unless and until an application is granted.

The process FDA has proposed for substantial equivalence applications for deemed combusted products that will remain on the market pending FDA action on such applications is not adequate to protect the public health unless the following conditions are imposed for such applications.

- (i) FDA should give first priority to the review of applications for products for which applications are filed by the submission deadline rather than focusing all of its resources on applications for products filed subsequent to the deadline. It is important for the public to be protected against products that are already on the market but do not meet the standards for substantial equivalence. Such a policy differs from the approach FDA has adopted with regard to its review of substantial equivalence applications for cigarettes and smokeless products.
- (ii) FDA should make it clear that applications must be *complete* by the date that is one year after the promulgation of the final rule and that applications that are not complete by that date will be rejected. Manufacturers can avoid rejections for incompleteness by submitting applications earlier than the due date and by consulting with FDA staff during the period between now and the submission deadline to determine what information would be required to make the application complete. For its part, FDA should make staff available for such consultations and provide clear responses to manufacturers.

- (iii) Once applications are submitted FDA should review them promptly. Applications that are either deficient or incomplete should be promptly rejected and the products covered by them should be removed from the market. Manufacturers should not be allowed to game the system by submitting inadequate applications and being allowed to market the product indefinitely pending FDA action.
- (iv) FDA should establish a target date for completion of the review of such applications. If FDA makes it clear to manufacturers from the outset that applications that are incomplete as of the submission date will be rejected, there is no reason why such review should not be completed promptly.
- (v) FDA should maintain clear records of all contacts with manufacturers regarding such applications so that it can document all such contacts if and when a manufacturer challenges a negative determination.

#### D. Substantive Standards for Review of Substantial Equivalence Applications

Assuming a substantial equivalence application is found to be complete, FDA should apply standards for determining substantial equivalence that are as strict as those applicable to cigarettes. There is no reason why such standards should be any less rigorous. These standards should include at least the following elements:

- The burden of proving each and every element of substantial equivalence is on the manufacturer;
- A tobacco product must be found substantially equivalent to a single predicate product;
- The statutory standard requiring that characteristics of a new product be “the same” as characteristics of the predicate product has a quantitative as well as a qualitative dimension and the words of the statute should be given the literal meaning;
- Increases in the likelihood of initiation or relapse by nonusers and decreases in the likelihood of cessation by existing users are “questions of public health” as that term is used in the definition of “substantial equivalence”;
- In order to satisfy the requirements for substantial equivalence, tobacco product manufacturers must demonstrate that modifications to a tobacco product are not likely to increase initiation of tobacco use, particularly by youth, even where the modification increases neither the toxicity nor the abuse liability of the product.

FDA can make it clear that these elements apply by promptly extending the applicability of the guidance for substantial equivalence applications for products already subject to FDA regulation to the newly deemed products. In doing so, FDA should supplement such guidance—both with regard to products already subject to FDA regulation and to deemed products—based on the results of decisions made on substantial equivalence applications since the guidance was promulgated in 2011.

The requirements for demonstrating that a new tobacco product is substantially equivalent to a product marketed on February 15, 2007 are less rigorous than those for demonstrating that the marketing of a new tobacco product is “appropriate for the protection of the public health.” However, there is significant question whether most e-cigarettes currently sold in the United States were marketed on February 15, 2007.

There are two ways in which a product can be found to be “substantially equivalent” to a product that was commercially marketed on February 15, 2007. A product can be found “substantially equivalent” if it (i) has “the same characteristics as the predicate tobacco product or (ii) has different characteristics and the information submitted [in the application]. . . demonstrates that . . .the product does not raise different questions of public health.”<sup>252</sup> The term “characteristics” is defined to mean “the materials, ingredients, design, composition, heating source or other features of a tobacco product.” Given how rapidly the market for e-cigarettes has developed, it appears that many e-cigarette products currently marketed do not have “the same characteristics” as a product marketed on February 15, 2007. Nor, given such changes and the aggressive marketing of e-cigarettes since 2007, is it likely that a current e-cigarette product could be found not to “raise different questions of public health” than products marketed more than seven years ago.

FDA’s guidance for substantial equivalence and the decisions on substantial equivalence announced to date make it clear that FDA considers both individual health effects and population level health effects relevant in determining whether a product is “substantially equivalent” to a predicate product.<sup>253</sup> Thus, a product that may have no higher level of toxicants or carcinogens and no higher nicotine content than a predicate product may still raise different questions of public health because of its effects on initiation or cessation. In evaluating the effects of a product on initiation or cessation, the way the product is marketed, advertised and promoted is relevant. The extraordinary expansion of e-cigarettes in recent years has affected the market position of every e-cigarette product so that it would be difficult for any e-cigarette manufacturer to maintain that its product does not “raise different questions of public health” than an e-cigarette marketed in 2007.

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<sup>252</sup> TCA, Sec. 910(a)(3)(i-ii).

<sup>253</sup> Docket No. FDA-2010-D-0635, 76 Fed. Reg. 789, January 6, 2011; Docket No. FDA-2011-D-0147, 76 Fed. Reg. 55927, September 9, 2011; Docket No. FDA-2010-N-0646, Fed. Reg. 737, January 6, 2011. See also FDA decisions on substantial equivalence applications listed at: <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm#3>.

FDA has chosen to develop criteria for substantial equivalence on a case-by-case basis. However, in announcing its decisions, FDA has not provided adequate information to the public to understand at a necessary level of detail how the criteria are being applied. The inadequacy of the information provided is particularly significant with regard to applications that are denied, where only general information has been made available about the matters that led to FDA's decision. Moreover, the large majority of dispositions of substantial equivalence applications have resulted in withdrawals of applications by manufacturers in response to FDA requests for additional information. No information has been provided about such applications and withdrawals. As a result, the public is not in a position to understand precisely what criteria FDA is applying for substantial equivalence determinations. FDA should disclose sufficient information about its processing of substantial equivalence applications for deemed tobacco products to permit the public to understand what criteria are actually being applied.

E. Substantive Standards for Review of New Product Applications

1. In considering new product applications for combusted products FDA should apply the same standards it applies to other products

The proposed deeming rule would permit manufacturers to put new deemed combusted tobacco products on the market and keep them on the market indefinitely unless and until FDA rejects a new product application, provided a manufacturer files a new product application by a date two years after the date a final deeming rule is promulgated. This provision has no parallel with regard to products currently subject to FDA regulation. The statute does not permit a manufacturer of products currently subject to FDA regulation who does not file a substantial equivalence application to market its product before FDA has granted its application. It must await the grant of a new product application before marketing the product.

If FDA permits such products to remain on the market while a new product application is under consideration, it is particularly important for FDA to review the application promptly so that the period during which the product is marketed in the absence of an order granting such an application is as short as possible. Consider, for example, the large number of flavored little cigars that were marketed shortly after the enactment of the Tobacco Control Act in an attempt to circumvent the requirements of the Act. Under the proposed deeming rule manufacturers of such products could continue to introduce such products until the expiration of the compliance period and continue to market them until FDA denied the new product application. If FDA chooses to provide a compliance period for combusted products, it should be prepared to issue decisions on new product applications promptly.

In evaluating new product applications for combusted products, FDA should apply the requirements set forth in its draft guidance for new product applications.<sup>254</sup> There is no reason to depart from such guidelines for combusted products.

2. FDA should apply the same standards in considering new product applications for e-cigarettes but the evidence is likely to be different

As very few e-cigarette products were on the market in 2007, it is unlikely that many e-cigarette products will qualify under the substantial equivalence gateway. As a result, most e-cigarette products will have to meet the requirements for new product marketing orders under Section 910. Evaluation of such applications will require examination of both the health effects of the product on individuals and the population-level effects of an order permitting the marketing of the product.

E-cigarette products have a more limited number of components than cigarettes or other traditional tobacco products. Therefore, the amount of ingredient information manufacturers will be required to submit in connection with a new product application will be smaller. Furthermore, the limited number of ingredients should make it possible for FDA to list with a higher degree of specificity what information regarding individual health effects will be required to support the grant of an application.

Section 910(c) requires FDA to reject a new product application unless the applicant demonstrates that “permitting the product to be marketed would be appropriate for the protection of the public health.” In making this determination, FDA is required to consider “the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”

An e-cigarette product could benefit the public health if its users are adults who are cigarette smokers who quit smoking cigarettes entirely and who would not have quit in the absence of the product. By contrast, an e-cigarette product would not benefit the public health if a substantial number of its users are not current users of combusted tobacco products or if current users of combusted products who otherwise would have quit, use the e-cigarette indefinitely in combination with continued use of combusted or other tobacco products, even if they reduce the number of cigarettes they smoke.

Evaluation of the net risks and benefits should be made on the basis of empirical evidence about how the product is actually being used by consumers. To date, the evidence regarding the overall impact of e-cigarettes at the population level is inconclusive. Substantial

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<sup>254</sup> Docket No. FDA-2011-D-0212, 76 Fed. Reg. 60055, September 28, 2011; see also <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM273425.pdf>.

additional information is likely to become available in the near future, most importantly from the Population Assessment of Tobacco and Health (“PATH”) study and from numerous other studies funded by FDA or other entities, many of which are already in progress. FDA should be in a much better position to evaluate the evidence on the actual impact of e-cigarettes by the time the compliance period concludes.

The effect of e-cigarettes is heavily dependent on how they are advertised, marketed, and promoted. There is massive evidence with regard to combusted products that the advertising, marketing and promotion of cigarettes by major tobacco companies contributed greatly to high rates of youth smoking. There is evidence that the leading manufacturer of e-cigarettes, Lorillard, has pursued a very similar advertising and marketing strategy with its e-cigarette brand, blu. Advertising by other e-cigarette manufacturers raise the same concerns. As part of its regulatory process, FDA should require manufacturers and others in the supply chain for e-cigarettes to supply copies of all advertising and promotional materials to FDA.

In addition, FDA should use its authority under Section 904(b)(3) to require e-cigarette manufacturers to submit all relevant marketing research with regard to e-cigarettes. Moreover, FDA should critically evaluate all such materials in determining whether a new product application should be granted. In addition, FDA should require e-cigarette manufacturers to describe in detail all policies designed to limit the extent to which minors are exposed to the promotion of such products and how marketing materials are designed to avoid appealing to minors. Careful review of such materials should be an indispensable part of FDA’s review of new product applications for e-cigarettes and the application of a company that pursues policies that are not designed to avoid this result should not be granted.

FDA may find that some e-cigarette brands meet the requirements for the grant of a new product application but others do not. In any event, if FDA finds that some brands are disproportionately used for initiation, particularly by youth, FDA should deny the applications for such brands. FDA should issue regulations or guidelines making clear that the effects of the advertising, marketing and promotion of a brand will be a relevant criterion in its decision. Given the broad authority FDA has over all tobacco products, it should not function as a mere bystander if manufacturers market e-cigarettes in ways that are not appropriate for the protection of the public health. In fact, as demonstrated in these comments, the current policies of some major e-cigarette manufacturers might well not meet these requirements.



## VIII. APPLICATION OF SECTION 911 TO DEEMED PRODUCTS WOULD PREVENT UNSUBSTANTIATED AND MISLEADING CLAIMS OF REDUCED RISK WHILE PROVIDING A PATHWAY FOR EVIDENCE-BASED MODIFIED RISK CLAIMS

The proposed rule would apply the provisions of Section 911 to modified risk and modified exposure claims for the deemed products. This section prohibits a manufacturer from making claims that its product presents a lower risk of tobacco-related disease or is less harmful than other tobacco products or that the product contains a reduced level of a substance unless FDA has granted an application permitting such claim. Congress explicitly stated the reasons for including this prohibition in Section 2(36)-(43) of the TCA. After reviewing the history of baseless health claims by tobacco companies, Congress concluded, “The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied to support claims be fully verified.”<sup>255</sup> Section 911 was designed to contain these requirements. Tobacco product manufacturers challenged the constitutionality of Section 911 but the United States Court of Appeals for the Sixth Circuit found that the requirement was constitutional.<sup>256</sup>

As noted above, all the deemed products are addictive, the deemed combusted products contain all or substantially all the same carcinogens and toxicants as cigarettes, and e-cigarettes are not free of carcinogens and toxicants. Thus, the policies underlying the modified risk provisions of the statute appropriately apply to these products. Absent such a provision, there would be a danger that consumers might be misled into believing that a deemed tobacco product was a safe and non-addictive product.

FDA has issued proposed guidelines for Section 911 establishing the requirements for applications under this section.<sup>257</sup> The proposed guidelines largely conform to recommendations made by the Institute of Medicine in a study commissioned by the statute.<sup>258</sup> These regulations are appropriate for the deemed products.

The concern that e-cigarette manufacturers may make unsubstantiated health claims is a valid one in light of the extensive number of health claims for such products that have been made to date in the advertising of some manufacturers. For example, in 2011, V2 Cigs claimed on its website, “V2 is a revolutionary new nicotine delivery system that provides a healthier alternative to traditional tobacco cigarettes.” See Tab L for additional examples.

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<sup>255</sup> TCA, Sec. 2(43).

<sup>256</sup> *Discount Tobacco City & Lottery, Inc. v. FDA*, 674 F.3d 509 (2012), cert. denied sub. nom. *American Snuff Co. v. FDA*, 133 S.Ct. 1996 (2013).

<sup>257</sup> Docket No. FDA-2012-D-0071, 77 Fed. Reg. 20026, April 3, 2012.

<sup>258</sup> Institute of Medicine, *Scientific Standards for Studies on Modified Risk Tobacco Products*, 2011.

Some e-cigarette manufacturers may contend that application of the provisions of Section 911 would prevent manufacturers from accurately informing consumers that their products contain far lower levels of toxicants and carcinogens than cigarettes and smokeless tobacco products. However, the provisions of Section 911 provide a pathway for verifiable claims that a deemed product is free of or contains a reduced level of a substance or presents a reduced exposure to a substance (i.e., “reduced exposure” claims) without the requirement for long-term epidemiological studies if “the scientific evidence available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.”<sup>259</sup>

This standard provides for FDA to permit reduced exposure claims even in the absence of long-term epidemiological studies based on the “likelihood” that the reduction in morbidity and mortality from the use of such products, compared to the use of cigarettes, would be “measurable and substantial.” Appropriately, a manufacturer seeking such an order would have to establish that the magnitude of the overall reductions in exposure to such substances are substantial and that the substances are harmful; that the reductions would occur as the product is actually used by consumers; that the use of the product would not expose consumers to higher levels of other harmful substances; and that consumer perception studies show that consumers would not be misled into believing that the product had been demonstrated to be less harmful or to present a lower disease risk. Moreover, such an order would have to take into account the effect of such a claim on the health of the population as a whole, including both users and nonusers.<sup>260</sup>

The rigorous enforcement of Section 911 of the statute can protect consumers from false or misleading health claims, and still permit claims as to which the manufacturer can demonstrate the likelihood of a measurable and substantial reduction in morbidity and mortality. In the case of e-cigarettes, claims of reduced exposure would have to be accompanied by evidence that use of e-cigarettes provides a pathway to a cigarette smoker switching entirely from cigarettes because the scientific evidence does not support a conclusion that dual use is likely to lead to a measurable and substantial reduction in morbidity or mortality.

## IX. FDA’S REGULATORY IMPACT ASSESSMENT SIGNIFICANTLY UNDERESTIMATES THE BENEFITS OF THE PROPOSED DEEMING RULE

The Regulatory Impact Assessment (“RIA”) accompanying the proposed rule underestimates the net welfare gain resulting from the proposed rule. The most significant error in the RIA is the exclusion of 70 percent of the welfare gain from people changing their status from smoker to non-smoker allegedly to take account of “lost consumer surplus,” i.e., the

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<sup>259</sup> P.L. 111-31, Sec. 911(g)(2), 21 USC § 387k(g)(2).

<sup>260</sup> Sec. 911(g)(2)(B).

“pleasure” that these people would give up by not smoking.<sup>261</sup> The discussion of consumer surplus in the RIA references and relies heavily upon the rationale in the earlier RIA submitted in connection with FDA’s rule requiring graphic warning labels.<sup>262</sup> However, that analysis is challenged by the paper presented in this docket by a group of distinguished economists (“Economists’ Evaluation”), which concludes that the consumer surplus analysis contained in that RIA was erroneous and resulted in an inappropriately large reduction in welfare gain.<sup>263</sup> One of the co-authors of that study, Professor Jon Gruber of MIT, is the co-author of the study cited in this RIA as the principal source for its approach.<sup>264</sup> As Professor Gruber makes clear, both in the paper discussing the RIA in the graphic warning label rule and in comments on this proposed rule, the RIA’s rationale is based on a misunderstanding and misuses his work. Professor Gruber concludes that the consumer surplus discount applied in this RIA vastly exceeds any conceivable such discount.

The welfare gains at issue are “the increase in health and longevity associated with smoking cessation or non-initiation” based on “high-quality, evidence-based comparisons of the expected life-cycle events of smokers with those of non-smokers.”<sup>265</sup> As the RIA notes, “Non-smokers tend to live longer and develop fewer cardiovascular, pulmonary, and other diseases, so the relevant benefits include the discounted value of life-years gained, health status improvements and medical services freed for other uses. They also include other financial effects tied to a person’s status as a smoker or nonsmoker.”

The RIA removes 70 percent of this welfare gain by assigning that value to the alleged “lost pleasure” of smoking.<sup>266</sup> The Economists’ Evaluation challenges this analysis. The concept of consumer surplus is predicated on the assumption that consumers are making well-informed rational choices. For fully-informed, rational consumers, consumer surplus reflects the difference between their willingness to pay for a product and the actual price they pay in the marketplace. Regulatory actions that reduce the demand for a product will lead to reductions in consumer surplus, reflecting “lost pleasure” that results from reduced consumption. FDA’s analysis values this “lost pleasure” at 70 percent of the welfare gains smokers achieve by quitting or not initiating. However, as noted in the Economists’ Evaluation, “if. . . smokers are addicted and suffer the disutility of wanting but being unable to quit, their persistent smoking has no implications for the amount of pleasure they receive from continued smoking. . . . [M]any, and likely the vast majority of smokers do not find smoking ‘pleasurable’ and derive little ‘consumer

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<sup>261</sup> RIA, p. 16, sec. II.A.1.b.; p. 52, sec. II.C. FDA proposes to “incorporate[e] a welfare gain ratio of 30 percent,” in effect excluding 70 percent of the welfare gains calculated elsewhere in the RIA.

<sup>262</sup> *Id.*

<sup>263</sup> Chaloupka FJ, Warner KE, et al., *An Evaluation of FDA’s Analysis of the Costs and Benefits of the Graphic Warning Label Regulation*, August 2014, submitted as a comment in this docket (Economists’ Evaluation).

<sup>264</sup> Gruber JH & Koszegi B, “Is addiction “rational”? Theory and evidence,” *Quarterly Journal of Economics* 116(4):1261-13-3, 2001.

<sup>265</sup> RIA at 16.

<sup>266</sup> The calculations underlying this conclusion yield a range of \$0.16 to \$0.33, the equivalent of a consumer surplus of 67 percent to 84 percent.

surplus' from smoking."<sup>267</sup> The Economists' Evaluation discusses the applicability of such notions as the principle of insufficient reason, present bias, and projection bias and considers the relevance of self-control problems documented in the literature.

The conclusions of the Economists' Evaluation are supported by data showing that most smokers regret having started smoking, wish they could quit, and smoke to avoid the withdrawal symptoms they would suffer if they stopped. Data from the 2002 wave of the ITC-US Survey shows that nine out of 10 smokers agreed with the statement "if you had it to do over again, you would not have started smoking" and the vast majority of smokers say they would quit smoking if they could.<sup>268</sup> In fact, a high percentage of smokers actually try to quit every year.<sup>269</sup> That very few actually succeed in quitting is a measure of nicotine's addictive power.<sup>270</sup> Whatever pleasure most smokers derive from smoking is offset by self-loathing and frustration at not being able to quit. Unwelcome addiction is not a pleasure; it is a burden, and smokers incur psychic costs from being addicted and lacking the self-control to quit.

The Economists' Evaluation also focuses on the fact that the majority of smokers became regular smokers before the legal age of smoking. For those smokers, "society has clearly decided that the decision to initiate smoking is an irrational decision and any changes in their conventionally-calculated consumer surplus resulting from [regulatory actions]. . . should not be counted as a cost in the economic impact analysis."<sup>271</sup> Simply applying this principle would eliminate about three-quarters of the consumer surplus applied by the RIA.<sup>272</sup> A strong argument could be made, based on the FDA's own conclusions regarding the effect of nicotine on brain development young adults,<sup>273</sup> for using an even higher age of demarcation, in which case an even greater portion of the consumer surplus would be eliminated.<sup>274</sup>

The RIA also fails to take account of other benefits incident to successful quitting that would further reduce consumer surplus. For example, it does not consider the very real psychic benefit that results from a smoker's successfully overcoming addiction. Moreover, it does not take account of the fact that a smoker who quits can use the money she or he is no longer

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<sup>267</sup> Economists' Evaluation at 11-12.

<sup>268</sup> Fong, GT, et al., "The near-universal experience of regret among smokers in four countries: Findings from the International Tobacco Control Policy Evaluation Survey," *Nicotine & Tobacco Research* 6(Suppl 3):S341-351, 2004.

<sup>269</sup> CDC, "Quitting Smoking Among Adults—United States, 2001-2010," *MMWR* 60(44):1513-1519, November 11, 2011.

<sup>270</sup> *Id.*

<sup>271</sup> Economists' Evaluation at 12. As the Economist's Evaluation observes, "most smoking initiation takes place during adolescence or young adulthood among individuals who are often less than fully aware of the health and economic consequences of smoking, have little to no conception of their own mortality, heavily discount, and perhaps most importantly, do not understand addiction." For example, about three out of four teen smokers end up smoking into adulthood, even if they intend to quit after a few years.

<sup>272</sup> *Id.* at 13.

<sup>273</sup> 79 Fed. Reg. at 23159.

<sup>274</sup> Economists' Evaluation at 13-14.

spending to buy cigarettes in order to purchase other goods. The pleasure derived from those goods is a direct result of having quit smoking.

There are numerous other ways in which FDA's analysis understates the benefits of the regulation. In its economic analysis, the RIA assumed that reductions in health care spending were spread out equally over time. This assumption ignores the evidence that many of the benefits of quitting occur almost immediately. Heart disease is the largest single smoking-related cause of death and there are both immediate and long-term substantial reductions in the risk of heart attacks and strokes after quitting.<sup>275</sup>

The RIA also erred in limiting its analysis of the economic benefit of not smoking to a comparison between smokers and current "non-smoking smokers."<sup>276</sup> The appropriate comparison would include comparisons between current smokers and never smokers.

The RIA also omits any recognition of the benefits to non-smokers. The most recent report of the Surgeon General states that exposure to secondhand smoke causes lung cancer, coronary heart disease, stroke and other diseases in adults and middle ear disease, impaired lung function, and respiratory illness in children as well as sudden-infant-death syndrome in infants. Secondhand smoke accounts for over 40,000 deaths per year, 8.5 percent of all deaths attributed to smoking. Ignoring these effects results in a substantial underestimate of the benefits achieved by a reduction in smoking.

In addition, FDA's assessment ignores the impact of smoking—and the benefits achieved by reductions in smoking—among maternal smokers during pregnancy. These benefits should be included in the analysis.

Furthermore, the RIA should consider the full range of reduction in health care costs by excluding consideration of a comprehensive set of health care services. The analysis omits benefits attributable to reduced cost for medication, home health care services and nursing home care.

FDA errs in assigning no value at all to the benefits of rule-induced new product requirements.<sup>277</sup> Such requirements are intended to protect the public health at both the individual and population level and to prevent the marketing of products that would increase smoking initiation or inhibit cessation.

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<sup>275</sup> For example, heart rate and blood pressure drop 20 minutes after quitting. As early as two weeks after quitting, circulation improves. One year after quitting, the excess risk of coronary heart disease drops to half that of a smoker's. Five to fifteen years after quitting, stroke risk is reduced to that of a non-smoker. And fifteen years after quitting, the risk of coronary heart disease becomes the same as a non-smoker's. CDC, "Within 20 Minutes of Quitting," [http://www.cdc.gov/tobacco/data\\_statistics/sgt/2004/posters/20mins/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgt/2004/posters/20mins/index.htm).

<sup>276</sup> A "non-smoking smoker" is someone who does not use cigarettes but otherwise exhibits the lifestyle and personal characteristics of the average smoker. 76 Fed. Reg. 36722, June 22, 2011.

<sup>277</sup> P. 19, Sec. I.A.2.a.

FDA requests comments on using consumers' willingness to pay for cessation programs as a measure of the value of cessation. Most smokers who attempt to quit do not use cessation programs. The fact that they do not use such programs is not indicative of how much or little they value cessation, but likely of their evaluation of the prospect that such programs will increase their chances of success. Moreover, even the best cessation programs require substantial individual efforts by the smoker in order to be successful. A smoker's valuation of cessation must take such costs into account as well. Thus, the value of cessation is many times larger than the dollar cost of what consumers are willing to pay to participate in cessation program.

We urge FDA to revise its regulatory impact assessment to take into account the factors discussed above.

## X. CONCLUSION

The deeming of all tobacco products subject to FDA's regulatory authority under the Tobacco Control Act is a vital step toward realizing the full potential of the statute to reduce tobacco-related disease and death. In moving forward toward a final deeming rule, FDA should be guided by three goals.

First, *the deeming rule should be comprehensive in scope*. In recent years, we have witnessed an explosion of novel tobacco products. As FDA itself notes, all of these tobacco products contain nicotine – a highly addictive chemical with its own health consequences – and all of these products, including dissolvables and electronic cigarettes, raise important public health issues. There is every likelihood that the tobacco product market will grow even more varied and dynamic in the future. FDA cannot hope to adequately respond to such an ever-changing market unless it first deems all products that meet the statutory definition of “tobacco product” subject to its regulatory authority. Any gaps in its regulatory authority will be an invitation to tobacco industry manipulation to ensure that addictive and dangerous products escape regulation, and threaten to addict young people and inflict inevitable disease and death. FDA should reject the regulatory option that would exempt “premium cigars” from the deeming rule.

Second, *the deeming rule should be sufficiently strong to protect the public, and particularly children, from the known or potential risks of the newly-deemed products*. FDA should apply to the newly deemed products the provisions of the TCA that automatically apply to products by virtue of their being deemed “tobacco products” subject to the statute. We also support FDA's proposal to require appropriate health warning labels. FDA also should exercise its discretion to adopt additional regulations for the deemed products appropriate to the protection of the public health. It should, for example, impose on the deemed products all the sales and marketing restrictions now imposed on cigarettes to protect young people, as well as

issue product standards prohibiting characterizing flavors in the deemed products that make them appealing to kids and requiring child-resistant containers for nicotine liquids for electronic cigarettes and similar nicotine delivery products. As to new deemed products on the market without the premarket review required by the TCA, FDA should exercise its enforcement discretion to allow them on the market only if their manufacturers submit appropriate new product or substantial equivalence applications and only if their manufacturers meet stringent conditions that protect against the risk that they will be used by children.

Third, *the deeming rule and additional related regulations should be issued within one year of the proposed rule, i.e., by April 25, 2015.* From the time FDA first indicated its intention to deem all tobacco products subject to its regulatory authority under the TCA, it took three full years for a proposed deeming rule to be published. During that period, the market for flavored cigars exploded and electronic cigarette companies began promoting their products using techniques long-ago developed by the cigarette companies to promote their products to young people. Every day that passes without FDA action will mean more young people exposed to the risk of nicotine addiction and tobacco-related disease. Therefore, FDA should ensure that it issues a final deeming rule within one year of publishing its proposed rule, i.e., no later than April 25, 2015. It also should take all necessary steps, beginning immediately, to propose additional sales, marketing and product regulations to further protect the public, and particularly children, from the risks posed by the deemed products and should make those regulations final coincident with the final deeming rule.

Respectfully submitted,

American Academy of Family Physicians  
American Academy of Pediatrics  
American Association for Respiratory Care  
American Cancer Society Cancer Action Network  
American College of Cardiology  
American Congress of Obstetricians and Gynecologists  
American Heart Association  
American Lung Association  
American Psychological Association  
American Public Health Association  
American Thoracic Society  
Association of Maternal & Child Health Programs  
Campaign for Tobacco-Free Kids  
Cancer Prevention and Treatment Fund  
Legacy  
Lung Cancer Alliance

National African American Tobacco Prevention Network  
National Association of City and County Health Officials  
National Latino Alliance for Health Equity  
Oncology Nursing Society  
Partnership for Prevention  
Prevention Partners  
Society for Public Health Education  
Trust for America's Health



## Appendix. Descriptions of the 24 Organizations Joining These Comments

The **American Academy of Family Physicians** (AAFP) is one of the largest medical organizations and represents more than 115,900 family physicians and medical students. The mission of the AAFP is to improve the health of patients, families, and communities by serving the needs of members with professionalism and creativity.

The **American Academy of Pediatrics** (AAP) is a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults. For decades, the AAP has dedicated itself to the goal of reducing the morbidity and mortality related to tobacco use by preventing youth initiation and exposure to secondhand smoke in the United States and across the globe.

The **American Association for Respiratory Care** (AARC) is the leading national and international professional association for respiratory care representing 50,000 respiratory therapists who treat patients with chronic lung disease in all care settings. The AARC also serves as an advocate for patients, their families, the public, the profession and the respiratory therapist.

The **American Cancer Society Cancer Action Network** (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society and has 1 million volunteers who come from every state and congressional district in the country. ACS CAN works in support of evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

The **American College of Cardiology** is a 47,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and improve heart health through education, research, quality care and health policy.

The **American Congress of Obstetricians and Gynecologists** (ACOG) represents over 56,000 women's health care physicians and strives to provide the highest quality education worldwide, continuously improve health care for women through practice and research, lead advocacy for women's health care issues nationally and internationally, and provide excellent organizational support and services for our members.

The **American Heart Association** is the nation's oldest, largest voluntary organization devoted to fighting cardiovascular diseases and stroke – the #1 and #4 leading causes of death in the U.S. This nationwide organization includes more than 22.5 million volunteers and supporters working together to build healthier lives, free of cardiovascular disease and stroke.

The **American Lung Association** is the nation's oldest voluntary health organization and the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The American Lung Association represents the 33 million Americans with lung disease, including those caused primarily by tobacco use, including lung cancer – the number one cancer killer of women and men in the United States – and chronic obstructive pulmonary disease (COPD), the third leading cause of death in the United States. The Lung Association has nine regional chartered associations which serve all 50 states and the District of Columbia, with over 340,000 volunteers nationwide.

The **American Psychological Association (APA)** is the largest scientific and professional organization representing psychology in the United States. APA is the world's largest association of psychologists, with nearly 130,000 researchers, educators, clinicians, consultants and students as its members.

The **American Public Health Association (APHA)** champions the health of all people and all communities. APHA is the only organization that influences federal policy, has a 140-plus year perspective and represents more than 25,000 individual members from all fields of public health and an additional 25,000 public health professionals who are members of our affiliated state and regional public health associations.

The **American Thoracic Society (ATS)** is an international educational and scientific organization founded in 1905 that represents more than 15,000 health care professionals. ATS works to prevent and fight respiratory disease around the globe through research, education, patient care, and advocacy. ATS publishes three peer-reviewed scientific journals that disseminate groundbreaking research, including studies on adverse health effects of tobacco and the treatment of tobacco related disease.

The **Association of Maternal & Child Health Programs (AMCHP)** is a national resource, partner and advocate for state public health leaders and others working to improve the health of women, children, youth and families, including those with special health care needs. AMCHP's members come from the highest levels of state government and include directors of maternal and child health programs, directors of programs for children with special health care needs, and other public health leaders who work with and support state maternal and child health programs.

The **Campaign for Tobacco-Free Kids** is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. We advocate for public policies proven to prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke. Our staff and thousands of grassroots advocates work on policy initiatives at the local, state, and national levels. Kick Butts Day, our annual advocacy event, reached over 1 million people at 1,500 youth-led events held across the country in 2014.

The **Cancer Prevention and Treatment Fund** helps children and adults reduce their risk of getting all types of cancer, and assists them in choosing the safest and most effective treatments.

It conducts research and also carefully scrutinizes scientific research from around the world, helping thousands of patients through its hotline, free materials, and policy work.

**Legacy**, the national non-profit foundation formed by the 1998 Master Settlement Agreement (MSA), envisions an America where tobacco is a thing of the past and where all youth and young adults reject tobacco use. Legacy's flagship truth® campaign is credited with preventing 450,000 teens from smoking and saving as much as \$5.4 billion in added health-care costs during its first four years alone.

**Lung Cancer Alliance** is the leading national organization dedicated to saving lives and advancing research by empowering those living with and at risk for lung cancer. Headquartered in Washington, DC, Lung Cancer Alliance reaches millions of people daily through its advocacy efforts, support services and awareness campaigns. Lung cancer is the number one cause of cancer death in the nation and one quarter of the 480,000 lives each year lost to tobacco use are lung cancer deaths. For two decades, our organization has worked to change these grim statistics by advocating for scientifically validated lung cancer screening and by securing over \$80 million in federal research funding for lung cancer.

The **National African American Tobacco Prevention Network** (NAATPN) is a non-profit public health organization whose mission is to facilitate the development and implementation of comprehensive and community competent public health programs to benefit communities and people of African descent. Our network consists of more than 2,500 individuals and organizations vested in the health and well-being of African Americans nationally and throughout the diaspora.

The **National Association of County and City Health Officials** (NACCHO) is the voice of the 2,800 local health departments across the country. Local health departments assist in the development of policies and environments that make it easier for people to be healthy and safe, including informing the public of the hazards of tobacco use, reducing youth access to tobacco, and limiting exposure to secondhand smoke.

The mission of the **National Latino Alliance for Health Equity** is to advocate for policies, regulations and programs that promote health equity and reduce health disparities for Latino communities in the US and Puerto Rico. The Alliance works with thousands of organizations and constituents to mobilize, educate and advocate to improve health for all.

The **Oncology Nursing Society** is a 35,000 strong national membership organization dedicated to promoting excellence in oncology nursing and the transformation of cancer care.

**Partnership for Prevention** seeks to create a "prevention culture" in America, where the prevention of disease and the promotion of health, based on the best scientific evidence, are the first priorities for policy makers, decision-makers and practitioners. ActionToQuit, Partnership's

tobacco control policy program, reaches 2,100 leaders and advocates daily with the latest information about tobacco policy and research.

The nonprofit **Prevention Partners** builds healthier places through a suite of products that guide workplaces, schools, hospitals and clinics. Our work targets tobacco use, poor nutrition, physical inactivity and obesity as root causes of leading preventable illnesses. We currently support 383 organizations through four products benefiting 630,077 employees, students and patients in 27 states.

The **Society for Public Health Education** (SOPHE) is a 501(c)(3) professional organization founded in 1950 to provide global leadership to the profession of health education and health promotion. SOPHE's 4,000 members include behavioral scientists, faculty, practitioners, and students that work in universities, medical/health care settings, businesses, voluntary health agencies, international organizations, and all branches of federal/state/local government.

**Trust for America's Health** (TFAH) is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. TFAH works with public health partners across the country to build a strong, effective and responsive public health system that works with communities to prevent illness in the first place.