

State Attorneys General

A Communication from the Chief Legal Officers of the Following States and Territories:

Alabama * California * Connecticut * Delaware * District of Columbia * Georgia
Hawaii * Idaho * Illinois * Indiana * Kentucky * Maine * Maryland * Massachusetts
Michigan * Mississippi * Missouri * Montana * New Hampshire * New Mexico
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September 29, 2015

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

Re: Docket No. FDA-2015-N-1514:

Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments

The undersigned state attorneys general (hereinafter “the attorneys general”) submit this Comment in response to the Food and Drug Administration’s (FDA) Advance Notice of Proposed Rulemaking, 80 Fed. Reg. 37555 (July 1, 2015) (hereinafter “ANPRM”). The attorneys general support the FDA’s adoption of rules requiring appropriate warning labels on all products containing nicotine. Furthermore, the attorneys general support the FDA’s adoption of rules requiring child-resistant packaging for all liquid nicotine¹ and nicotine-containing products.

I. INTRODUCTION AND SUMMARY OF RECOMMENDATIONS

State attorneys general have long sought to protect their citizens, particularly youth, against the dangers of tobacco products. Such tobacco products—both old and new—contain nicotine, a potent chemical that may cause acute toxicity in high-enough doses² and long-term and functional changes in adolescent brains.³

¹ As used in this Comment, liquid nicotine means liquid nicotine and nicotine-containing e-liquids.

² As reported by the American Association of Poison Control Centers (AAPCC), “[o]ne teaspoon of liquid nicotine could be lethal to a child, and smaller amounts can cause severe illness, often requiring trips to the emergency room.” Press Release, Am. Acad. of Pediatrics, New E-Cigarette Poisoning Data Reinforce Need for Immediate Government Action to Protect Children (Nov. 18, 2014), *available at* https://aapcc.s3.amazonaws.com/pdfs/releases/AAPCC-AAP_Joint_CNPPA_Release.pdf.

³ U.S. Dep’t of Health & Human Serv., *The Health Consequences of Smoking—50 Years of Progress—A Report of the Surgeon General*, at 126 (2014) [hereinafter *The Health Consequences of Smoking*]; *Emergency Response Safety and Health Database: NICOTINE: Systemic Agent*, Ctrs. for Disease Control

The unchecked growth of the e-cigarette⁴ industry⁵ has been accompanied by a correspondingly alarming increase in youth use of e-cigarettes.⁶ In addition, this period of unregulated expansion has corresponded with a rapid escalation in accidental poisonings from exposure to liquid nicotine.⁷ Given the apparent growing popularity of “tank”-style vaping devices,⁸ which require periodic refilling with liquid nicotine by the consumer and some of which can generate enough heat to create carcinogenic compounds,⁹ public health threats from nicotine exposure will increase in the absence of appropriate FDA regulation.

Clearly, FDA action is warranted: in a recent survey, 87% of adult respondents supported FDA requirements for child-resistant packaging for all e-cigarettes and liquid nicotine refills.¹⁰ In 2014, there were 3,783 reported exposures to liquid nicotine,¹¹ just over half of which involved a child under the age of six.¹² As compared to the number of liquid nicotine exposures in 2012, these 2014 figures represent a more than an 800%

and Prevention (“CDC”), The Nat’l Inst. for Occupational Safety and Health, http://www.cdc.gov/niosh/erashdb/emergencyresponsecard_29750028.html (last visited August 10, 2015) [hereinafter *NICOTINE: Systemic Agent*]; Lucinda J. England, M.D. et al., *Nicotine and the Developing Human—A Neglected Element in the Electronic Cigarette Debate*, 49 *Am. J. Prev. Med.* 286, 290-92 (2015).

⁴ 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.

⁵ See, e.g., *Electronic Cigarette Growth Re-Accelerates*, CSP Daily News (April 1, 2015), <http://www.cspnet.com/category-news/tobacco/articles/electronic-cigarette-growth-re-accelerates> (noting a “proliferation of vapors/tanks/mods”); *Vape ‘em if you got ‘em*, *The Economist* (March 23, 2013), <http://economist.com/news/business/21573985-challenge-big-tobacco-vape-em-if-you-got-em> (citing a leading industry analyst’s belief that “sales of e-cigarettes could overtake sales of the normal sort within a decade”); *Vapor Devices to Reach \$50 Billion by 2030*, CSP Daily News (June 26, 2015), <http://www.cspnet.com/category-news/tobacco/articles/vapor-devices-reach-50-billion-2030> (noting a near doubling in size of e-cigarette and e-liquid sales from 2013 to 2014).

⁶ According to the CDC and the FDA’s Center for Tobacco Products, current e-cigarette use among middle and high school students tripled from 2013 to 2014. Press Release, CDC, E-cigarette use triples among middle and high school students in just one year (April 16, 2015) (on file at <http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html>).

⁷ *E-Cigarette Devices and Liquid Nicotine*, Am. Assoc. of Poison Control Ctrs., <http://www.aapcc.org/alerts/e-cigarettes/> (last visited Aug. 10, 2015).

⁸ Mike Esterl, *Big Tobacco’s E-Cigarette Push Gets a Reality Check*, *The Wall Street Journal* (Aug. 26, 2014, 2:38 PM), <http://www.wsj.com/articles/bog-tobaccos-e-cig-push-gets-a-reality-check-1409078319>; Jilian Mincer, *Trendy vapor tanks muscling into e-cigarette sales*, Reuters (Aug. 1, 2014, 6:02 PM), <http://www.reuters.com/article/2014/08/01/tobacco-ecigarettes-idUSL2N0Q529P20140801>.

⁹ Leon Kosmider, PharmD et. al., *Carbonyl Compounds in Electronic Cigarette Vapors: Effects of Nicotine Solvent and Battery Output Voltage*, 16 *Nicotine Tobacco Res.* (10) 1319, 1319-20 (2014), available at <http://ntr.oxfordjournals.org/content/16/10/1319.full>.

¹⁰ *Poll Results on FDA Regulation of Tobacco Products*, Campaign for Tobacco-Free Kids (April 14, 2015), http://www.tobaccofreekids.org/content/press_office/2015/2015_04_14_poll_memo.pdf.

¹¹ *E-Cigarette Devices and Liquid Nicotine*, *supra* note 7.

¹² *Id.*

increase in such exposures.¹³ In 2015 (January 1 to June 30), there were 1,732 reported cases of liquid nicotine exposures.¹⁴ Unfortunately, for children, “e-cigarettes now account for roughly 25 percent of nicotine exposures, while in other age groups, e-cigarettes exposures have surpassed other tobacco products and account for as many as 65 percent of exposures.”¹⁵

While some states have enacted legislation imposing child-resistant packaging requirements on liquid nicotine or other e-cigarette solutions,¹⁶ the vast majority of states have not done so. Only one state has enacted legislation requiring warning labels to be affixed to e-cigarettes and liquid nicotine.¹⁷ Without FDA regulation, children and vulnerable populations¹⁸ will remain at risk for accidental poisoning and other nicotine-related dangers. That said, some companies already provide health warnings about some of the risks of nicotine exposure. It is essential that any requirement the FDA imposes for health warnings not dilute effective measures that companies currently take to inform customers of the risks. Although one state, at this time, requires such warning labels, and some companies voluntarily provide them, the FDA should provide guidelines through minimal warning requirements on all nicotine-containing products, while offering states and industry the opportunity to build on these minimal warning requirements without the risk of preemption or noncompliance actions.

In short, FDA action to require appropriate warning labels¹⁹ and child-resistant packaging is necessary to protect the public health against inadvertent nicotine exposure. The risks of not establishing requirements for clear warning labels and child-resistant packaging will be borne by those who are most susceptible to inadvertent nicotine exposure: children and vulnerable populations. In addition, there is a substantial body of evidence that warning labels and child-resistant packaging can be and are effective. Properly crafted warnings should serve to deter tobacco product use by those who are not current users and perhaps even by current users, and in no sense can be seen as undermining the prevention or cessation of tobacco product use. Thus, the FDA should find that it is appropriate for the protection of the public health to take the measures recommended herein, as authorized by the federal Food, Drug and Cosmetic Act (“FD&C Act”), as amended by the Family Smoking Prevention and Tobacco Control Act.²⁰

¹³ *Electronic Cigarettes and Liquid Nicotine Data*, Am. Ass’n of Poison Control Ctrs., https://aapcc.s3.amazonaws.com/files/library/E-cig_Nicotine_Web_Data_through_6.2015.pdf (last visited Aug. 10, 2015).

¹⁴ *Id.*

¹⁵ Press Release, Am. Ass’n of Poison Control Ctrs., Am. Ass’n of Poison Control Ctrs. Releases Annual Poison Exposure Report (December 29, 2014) (on file at <http://www.aapcc.org/press/38>).

¹⁶ *See infra* note 51.

¹⁷ Cal. Health & Safety Code § 25249.6 (2015).

¹⁸ Such populations include, but are not necessarily limited to, pregnant women, adults with medical conditions, and pets. *See* ANPRM, at 6.

¹⁹ As explained in more detail below, warnings should address risks to children, as well as risks to vulnerable populations.

²⁰ 21 U.S.C. §§ 301 et seq. (2015); Family Smoking Prevention Act, 21 U.S.C. §§ 387 et seq. (2015).

II. NICOTINE EXPOSURE WARNINGS

A. The FDA Should Require Nicotine Exposure Warnings on All Liquid Nicotine and All Other Tobacco Products, Including Novel Tobacco Products

As discussed above, nicotine itself can be dangerous and poses a significant threat to public health.²¹ For this reason, the FDA should require nicotine warning labels on liquid nicotine and on all tobacco products, including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. The FDA should further contemplate the product risks and methods of nicotine exposure, both intentional and inadvertent, and require warning labels that accurately convey to consumers the risks of nicotine exposure for themselves, children, and vulnerable populations.

The broad dangers of over-exposure to nicotine are well-known and well-documented.²² The risks can be from oral, dermal, and ocular exposure. Even simple exposure can lead to significant side effects. For example, if less than a palm-sized area of skin is exposed to a nicotine/water solution of between 10 and 50% concentration for a period of 15 minutes, the amount of nicotine absorbed equals or exceeds 30 mg, the amount considered a “deadly dose.”²³ Once skin is exposed to nicotine for a long enough time to start absorption, even washing the skin with soap and water does not draw the absorbed nicotine out, as the skin acts as a reservoir to continue releasing nicotine into the body.²⁴ Absorption through the skin may result in whole-body toxicity.²⁵

In addition, exposure to nicotine in utero and through childhood and adolescence is known to lead to a variety of adverse health consequences. For example, fetal exposure to nicotine can damage neuro-cellular development, synaptic activity, and brain cell maintenance.²⁶ In utero, nicotine exposure can also affect lung size and function, and may have multi-generational effects.²⁷ Adolescent brains are also likely to suffer permanent and significant neurological changes when exposed to nicotine.²⁸

Moreover, recent research indicates that e-cigarette vapor contains harmful toxicants that may cause similar types of adverse health effects to those caused by conventional cigarettes.²⁹ Results of recent studies demonstrate that e-cigarette vapor contains free radicals, which, in other contexts, have been shown to cause cell damage.³⁰

²¹ See *supra* notes 2-3 and accompanying text.

²² See generally The Health Consequences of Smoking, *supra* note 3.

²³ Sara Zorin et al., *In Vitro Test of Nicotine's Permeability through Human Skin. Risk Evaluation and Safety Aspects*, 46 Ann. Occup. Hygiene (6) 405, 412 (1999).

²⁴ *Id.* at 406, 410-12 (“Nicotine is a compound with high acute toxicity and should be treated as such.”).

²⁵ See *NICOTINE: Systemic Agent*, *supra* note 3.

²⁶ See England et al., *supra* note 3, at 287.

²⁷ *Id.* at 288.

²⁸ *Id.* at 289.

²⁹ See Thomas E. Sussan et al., *Exposure to Electronic Cigarettes Impairs Pulmonary Anti-Bacterial and Anti-Viral Defenses in a Mouse Model*, PLOS ONE (Feb. 4, 2015), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0116861>; Chad A. Lerner et al., *Vapors Produced by Electronic Cigarettes and E-Juices with Flavorings Induce Toxicity, Oxidative Stress, and*

B. The FDA Should Require Warning Labels Related to the Exposure Risks Associated with Liquid Nicotine and Other Tobacco Products, Including Novel Tobacco Products

Under Chapter V of the FD&C Act, the FDA already regulates certain nicotine-containing products—drugs and devices marketed and sold for the purpose of smoking cessation. Before being marketed as such drugs and devices, these products are required to undergo significant FDA testing and approval.³¹ In addition to directions on use, these products also bear warning labels on the dangers of nicotine to the user, children, and to vulnerable populations.³²

Liquid nicotine and other tobacco products, including novel tobacco products, are not being sold and marketed as smoking cessation aids, and, as a result, they are not subject to pre-market FDA review under FD&C Act Section 505.³³ However, the risks of exposure to nicotine with use of novel tobacco products are similar to the risks associated with use of some FDA-approved smoking cessation products, such as lozenges and gum. There are additional risks of exposure associated with liquid nicotine. The fact that approved drugs and devices are required to have nicotine warning labels illustrates the obvious need for warning labels on liquid nicotine and other tobacco products, including but not limited to novel tobacco products. At a minimum, those products should bear a similar nicotine-exposure warning.

Any FDA regulation that addresses warnings on e-cigarette products, liquid nicotine, or novel tobacco products should ensure that companies can continue to provide warnings that surpass the FDA's minimum requirements, whether on a voluntary basis or

Inflammatory Response in Lung Epithelial Cells and in Mouse Lung, PLOS ONE (Feb. 6, 2015), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0116732> (Analyses of e-cigarette vapor have identified many different chemicals that could be potentially toxic or carcinogenic, including particulates, formaldehyde, nitrosamines, metals, carbonyls, volatile organic compounds and polycyclic aromatic hydrocarbons); Reema Goel et al. *Highly Reactive Free Radicals in Electronic Cigarette Aerosols*. 28 *Chemical Res. in Toxicology* (Articles ASAP) *1-*2 (Aug. 6, 2015), <http://pubs.acs.org/doi/abs/10.1021/acs.chemrestox.5b00220?src=recsys&>

³⁰ *Id.*

³¹ See Approval Letter from the FDA to GlaxoSmithKline (May 18, 2009), available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022360s000_Approv.pdf (Nicorette lozenges); Approval Letter from the FDA to David Schiffkovitz, SmithKline Beecham (Dec. 23, 1998), available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/18-612S025_Nicorette_Approv.pdf (Nicorette gum), Approval Letter from the FDA to Pharmacia and Upjohn Co. (May 2, 1997), available at; http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20714_NICOTROL%20INHALER%2010MG.%20CARTRIDE_APPROV.PDF (Nicotrol inhaler system).

³² Packaging for Nicorette Gum, FDA (Oct. 30, 2014), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/018612Orig1s074.%20020066Orig1s0551bl.pdf; NICOTROL Inhaler: nicotine inhalation system, Nicotrol.com, <http://www.nicotrol.com/inhaler> (last visited Aug. 14, 2015)

³³ See FDA, Report to Congress: Innovative Products and Treatments to Achieve Abstinence from Tobacco Use, Reductions in Consumption of Tobacco, and Reductions in the Harm Associated with Continued Use, at 6-9 (submitted April 22, 2013), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM348930.pdf>.

in compliance with more stringent or additional state or local warning laws. For example, pursuant to California's Proposition 65, many companies provide a separate warning on nicotine-containing products specific to the risk of developmental harm.³⁴ Proposition 65 requires companies, prior to exposing individuals to nicotine, to provide a "clear and reasonable" warning that it is known to cause reproductive toxicity. Warning requirements adopted pursuant to this ANPRM should establish a floor for health warnings, which might be lower than what some companies already do when complying with state or local laws, rather than a ceiling.

C. Rotation of Graphic and Color Warnings Enhances the Salience of Warnings and Increases Recall by Consumers

One way to increase efficacy of warning labels is to require stronger and more salient warning labels that are frequently rotated.³⁵ Using strong signal words, symbols, and colors can indicate higher risk products.³⁶ The United States Environmental Protection Agency recommends the use of specific signal words—for example, Danger, Warning, or Caution—to indicate poisonous or toxic products that children should not touch or consume.³⁷ One recent study investigating warning labels on drug containers and their effects on perceived dangers found that the skull-and-crossbones symbol was perceived as indicating a higher degree of serious danger than other symbols, including the interdiction sign.³⁸

Studies have shown that a person's familiarity with a warning results in reduced attention and recall.³⁹ Enhancing the vividness of the label has been positively correlated to increased attention, comprehension, and recall.⁴⁰ Research has shown that consumers recall warnings better when the warnings have color rather than only black and white.⁴¹

³⁴ Cal. Health & Safety Code § 25249.6 (2015).

³⁵ 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, 239 (2011), available at <http://www.biomedcentral.com/content/pdf/1471-2458-11-238.pdf> (citing E.J. Strathan et al., *Enhancing the Effectiveness of Tobacco Package Warning Labels: A Social Psychological Perspective*, 11 Tobacco Control 183, 183-190 (2002)).

³⁶ *Learn About Chemicals Around Your House*, EPA, <http://www.epa.gov/pesticides/kids/hometour/labels.htm> (last visited Aug. 11, 2015).

³⁷ *Id.*

³⁸ Chun-Fe Chen et al., *Characteristics of Warning Labels for Drug Containers and Their Effects on Perceived Hazardousness*, 78 Safety Sci. 149, 151-52 (2015).

³⁹ 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).

⁴⁰ Andrew A. Strasser et al., *Graphic Warning Labels in Cigarette Advertisements Recall and Viewing Patterns*, 43 Am. J. Prev. Med. 41, 45-47 (2012), available at [http://www.ajpmonline.org/article/S0749-3797\(12\)00207-3/pdf](http://www.ajpmonline.org/article/S0749-3797(12)00207-3/pdf).

⁴¹ See Chen et al., *supra* note 38 at 152; see, e.g., *Safety Colors*, ANSI Z535.1-2006, Am. Nat'l Standards Inst. (2011).

Yellow is perhaps the most attention-grabbing color.⁴² Thick borders and bold lettering have also been shown to increase consumer attention.⁴³

A system of rotation of warnings maintains variety by counteracting overexposure and allows for the coverage of a wide variety of health risks.⁴⁴ Liquid nicotine often is marketed to consumers in small containers that would not allow for lengthy, comprehensive warnings. In order to warn consumers of liquid nicotine of the risks of nicotine exposure, warnings should be varied, but due to the limited space, warnings should be rotated. This would also serve to keep the warnings fresh to maximize recall.

Policymakers in others countries have already adopted rotating graphic warnings of tobacco products.⁴⁵ The opportunity exists for the FDA to increase awareness by requiring rotation of graphic and colored warning labels for liquid nicotine and other tobacco products, including novel tobacco products. Finally, the U.S. government already requires rotation of health warnings on combustible tobacco products.⁴⁶

Recommendations

All liquid nicotine and other tobacco products, including novel tobacco products, should contain warnings of exposure risks to protect children and vulnerable populations. Risks of oral, ocular, and dermal exposure dangers should be addressed in these warnings. To maximize the effect, the warnings should contain text, graphics, and colors and should be rotated. Finally, any exposure warnings required by the FDA should establish a floor for health warnings on packaging and not the ceiling.

III. CHILD-RESISTANT PACKAGING

A. The FDA Should Require Child-Resistant Packaging for Liquid Nicotine

Liquid nicotine is a naturally-occurring toxin that presents an immediate poison risk when ingested or absorbed through the skin or through mucous membranes.⁴⁷ Small amounts, whether ingested or absorbed through the skin, can cause vomiting and

⁴² Carlton Wagner, *Color Cues: Understanding the Cues in Color*, Marketing Insights, Spring 1990, at 45-46.

⁴³ Michael S. Wogalter et al., *Research-based Guidelines for Warning Design and Evaluation*, 33 Applied Ergonomics 219, 221 (2002), available at <http://www.who.int/fctc/guidelines/ArtElevenWogalterNine.pdf>.

⁴⁴ Patrick Shanahan & David Elliot, *Evaluation of the Effectiveness of Graphic Health Warnings on Tobacco Product Packaging 2008*, Austl. Gov't, Dep't of Health & Ageing (2009), available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/phd-tobacco-eval-graphic-health-warnings-full-report>; Campaign for Tobacco-Free Kids, *Tobacco Warning Labels: Evidence of Effectiveness*, Mar. 19, 2013, available at <https://www.tobaccofreekids.org/research/factsheets/pdf/0325.pdf>.

⁴⁵ See, e.g., Shanahan & Elliot, *supra* note 44.

⁴⁶ Federal Cigarette Labeling and Advertising Act of 1966, 15 U.S.C. §§ 1331-1330 (2015).

⁴⁷ See *NICOTINE: Systemic Agent*, *supra* note 3.

seizures.⁴⁸ Death may occur within one hour after severe exposure.⁴⁹ Despite the dangers posed to children by these products, “there are currently no [federal] standards set in place that require child-resistant packaging.”⁵⁰ As of July 31, 2015, although 17 states have enacted laws requiring child-resistant packaging for liquid nicotine,⁵¹ more than half of the states have no child-resistant packaging laws to protect children from accidental exposure to liquid nicotine.⁵²

Of the states with child-resistant packaging laws for liquid nicotine, nine have adopted the federal standards for child-resistant packaging as set forth in Title 16, Code of Federal Regulations, Part 1700.⁵³ Of the eight remaining states, four have adopted verbatim the federal definition for child-resistant packaging, which is referred to as “special packaging”⁵⁴ and defined as follows: “packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.”⁵⁵ Considering the number of state laws on liquid nicotine already relying upon existing federal law for child-resistant packaging standards, the FDA should adopt minimum standards and testing for child-resistant packaging specific to liquid nicotine that are consistent with the standard set forth in the regulations promulgated pursuant to the

⁴⁸ Matt Richtel, *Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes*, N.Y. Times (May 23, 2014), http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?_r=0.

⁴⁹ See *NICOTINE: Systemic Agent*, *supra* note 3.

⁵⁰ Press Release, Am. Acad. of Pediatrics, New E-Cigarette Poisoning Data Reinforce Need for Immediate Government Action to Protect Children (Nov. 18, 2014) (on file at https://aapcc.s3.amazonaws.com/pdfs/releases/AAPCC-AAP_Joint_CNPPA_Release.pdf). Federal Law is pending in the U.S. Senate. S. 142, 114th Cong. (2015). The Child Nicotine Poisoning Prevention Act of 2015 would require special packaging for liquid nicotine, as the term is defined in section 2 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. § 1471) and would authorize the Consumer Products Safety Commission to promulgate a rule establishing standards and enforcement. A similar bill is also pending before the House of Representatives, but it saves authority for the Secretary of Health and Human Services to regulate liquid nicotine and requires the Secretary to consult with the Commission, taking into consideration the expertise of the Commission in implementing and enforcing the Acts. H.R. 1375, 114th Cong. (2015).

⁵¹ [Ark. Code Ann. § 26-57-254 \(2015\)](#), [430 Ill. Comp. Stat. 40/10 \(2014\)](#), [Ind. Code § 24-3-7-2 \(2015\)](#), [Me. Rev. Stat. tit. 22, § 1560-B \(2015\)](#), [Minn. Stat. Ann. § 461.20 \(2014\)](#), [Mo. Rev. Stat. § 407.926 \(2015\)](#), [N.M. Stat. Ann. § 30-49-3\(D\) \(2015\)](#), [N.Y. Gen. Bus. Law § 399-gg\(1\) \(2015\)](#), [N.C. Gen. Stat. § 14-401.18A \(2015\)](#), [N.D. Cent. Code § 12.1-31-03.2 \(2015\)](#), [Or. Rev. Stat. § 431.840\(2\)\(e\) \(2015\)](#), [Tenn. Code Ann. § 39-17-1509 \(2015\)](#), [Tex. Health & Safety Code Ann. § 161.0875 \(2015\)](#), [Utah Code § 26-57-103 \(2015\)](#), [Vt. Stat. Ann., tit. 7, § 1012 \(2015\)](#), [Va. Code Ann. § 18.2-371.2 \(2015\)](#), and [Wyo. Stat. Ann. § 35-7-1802 \(2015\)](#). Utah’s law only requires that the Department of Health adopt rules establishing “standards for electronic cigarette substance . . . packaging. . . .” Said rules will not be implemented until July 1, 2016.

⁵² Although several states have pending legislation, e.g., California, Massachusetts, Michigan, New Jersey, Ohio, Pennsylvania, and Rhode Island.

⁵³ Arkansas, Illinois, Maine, Minnesota, Missouri, North Dakota, Tennessee, Texas, and Virginia.

⁵⁴ Indiana, New Mexico, North Carolina, and Vermont.

⁵⁵ Poison Prevention Packaging Act, 15 U.S.C. § 1471(4) (2015).

Poison Prevention Packaging Act.⁵⁶ By adopting these standards, the FDA would ensure that there are consistent minimum standards nationwide for liquid nicotine.

Most states with child-resistant packaging laws provide an exemption to their child-resistant packaging requirement for products sold in a closed system (liquid nicotine in permanently sealed, prefilled, and/or disposable cartridges) and not intended to be opened by the consumer.⁵⁷ However, other states do not have such an exemption.⁵⁸ Because closed system cartridges may leak or be tampered with,⁵⁹ we urge the FDA to consider carefully these potential problems before adopting any closed system exemption. Such an exemption, if provided, should not be so broad that it would lead to unintended consequences or provide a loophole to manufacturers seeking to circumvent a child-resistant packaging requirement.

In promulgating rules for child-resistant packaging for liquid nicotine, the FDA should seek to mitigate all types of exposure risks, including oral, ocular, and dermal risks.⁶⁰ From September 2010 to February 2014, the CDC received 2,405 calls regarding e-cigarette exposures, which were reported as inhalations, eye exposures, and skin exposures, and in more limited instances as ingestions.⁶¹ Risks of oral, ocular, and dermal exposure can be mitigated with torque-dependent push and turn type bottles or by any other approved method of child-resistant packaging.⁶² In fact, since the implementation of regulations issued pursuant to the Poison Prevention Packaging Act requiring child-protective packaging for medicines and hazardous household products, child fatalities have declined from 216 in 1972 to an average of about 36 each year from January 1, 2009 through December 31, 2011.⁶³ We recommend that torque-dependent push and turn containers be required for liquid nicotine.

⁵⁶ Poison Prevention Packaging Act Regulation, 16 C.F.R. §§ 1700-1702 (2015).

⁵⁷ Arkansas, Illinois, Indiana, Maine, Missouri, New Mexico, North Carolina, North Dakota, Texas, Utah, Vermont, and Virginia.

⁵⁸ Maine, New York, Oregon, Tennessee, and Wyoming.

⁵⁹ Rachel Grana et al., *Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems)*, Ctr. for Tobacco Control Res. and Ed., Univ. California, S.F., WHO Collaborating Ctr. on Tobacco Control (2013), available at <http://escholarship.org/uc/item/13p2b72n#page-1>.

⁶⁰ See, e.g., Nan Feyler, *Without Regulation, e-Cigarette Liquid is Used for . . . Eye Drops*, Philly.com, The Phila. Inquirer (May 5, 2014, 3:45 PM), http://www.philly.com/philly/blogs/public_health/Without-regulation-e-cigarettes-liquid-is-used-for---eye-drops.html (liquid nicotine accidentally used as eye drops); Paige Hill, *Oklahoma Mother Warns e-Cigarette Users About Children and Liquid Nicotine*, NewsChannel 4, (Mar. 25, 2014, 6:21 PM), <http://kfor.com/2014/03/25/oklahoma-mother-warns-e-cigarette-users-about-children-and-liquid-nicotine/> (four-year-old gets sick from ingestion and dermal exposure to liquid nicotine); Lee Moran, *Upstate New York Boy, 1, Dies After Ingesting Liquid Nicotine*, N.Y. Daily News, (Dec. 15, 2014, 8:17 AM), <http://www.nydailynews.com/news/national/1-year-old-n-y-boy-dies-ingesting-liquid-nicotine-article-1.2045532> (one-year-old child dies from ingesting liquid nicotine).

⁶¹ *Id.*

⁶² The torque-dependent push and turn bottle is one type of bottle subjected to this type of special packaging testing. 16 C.F.R. § 1700.20 (2015).

⁶³ Angie Qin, *Pediatric Poisoning Fatalities from 1972 through 2011*, U.S. Consumer Prod. Safety Comm'n, at 3-4, (2014), available at <http://www.cpsc.gov/Global/Research-and-Statistics/Injury-Statistics/Pediatric-Poisonings/PPPMortality2011.pdf>.

The FDA should also require certain physical characteristics of the packaging, such as flow restrictors. While child-resistant closures are helpful in delaying children from accessing toxic substances, in the event closures are not fully re-secured or if children are able to breach them, flow restrictors may limit the amount of liquid nicotine that children can access.⁶⁴ The importance of flow restrictors has been recognized by the Preventing Overdoses and Treatment Exposures Task Force (PROTECT), which is a public-private initiative formed in 2008⁶⁵ in an effort to reduce unintentional medication overdoses in children.⁶⁶ PROTECT recommends supplementing child-resistant packaging with passive mechanisms of protection such as passive flow-restrictors.⁶⁷

In establishing rules requiring packaging such as torque-dependent push and turn type bottles, the FDA should require that child-resistant packaging for liquid nicotine undergo and pass performance-based tests, similar to the child and senior adult tests and the adult re-securing procedure that the U.S. Consumer Product Safety Commission (CPSC) requires for other types of products that can cause serious harm to children.⁶⁸ The CPSC applies these tests to many substances regulated by the FDA, including some products falling under the FD&C Act.⁶⁹ The FDA should continue this practice and apply the tests and special packaging requirements to liquid nicotine. Other public health organizations also endorse the CPSC's standards and testing for child-resistant packaging. For example, an August 2014 letter from 30 public health organizations (including among others, the American Academy of Pediatrics, Campaign for Tobacco-Free Kids, and AAPCC) to Senator Bill Nelson provides that CPSC "currently requires such packaging on toxic household substances like bleach, as well as FDA-regulated products like prescription drugs. Parents have come to expect that household products that can cause serious harm to children come in child-resistant packaging. Liquid nicotine should be no different."⁷⁰

B. The FDA Should Require Child-Resistant Packaging for Tobacco Products Other Than Liquid Nicotine, Including Novel Tobacco Products

⁶⁴ M.C. Lovegrove et al., *Efficacy of Flow Restrictors in Limiting Access of Liquid Medications by Young Children*, 163 J. Pediatrics, 1134, 1136-39 (2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/23896185>.

⁶⁵ PROTECT is a public-private initiatives consisting of partners from government agencies (CDC, the FDA, and CPSC); non-profit organizations (such as AAPCC, Georgia Poison Control Center, Upstate New York Poison Center); professional organizations (such as the American Academy of Pediatrics, American College of Preventive Medicine, Academic Pediatric Association); and industry partners (such as Pfizer Consumer Healthcare, Proctor & Gamble Company, GlaxoSmithKline Consumer Healthcare). A complete list of all partners is available at *Mediation Safety Program*, CDC, http://www.cdc.gov/MedicationSafety/protect/pi_partners.html (last visited Aug. 7, 2015).

⁶⁶ Daniel Budnitz & Spencer Salis, *Preventing Medication Overdoses in Young Children: An Opportunity for Harm Elimination*, 127 Pediatrics, 1597, 1597-99 (2011), available at <http://pediatrics.aappublications.org/content/127/6/e1597.full>.

⁶⁷ *Id.*

⁶⁸ Poison Prevention Packaging Regulation, 16 C.F.R. § 1700.20 (2015).

⁶⁹ *FDA Authority Over Cosmetics*, FDA (Mar. 20, 2014), <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm>.

⁷⁰ Letter from Am. Acad. of Otolaryngology et al. to Sen. Bill Nelson (Aug. 11, 2014), available at http://apha.org/~media/files/pdf/advocacy/letters/140811_nicotinepoisoning.ashx.

The FDA should also require child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products. Novel products come in many forms, such as dissolvables, lotions, gels, and drinks. Camel Orbs, a novel product by R.J. Reynolds Tobacco Company, comes in the form of dissolvable compressed pellets about the size of a Tic Tac candy and contains approximately 1 mg of nicotine per pellet.⁷¹ At least one case of ingestion of Orbs by a three-year-old child in Oregon has been reported.⁷² It is important that the FDA take steps to protect children from these types of products by requiring child-resistant packaging.

C. The FDA Should Prohibit Cartoon Imagery, Any Reference to Fragrances or Flavors and Any Resemblance to Candy and Fruit on Packaging

To further prevent or discourage people, especially infants and children, from inadvertently consuming or being exposed to liquid nicotine, the FDA should consider the following factors: (1) attractiveness of the product or packaging, such as cartoon imagery or other appealing images, fragrance, flavors;⁷³ (2) resemblance of packaging images to food and drink items, like candy and fruit;⁷⁴ and (3) color of the product, such as the resemblance to beverages such as juice.⁷⁵

A recent study concluded that the “use of food metaphor in marketing strategies to improve the sales of hygiene products constitutes a serious health problem” because these strategies have led to unintentional self-poisonings and deaths.⁷⁶ After conducting a qualitative analysis on real-life cases of household cleaners and personal care products-related phone calls at a poison control center, the researcher determined that food

⁷¹ Gregory Connolly, et al., *Unintentional Child Poisonings Through Ingestion of Conventional and Novel Tobacco Products*, 125 *Pediatrics*, 896, 896-99 (2010), available at <http://pediatrics.aappublications.org/content/125/5/896.full.html>.

⁷² *Id.*

⁷³ See, e.g., *Affordable Vaping Captain Crunch*, <http://www.affordablevapingny.com/captain-crunch/>, (last visited Aug. 11, 2015); *E-Liquid Planet Arctic Mint*, <http://www.eliquidplanet.com/e-liquid/pg-e-liquid/arctic-mint-10ml/> (last visited Aug. 11, 2015); *Papa Smurf E Juice*, <http://www.centralvapors.com/Item/papasmurf-ejuice> (last visited Aug. 11, 2015); <http://sweet-vapes.com/e-liquid/candy/wild-berry-skittlez.html>; *Vapor Hut Barb-e*, <http://www.thevaporhut.com/product/barb-e/> (last visited Aug. 4, 2015); *Zeus E-Juice Toasted Almond*, <http://www.ZeusEJuice.com/splendid-spices/toasted-almond-eliqum-flavor> (last visited Aug. 11, 2015).

⁷⁴ See, e.g., *E-Liquid.com Caramel Fudge Brownie*, <http://e-liquid.com/caramel-fudge-brownie> (last visited Aug. 11, 2015); *Sweet Vapes Wild Berry Skittlez*, <http://sweet-vapes.com/e-liquid/candy/wild-berry-skittlez.html> (last visited Aug. 11, 2015); *Vaporfi Strawberry Milk*, <http://www.vaporfi.com/e-liquid-cartridges/strawberry-milk.html>, (last visited Aug. 11, 2015).

⁷⁵ See, e.g., *Nine e-juice flavors that sound just like kids' favorite treats: Industry Leader Lorillard Even Admits “Fun Flavors” Attract Kids*, Campaign for Tobacco Free Kids (June 11, 2014) http://www.tobaccofreekids.org/tobacco_unfiltered/post/2014_06_11_ecigarettes.

⁷⁶ Frederick Basso et al., *Why People Drink Shampoo? Food Imitating Products are Fooling Brains and Endangering Consumers for Marketing Purposes*, 9 *PlosOne* (9) 1, 13-14 (2014), available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0100368>.

imitating products are non-verbal food metaphors that can fool the brains of consumers.⁷⁷ They concluded that healthy adults can unintentionally categorize a personal care product as something edible when a food-like package is employed to market nonedible and/or dangerous products.⁷⁸ The study suggests that this test and its results can be used to discuss cases of accidental child poisoning in other areas, such as tobacco.⁷⁹

Similarly, a report by the European Commission's Scientific Committee on Consumer Safety states that children are "attracted to products that picture a cartoon character or other characters or objects that they are familiar with from other contexts, e.g. from TV or books."⁸⁰ A product that has a food-resembling shape, color, and smell, with packaging that displays food imagery, may be more likely to be mistaken for food.⁸¹ Further, a product that displays cartoon characters on the packages and tastes and smells sweet may be more child-appealing than a product that simply tastes sweet.⁸²

While child-resistant packaging will make it difficult for children to consume significant quantities of a toxic product,⁸³ prohibiting manufacturers of liquid nicotine from using cartoon imagery and likening their product to food, such as candy and fruit, would further protect children from accidental exposure.

D. The FDA Should Educate the Public About the Dangers of Circumventing Child-Resistant Packaging by Issuing Public Service Announcements

There is a risk that users of products with child-resistant packaging will defeat the purpose of the packaging by leaving the container open, by disabling the protection mechanism, or by moving the product to a different container. One way for the FDA to mitigate this risk is to educate the public about the dangers of these acts and of the harm liquid nicotine can pose to children. The FDA should issue a series of Public Service Announcements (PSAs) to discuss the toxic nature of liquid nicotine and the importance of keeping child-resistant packaging and other safety mechanisms such as flow restrictors intact.⁸⁴ It is important that consumers be made aware of real-life incidents involving

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ Scientific Comm. on Consumer Safety, Opinion on the Potential Health Risks Posed by Chemical Consumer Products Resembling Food and/or Having Child-Appealing Properties (Mar. 22, 2011), available at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_056.pdf.

⁸¹ *Id.* at 20-22.

⁸² *Id.* at 21-22, 26.

⁸³ *Id.* at 20-22.

⁸⁴ PSAs are effective. See, e.g., John P. Pierce et al., *Promoting Smoking Cessation in the United States: Effect of Public Service Announcements on the Cancer Information Service Telephone Line*, 84 J. Nat'l Cancer Inst. (9) 677, 679-82 (1992), available at http://www.psaresearch.com/images/SMOKING_CESSATION-PSAS_AND_PHONE_CALLS.pdf; Press Release, Nat'l Inst. On Drug Abuse, Research Shows TV PSAs Effective (Jan. 31, 2001) (reprinted at <http://cannabisnews.com/news/8/thread8534.shtml>); Doug Hill, *Don't Make Your Bath Water Too Hot and Keep Your Dogs Away From the Antifreeze*, PSA Bibliography, PSA Research Center (last updated Mar. 18, 2014), <http://www.psaresearch.com/bib4210.html>.

children being poisoned.⁸⁵ Vicarious or personal exposure to a child poisoning incident is a dominant motivator for a review of safety behaviors among parents.⁸⁶

Recommendations

The FDA should act promptly to adopt or establish standards for child-resistant packaging for both liquid nicotine and other tobacco products, including novel tobacco products. Proven standards currently exist that have been promulgated by the CPSC. The FDA does not have to begin anew or re-invent the wheel; it can rely upon the expertise of the CPSC in formulating an appropriate minimum special packaging standard and tests for liquid nicotine. It is important that children be protected from accessing the poisonous nicotine, in its various forms. Child-resistant packaging will provide the best way to deter children from this access. The FDA should also require that containers of liquid nicotine have physical characteristics such as flow restrictors to further protect children from accidental exposure to the liquid nicotine. Finally, to mitigate against the possibility that consumers will circumvent the protections afforded by child-resistant packaging, the FDA should issue a series of PSAs to educate the public about the dangers of nicotine exposure and the necessity of child-resistant packaging.

IV. CONCLUSION

As e-cigarettes have grown in popularity, so have youth exposure concerns and risks related to liquid nicotine. The FDA must act to require appropriate warning labels and child-resistant packaging to protect the public health against inadvertent nicotine exposure. All liquid nicotine, as well as other tobacco products, including novel tobacco products, should contain warnings of exposure risks, but those requirements should not prevent companies from including additional warnings on their products. Child-resistant packaging requirements will help avoid accidental exposure to liquid nicotine, hopefully stemming the recent increases in calls to poison control centers. Without FDA regulation, children and vulnerable populations remain at risk of accidental poisoning and nicotine exposure.

Sincerely,



Lisa Madigan
Illinois Attorney General



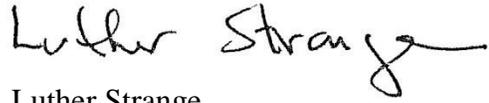
Greg Zoeller
Indiana Attorney General

⁸⁵ See *supra* note 60.

⁸⁶ L.F. Gibbs et al., *Understanding parental motivators and barriers to update of child poison safety strategies: a qualitative study*, 11 *Injury Prevention* 373, 376 (2005), available at <http://injuryprevention.bmj.com/content/11/6/373.full>.



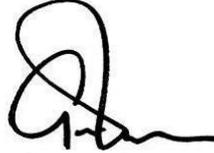
Eric T. Schneiderman
New York Attorney General



Luther Strange
Alabama Attorney General



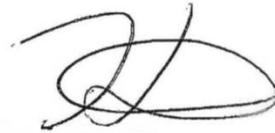
Kamala Harris
California Attorney General



George Jepsen
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Matthew P. Denn
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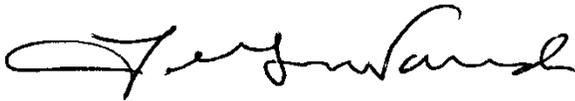
Karl A. Racine
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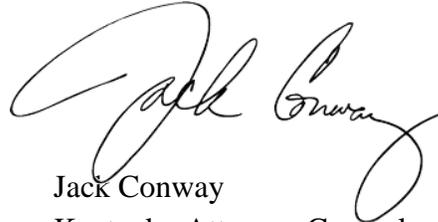
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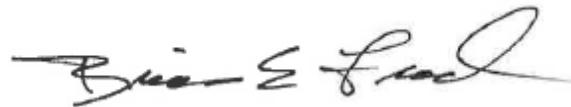
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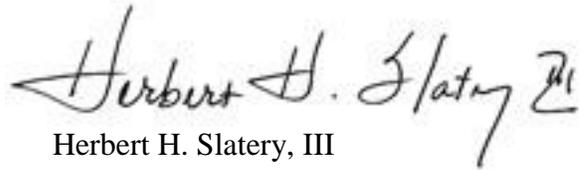
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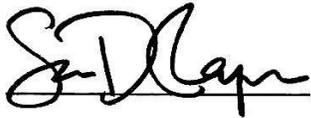
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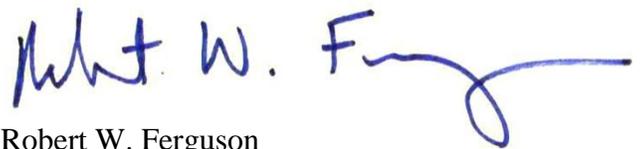
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