

August 8, 2014

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:

Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

The undersigned state attorneys general (hereinafter “the attorneys general”) submit this Comment in response to the Food and Drug Administration’s (FDA) Notice of Proposed Rule, 79 Fed. Reg. 23142 (April 25, 2014), to support the FDA’s proposed rule deeming certain tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).¹ We support the FDA’s Proposed Rule, but also propose that the FDA take additional steps within its authority under the FD&C Act as appropriate for the protection of the public health and, in particular, to protect youth from the dangers of tobacco use.

I. INTRODUCTION AND SUMMARY OF RECOMMENDATIONS

State attorneys general have long fought to protect their citizens, particularly youth, from the dangers of tobacco products. For example, every state attorney general sued the major tobacco companies for the harm their products caused, and, as a result, reached settlement agreements, including the 1998 Master Settlement Agreement (MSA) that placed restrictions on the advertising, marketing, and promotion of those products. The MSA, entered into between 46 states and six other jurisdictions and the major cigarette manufacturers and numerous smaller manufacturers, committed the parties to “reducing underage tobacco use by discouraging such use and by preventing Youth access to Tobacco Products.” MSA § I. The MSA also prohibited signatory tobacco product manufacturers from taking any action to target youth or initiate youth smoking. MSA § III(a). Thanks in part to the MSA, youth smoking has declined significantly in the past 15 years.

State attorneys general have on several occasions recommended that the FDA take additional steps to protect the public, particularly youth, from the dangers of tobacco use. On September 24, 2013, 40 state attorneys general wrote to the FDA to urge it to promptly issue regulations addressing the advertising, ingredients, and sale to minors of electronic cigarettes (also known as e-cigarettes).² The letter noted the rapidly increasing advertising and sales of e-

¹ Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142-01 (proposed Apr. 25, 2014) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) [hereinafter Proposed Rule].

² When referring to e-cigarettes, we include any device known as an e-cigarette, vaping device, vape pen, vaporizer, smokestik, e-hookah, e-cigar, e-pipe, and/or any other electronic alternative tobacco product. Hereinafter, we will refer to them solely as e-cigarettes.

cigarettes; their increased usage by youth; their sale in flavors appealing to youth; the use of advertising methods reminiscent of past cigarette campaigns that targeted youth; and potential dangers posed by the toxicity of nicotine solutions often sold without any verification of the purchaser's age. On November 8, 2013, 27 state attorneys general wrote to the FDA to support a ban on menthol flavored cigarettes to help deter adolescents from smoking and to prevent tobacco companies from targeting African Americans and youth. And, on January 19, 2012, the Co-Chairs of the Tobacco Committee of the National Association of Attorneys General (NAAG) wrote to the FDA urging a ban on the sale of tobacco products over the Internet to stem that significant source of sales to minors.

As explained more fully below, the Proposed Rule addresses some, but not all, of the concerns expressed in the letters described above. In particular, we believe the FDA can and should take action to:

- Prohibit characterizing flavors other than tobacco and menthol in e-cigarettes and other tobacco products;
- Restrict the advertising, marketing, and promotion of e-cigarettes in the same respects it has restricted the advertising, marketing and promotion of cigarettes and smokeless tobacco, as well as strengthening and updating those restrictions;
- Strengthen the health warnings for the deemed tobacco products;
- Restrict the advertising, promotion, and sale of all tobacco products over the Internet;
- Define e-cigarette components and parts and apply the proposed restrictions on age verification, vending machine sales, and health warnings, regardless of whether such components and parts contain nicotine;
- Include "premium" cigars in the deeming rule; and
- Regulate pipe tobacco to prevent avoidance of regulations applicable to tobacco actually used as roll-your-own tobacco.

In this submission, we first offer general comments in support of the Proposed Rule, which we believe is appropriate for the protection of the public health insofar as it brings all tobacco products within the FDA's jurisdiction under the FD&C Act, as amended; subjects such tobacco products to certain mandatory provisions of the Act; and imposes on all tobacco products minimum age and identification requirements for retail sales, health warnings, and a prohibition against vending machine sales. We then explain why we believe the FDA should take the additional recommended actions specified above.

II. GENERAL COMMENTS RELATING TO PROPOSED RULE

A. The Proposed Deeming of All Tobacco Products Is Appropriate for the Protection of the Public Health

We support the FDA's proposal to bring all tobacco products (as defined in Section 201(rr) of the FD&C Act) within its regulatory jurisdiction. The FDA's discussion of the Proposed Rule in its notice published April 25, 2014, contains ample evidence to support the conclusions that:

- In recent years there has been an increase in youth using tobacco products other than combustible cigarettes and smokeless tobacco, as well as using multiple tobacco products;
- All products containing nicotine are addictive and pose a health threat to youth; and

- Allowing any tobacco products to be manufactured, marketed, and sold in an unregulated environment creates risks to the public health and an uneven competitive environment among different categories of tobacco products.

For these and other reasons, we believe the FDA’s Proposed Rule is appropriate for the protection of the public health.

For much the same reasons, as well as other reasons set forth in the FDA’s notice, we also support the FDA’s proposal to subject the newly deemed tobacco products to minimum age and identification requirements for retail sales; to require that they carry health warnings; and to prohibit their sale in vending machines (except in facilities where persons under 18 years of age are not allowed entry).

B. The FDA Should Prohibit Non-Face-to-Face Sales of Tobacco Products

At present, no FDA rule or regulation appears to address non-face-to-face sales of tobacco products. The regulations that FDA promulgated on March 19, 2010, pursuant to section 102 of the Tobacco Control Act contain an exception to age verification requirements for “mail-order sales” of cigarettes and smokeless tobacco, 21 C.F.R. §§ 1140.14(a)(2)(i), 1140.16(c)(2)(i), and the Proposed Rule would appear to maintain that exception for all tobacco products. It is unclear whether or how that exception applies to Internet sales, which were all but nonexistent when the predecessor to the § 102 regulations was promulgated in 1996. Even if the exception does not apply, the age verification methods prescribed in the regulations (“photographic identification containing the bearer’s date of birth”) are ineffective as applied to Internet sales.

The Prevent All Cigarette Trafficking Act (PACT Act), enacted in March 2010, does address the sale and distribution of cigarettes and smokeless tobacco via the Internet, e-mail, telephone, direct mail and other non-face-to-face means (which the PACT Act refers to as “remote sales”), but the PACT Act does not apply to other categories of tobacco products.

As noted above, on January 19, 2012, the Co-Chairs of the NAAG Tobacco Committee submitted comments in docket No. FDA-2011-N-1467 on the FDA’s advance notice of proposed rulemaking concerning the non-face-to-face promotion and sale of tobacco products. Despite that notice and the public comments it generated, the FDA has not exercised its authority under FD&C Act § 906(d) to promulgate regulations on those subjects.

The January 19 letter concluded that “[n]either the PACT Act nor the state laws now in effect have proven adequate to protect the public health against the two principal adverse effects of non-face-to-face sales of tobacco products – *i.e.*, making such products less expensive through evasion of state taxes and making them more readily available to youth.” The letter further concluded that “the only way to remedy the adverse public health consequences of such sales is to . . . ban them” or at least for the FDA to “work with other federal agencies toward more effective enforcement of the PACT Act.”

The comments in the January 19 letter regarding non-face-to-face tobacco sales are still relevant today. The PACT Act has not adequately protected the public health with respect to the non-face-to-face sale and distribution of tobacco products for the reasons set forth in the letter. The intervening two years have only strengthened that conclusion. For example:

- Some delivery sellers continue to refuse to comply with the Act’s registration and reporting requirements;

- Some Native American-owned businesses contend that the Act does not apply to them;
- Enforcement against delivery sellers in foreign countries has proven ineffective;
- There has been widespread evasion of the non-mailability provisions through use of private means of transport and other means;
- Maintenance of the Act’s noncompliant list of delivery sellers requires constant monitoring by states, which are unable to keep up with the constantly shifting roster and identities of noncompliant sellers; and
- Age-verification methods employed by some delivery sellers have not effectively prevented the purchase of tobacco products by underage persons in non-face-to-face sales.

These conclusions are equally applicable to the newly deemed tobacco products.

Recommendations

Accordingly, we recommend that the FDA should promptly issue proposed regulations under Sections 906(d)(1) and (4) and any other relevant statutory provisions to ban the non-face-to-face sales of all tobacco products.

C. The Newly Deemed Tobacco Products Should Be Made Subject to the Section 907 Ban on Any Characterizing Flavor Other Than Tobacco and Menthol

It is well known that the vast majority of smoking initiation occurs among teenagers and young adults.³ Federal, state, and local organizations have worked hard to reduce youth access to cigarettes and discourage children from using tobacco. While there has been a decline in traditional cigarette smoking among youth, youth are increasingly using other tobacco products, as discussed in Sections III and IV. The 2014 U.S. Surgeon General’s Report warned that a substantial proportion of youth tobacco use occurs with products other than cigarettes, such as e-cigarettes, and encouraged incorporating additional tobacco products in organized efforts to monitor and prevent youth tobacco use.⁴

There is strong evidence that youth are attracted to flavored tobacco products⁵ and are much more likely to use candy and fruit flavored tobacco products than adults.⁶ In 2004, 22.8

³ U.S. Dep’t of Health and Hum. Servs., *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 134 (2012), available at <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf> [hereinafter 2012 U.S. Surgeon General’s Report].

⁴ U.S. Dep’t of Health and Hum. Servs., *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, 742 (2014), available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf> [hereinafter 2014 U.S. Surgeon General’s Report].

⁵ As used in this section, flavored tobacco products include e-cigarettes, cigars, pipe tobacco, hookah tobacco, gels, and dissolvables, all of which should be made subject to the Section 907 ban on any characterizing flavor other than tobacco and menthol. Our use of the term characterizing flavors throughout this Comment refers to all characterizing flavors other than tobacco and menthol.

⁶ Brian A. King et al., *Flavored Cigar Smoking Among U.S. Adults: Findings from the 2009-2010 Adult Tobacco Survey*, 15 *Nicotine & Tobacco Res.* 608, 608-614 (Feb. 2013); Andrea C. Villanti et al.,

percent of 17-year-old smokers reported using flavored cigarettes in the past month, as compared to 6.7 percent of smokers over the age of 25.⁷ A poll conducted in March 2008 found that one in five youngsters between the ages of 12 and 17 had seen flavored tobacco products or ads, while only one in 10 adults reported having seen them.⁸ In fact, the FDA has recognized that flavored tobacco products “containing flavors like vanilla, orange, chocolate, cherry and coffee are especially attractive to youth” and “are widely considered to be ‘starter’ products, establishing smoking habits that can lead to a lifetime of addiction.”⁹ Because nicotine, which is one of the harshest chemicals in tobacco smoke and the most important factor in tobacco dependence, is usually highly unpalatable for first-time users,¹⁰ tobacco product manufacturers may use flavors to mask the harshness of smoke to allow inhalation and build tolerance.¹¹ There is also evidence that users of flavored tobacco products have a lower intent to quit than users of non-flavored tobacco products, which indicates increased dependence among younger individuals using flavored tobacco products.¹²

The tobacco industry is well aware that flavored tobacco products appeal to youth. As early as 1978, Lorillard conducted new flavors focus group sessions to determine how flavors such as orange, cherry, tutti fruit, and marshmallow were received.¹³ Flavored cigarettes were viewed as for “young people in general,” “beginner smokers,” “very young,” “teenagers,” and “young girls starting to smoke,” and specific impressions included “like eating candy,” “chewing gum,” “Jello,” and “lollipops.”¹⁴ The report also noted that smelling a flavor in smoke can induce interest in smoking.¹⁵ Even today, Lorillard’s sponsored Youth Smoking Prevention Program website advises that “[k]ids may be particularly vulnerable to trying e-cigarettes due to

Flavored Tobacco Product Use Among U.S. Young Adults, 44 Am. J. of Preventive Med. 388, 388–91 (2013).

⁷ Sarah M. Klein et al., *Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005*, 10 Nicotine & Tobacco Res. 1209, 1209-14 (2008).

⁸ Campaign For Tobacco Free Kids, *New Poll: Teens Still Feel Targeted By Tobacco Ads & Find It Easy to Buy Cigarettes, 13th Annual ?Kick Butts Day? Calls For FDA Regulation of Tobacco Products* (April 2008) (citing Int’l Commc’ns Res. (ICR), National telephone survey of teens aged 12 to 17 and adults (Mar. 2008)).

⁹ U.S. Food and Drug Admin., *Flavored Tobacco Product Fact Sheet*, available at <http://www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/UCM183214.pdf> (last visited July 10, 2014).

¹⁰ *Id.*

¹¹ 2012 U.S. Surgeon General’s Report, *supra* note 3, at 535.

¹² Brian A. King et al., *Flavored-Little-Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students*, 54 J. of Adolescent Health 40, 40-46 (July 29, 2013), available at <http://www.sciencedirect.com/science/article/pii/S1054139X13004151>.

¹³ See generally R.M. Manko Associates, *Summary Report: New Flavors Focus Group Sessions*, (Aug. 1978), available at <http://legacy.library.ucsf.edu/tid/ot176b00/pdf> (last visited July 10, 2014).

¹⁴ *Id.* at 9-25.

¹⁵ *Id.* at 4-5.

an abundance of fun flavors such as cherry, vanilla, pina colada and berry.”¹⁶ This admission is particularly alarming considering that Lorillard owns blu eCigs, an e-cigarette company, whose product comes in cherry, vanilla, and pina colada flavors.¹⁷

In response to the mounting evidence linking flavored tobacco products and children, Congress enacted the Tobacco Control Act in 2009, which, among other things, banned characterizing flavors (other than tobacco and menthol) in cigarettes. In deciding to ban flavored cigarettes, Congress determined that “[f]lavors and product modification not only make the products more appealing to youth, but often result in exposure to additional carcinogens and other toxic constituents.”¹⁸ It cited recent flavored cigarettes such as “Mandalay Lime,” “Warm Winter Toffee,” “Mocha Taboo,” and “Midnight Berry” as appealing to youth and subject to the federal law.¹⁹

A Reuters report dated May 18, 2014, citing Nielsen market scanner data, states that between 2008 and 2011, revenue from flavored cigar sales in convenience stores increased by 53 percent and that by 2011, flavored cigar sales made up almost half of all cigar sales in convenience stores.²⁰ Surveys cited in the Proposed Rule “have confirmed the popularity of small cigars and cigarillos is due at least in part to the availability of a wide variety of flavors.”²¹

Despite the federal ban on characterizing flavors other than tobacco and menthol in cigarettes, other tobacco products continue to be sold in many flavors that are attractive to youth. These products are especially appealing to children with their sweet flavors²² and bright packaging.²³ With one exception, the top cigar brands preferred by adolescents and young adults

¹⁶ Real Parents Real Answers, *What you need to know about e-cigarettes – Infographic*, (Apr. 23, 2014) available at <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/> (last visited July 10, 2014).

¹⁷ blu e-cigarettes offers flavor cartridges in pina colada, peach schnapps, cherry, vanilla, java, and menthol. Lorillard Tech., Inc., *blu Cartridge Flavors*, available at <http://www.blucigs.com/product/flavor-cartridges/> (last visited July 10, 2014).

¹⁸ H.R. Rep. No. 111-58, pt. 1, at 4 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468.

¹⁹ *Id.* at 37-40.

²⁰ Kathryn Doyle, *Flavored cigars appeal to youth: study*, Reuters (Apr. 18, 2014, 11:06 AM), available at <http://www.reuters.com/article/2014/04/18/us-flavored-cigars-idUSBREA3H0GO20140418>.

²¹ Proposed Rule, *supra* note 1, at 23167. An additional concern regarding flavored little cigars arises from anecdotal reports of their use by youth to smoke marijuana, *i.e.*, flavored little cigars are emptied and “spiked” either with marijuana alone or a mixture of marijuana and tobacco. The result is a “joint” with a mild fruit or candy flavor.

²² It is no coincidence that youth like the taste of flavored tobacco products. Portland State University researchers recently reviewed the flavor chemicals and levels in several brands of candy and Kool-Aid drink mix and concluded that the chemicals largely overlapped with similarly labeled “cherry,” “grape,” “apple,” “peach,” and “berry” tobacco products. Jessica E. Brown et al., *Candy Flavorings in Tobacco*, 370 *New Eng. J. Med.* 2250, 2250-2252 (June 5, 2014), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMc1403015>. In some instances, the tobacco products contained flavor chemicals at much higher levels per serving than the non-tobacco products. *Id.*

²³ ChangeLab Solutions, *In Bad Taste: What Communities Can Do About Fruit- and Candy-Flavored Tobacco Products* (Jan. 2014), available at http://changelabsolutions.org/sites/default/files/InBadTaste-FlavoredTobacco_FactSheet-FINAL-20140107.pdf.

“include various flavorings, such as peach, grape, apple, and chocolate.”²⁴ By 2007, flavored little cigar brands comprised nearly four-fifths of the little cigar market share.²⁵ In 2011, more than two-fifths of U.S. middle and high school smokers reported using flavored little cigars²⁶ or cigarettes.²⁷ Similarly, in a recent survey of more than 3,000 adults, all young adults (ages 18-24) who tried e-cigarettes reported also trying a menthol or fruit flavored device, as compared with only 65 percent of those 25 and older who had tried menthol or fruit flavored ones.²⁸

Recommendations

We urge the FDA to ban all characterizing flavors other than tobacco and menthol in newly deemed tobacco products.²⁹ The primary basis for doing so is the protection of public health, particularly of youth. However, quite apart from these health benefits, a complete prohibition of characterizing flavors offers many advantages for enforcement. Consumers and manufacturers would have clarity and certainty. Enforcers would not have to make difficult determinations about whether a word, phrase, logo, or packaging connoted a flavor. Regulators would not face years of disputes, laboratory tests, and litigation about whether, regardless of the name, labeling, and marketing, a tobacco product’s flavor does or does not appeal to youth, or is substantially equivalent, misbranded, or adulterated.

In the event that the FDA does not impose a complete ban on characterizing flavors (other than tobacco and menthol) in cigars, it is essential that the FDA take steps to ensure that a limited prohibition is effective. The FDA should at a minimum (i) require that allowed flavors not be attractive to youth; (ii) place the burden on the manufacturer to demonstrate this lack of attraction to youth; (iii) not grandfather any existing product or product that has a pending application; and (iv) require that all cigars with characterizing flavors receive final FDA approval prior to sale in the United States.

The FDA has requested comment on the characteristics it should consider in determining whether a particular tobacco product is a “cigarette” and therefore subject to the already-existing prohibition against characterizing flavors in cigarettes, despite being labeled as a little cigar.³⁰ We believe the FDA can and should promptly use its existing authority to deem these little cigars to be cigarettes within the meaning of the FD&C Act for purposes of enforcing the FD&C Act

²⁴ 2012 U.S. Surgeon General’s Report, *supra* note 3, at 164.

²⁵ King, *supra* note 12, at 44.

²⁶ As used in this Comment, the term “little cigars” refers to tobacco products that are similar in size and appearance to cigarettes but are wrapped in paper that contains some tobacco.

²⁷ King, *supra* note 12, at 44.

²⁸ Samantha Olson, *81% of Young Parents Say E-Cigarettes Are Less Harmful To The People Around Them; But Are They Really?*, Med. Daily (May 4, 2014, 1:14 PM), available at <http://www.medicaldaily.com/81-young-parents-say-e-cigarettes-are-less-harmful-people-around-them-are-they-really-280168>.

²⁹ If the FDA does not ban all characterizing flavors in pipe tobacco, it should prohibit all characterizing flavors that were not available in pipe tobacco for retail purchase in the United States on a date certain prior to the 2009 enactment of the Children’s Health Insurance Program Reauthorization Act (CHIPRA) in order to reduce the availability of pipe tobacco in flavors that are attractive to youth.

³⁰ Proposed Rule, *supra* note 1, at 23144.

ban on characterizing flavors. Moreover, if the FDA does act to bring little cigars within the existing prohibition against cigarettes with a characterizing flavor, the remaining cigars should be made subject to a flavorings ban to prevent circumvention of that prohibition.

Given the mounting evidence that youth are attracted to flavored tobacco products, that youth are increasingly using flavored little cigars and e-cigarettes, and that using flavored tobacco products can increase dependence, hinder smoking cessation efforts, and create a lifetime of addiction, it is imperative that the FDA act now to impose the same flavor ban on other tobacco products that is currently in place for cigarettes. Such a ban would complement the FDA's proposal to age-restrict these products. The FDA has this authority under sections 906(d) and 907 of the Tobacco Control Act and should implement this ban in its deeming rule. Time is of the essence. Permitting flavored tobacco products to remain on the market has significant public health implications, which will continue to multiply and worsen if the FDA chooses to wait to address flavors in a subsequent regulation (likely several years away) after this one becomes final.

III. COMMENTS RELATING TO E-CIGARETTES

A. FDA Regulation of E-Cigarettes Is Appropriate for the Protection of the Public Health

Youth are increasingly using e-cigarettes. In 2013, for example, the Centers for Disease Control and Prevention (CDC) reported that from 2011 to 2012, the percentage of middle and high school students using e-cigarettes had more than doubled—from 4.7 percent in 2011 to 10.0 percent in 2012 (or approximately 1.78 million students).³¹ In a study conducted this year, the authors found that among 13- to 17-year-olds, 14 percent were using e-cigarettes.³² These findings are troublesome for several reasons.

First, e-cigarettes contain and deliver nicotine—a well-recognized addictive chemical—in amounts comparable to traditional cigarettes.³³ Accordingly, e-cigarettes should be assumed to be both harmful and addictive.³⁴ Second, youth are “particularly vulnerable” to nicotine’s adverse effects on the central nervous system.³⁵ As recently determined by the Surgeon General in the latest Report, nicotine exposure during adolescence adversely affects cognitive function and development, potentially resulting in “lasting deficits in cognitive function.”³⁶ As a result,

³¹ Press Release, Ctrs. for Disease Control and Prevention, E-cigarette use more than doubles among U.S. middle and high school students from 2011–2012 (Sept. 5, 2013), *available at* <http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html> (last visited July 10, 2014).

³² Legacy for Health, *Vaporized: E-Cigarettes, Advertising, and Youth*, at 11 (May 2014), *available at* http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf.

³³ Megan J. Schroeder & Allison C. Hoffman, *Electronic cigarettes and nicotine clinical pharmacology*, 23 *Tobacco Control* ii30, ii33 (accepted Feb. 11, 2014), *available at* http://tobaccocontrol.bmj.com/content/23/suppl_2/ii30.full.pdf+html (last visited July 10, 2014).

³⁴ *See* 2014 U.S. Surgeon General’s Report, *supra* note 4, at 780 (“all products containing tobacco and nicotine should be assumed to be both harmful and addictive.”).

³⁵ *Id.* at 122.

³⁶ *Id.* at 122, 125.

“the potential long-term cognitive effects of exposure to nicotine in this age group are of great concern.”³⁷

Third, the evidence suggests that among youth, e-cigarettes may be a “gateway” to the use of traditional cigarettes. As noted by the CDC, one in five middle school students who reported using e-cigarettes stated that they had never tried conventional cigarettes.³⁸ The same study also found that of the middle and high school students who reported using e-cigarettes (within the last 30 days), over 76 percent had also smoked conventional cigarettes.³⁹ Drawing from this data, the CDC concluded that “there may be young people from whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes.”⁴⁰

Other harms relating to the use of e-cigarettes are also likely to exist beyond their growing use by youth. For example, the vapor from e-cigarettes has been found to contain formaldehyde and propylene glycol.⁴¹ Formaldehyde is a known human carcinogen. Propylene glycol when heated and vaporized can form propylene oxide, also a known human carcinogen.⁴²

E-cigarettes have furthermore been found to deliver particulate matter, in the same number and size as traditional cigarettes.⁴³ The inhalation of such particles—*e.g.*, through tobacco smoke or air pollution—has been found to contribute to pulmonary and systemic inflammatory processes and increase the risk of cardiovascular and respiratory disease and death.⁴⁴ The particles from e-cigarettes have also been found to contain metals, such as tin and nickel, in amounts two to 100 times higher than those found in a traditional Marlboro cigarette smoke.⁴⁵ These metal nanoparticles can deposit into the lungs, causing adverse respiratory effects.⁴⁶

The liquid nicotine used in e-cigarettes also presents increasing dangers. The number of phone calls made to poison centers involving e-cigarette liquids, has increased dramatically over

³⁷ *Id.* at 122.

³⁸ Ctrs. for Disease Control and Prevention, *supra* note 31.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Rachel Grana, Neal Benowitz, & Stanton A. Glantz, *E-Cigarettes: A Scientific Review*, 129 *Circulation* 1972, 1975-77 (2014), available at <http://circ.ahajournals.org/content/129/19/1972.full.pdf+html> (last visited July 10, 2014).

⁴² U.S. Dep’t of Health and Hum. Servs., *Report on Carcinogens, 12th Ed.*, 195, 366-71 (2011), available at <http://ntp.niehs.nih.gov/ntp/roc/twelfth/roc12.pdf> (last visited July 10, 2014); Grana, *supra* note 41, at 1978 (noting that propylene glycol in its heated form, is propylene oxide); See also, M. Goniewicz, et al., “Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes,” 23 *Tobacco Control* 133-39, (Mar. 2013); M. Williams, et al., *Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol*, *PlosOne*, (Mar. 20, 2013), available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0057987> (last visited July 23, 2014).

⁴³ Grana, *supra* note 41, at 1977.

⁴⁴ *Id.* at 1976.

⁴⁵ *Id.* at 1977.

⁴⁶ *Id.*

the past four years—from one per month to 215 per month nationwide.⁴⁷ As CDC Director Tom Frieden has explained, “[e]-cigarette liquids as currently sold are a threat to small children because they are not required to be childproof, and they come in candy and fruit flavors that are appealing to children.”⁴⁸ Indeed, over half of the phone calls made to poison centers during the past four years regarding e-cigarettes involved young children under the age of five.⁴⁹

Finally, there is a widespread misperception among youth about the safety of e-cigarettes. As the FDA has already noted, young adults often “mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes.”⁵⁰ Indeed, although no manufacturer of e-cigarettes has yet applied to have its product considered a nicotine replacement therapy, over 85 percent of e-cigarette users reported in an international survey that they assumed such products would help them quit smoking.⁵¹ For additional discussion regarding the harmful effects of nicotine, see Section III.C.2, *infra*.

Given these facts and those set forth in the Proposed Rule, we agree with the FDA’s conclusion that regulation of e-cigarettes is appropriate for the protection of the public health.

B. E-Cigarettes Should Be Subject to the Same Restrictions on Advertising and Marketing to Youth as Those Applicable to Combustible Cigarettes and to a Ban on Advertising in Electronic Media

The FDA should address the threat to youth from e-cigarette advertising and marketing by subjecting such advertising and marketing to all of the regulations promulgated under section 102 of the Tobacco Control Act, not just the age-verification requirements, by bringing those regulations up to date to reflect modern marketing methods, and by instituting a ban on e-cigarette advertising in electronic media.

Youth are increasingly bombarded with e-cigarette advertising in print, radio, and television. E-cigarette industry advertising has increased exponentially in recent years, from \$5.6 million in 2010 to \$82.1 million in 2013.⁵² A survey of five leading e-cigarette companies indicated that their marketing expenditures increased by 164 percent from 2012 to 2013.⁵³ Current marketing of e-cigarettes parallels strategies used in traditional cigarette marketing

⁴⁷ Press Release, Ctrs. For Disease Control and Prevention, New CDC study finds dramatic increase in e-cigarette-related calls to poison centers (Apr. 3, 2014, 1:00 PM), *available at* <http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html> (last visited July 10, 2014).

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ Proposed Rule, *supra* note 1, at 23146.

⁵¹ Sarah E. Adkinson et al., *Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey*, 44 *Am. J. Preventive Med.* 207, 207 (2013).

⁵² Legacy for Health, *supra* note 32, at 8.

⁵³ Staff of H.R. Comm. on Energy & Com. Democrats, 113th Cong., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, 18 (Apr. 14, 2014), *available at* <http://democrats.energycommerce.house.gov/sites/default/files/documents/Report-E-Cigarettes-Youth-Marketing-Gateway-To-Addiction-2014-4-14.pdf>.

before FDA regulation and state settlements restricted cigarette advertising.⁵⁴ Specifically, the industry has seized upon the lack of regulation to expose youth to advertising campaigns that would be prohibited for other tobacco products under current law and agreements.⁵⁵ This advertising—especially when viewed in light of the known research concerning traditional cigarette advertising and marketing—most likely will cause an increase in e-cigarette use among youth.⁵⁶

While federal law prohibits advertising of cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission, 15 U.S.C. § 1335, and Section III(a) of the MSA prohibits advertisements of cigarettes that target youth, the lack of parallel restrictions on e-cigarette companies has resulted in the explosion of e-cigarette advertisements in television as well as print media. In 2013, e-cigarette television advertisements reached 14.1 million teens and e-cigarette magazine advertisements reached 9.5 million teens.⁵⁷ Recent studies have found that youth exposure to e-cigarette advertisements on television increased by 256 percent from 2011 to 2013 and that e-cigarette advertisements appeared on programs that were among the highest-rated youth programs (e.g. *The Bachelor*, *Big Brother*, and *Survivor*).⁵⁸ In the 2013 Super Bowl broadcast, NJOY, an e-cigarette company, purchased a 30-second television advertisement slot for its product which reportedly resulted in a dramatic 30-40 percent increase in sales.⁵⁹

E-cigarette advertisements have recently appeared in magazines with high youth readerships, such as *Star*, *OK!*, *Entertainment Weekly*, *US Weekly*, *Men's Journal*, and *Rolling Stone*.⁶⁰ The 2014 *Sports Illustrated* Swimsuit Issue, an issue that is no doubt popular with teenage boys, contained a prominent and provocative blu eCigs advertisement, including an online version which allowed viewers to zoom in on a woman's bikini line.⁶¹ With the recent

⁵⁴ See Nat'l Cancer Inst., "Influence of Tobacco Marketing on Smoking Behavior," *The Role of the Media in Promoting and Reducing Tobacco Use*, Tobacco Control Monograph No. 19, U.S. Dep't of Health and Hum. Servs., NIH Pub. No. 07-6242, at 281 (2008) (noting that the "total weight of evidence from multiple types of studies ... demonstrates a causal relationship between tobacco advertising and promotion and increased tobacco use").

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Legacy for Health, *supra* note 32, at 16-17.

⁵⁸ Jennifer C. Duke et al., *Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults*, 134 *Pediatrics* e29, e29-e36 (July 2014), available at <http://pediatrics.aappublications.org/content/134/1/e29.full.pdf+html> (last visited July 24, 2014).

⁵⁹ Benjamin Wallace, *Smoke Without Fire*, *N.Y. Mag.*, April 28, 2013, available at <http://nymag.com/news/features/e-cigarettes-2013-5/>; see also, Ken Alltucker *E-Cigarette Commercial During Super Bowl has Lung Association Officials Fuming*, *The Ariz. Republic*, February 8, 2013, available at <http://www.azcentral.com/business/consumer/articles/20130207super-bowl-e-cigarette-commercial-lung-association-officials-fuming.html> (last visited July 23, 2014).

⁶⁰ Legacy for Health, *supra* note 32, at 17.

⁶¹ Campaign for Tobacco Free Kids, *An e-cigarette ad on an itsy, bitsy bikini*, (Feb. 24, 2014), available at http://www.tobaccofreekids.org/tobacco_unfiltered/post/2014_02_24_si (last visited Jul. 27, 2014).

entry of Reynolds American into the national e-cigarette market and the expected entry of Altria in the national e-cigarette market by the end of 2014, the level of e-cigarette advertisements will likely grow dramatically. It was recently reported that Reynolds plans to conduct a national marketing campaign that includes television advertisements in major markets.⁶² With the three largest tobacco companies active in the national e-cigarette market by the end of the year, it is essential that the FDA act promptly to impose restrictions on advertising to ensure that youth are not targeted and reached by the companies' marketing campaigns.

E-cigarette companies are also targeting youth by sponsoring athletic, musical, artistic, and other social or cultural events, and, in some instances, handing out free e-cigarette samples – actions prohibited under the current FDA rule for combustible cigarettes.⁶³ Although the proposed deeming rule would subject all newly deemed tobacco products to the ban on free samples imposed by 21 CFR § 1140.16(d), e-cigarette companies have seized the opportunity to distribute free samples of their products in the absence of FDA regulation. In 2012 and 2013 alone, six e-cigarette manufacturers sponsored or provided free samples at 348 events, many of which were youth-oriented.⁶⁴ These practices mirror the marketing tactics of tobacco companies before they were restricted by state litigation settlements and the FDA Rule. For example, R.J. Reynolds once promoted its Kool cigarette brand by sponsoring the “Kool Jazz Festival”; now, blu eCigs sponsors a nationwide “Freedom Project” concert tour in which the tour’s promotional material contains blu’s marketing slogan, “Take Back Your Freedom.”⁶⁵ Blu has offered free e-cigarette samples at its Freedom Project concerts, many of which have been all-ages events open to minors. In addition, in 2013, Lorillard extensively advertised blu eCigs at Six Flags Discovery Kingdom, a youth-oriented amusement park in California. Swisher, blu, and Green Smoke all have NASCAR team sponsorships, an action prohibited under FDA regulations if the product were combustible cigarettes.⁶⁶

E-cigarette companies are relying on yet other forms of marketing that target youth. Major e-cigarette companies have hired celebrities to endorse their product, capitalizing on themes of masculinity, sex appeal, glamour, and romance that appeal to youth in a manner nearly identical to their traditional tobacco predecessors.⁶⁷ Absent FDA action, these advertisements will lead to the normalization of smoking and undermine years of anti-smoking efforts that have successfully dispelled the myths of masculinity, sex appeal, glamour, and romance that tobacco companies wish to associate with their products. Additionally, some companies utilize cartoon imagery to promote their products to youth. As one study recently observed, R.J. Reynolds used to target youth with the rebellious Joe Camel much in the way blu eCigs has marketed its

⁶² Matt Richtel, *A Bolder Effort by Big Tobacco on E-Cigarettes*, N.Y. Times, June 17, 2014, available at <http://www.nytimes.com/2014/06/17/business/a-bolder-effort-by-big-tobacco-on-e-cigarettes.html?action=click&contentCollection=Business%20Day®ion=Footer&module=MoreInSection&pgtype=article&r=0>.

⁶³ *Gateway to Addiction*, *supra* note 53, at 9-10.

⁶⁴ *Id.*

⁶⁵ Staff of H.R. Comm. on Energy & Com. Democrats, 113th Cong., *E-Cigarette Flashbacks*, (2013), available at <http://democrats.energycommerce.house.gov/index.php?q=page/e-cigarette-flashbacks>.

⁶⁶ *Id.*

⁶⁷ *Id.*

products using the "Mr. Cool" cartoon character, and eJuiceMonkeys.com and Magic Puff City e-cigarettes have used cartoon monkeys to sell their products.⁶⁸

In addition, e-cigarette companies are reaching youth through social media. Researchers at Washington University School of Medicine recently found that more than one in ten children reported receiving tobacco coupons recently on their Facebook or MySpace pages or through text messages.⁶⁹ Many e-cigarette companies market their products on social media sites such as Facebook, Twitter, Pinterest, YouTube, and Instagram.⁷⁰ In many cases, these sites are not age-restricted.⁷¹ The total lack of regulation of e-cigarette advertising on social media allows any child with access to the Internet to be exposed to e-cigarette marketing.

Unfortunately, these e-cigarette marketing campaigns appear to be successful: the vast majority of teenagers (89 percent) and nearly all young adults (94 percent) are aware of e-cigarettes. E-cigarette advertising targeted at youth poses a threat to the public health. The 2014 U.S. Surgeon General's Report found sufficient evidence to conclude the following:

- Advertising and promotional activities by the tobacco companies cause the onset and continuation of smoking among adolescents and young adults; and
- Tobacco product regulation has the potential to contribute to public health through reductions in tobacco product addictiveness and harmfulness, and by preventing false or misleading claims by the tobacco industry of reduced risk.⁷²

Much like traditional tobacco advertising, the advertising and promotional activities of e-cigarette manufacturers cause the onset and continuation of e-cigarette use among adolescents and young adults, and should be strictly regulated by the FDA. Youth are particularly vulnerable to the tactics employed by e-cigarette companies, and the exponential rise in e-cigarette marketing has correlated with a rise in e-cigarette use among youth.

Recommendations

The FDA should act promptly to prevent the advertising and marketing tactics of the e-cigarette industry from initiating a new generation of youth into nicotine addiction. At the least, the FDA should subject e-cigarette advertising and marketing to the same restrictions as those applicable to combustible cigarettes and smokeless tobacco under the regulations promulgated pursuant to Section 102 of the Tobacco Control Act. Moreover, the FDA should consider using its authority under Section 906(d) of the Act to revise those regulations to address the other tactics and methods (for example, cartoons, celebrity endorsements, and marketing in social media) that, as described in this Comment, target youth in the advertising and marketing of tobacco products.

⁶⁸ *Id.*

⁶⁹ Patricia A. Cavazos-Rehg et al., *Hazards of New Media: Youth's Exposure to Tobacco Ads/Promotions*, 16 *Nicotine & Tobacco Res.* 437, 437-444 (Apr. 2014).

⁷⁰ *Gateway to Addiction*, *supra* note 53 at 24.

⁷¹ *Id.* at 18.

⁷² 2014 U.S. Surgeon General's Report, *supra* note 4, at 827.

C. The Proposed Health Warning for E-Cigarettes Should Be Strengthened

The FDA should strengthen the proposed health warning for e-cigarettes in order to effectively inform the public about the dangers of nicotine and other chemicals, prevent consumers from initiating nicotine use, and encourage them to quit.

Although the first Surgeon General’s report on the dangers of smoking came out in 1964, it took another 20 years for comprehensive labeling reform.⁷³ More than 20 million Americans have died from smoking in the years since 1964.⁷⁴

As the large tobacco companies purchase e-cigarette companies and spend enormous amounts of money marketing e-cigarettes and other non-cigarette nicotine products, it is likely that more people will become exposed and addicted to nicotine outside of traditional cigarette smoking.⁷⁵ Considerable research has shown that nicotine is more than addictive—it is harmful in its own right.⁷⁶ The FDA should take this opportunity to establish effective warning notices about nicotine and other harmful chemicals in e-cigarettes now.

1. The warning proposed by the FDA—that e-cigarettes contain nicotine, which is addictive—will not prevent consumers from starting nicotine use or encourage them to quit

A survey of how cigarette health warning notices influence quitting found that “the stronger the warnings, the greater they stimulate cognitive and behavioural reactions.”⁷⁷ The FDA warnings need to be designed to encourage reducing nicotine use for those already using, and as prevention against those considering nicotine use.

The tobacco and e-cigarette companies spend billions of dollars on marketing to young adults and adolescents.⁷⁸ To combat an onslaught of such advertising, the FDA should use its authority to require more effective warnings on e-cigarettes so that the public may be more informed about the dangers of products containing nicotine.

a. The content of effective warnings on e-cigarettes should be varied, explicit, vivid, and emotionally persuasive

Studies have shown that a person’s familiarity with a warning results in reduced attention and recall.⁷⁹ Enhancing the vividness of the label has been positively correlated to increased

⁷³ Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (2013) (compare the 1965 Amendment to the 1985 Amendment of § 1333).

⁷⁴ 2014 U.S. Surgeon General’s Report, *supra* note 4, at i.

⁷⁵ *See generally Id.*; *see also* Richtel, *supra* note 62.

⁷⁶ *See generally* 2014 U.S. Surgeon General’s Report, *supra* note 4, at 107-38.

⁷⁷ Ron Borland, et al., *How Reactions to Cigarette Packet Health Warnings Influence Quitting: Findings from the ITC Four-Country Survey*, 104 *Addiction* 669, 673 (2009).

⁷⁸ 2012 U.S. Surgeon General’s Report, *supra* note 3, *Message from Howard Koh, Assistant Secretary for Health*.

⁷⁹ *See* Caroline Miller, *Market Impact of Tobacco Pack Warnings- Current Warning Labels and Beyond*, 36 *Cancer Forum* (2012), available at http://www.cancerforum.org.au/file/2012/Forum/CFMAR2012_Forum3.pdf (last visited July 10, 2014).

attention, comprehension, and recall. For example, research has shown that consumers recall warnings better when the warnings have color rather than only black and white.⁸⁰ Yellow is perhaps the most attention-grabbing color.⁸¹ Thick borders and bold lettering have also been shown to increase consumer attention.⁸²

The potential consequences of nicotine use need to be listed explicitly, as explicit warnings are associated with greater perception of potential danger than vague or general warnings.⁸³ Also, serious and emotionally persuasive warnings have been shown to have more impact than less emotionally persuasive warnings.⁸⁴

b. Size and placement

The World Health Organization Framework Convention on Tobacco Control requires that all member parties eventually enact laws requiring tobacco package warnings and messages to cover 50 percent or more of the principal display area.⁸⁵

The warning on the front of the package should be a short and explicit warning statement that is large enough to be readily visible and readable, and the warning on the back should be large enough to more fully develop the basis for the front warning statement. The combination of short and salient health claims on the front of the package with more fully developed health claims on the back produces better consumer awareness and understanding, and greater believability of the health claim in the mind of the consumer.⁸⁶

2. The need for more effective warnings is justified by the substantial number of harmful consequences that result from exposure to nicotine, especially among youth

The last decade has seen numerous experiments on the effect of nicotine exposure on the brain. Researchers have focused on the effects of nicotine exposure on the adolescent brain in particular because, “most likely owing to its ongoing development, the adolescent brain is more vulnerable to the effects of nicotine than the adult brain.”⁸⁷ The adolescent brain is particularly

⁸⁰ *Id. See, e.g., ANSI Z535.1-2006, Safety Colors, Am. Nat’l Standards Inst. (2011).*

⁸¹ Carlton Wagner, *Color Cues: Understanding the Cues in Color, Marketing Insights*, 45-46 (Spring 1990).

⁸² Michael S. Wogalter et al., *Research-based Guidelines for Warning Design and Evaluation*, 33 *Applied Ergonomics* 219, 221 (2002).

⁸³ *Id.* at 221-22.

⁸⁴ Caroline L. Miller et al., *Smokers’ recall of Australian graphic cigarette packet warnings & awareness of associated health effects, 2005-2008*, 11 *BMC Pub. Health* 238 (2011).

⁸⁵ World Health Organization, *WHO Framework Convention on Tobacco Control*, Art. 11 (2003).

⁸⁶ Brian Wansink, *How do Front and Back Package Labels Influence Beliefs about Health Claims?*, 37 *J. of Consumer Aff.* 305, 307-08 (2003).

⁸⁷ Natalia A. Goriounova & Huibert D. Mansvelder, *Short- and Long-Term Consequences of Nicotine Exposure during Adolescence for Prefrontal Cortex Neuronal Network Function*, *Cold Spring Harbor Persp. in Med.*, 3 (2012). For the legitimacy of using animal models to extrapolate nicotine’s effects on humans, see L.P. Spear, *The Adolescent Brain and Age-Related Behavioral Manifestations*, 24 *Neuroscience and Biobehavioral Rev.* 417, 418 (2000).

vulnerable to nicotine addiction. Adolescents are also less susceptible to withdrawal symptoms, creating an all-reward, no-regret system for psychostimulant use.⁸⁸ Exposure to nicotine, particularly in adolescence, permanently alters the physical structure and gene expression of the brain, lowers adult impulse control and attention performance, and causes other structural changes.⁸⁹

Multiple studies have found significant permanent cognitive effects from exposure to nicotine during adolescence. Adolescent brains exposed to nicotine lose memory accuracy and show long-term reductions in impulse control and short-term reductions in verbal memory during withdrawal.⁹⁰

Another consequence of adolescent exposure to nicotine is the increased likelihood of psychiatric illness. Repeated studies over tens of thousands of adolescents have shown nicotine use as an adolescent leads to and predicts psychiatric disorders, in particular depression, in adolescents and adults.⁹¹

Nicotine has other significant dangers associated with contact and exposure. Nicotine can affect the body if it is inhaled, comes in contact with the eyes or skin or is swallowed.

⁸⁸ David A. Sturman & Bitu Moghaddam, *Striatum Processes Reward Differently in Adolescents versus Adults*, 109 Proc. of the Nat'l Acad. of Sci. of the USA 1719, 1719-1724 (2012); Walter Adriana et al., *Evidence for Enhanced Neurobiological Vulnerability to Nicotine during Periadolescence in Rats*, 21 J. of Neuroscience 4712, 4712-16 (2003); Laura E. O'Dell et al., *Diminished Nicotine Withdrawal in Adolescent Rats: Implications for Vulnerability to Addiction*, 186 Psychopharmacology 612, 612-19 (2006).

⁸⁹ See Oskana O. Polesskaya et al., *Nicotine Causes Age-Dependent Changes in Gene Expression in the Adolescent Female Rat Brain*, 29 Neurotoxicology and Teratology 126, 126-40 (2007); Counotte et al., *Lasting Synaptic Changes Underlie Attention Deficits Caused by Nicotine Exposure during Adolescence*, 14 Nature Neuroscience 417, 417-19 (2011); Natalia A. Goriounova & Huibert Mansvelder, *Nicotine Exposure during Adolescence Leads to Short- and Long-Term Changes in Spike Timing-Dependent Plasticity in Rat Prefrontal Cortex*, 32 J. of Neuroscience 10484, 10484-93 (2012); Jennifer B. Dwyer et al., *The Dynamic Effects of Nicotine on the Developing Brain*, 122 Pharmacology and Therapeutics 125, 125-39 (2009); R. Brown & B. Kolb, *Nicotine Sensitization Increases Dendritic Length and Spine Density in the Nucleus Accumbens and Cingulate Cortex*, 889 Brain Res. 94, 94-100 (2001); Leslie K. Jacobsen et al., *Prenatal and Adolescent Exposure to Tobacco Smoke Modulates the Development of White Matter Microstructure*, 27 J. of Neuroscience 13491, 13491-98 (2007).

⁹⁰ Theodore A. Slotkin, *Nicotine and the Adolescent Brain: Insights from an Animal Model*, 24 Neurotoxicology and Teratology 369, 369-84 (2002); Danielle S. Counotte et al., *Long-Lasting Cognitive deficits Resulting from Adolescent Nicotine Exposure in Rats*, 34 Neuropsychopharmacology 299, 299-306 (2009); Leslie K. Jacobsen et al., *Effects of Smoking and Smoking Abstinence on Cognition in Adolescent Tobacco Smokers*, 57 Biological Psychiatry, 56, 56-66 (2005).

⁹¹ Brown et al., *Cigarette Smoking, Major Depression, and Other Psychiatric Disorders among Adolescents*, 35 J. of the Am. Academy of Child & Adolescent Psychiatry 1602, 1602-10 (1996); Elizabeth Goodman & John Capitman, *Depressive Symptoms and Cigarette Smoking among Teens*, 106 Pediatrics 748, 748-55 (2000); Won S. Choi et al., *Cigarette Smoking Predicts Development of Depressive Symptoms among U.S. Adolescents*, 19 Annals of Behav. Med. 42, 42-50 (1997); Judith S. Brook et al., *Cigarette Smoking and Depressive Symptoms: a Longitudinal Study of Adolescents and Young Adults*, 95 Psychological Reports 159, 159-166 (2004); Iñiguez et al., *Nicotine Exposure During Adolescence Induces a Depression-like State in Adulthood*, 34 Neuropsychopharmacology 1609, 1609-24 (2009).

Overexposure to nicotine in the short term may cause such symptoms as vomiting, diarrhea, headache, lack of physical coordination, and cause the heart to beat irregularly or even stop.⁹² Nicotine also has increased health risks for pregnant women, with research showing adverse effects on a fetus's lungs, heart, and central nervous system.⁹³ As e-cigarettes increase in popularity, calls to the nation's poison control centers about exposure to the liquid nicotine used in many of the devices have surged, according to the CDC.⁹⁴ More than half of the calls to poison control centers recorded by the CDC concerned children age five and younger who had been exposed to toxic levels of nicotine.⁹⁵ In many states, the cartridges of liquid nicotine used to fill or refill e-cigarettes are not required to be childproof, and some packaging and point of sale displays for e-cigarettes and nicotine refill cartridges lack any warnings about nicotine toxicity.

In addition to nicotine, other chemicals not mentioned in the proposed warning but found in e-cigarettes, including propylene glycol, also pose health risks.⁹⁶ Propylene glycol has not been approved for safe inhalation and is a known irritant.⁹⁷ Even though propylene glycol is often believed to be "safe" because the FDA has approved its use in certain foods,⁹⁸ the extent of any physiological reaction to inhaling vaporized propylene glycol is still being studied.⁹⁹ However, a study published in the *Journal of Occupational and Environmental Medicine* concluded that only a short exposure to propylene glycol mist from an artificial smoke generator

⁹² Dep't of Health and Hum. Serv., *Occupational Health Guideline for Nicotine* (Sept. 1978), available at <http://www.cdc.gov/niosh/docs/81-123/pdfs/0446.pdf> (last visited July 10, 2014). See, Ctr. for Disease Control and Prevention, *The Emergency Response Safety and Health Database: Nicotine: Systemic Agent*, available at http://www.cdc.gov/niosh/ershdb/EmergencyResponseCard_29750028.html (last visited July 10, 2014).

⁹³ 2014 U.S. Surgeon General's Report, *supra* note 4.

⁹⁴ See Ctr. For Disease Control and Prevention, *Calls to Poison Centers for Exposures to Electronic Cigarettes - United States, September 2010 – February 2014*, 63 *Morbidity and Mortality Weekly Report* (MMWR) 277, 292-293 (Apr. 4, 2014) (Phone calls to poison centers rose from one per month in September of 2010 to 215 per month by February of 2014, according to researchers at the CDC).

⁹⁵ *Id.*

⁹⁶ U.S. Food & Drug Admin., *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by the FDA* (July 22, 2009), available at <http://www.fda.gov/newsevents/publichealthfocus/ucm173146.htm> (last visited July 10, 2014). See generally *infra* notes 89-92.

⁹⁷ See, e.g., Am. Chemistry Council's Propylene Oxide/Propylene Glycol Panel, *Propylene Glycol Information Update: Considerations against use in theatrical fog* (July 2001), available at http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0046/0901b80380046c79.pdf?filepath=propyleneglycol/pdfs/noreg/117-01659.pdf&fromPage=GetDoc (last visited July 10, 2014). See Vape Ranks, *Propylene Glycol vs. Vegetable Glycerin E-Liquid – What's the Difference?* (Mar. 28, 2013) available at <http://vaperanks.com/propylene-glycol-vs-vegetable-glycerin-e-liquid-whats-the-difference/> (last visited July 10, 2014). see also, Agency for Toxic Substances and Disease Registry (ATSDR), *Addendum to the Toxicological Profile for Propylene Glycol* (Dec. 2008) available at http://www.atsdr.cdc.gov/toxprofiles/propylene_glycol_addendum.pdf (last visited July 10, 2014).

⁹⁸ 21 C.F.R. § 184.1666 (1982).

⁹⁹ See ATSDR, *supra* note 97.

was enough to cause “acute ocular and upper airway irritation in non-asthmatic subjects. [. . .]A few [test subjects] may also react with minor lower airway obstruction, cough, and mild dyspnea [(shortness of breath)].”¹⁰⁰

As discussed in Section III.A. of this Comment, the FDA should consider the significant risk from exposure to nicotine and other chemicals in e-cigarettes, and should properly inform the public of these dangers through effective warning notices.

Recommendations

The warnings should effectively inform the public about the dangers of exposure to nicotine and other chemicals. To accomplish this, the FDA should use the Tobacco Control Act and the Federal Cigarette Labeling and Advertising Act (FCLAA) as guideposts. In the Tobacco Control Act, Congress found that nicotine is an addictive drug, almost all new users of tobacco products are under the legal minimum age to purchase tobacco products, young people are a vital segment of the tobacco market, and because past attempts to reduce adolescent use of tobacco products had all failed, “comprehensive restrictions on the sale, promotion, and distribution of such products are needed.”¹⁰¹

In another attempt to warn the public of the dangers of tobacco use, Congress passed the FCLAA, which informs the public about the adverse health effects of smoking through warning notices on each package.¹⁰² In particular, in the Tobacco Control Act amendments to FCLAA, Congress established nine rotating warning notices that all cigarette packages were required to bear at some time.¹⁰³ The harms noticed in these warnings vary from addiction to cancer to fetal harm.¹⁰⁴ A recent Australian study showed that even when presented in conjunction with graphic images, warning about addiction is far less effective than warning about other harms, such as sickness, death, and injury to the smoker’s fetus.¹⁰⁵

Similar to Congress’s intent in the Tobacco Control Act and FCLAA, the warnings placed on the front of e-cigarette packaging need to be in an attention-grabbing color, with the messages varied regularly. Statements made in the text must be short enough to be comprehended easily, and emotionally persuasive. The warnings on the front of the packaging need to be large enough to be readily visible and the writing needs to be in bold lettering. For those consumers looking for more information, the backs of e-cigarette packages should contain

¹⁰⁰ G. Wieslander et al., *Exposure to propylene glycol mist in aviation emergency training: acute ocular and respiratory effects*, 58 Occupational and Env'tl. Med. 649, 649-655 (Oct. 2001), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740047/> (last visited July 10, 2014).

¹⁰¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1777 (June 22, 2009).

¹⁰² See generally Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (2013).

¹⁰³ 15 U.S.C. § 1333 (2012).

¹⁰⁴ *Id.*

¹⁰⁵ See Miller, *supra* note 79, at 7 (even when attention-grabbing graphic was added to older warning “Smoking is Addictive,” both awareness and recall of the harm stayed low among smokers.)

more detailed information related to the specific warning on the front. The FDA should also consider developing graphic warnings for e-cigarettes using similar criteria.¹⁰⁶

Finally, the FDA proposes requiring companies to provide warnings on packages and in advertising for covered tobacco products, including e-cigarettes, that nicotine is an addictive chemical. For the reasons discussed above, the FDA should require companies to provide warnings about the numerous other health risks as well. In addition, the FDA should clarify that the warning statements this rule prescribes establish a floor for health warnings on packaging and in advertising, not the ceiling. There is no basis in the record to preempt other health warnings imposed by states and localities for these products,¹⁰⁷ and many companies already provide additional warnings.¹⁰⁸ We do not read the Proposed Rule to preclude other health warnings, but the FDA needs to make this point clear. Changing the heading of Part 1143 from “Required Warning Statements” to “Minimum Required Warning Statements” is one way to achieve this. It would make explicit what is implicit in the Proposed Rule—that the FDA’s required warning statements for covered tobacco products are intended to supplement, not to preempt, other health warnings and warning requirements.

¹⁰⁶ Recent changes in cigarette labels across the world have shown the effectiveness of graphic labels. See Miller, *supra* note 79; Jennifer Cantrell et al., *Impact of Tobacco Related Health Warning Labels across Socioeconomic, Race and Ethnic Groups: Results from a Randomized Web-Based Experiment*, 8 PLOS One e52206 (2013); Hammond et al., *Perceived Effectiveness of Pictorial Health Warnings among Mexican Youths and Adults: a Population-Level Intervention with Potential to Reduce Tobacco-Related Inequities*, 23 *Cancer Causes Control* 57, 57-67 (2012).

¹⁰⁷ For example, California requires companies whose products contain nicotine to provide a clear and reasonable warning to California consumers that nicotine is a reproductive toxin. Cal. Health & Safety Code, §§ 25249.5-25249.13.

¹⁰⁸ See, e.g., MarkTen e-cigarettes warning: “This product is not a smoking cessation product and has not been tested as such. This product is intended for use by persons of legal age or older, and not by children, women who are pregnant or breast feeding, or persons with or at risk of heart disease, high blood pressure, diabetes, or taking medicine for depression or asthma. Nicotine is addictive and habit forming, and it is very toxic by inhalation, in contact with the skin, or if swallowed. Nicotine can increase your heart rate and blood pressure and cause dizziness, nausea, and stomach pain. Inhalation of this product may aggravate existing respiratory conditions. Ingestion of the non-vaporized concentrated ingredients in the cartridges can be poisonous. CA Proposition 65 WARNING: This product contains nicotine, a chemical known to the state of California to cause birth defects or other reproductive harm.” MarkTen Product Health Issues, available at <http://www.nu-mark.com/our-products/mark-ten/health-issues/Pages/default.aspx?src=topnav> (last visited July 14, 2014). See also NJOY e-cigarette warning: “NJOY® products are not smoking cessation products and have not been tested as such. NJOY products are intended for use by adults of legal smoking age (18 or older in California), and not by children, women who are pregnant or breastfeeding, or persons with or at risk of heart disease, high blood pressure, diabetes or taking medicine for depression or asthma. NJOY products contain nicotine, a chemical known to the state of California to cause birth defects or other reproductive harm. Nicotine is addictive and habit forming, and it is very toxic by inhalation, in contact with the skin, or if swallowed. Ingestion of the non-vaporized concentrated ingredients can be poisonous. NJOY Reservoirs may be a choking hazard. Keep all components away from children and pets. If any components are ingested, immediately consult your doctor or vet.” NJOY Website, available at <https://www.njoy.com/faq> (last visited July 14, 2014).

D. The Deeming Rule Should Define E-Cigarette Components and Parts and Should Not Exempt Them from the Age Verification Requirements, Health Warnings, and Vending Machine Sales Ban Applicable to E-Cigarettes

The FDA requests comment on whether it should define components and parts of tobacco products. Further, the FDA also seeks comment on its proposal to exclude components and parts that do not contain nicotine from restrictions on age verification, vending machine sales, and health warnings.

As discussed more fully below, the FDA should define components and parts of e-cigarettes to standardize enforcement nationally, prevent confusion in the marketplace, and close any potential loopholes to circumvent compliance with the law. Moreover, the FDA should not exclude components and parts of e-cigarettes that do not contain nicotine from restrictions on age verification, vending machine sales, and health warnings.

We support the regulation of components and parts of e-cigarettes and the decision not to regulate accessories. However, the FDA is proposing to treat components and parts that do not contain nicotine differently within the deeming regulations from those that do, and we believe that this different treatment may lead to confusion in the marketplace and inconsistent enforcement.

1. The FDA should define “components and parts” and “accessories” for e-cigarettes

The Executive Summary of the Proposed Rule provides that “components and parts of tobacco products are those items that are included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product. . . . [and] accessories to be those items that are not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product, but may be used, for example, in the storage or personal possession of a proposed deemed product.”¹⁰⁹ “[C]omponents and parts of the proposed deemed tobacco products would fall under the scope of this rule, but accessories would not.”¹¹⁰ The FDA goes on to state that it is “not proposing definitions for components, parts, or accessories[, but that if it] were to develop definitions of these categories of products, the definitions likely would include factors such as whether these items are directly involved in the consumption, storage, or personal possession of tobacco products [and] would take into account the foreseeable effect on public health of these items and whether a tobacco product can effectively be consumed without such item.”¹¹¹

Thus, the FDA is not proposing definitions for components, parts, or accessories. However, we believe that the new and evolving nature of the e-cigarette requires clear and concise definitions for its components, parts, and accessories to prevent any confusion that may arise.

The component of e-cigarettes that brings them within the scope of the Proposed Rule is the liquid nicotine solution, often called e-liquid.¹¹² However, there are several other portions to

¹⁰⁹ Proposed Rule, *supra* note 1, at 23153.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Grana, *supra* note 41, at 1972.

the e-cigarette device, i.e., battery, atomizer, and either a cartridge or tank, that are essential in the consumption or use of the tobacco product and therefore should be classified as a component and/or part even though they do not contain nicotine. Liquid nicotine cannot be consumed without each of these components working in conjunction with each other to deliver the nicotine to the consumer.¹¹³ Furthermore, any item that charges the battery, such as a USB charger, should also fall within the definition of components and parts. The USB charger is typically a proprietary device that attaches directly to the battery of an e-cigarette and is inserted into a generic USB port. Although the USB charger is not used during the consumption of a tobacco product, the device must be charged in order for the tobacco product to be consumed. The FDA should settle any ambiguity between what is a component and part and what is an accessory as it is foreseeable that manufacturers may market batteries, atomizers, and tanks or cartridges as accessories in order to avoid the requirements and restrictions imposed on them once e-cigarettes are deemed a tobacco product. Some e-cigarette retailers currently list items such as batteries and tanks on their websites as “accessories.”¹¹⁴

We therefore propose the FDA define the term “components and parts” as follows: A component or part is anything that is used or could be used to make or use the finished product that affects the nicotine, controls the nicotine, is affected by the nicotine, can be mixed with the nicotine, is required for proper function of the device, or monitors nicotine use either for refill level or for user data to measure user habits and personal use of nicotine.¹¹⁵ The language, “make or use the finished product” would apply to both the consumer and the manufacturer. The e-cigarette user can select the device, the battery and the composition of the liquid, including the amount of nicotine and type of flavoring, and assemble the parts to create the product the user desires. As a result, each such item, whether or not it contains nicotine, should be deemed a component or part.

By contrast, an accessory would be anything not required to make or use the finished product. The finished product can effectively work standing alone without necessity of a non-essential item.¹¹⁶ We agree that accessories should not be deemed covered tobacco products.

¹¹³ Eversmoke, *Parts of an E-cigarette and How They Work Together*, <http://www.learn.eversmoke.com/parts-of-an-e-cigarette.html> (last visited July 14, 2014).

¹¹⁴ blu, <http://store.blucigs.com/accessories/> (last visited July 14, 2014); Pro-Vape, <http://www.provape.com/ecig-accessories-s/20.htm#> (last visited July 14, 2014); South Beach Smoke, <http://www.southbeachsmoke.com/e-cigarette-accessories/e-cigarettes/> (last visited July 14, 2014); Tasty Puff, <https://www.tastypuff.com/product-category/vapor-cigarette/> (last visited July 14, 2014).

¹¹⁵ Examples of components and parts would include but not be limited to e-liquid, e-juice, waxes, herbs, batteries, battery connectors, cartridges, drip tips, drip-tip adapters, atomizers, tanks, tank tubes, cartomizer, rebuildable dripping atomizer (RDA), drip cartridge tips (DCT), microprocessors, memory chips, replacement coils, tubes, caps, RSST (device that allows interchange of parts between different e-cig brands), omnidapters, atomizer tube connectors, airflow caps, tank airflow controllers, fuse, circuit boards, extensions, refilling drip tips, regulators, switches, actuators, LEDs, DIY (do-it-yourself) parts, syringes, e-juice bottles, needle slip tip syringe, needles, gauges, and USB charger.

¹¹⁶ Examples of accessories would include but not be limited to carrying cases, power cords, acrylic device holders, battery case, cartridge opener (aka cartomizer punch), drip tip cover, instruction manual/brochure, lanyards, cones, mod claw, assembled volt indicator, omnitester, Atomizer Ohm meter.

2. The FDA should not exempt any component or part of e-cigarettes from age verification requirements, vending machine restrictions, or health warnings

a. Minimum age and vending machine requirements for e-cigarette components and parts

The FDA rationalizes excluding components and parts from minimum age and vending machine restrictions by stating, “that applying minimum age and identification restrictions to covered tobacco products only (and not to the components and parts that do not contain nicotine or tobacco) would be sufficient to protect the public health, because youth will not be able to use such components and parts and potentially suffer the consequences without also obtaining the covered tobacco product.”¹¹⁷ We disagree and urge the FDA to treat components and parts the same in Part 1140 as in Part 1100. Not only would the Proposed Rule’s exclusion of components and parts that do not include nicotine under Part 1140 (but not under Part 1100) create confusion in the marketplace, but also the components and parts of e-cigarettes should not be accessible to youth under 18 years of age.

The nature of e-cigarette products requires that all components and parts, not merely the liquid nicotine or the cartridge containing the liquid nicotine, be regulated. Exemption of components and parts from certain provisions of the Proposed Rule would confuse retailers. For example, all components of disposable e-cigarettes would be covered under Parts 1100 and 1140 as they are contained in the finished product that includes nicotine. However, in reusable e-cigarettes, which have a battery and cartridge that are intended to be replaced, only the liquid nicotine itself and the cartridge when filled with nicotine would be classified as a component of a covered tobacco product and therefore subject to minimum age and vending machine requirements.

The Proposed Rule’s exemption of components and parts of e-cigarettes from certain requirements is also inconsistent with state and federal treatment of other tobacco product paraphernalia. Many states already have laws that prohibit the sale to minors of not only tobacco products, but also smoking paraphernalia and tobacco accessories, including cigarette paper.¹¹⁸ The FDA also currently regulates papers under the FD&C Act.¹¹⁹ Cigarette papers are components and parts of roll-your-own cigarettes just as the batteries, atomizers, and cartridges or tanks are components and parts of e-cigarettes. All of these components are parts of the finished product and are necessary for consumer use in the consumption of the nicotine.

At least 39 states now prohibit the sale of e-cigarettes to minors.¹²⁰ Many of these laws also prohibit the sale to minors of the electronic device as well as any cartridge or component of

¹¹⁷ Proposed Rule, *supra* note 1, at 23178.

¹¹⁸ Some states that prohibit the sale to minors of tobacco accessories and paraphernalia are AZ (Ariz. Rev. Stat. Ann. § 13-3622 (2013)), CA (CA Health & Safety Code § 119405 (2010)), IL (720 Ill. Comp. Stat. 685/2 (1982)), NY (N.Y. Pub. Health Law § 1399-cc (2013)), TN (Tenn. Code Ann. § 39-17-1504 (2013)), and UT (Utah Code Ann. §§ 76-10-104, 76-10-104.1 (2010)).

¹¹⁹ 21 U.S.C. §§ 387(d)(a)(1), 387(e)(j), 387(j)(a)(1), (b)(1)(B).

¹²⁰ AL, AK, AZ, AR, CA, CO, CT, DE, FL, HI, ID, IL, IN, KS, KY, LA, MD, MN, MS, NV, NH, NJ, NY, NC, OH, OK, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, and WY. Nat’l Conf. of St. Legislatures, *Alternative Nicotine Products: Electronic Cigarettes* (June 30, 2014), available at

the device.¹²¹ Federal regulation to prohibit sale to minors of e-cigarettes, including their components and parts whether or not they contain nicotine, would close the federal-state regulatory disconnect, and complement the states' efforts to protect minors and the population as a whole. On the other hand, failure of the FDA to regulate the components and parts of e-cigarettes with regard to age verification, vending machine restrictions, and health warnings, and to provide a regulatory scheme to govern any such future electronic alternative tobacco products in their entirety would result in inconsistent regulation at the state and federal levels. While states would prohibit the sale to minors of e-cigarette cartridges and other components not containing nicotine, federal regulation would not.

Any type of liquid solution that may be used in an e-cigarette device, regardless of whether it contains nicotine, should be classified as a component because it can be mixed with a solution that does contain nicotine. In particular, if the FDA bans flavored nicotine solutions, end users, including minors, may purchase flavored non-nicotine solutions to use (either alone or in conjunction with nicotine solutions) in an e-cigarette. The FDA has proposed to bring under its authority flavor enhancers for hookahs as a component or part,¹²² even though not all hookah flavor enhancers contain nicotine.¹²³ The FDA should similarly exercise such authority as to flavored solutions that can be used in e-cigarettes. The need to include e-liquids, whether or not they contain nicotine, in the Part 1140 restrictions is particularly urgent because they are easily accessible to minors online.¹²⁴ Some websites that sell e-liquids either do not require age verification or merely require the statement of a birthdate, which can easily be falsified.¹²⁵ The ease of access to e-liquids via the web is a reason why all components and parts should be subject to the restrictions on underage sales.

Another reason components and parts should not be limited to those containing nicotine is that e-cigarettes, such as vape pens and tanks, can be customized by the user to smoke liquid

<http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx> (last visited July 29, 2014). IA also recently passed legislation prohibiting the sale of e-cigarettes to minors. *See* H. 2109, 85th Gen. Assemb. (Iowa 2014), available at <http://coolice.legis.iowa.gov/Cool-ICE/default.asp?Category=billinfo&Service=Billbook&menu=false&hbill=hf2109> (last visited July 30, 2014).

¹²¹ Some states that prohibit the sale to minors of any components and parts of e-cigarettes are CT (Public Act No. 14-76), FL (SB 224 (2014)), HI (Hawaii Rev. Stat. §709-908), ID (Idaho Code §39-5705 (2013)), IL (720 ILCS 675/1.5), IN (Ind. Code §35-46-1-10), KY (SB 109 (2014)), MN (Minn. Stat. §609.6855), NJ (N.J. Stat. Ann. §2A:170-51.4 (2013)), NC (N.C. Gen. Stat. §14-313) and WA (Wash. Rev. Code §26.28.080). *Id.*

¹²² Proposed Rule, *supra* note 1, at 23153.

¹²³ Legalbuds.com, <http://www.legalbuds.com/shisha-tobacco-free-.html> (last visited July 14, 2014); Hydro Herbal 50g Kali Drizzle Hookah Shisha Tobacco Free Molasses, <http://www.amazon.com/Herbal-DRIZZLE-Hookah-Tobacco-Molasses/dp/B007KFXL72> (last visited July 14, 2014); Tasty Puff, <https://www.tastypuff.com/about-us/product-facts/> (last visited July 14, 2014); Hookah Company, http://www.hookahcompany.com/all_shisha_32_ctg.htm (last visited July 14, 2014).

¹²⁴ *Gateway to Addiction*, *supra* note 53, at 13-14.

¹²⁵ Cig, www.e-cig.com (last visited July 14, 2014); Madvapes, <https://www.madvapes.com> (last visited July 14, 2014); Vapage, <http://vapage.com/> (last visited July 14, 2014); E-Liquid-USA, <https://eliquid-usa.com> (last visited July 14, 2014).

marijuana, hashish, shisha, oils, whole tobacco, herbs and other drug products. A lifelong marijuana user confessed to using a vapor pen to smoke liquid marijuana on a train commute from New York to Baltimore undetected.¹²⁶ The Konyo complete 3-in-One Vaporizer portable vape pen¹²⁷ has been described by Susanne E. Tanski, MD, MPH, FAAP, a pediatrician with the American Academy of Pediatrics, as the marijuana vape pen.¹²⁸

b. Warning labels for components and parts of e-cigarettes

Many e-cigarettes that are sold as a finished product, including disposable e-cigarettes and those with pre-filled nicotine replacement cartridges, will contain the health warning that nicotine is addictive. However, other e-cigarette products that are marketed separately as replacement components and parts would not contain the warning under proposed § 1143.1 unless the component or part contains nicotine. Some components and parts are marketed and sold to be used in conjunction with e-liquid, which does contain nicotine.¹²⁹ Because these components and parts are intended for use in e-cigarettes and many are easily available via the Internet, they should contain a broader warning. We propose a variation of the proposed nicotine warning for those components and parts which do not contain nicotine: “WARNING: This product is intended for use in the consumption of tobacco products, which contain nicotine derived from tobacco. Nicotine is a harmful and addictive chemical.”

Recommendations

The FDA should include all components and parts of e-cigarettes and electronic alternative tobacco products that may be designed in the future as covered tobacco products, whether or not they contain nicotine. Failure to do so may result in public misuse of the products, access by minors, and inconsistent enforcement. Regulation of components and parts is necessary for the protection of public health.

For these reasons, the FDA should define components and parts to standardize enforcement nationally, prevent confusion in the marketplace, and close any potential loopholes to circumvent compliance with the law. Moreover, the FDA should not exclude components and parts that do not contain nicotine from restrictions on age verification, vending machine sales, and health warnings.

¹²⁶ More and more, people are smoking marijuana out of e-cigarettes and vapor pens—right out in the open with little or no fear of getting caught. Such misuse is easy as marijuana emits no odor when smoked in its liquid or wax forms in an e-cigarette vaporizer. Concealing the e-cigarette device or vaporizer is also easy as there is no flame. Ann Givens & Pei-Sze Cheng, *I-Team: E-cigarettes, Used to Smoke Marijuana, Spark New Concerns*. NBC Channel 4 N.Y., (Oct. 11, 2013, 9:54 AM), available at <http://www.nbcnewyork.com/investigations/ECigarettes-Drugs-Marijuana-Vapor-Pens-Smoking-I-Team-227269001.html> (last visited July 14, 2014).

¹²⁷ Konyo, *Triad Vape Pen – The Only true 3 in 1 Vaporizer Pen*, <http://konyovapepen.com/vaporizers/vaporizer-pens/triad-vape-pen> (last visited July 14, 2014).

¹²⁸ Webcast, Julius B. Richmond Center of Excellence, *E-cigarettes—All that Vapes is not Nicotine* (June 3, 2014) available at <http://www2.aap.org/richmondcenter/RichmondCenterWebinarSeries.html>.

¹²⁹ Vapage.com, <http://vapage.com/tanks/crystal-xl-bdc-tank.html> (last visited July 14, 2014); Madvapes.com, <http://www.madvapes.com/2-5ml-nbc-tanks.html> (last visited July 14, 2014).

IV. CIGARS

A. The FDA's Proposal to Classify Cigars as "Covered Tobacco Products" Is Appropriate for the Protection of the Public Health

We agree with the FDA's proposal to classify cigars as subject to the FD&C Act provisions applicable to "tobacco products" because doing so is appropriate for the protection of the public health. In addition, the FDA should finalize the proposals setting a minimum age of purchase for cigars, prohibiting vending machine sales of cigars, and prescribing health warnings for cigars. We also urge the FDA to take additional steps to regulate all cigars (Option 1) and not except premium cigars from regulation (Option 2).

The use of cigars by minors and young adults has increased significantly in recent years. The Proposed Rule includes data indicating "that small and large cigars are no longer an 'alternative' to cigarette use, but rather they are the most popular tobacco product for many young people."¹³⁰ Between 1997 and 2007 little cigar sales increased 240 percent, with flavored brands comprising nearly four-fifths of the market share.¹³¹

Moreover, as mentioned above, there has been an overall increase in cigar consumption in recent years even as the use of cigarettes has decreased. The Proposed Rule points out that between 2000 and 2011 there was a rapid increase in consumption of cigars, cigarillos and pipe tobacco in the U.S., and a one-third decrease in consumption of cigarettes.¹³² If anything, the reported numbers regarding cigars are too low because "cigar use is underreported by adolescents in part due to misunderstanding of the definition of 'cigar.'"¹³³

It is also evident from many studies cited in the Proposed Rule that cigars contain nicotine, are combustible, contain the same toxic and carcinogenic compounds as cigarettes, are addictive, and create a risk of increased initiation of tobacco use and concomitant harm.¹³⁴ A large cigar may contain as much tobacco as an entire pack of cigarettes, and nicotine levels in cigar smoke can be up to eight times higher than levels in cigarette smoke.¹³⁵ These are potent reasons why the FDA should regulate cigars in the same fashion as cigarettes.

Cigars, however, have escaped regulation by the FDA despite the fact that many cigars are for all practical purposes indistinguishable from cigarettes. "Little cigars are comparable to cigarettes with regard to shape, size, filters, and packaging, and the tobacco industry has promoted little cigars as a lower-cost alternative to cigarettes."¹³⁶ Moreover, the price of a pack

¹³⁰ Proposed Rule, *supra* note 1, at 23167.

¹³¹ *Id.* at 23144.

¹³² *Id.* at 23147.

¹³³ "For example, when a group of students were re-administered a national survey but asked whether they had used cigars with the brand name 'Black and Mild' in the past 30 days rather than just 'cigars, little cigars, or cigarillos,' the percentage of students reporting cigar use nearly doubled—from 12.9 percent to 20.7 percent." *Id.* at 23155.

¹³⁴ *Id.* at 23150-23151; Nat'l Cancer Inst., *Cigars: Health effects and trends*, Smoking and Tobacco Control Monograph No. 9, U.S. Dep't of Health and Hum. Servs. at 3 (1998), available at <http://cancercontrol.cancer.gov/tcrb/monographs/9/>.

¹³⁵ Proposed Rule, *supra* note 1, at 23151.

¹³⁶ King, *supra* note 12, at 41.

of these cigarette-like little cigars is typically much lower than that of a pack of cigarettes, and the price of two flavored foil-wrapped cigarillos is often as little as \$1.00.¹³⁷ We share the FDA's concern that these little cigars have escaped meaningful regulation.¹³⁸

Compounding these concerns are commonly held misperceptions, including by youth, that cigars are not as harmful as cigarettes or are safe alternatives to cigarettes.¹³⁹ It is perhaps for this reason that among middle- and high-school smokers, "the prevalence of those not thinking about quitting tobacco use was higher among current flavored-little-cigar and menthol cigarette users than nonusers."¹⁴⁰ The Proposed Rule states that a study "showed that adult cigar smokers (including cigarillo smokers) were three times as likely as non-cigar smokers to believe, mistakenly, that switching from cigarettes to cigars reduces a smoker's chance of illness (32.3 percent versus 11.2 percent), with former cigarette smokers the most likely among cigar smokers to believe that cigars are a safer alternative (47.9 percent)."¹⁴¹ Cigars should be regulated under the FD&C Act for the same reasons and in similar ways to how cigarettes and smokeless tobacco are now regulated.

B. "Premium Cigars" Should Not be Exempted from the Proposed Rule, Although it May be Appropriate to Apply Different Requirements to Them in Certain Narrow Respects

We do not disagree with the proposition that certain older adults who are unlikely to take up cigarette smoking may on occasion consume premium cigars, but it does not follow that premium cigars should be altogether exempt from FDA regulation.¹⁴² That would ignore the fact that young people do, increasingly, consume premium cigars, and that premium cigars are in numerous respects no different from other cigars. Further, there is no reason why adult occasional smokers of premium cigars and those in their proximity should not receive the benefits of warnings about health risks. The FDA should implement the Proposed Rule's Option 1, thereby regulating all cigars, and reject Option 2 excepting premium cigars.

Premium cigar consumption is not confined to occasional use by older adults. Rather, as the Proposed Rule notes, younger people actually use premium cigars at higher rates than older people.¹⁴³ While 2.5 percent of adults aged 18 to 29 reported current use of premium cigars, less than half that number (1.2 percent) of adults aged 45 to 64 did so, and less than a sixth of that number (0.4 percent) of those over 65 did so.¹⁴⁴ It appears that the myth of the older smoker of premium cigars is just that. It is also significant that overall sales of premium cigars are increasing.¹⁴⁵ As noted above, the Proposed Rule summarizes evidence regarding high levels of

¹³⁷ These items are frequently available through promotions for "2-for-\$1.19" or "3-for-\$2."

¹³⁸ Proposed Rule, *supra* note 1, at 23147.

¹³⁹ *Id.* at 23158.

¹⁴⁰ King, *supra* note 12, at 42-43.

¹⁴¹ Proposed Rule, *supra* note 1, at 23158.

¹⁴² "Premium cigars" are defined in the Proposed Rule. *See Id.* at 23150.

¹⁴³ *Id.* at 23151.

¹⁴⁴ *Id.*

¹⁴⁵ "The Nielsen data shows that cigar units and sticks have been enjoying steady monthly growth over the past two years: as of March 2014, both units and stick sales of non-little cigars sales were up nearly

nicotine in premium cigars.¹⁴⁶ The 2014 U.S. Surgeon General’s Report states that nicotine is addictive and an acute toxin, that medical evidence is sufficient to infer that nicotine exposure during pregnancy has lasting adverse consequences for fetal brain development and adversely affects maternal and fetal health (contributing to stillbirth and pre-term delivery), and that nicotine activates the biological pathways through which smoking increases risk for disease.¹⁴⁷ The Report also states it is likely that exposure to nicotine contributes to increasing cardiovascular risk in smokers.¹⁴⁸ Because of the growing use of premium cigars by youth and the adverse health consequences arising from cigar use, the FDA should not except premium cigars from the Proposed Rule.

A further reason not to except premium cigars from regulation is that the complexity of the proposed definition of premium cigars is likely to cause confusion on the part of enforcers, retailers, and possibly others. Terms such as “long filler tobacco,” “leaf tobacco binder,” and “whole tobacco leaf” invite challenge.¹⁴⁹ It may not be reasonable for a retailer, distributor or inspector to be expected to know whether or not a product was wrapped or capped by hand, or to have available one thousand of the same item so as to be able to determine the weight and thus whether a specific cigar is or is not a premium cigar. The \$10.00 minimum retail price provision is likely to be difficult to enforce effectively. Because the price can only be confirmed at the point-of-sale, regulators, manufacturers, wholesalers, distributors and marketers will be unable to make definite or well-informed determinations about specific cigars until they are actually sold or available for sale. In addition, the \$10.00 minimum price may be eviscerated by promotions, such as 2-for-1 offers, coupons and/or gift cards. In sum, although the notion of an exception for premium cigars might have a superficial attraction, excepting premium cigars will likely result in numerous enforcement difficulties.

The FDA should also reject Option 2 because it invites cigar manufacturers to manipulate their little cigars just enough to fall within the exception and thus evade regulation. This would undermine the regulation’s purpose. As is notorious in this field, when the government treats similar tobacco products differently, the market responds by producing a modified product that will be more loosely regulated.¹⁵⁰ The FDA has mentioned that this occurred in the early 1970s when cigars were taxed at a lower rate than cigarettes and when advertisements were banned for cigarettes but not for cigars, as well as more recently when the consumption of large cigars increased as a result of the differential in tax treatment among classifications of cigars.¹⁵¹ To the extent that there are meaningful differences between premium and other cigars, they should at most result in specific narrow exceptions from regulation for premium cigars, such as permitting

12% in large c[onvenience]-store chains.”; Melissa Vonder Haar, *The Natural Cigar Advantage: Swedish Match’s Joe Teller breaks down the growing natural leaf business* CSPnet.com (May 14, 2014), available at <http://www.cspnet.com/category-news/tobacco/articles/natural-cigar-advantage> (last visited July 14, 2014).

¹⁴⁶ Proposed Rule, *supra* note 1, at 23154.

¹⁴⁷ 2014 U.S. Surgeon General’s Report, *supra* note 4, at 111-112, 117-123, 126.

¹⁴⁸ *Id.* at 116

¹⁴⁹ Proposed Rule, *supra* note 1, at 23150.

¹⁵⁰ *Id.* at 23147.

¹⁵¹ *Id.*

the sale of individual premium cigars. The few distinctions that do exist between premium and other cigars are not significant from the point of view of public health or regulatory enforcement and should not be a basis for an absence of all regulation over premium cigars.

The FDA should also reject Option 2 because the arcane distinction between premium and other cigars is likely to increase consumer misperceptions in an area where confusion is already rife, *i.e.*, regarding the relative risk of different categories of tobacco products.¹⁵² Excepting a certain category of cigars will only foster such misperceptions.

C. Cigars Should be Subject to a Minimum Pack Size

Noting the efficacy and importance of existing statutory and regulatory limits on cigarette pack size and on the sale of individual cigarettes or open packs of cigarettes, we are concerned that the Proposed Rule does not propose comparable standards for cigars (except to propose that under Option 2 premium cigars could be sold individually).

The FDA should prohibit the sale of individual cigars, prohibit the sale of open packs of cigars, and set a minimum pack size for cigars. Doing so would ensure that these products, widely misperceived by youth to be less harmful than cigarettes, are not available at a lower cost. This would also address the possibility of little cigars that are essentially cigarettes being sold individually, and would prohibit the sale of slightly larger cigarillos with fruit, candy or tropical drink flavors, in foil-wrapped packages of one, two or three cigars. These packs are priced between \$1 and \$2, making them affordable to youth and considerably cheaper than cigarettes. In this narrow respect, the FDA may consider an exception for premium cigars, in recognition of the fact that such products have long been sold individually at a sufficiently high price to deter purchases by youth.

D. Health Warnings Are Warranted Because of the Evidence of Health Risks of Cigars and the Extent of Public (Including Youth) Confusion Regarding Health Risks of Cigars

We support the Proposed Rules regarding the placing of warnings on the packaging of cigars. As discussed above, smoking cigars presents a number of serious health risks, and there is a significant degree of consumer confusion and misperception regarding the risks of exposure to cigar smoke. Warnings will assist in addressing these problems.

The FDA should require warnings on the packaging of all cigars, with the possible exception of premium cigars that contain no labeling, insignia or packaging other than the whole tobacco leaf wrapping itself. For such premium cigars, the FDA should require point-of-sale warnings to ensure that a purchaser sees warnings before making the purchase. If the purchaser receives with the premium cigar any wrapper, container, pack or bag, the FDA should require that it include a warning. This would ensure that if the premium cigar is given to someone else for a celebratory occasion, as noted in the Proposed Rule is sometimes the case, the actual smoker and those in the vicinity will not be deprived of all warning regarding the health risks. Similarly, in the event that a minor obtained a premium cigar from an adult and did not enter a retail outlet and see the point-of-sale warning, the minor would nevertheless be notified about health risks.

¹⁵² See discussion *supra* paragraph IV.A.

With regard to content, the FDA should require a warning on cigars regarding reproductive health risks, just as these warnings appear on cigarette packs.¹⁵³ While we recognize that scientific evidence of such risks to cigar smokers or from secondhand cigar smoke may not be clearly established, this is because existing studies have involved cigarette rather than cigar smokers.¹⁵⁴ It is important to note that nicotine levels are considerably higher in cigar smoke than in cigarette smoke.¹⁵⁵ The Proposed Rule cites a study to the effect that the nicotine level in the smoke of a filtered cigarette is 1.1 mg, but 13.3 mg in that of a premium cigar.¹⁵⁶ These facts should counsel the FDA to act with prudence by including a reproductive health warning. We also note that the reproductive health warning referenced in the Proposed Rule does not state that smoking cigars has such effects, but is a more general warning regarding tobacco use: “Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.” This statement, attached to a package of cigars, is accurate and informative.

For all of these reasons, we urge the FDA to include a reproductive health risk warning on cigars.

Recommendations

The FDA should apply Option 1, which will regulate all cigars, and should not exempt premium cigars from regulation, as proposed in Option 2. All cigars, including premium cigars, contain tobacco, are combustible, contain the same toxic and carcinogenic compounds as cigarettes, are addictive, and pose similar public health concerns as cigarettes. We support the proposed health warnings and urge that the warning regarding reproductive health risks be required.

The FDA should also impose a minimum pack size on cigars and prohibit the sale of individual cigars or open packs of cigars except in limited circumstances for premium cigars, which have traditionally been sold individually. Such requirements would limit youth access to inexpensive cigars.

V. PIPE TOBACCO

A. The FDA Should Deem Pipe Tobacco as a Covered Tobacco Product

The FDA should also classify pipe tobacco as subject to the FD&C Act provisions applicable to “tobacco products” as studies have found similar risks to pipe smokers as to those who smoke cigarettes or inhale cigar smoke.¹⁵⁷ Consumption of pipe tobacco has grown rapidly in the U.S. even while consumption of cigarettes and RYO tobacco has declined. Between 2000 and 2011, pipe tobacco consumption increased 482.1 percent, whereas cigarette consumption

¹⁵³ Proposed Rule, *supra* note 1, at 23168.

¹⁵⁴ *Id.*; *see also* 2014 U.S. Surgeon General’s Report, *supra* note 4, at 459-521.

¹⁵⁵ Proposed Rule, *supra* note 1, at 23154

¹⁵⁶ *Id.* at 23154; *see also generally*, Nat’l Cancer Inst., *Cigars: Health Effects and Trends*, Smoking and Tobacco Control Monograph 9, U.S. Dep’t of Health and Hum. Serv. (1998), *available at* http://cancercontrol.cancer.gov/BRP/tcrb/monographs/9/m9_complete.pdf.

¹⁵⁷ S. Jane Henley et al., *Association Between Exclusive Pipe Smoking and Mortality from Cancer and Other Diseases*, 96 J. Nat’l Cancer Inst. 853, 853-861 (Apr. 2004) *available at* <http://jnci.oxfordjournals.org/content/96/11/853.full>.

decreased 32.8 percent.¹⁵⁸ The trend began in 2009 with the ban on characterizing flavors (other than menthol) in the Tobacco Control Act and the tax differential favoring pipe over RYO tobacco in CHIPRA,¹⁵⁹ when sales of RYO plummeted and sales of pipe tobacco skyrocketed.¹⁶⁰ A sales-data research firm reported that convenience store pipe tobacco sales nearly tripled between September 2010 and April 2014.¹⁶¹ Unit sales of pipe tobacco in convenience stores increased 15.3 percent during the 52-week period ending December 29, 2013, whereas cigarette unit sales declined 2.1 percent and RYO tobacco declined by 16.3 percent.¹⁶² In these circumstances, it is urgent that the FDA exercise jurisdiction over pipe tobacco.

B. Pipe Tobacco Should be Subject to the Age Verification Requirements, Health Warnings, and Vending Machine Sales Ban

We agree that the FDA should prohibit sales of pipe tobacco to minors, as well as ban the sale of pipe tobacco from vending machines unless the vending machine is located in a facility where individuals under the age of 18 are prohibited from entering at any time.

The FDA should require warnings on all packages of pipe tobacco. This is important because pipe smokers face health risks similar to those faced by cigarette and cigar smokers.¹⁶³ The Proposed Rule refers to studies showing an association between pipe smoking and oral, laryngeal, lung, esophageal and colorectal cancers, coronary heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, and other health risks.¹⁶⁴ One study found that even men who smoked less than three pipefuls a day had significantly higher health risks than men who did not smoke.¹⁶⁵

We are concerned that under the Proposed Rule only the following warning will appear on pipe tobacco products: “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”¹⁶⁶ As described in Section III.C., this warning is inadequate

¹⁵⁸ Proposed Rule, *supra* note 1, at 23147.

¹⁵⁹ Prior to April 1, 2009, the federal excise tax (“FET”) on RYO tobacco and pipe tobacco was set at the same rate of \$1.0969 per pound. Effective April 1, 2009, under the Children’s Health Insurance Program Reauthorization Act, the FET on RYO tobacco increased to \$24.78 per pound. The purpose of the increased FET was to equalize the FET on cigarettes and RYO tobacco. The FET on pipe tobacco was increased only slightly to \$2.8311 per pound. It is estimated that over \$1.3 billion in state and federal revenue has been lost due to the sale of “pipe” tobacco for RYO use. U.S. Gov’t Accountability Off., *Tobacco Taxes: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes*, 14 (Apr., 2012), available at <http://www.gao.gov/assets/600/590192.pdf>.

¹⁶⁰ *Id.*

¹⁶¹ Melissa Vonder Haar, *The C-Store Pipe-Tobacco Opportunity*, CSPnet.com (May 21, 2014), available at <http://www.cspnet.com/category-news/tobacco/articles/c-store-pipe-tobacco-opportunity> (last visited July 14, 2014).

¹⁶² CSP, *Category Management Handbook*, 2014 CSP Magazine 35 (2014), available at http://www.cspnet.com/sites/default/files/magazine-files/Cigs_Tobacco_CMH_2014.pdf.

¹⁶³ Proposed Rule, *supra* note 1, at 23156.

¹⁶⁴ *Id.* at 23156, 23168.

¹⁶⁵ *Id.* at 23156.

¹⁶⁶ *Id.* at 23162.

in numerous respects, not least because the first sentence suggests that it is targeted at e-cigarettes whose nicotine is derived from tobacco, not tobacco itself. Further, not only should an improved warning regarding addiction be placed on packages of pipe tobacco, but other warnings should also be used. The FDA should require rotating warnings on packages of pipe tobacco similar to those proposed for cigars, namely:

“WARNING: Smoking a Pipe Can Cause Cancers of the Mouth and Throat, Even if You Do Not Inhale.”

“WARNING: Smoking a Pipe Can Cause Lung Cancer and Heart Disease.”

“WARNING: Smoking a Pipe Is Not a Safe Alternative to Cigarettes.”

At a minimum, the FDA should include the following proposed cigar warning as an alternative on pipe tobacco: “WARNING: Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers.”

Recommendations

The FDA should exercise jurisdiction over pipe tobacco for the same reasons cigarettes and RYO are now regulated. In particular, pipe tobacco that is being used as a substitute for cigarettes should be subject to the same regulations as cigarettes. Products that are mislabeled as pipe tobacco should be considered to be misbranded. Finally, the FDA should require that pipe tobacco be sold in the original packaging to ensure that consumers are exposed to the required warnings.

VI. CONCLUSION

State attorneys general have long championed on behalf of our citizens, particularly youth, to protect them from the dangers of tobacco products. Twenty years ago the first state lawsuit was filed against tobacco product manufacturers, leading to settlement agreements, including the MSA, which restricted the marketing and advertising of these products to help reduce youth smoking. While cigarette smoking has declined among youth, their usage of other tobacco products, including cigars and e-cigarettes, has increased in recent years. We have engaged with the FDA on some of these issues and support the Proposed Rule as appropriate for the public health. While the Proposed Rule addresses some of our concerns, it fails to address matters of particular concern, such as characterizing flavors, the marketing of e-cigarettes, and the sale of tobacco products over the Internet. We urge you to not only adopt the proposed deeming rule, but to also take the actions recommended herein as appropriate for the protection of public health.

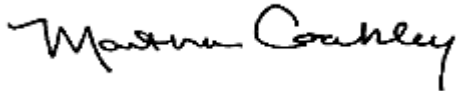
Sincerely,



Lisa Madigan
Illinois Attorney General



Greg Zoeller
Indiana Attorney General



Martha Coakley
Massachusetts Attorney General



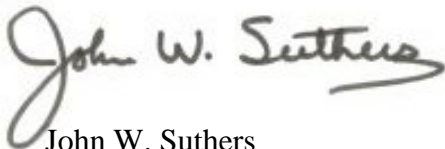
Eric Schneiderman
New York Attorney General



Tom Horne
Arizona Attorney General



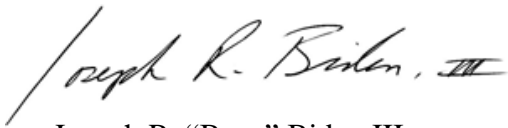
Kamala Harris
California Attorney General



John W. Suthers
Colorado Attorney General



George Jepsen
Connecticut Attorney General



Joseph R. "Beau" Biden III
Delaware Attorney General



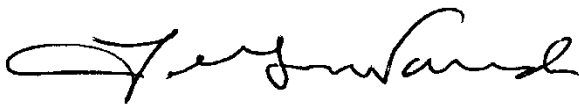
Irvin Nathan
District of Columbia Attorney General



Lenny Rapadas
Guam Attorney General



David Louie
Hawaii Attorney General



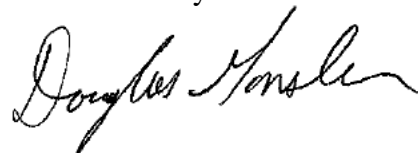
Lawrence Wasden
Idaho Attorney General



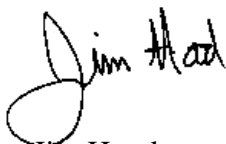
Tom Miller
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Janet Mills
Maine Attorney General



Douglas F. Gansler
Maryland Attorney General



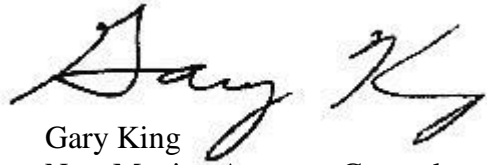
Jim Hood
Mississippi Attorney General



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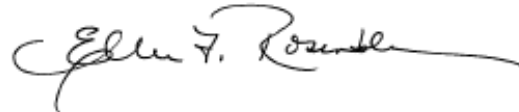
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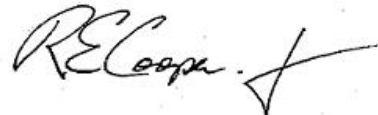
Kathleen Kane
Pennsylvania Attorney General



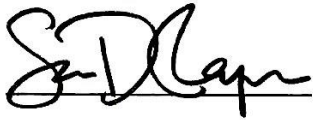
Peter Kilmartin
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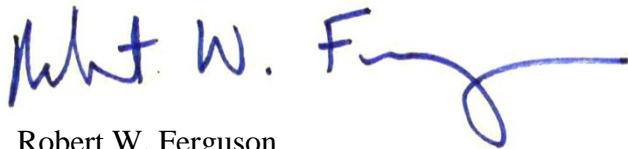
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