Tobacco Control Legal Consortium

Law. Health. Justice.

July 2, 2015

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

Re: Electronic Cigarettes and the Public Health

Docket No. FDA-2014-N-1936

Dear Commissioner Hamburg:

The Tobacco Control Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the public health impact of e-cigarettes. The Tobacco Control Legal Consortium is a national network of nonprofit legal centers providing technical assistance to public officials, health professionals and advocates concerning legal issues related to tobacco and public health.[1]

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

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

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Over the last few years, e-cigarettes have enjoyed a boom in popularity, thanks largely to marketing claims that promote them as less hazardous alternatives to combustible cigarettes and tout their safety, convenience and cost-effectiveness over conventional tobacco products. Because of the lack of clinical research on e-cigarettes, many public health organizations and policymakers are concerned about their safety and health impact on users. Because the federal government has yet to exercise its regulatory authority over these products, e-cigarettes are manufactured without regulatory oversight or quality controls, and promoted and advertised broadly without appropriate health warnings or legal age restrictions.

It is not enough for the FDA to simply assert its jurisdiction over e-cigarettes, establish minimum purchase age requirements to only the parts and components of the devices that contain nicotine, and mandate the blandest of warning labels, as it has proposed to do with the deeming regulation. We urge the agency to revise the proposed regulation or issue additional regulations to do much more in the face of the exploding market for e-cigarettes and the potential risk to public health.

I. The Public Health Standard in the Family Smoking Prevention and Tobacco Control Act provides the FDA with significant authority to stringently regulate e-cigarettes in the absence of a significant evidence base.

The Tobacco Control Act established a public health standard of review, entirely different from FDA's traditional "safe and effective" standard to evaluate drugs and medical devices.[2] In establishing new tobacco product regulations, Congress directs the FDA to determine that a regulation is "appropriate for the protection of public health" and frames this requirement in terms of "risks and benefits to the population as a whole" and "increased or decreased likelihood" of tobacco product cessation or initiation.[3] Congress intended this new "public health standard" to be a "flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products."[4]

Due to the newness of e-cigarettes, significant amounts of data and evidence are not yet available for the products. However, the social studies and scientific body of evidence available as of now provide enough evidence for stringent regulation under the public health standard.[5] Each new

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

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

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

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

published study seems to indicate that the agency ought to act soon and act boldly to protect our youth from initiation into tobacco product use. A 2015 study by the CDC reports e-cigarette use has tripled in among middle and high school students in just one year.[6] The potential for initiation is clear and the FDA must not only assert jurisdiction over e-cigarette but must also impose additional requirements to protect the public.

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

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

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

Not long after the introduction of e-cigarettes to the U.S. market, the FDA recognized their danger. Rather than allowing e-cigarettes to remain unregulated in an exponentially growing market, the FDA attempted to regulate e-cigarettes under the drug and drug delivery device provisions of the Food, Drug, and Cosmetic Act. This action was initiated after FDA analysis of commercially marketed e-cigarettes revealed that the nicotine content in many devices did not correspond with the advertised levels. Several products were advertised as not containing nicotine while FDA tests revealed low levels of the drug.[7] The FDA analysis also found known toxicants and carcinogens including diethylene glycol and tobacco-specific nitrosamines. When the FDA's attempt at regulation was challenged by e-cigarette manufacturers, the U.S. Court of Appeals for the D.C. Circuit ruled in December 2010 that unless they are marketed as therapeutic devices (cessation aids), e-cigarettes containing tobacco-derived nicotine could only be regulated by the FDA under its authority to regulate tobacco products.[8] The FDA stated its intent to regulate e-cigarettes as tobacco products on April 25, 2011.[9] Since then, the FDA has taken a very cautious approach to e-cigarettes and the few public statements that it has made have emphasized the potential dangers of the product. The FDA's website explains:

[6] Press Release, Centers for Disease Control and Prevention, *E-cigarette use triples among middle and high school students in just one year* (Apr. 16, 2015), http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html
[7] Memorandum from B.J. Westenberger, Deputy Dir., Center for Drug Evaluation and Research, to Michael Levy, Supervisor Regulatory Counsel, Center for Drug Evaluation and Research (May. 4, 2009), http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf.
[8] Sottera, Inc. v. Food & Drug Admin., 627 F.3d 891, 898 (D.C. Cir. 2010).
[9] Letter from Dr. Lawrence Deyton, Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Stakeholders (Apr. 25, 2011), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm.

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

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

Additionally, FDA justifies inactivity in e-cigarette regulation as lack of evidence to firmly conclude that e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are proven to cause disease and lead to premature death.[10] The very real possibility that e-cigarettes could become a popular youth initiation product has been a concern of numerous health organizations such as the American Cancer Society, American Legacy Foundation, and the American Academy of Pediatrics.[11] Several state attorneys general echo this apprehension.[12] In addition, members of both houses of Congress have called on the FDA to take sweeping action to protect children from the potential harms of e-cigarettes.[13]

The legitimacy of the concerns about youth initiation should no longer be questioned. A 2015 CDC report discloses that e-cigarette use among middle and high school students tripled from 2013 to 2014.[14] The 2014 National Youth Tobacco Survey show that current e-cigarette use

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

[11] Am. Cancer Soc'y, *What about electronic cigarettes? Aren't they safe?,* AM. CANCER SOC'Y (July 8, 2013), http://www.cancer.org/cancer/cancercauses/tobaccocancer/questionsaboutsmokingtobaccoandhealth/questionsabout-smoking-tobacco-and-health-e-cigarettes; AM. LEGACY FOUND., TOBACCO FACT SHEET: ELECTRONIC CIGARETTES (E-CIGARETTES) (2013), http://www.legacyforhealth.org/content/download/582/6926/file/LEG-FactSheet-eCigarettes-JUNE2013.pdf. *See also,* AM. ACAD. OF PEDIATRICS E-CIGARETTES (2014), http://www2.aap.org/richmondcenter/pdfs/ECigarette_handout.pdf.

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

[13] 100 Press Release, Senator Barbara Boxer, Senators Call on FTC and FDA to Protect Consumers from False Advertising Claims by E-Cigarette Makers (Apr. 7, 2014)(publishing full text of a letter to the FDA), http://www.boxer.senate.gov/en/press/releases/040714a.cfm; Letter From Senator Tom Harkin to Margaret Hamburg, Comm'r, U.S. Food & Drug Admin. (Mar. 25, 2014), http://www.help.senate.gov/newsroom/press/release/?id=4b79e9c0-3faa-4a2f-bfd6-4a6099e0db2d; Letter from Senator Richard J. Durbin, et al. to Margaret Hamburg, Comm'r U.S. Food & Drug Admin. (Apr. 16, 2013), http://www.durbin.senate.gov/public/index.cfm/files/serve?File_id=90eae776-6b4f-471b-a2d2-fe1525d2ed74; STAFF OF SENATOR RICHARD J. DURBIN ET AL., GATEWAY TO ADDICTION (2014), available at http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f; Letter from Senator Richard J. Durbin to Sylvia Mathews Burwell, Dir., Office of Mgmt. & Budget (Dec. 20, 2013), http://www.durbin.senate.gov/public/index.cfm/pressreleases?ID=1143c7a6-95ee-4d89-a67d-4078e1db75fc; Letter from Senator Edward J. Markey, et al. to Margaret Hamburg, Comm'r, U.S. Food & Drug Admin. (May 8, 2014), http://www.markey.senate.gov/imo/media/doc/2014-5-8_Hamburg_E-Cigs.pdf; Press Release, Senator Barbara Boxer, Members of Congress: More and More Children being Exposed to ECigarette Marketing are Picking Up Habit (Aug. 4, 2014), http://www.boxer.senate.gov/en/press/releases/080414.cfm

[14] René A. Arrazola et al.,*Tobacco Use Among Middle and High School Students — United States, 2011–2014.* 64(14) MORBIDITY & MORTALITY WKLY. REP., Apr.17, 2015 at 381 *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm?s_cid=mm6414a3*

among high school students increased from 4.5 percent in 2013 to 13.4 percent in 2014, rising from approximately 660,000 to 2 million students. Among middle school students, current e-cigarette use more than tripled from 1.1 percent in 2013 to 3.9 percent in 2014—an increase from approximately 120,000 to 450,000 students.[15]

This is the first time since the survey started collecting data on e-cigarettes in 2011 that current e-cigarette use has surpassed current use of every other tobacco product overall, including conventional cigarettes.[16] However, there was no decline in overall tobacco use between 2011 and 2014. Overall rates of any tobacco product use were 24.6 percent for high school students and 7.7 percent for middle school students in 2014.[17] It is clear that youth are beginning to experiment with e-cigarettes more than other products and that this uptick in experimentation is now slowing the historical gains in declining use of tobacco products by youth.

In 2009 a web-based study from eight colleges in North Carolina reports ever use of e-cigarettes by 4.9% of students, with 1.5% reporting past month use.[18] The study also found that 12% of ever e-cigarette users had never smoked conventional cigarettes previously.[19] Additionally, e-cigarette use was more common among conventional cigarette smokers, it was not exclusive to them.[20] E-cigarette use was not associated with intentions to quit smoking among a sub-sample of conventional cigarette smokers.[21] Unlike older, more established cigarette smokers, e-cigarette use by college students does not appear to be motivated by the desire to quit cigarette smoking.[22]

Data from the 2009 and 2010 national Consumer Styles surveys found that awareness of e-cigarettes by U.S. adults doubled from 16.4% in 2009 to 32.2% in 2010.[23] Ever use of e-cigarettes increased over the same period, from 0.6% in 2009 to 2.7% in 2010.[24] National survey data also indicates an increase in awareness from 2010 to 2011 (40.9% to 57.9%), as well as ever use (3.3% to 6.2%).[25] In these studies, current smokers and former smokers reported higher use of e-cigarettes than non-smokers.[26] These may be early indications that e-cigarettes increase dual- and poly-use of tobacco products and could be reducing rates of cessation.

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[15] *Id.*
[16] *Id.* at 381
[17] *Id.*
[18] Erin L. Sutfin et al., *Electronic cigarette use by college students*. 131 DRUG & ALCOHOL DEPENDENCE 214 (2013).
[19] I*d*
[20] *Id.*
[21] *Id*
[22] *Id.*
[23] Annette K. Regan et al., *Electronic Nicotine Delivery Systems: Adult Use and Awareness of the 'e-Cigarette' in the USA*, 22 *Tobacco Control* 19, 20 (2013)
[24] *Id.*
[25] Brian A. King et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, 15(9) NICOTINE & TOBACCO RES. 1623, 1625 at tbl.1. The 2010 data is echoed by the findings published in Pearson et al. Jennifer L. Pearson et al., *E-Cigarette Awareness, Use, and Harm Perceptions in US Adults*, 102 AM. J. PUB. HEALTH 1758, 1760-1762 tbl.2 (2012). Pearson et al. presents data from another national, web-based survey administered in 2010 which found 40.2% awareness of e-cigarettes and 3.4% ever use of cigarettes among surveyed adults.
[26] Brian A. King et al., *supra* note 25 at tbl.1. (finding, in the 2011 web-based survey, that 21.2% of current smokers, 7.4% of former smokers, and 1.3% of never-smokers reported ever use of cigarettes); Pearson et al., *supra* note 25 at 1760, 1762 tbl.2 (finding that 11.4% of current smokers and 2.0% of former smokers had ever used an e-cigarette, in comparison to 0.8% of never smokers); Regan et al., *supra* note 23, at 21 (finding, in 2010, that 18.2%

January 2012 data from the nationally representative Legacy Young Adult Cohort Study found that ever use of e-cigarettes among 18-34 year old men was reported by 16.4% of U.S.-born Hispanics, 4.8% of non-Hispanic Blacks, and 8.8% of non-Hispanic Whites; current use was 5.3%, 3.5%, and 1.7%, respectively.[27] Ever use of e-cigarettes among 18-34 year old women was 5.1% for U.S.-born Hispanics, 5.3% for non-Hispanic Blacks, and 8.0% for non-Hispanic Whites; current use was 1.6%, 4.0%, and 1.8%, respectively.[28] The appeal of e-cigarettes to youth and young adults is clear from the data. The FDA must take swift and decisive action to regulate e-cigarettes so that future generations are not burdened by nicotine addiction.

Many have claimed that e-cigarettes, when used in isolation, are less harmful than cigarettes and could be a potentially successful cessation product.[29] E-cigarettes currently are not approved smoking cessation devices and may not be marketed as such without prior FDA authorization, yet many consumers believe that e-cigarettes are effective for cessation and purchase the product with that purpose in mind.[30] Moreover, these consumers believe that e-cigarettes are a safer alternative than conventional cigarettes despite the lack of sound support for harm reduction.[31] While there is some evidence that e-cigarette aerosol contains lower levels of cigarette associated toxins than cigarette smoke,[32] the mixture of chemicals in e-cigarette aerosol has not been well

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of current smokers and 6.2% of former smokers had ever tried an e-cigarette, in comparison to 3.8% of never-smokers).

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

[28] *Id.*

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

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

[31] Comments following the AAPHP Citizen Petition show this viewpoint: 1) "It took over a 100 years for someone to finally produce a nicotine delivery system that is much safer than burning cigarettes." 2) "Some of these individuals have found e-cigarettes and in the process have decreased or eliminated their exposure to deadly smoke even if all risks are not eliminated with certainty." 3) "[H]undreds of thousands of smokers already have significantly reduced their health risks by switching to e-cigarettes." AAPHP Citizen Petition, *supra* note 30. There are many such claims by e-cigarette smokers online also. See, e.g., Yahoo News, First Person: Electronic Cigarettes Key to My Quitting Smoking, YAHOO! NEWS, http://news.yahoo.com/first-person-electronic-cigarettes-key-quittingsmoking-182000482.html (Nov. 15, 2012). ("It was not until recently I found a way I could smoke without getting all of the extra stuff in cigarettes that makes is so much unhealthier. I started smoking an electronic cigarette.").

[32] Maciej Lukasz Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes*, TOBACCO CONTROL 1, 3-6 (2013) (published online ahead of print), doi:10.1136/tobaccocontrol-2012-050859 (finding that e-cigarette aerosol contains small amounts of toxicants associated with tobacco smoke –

studied and there is evidence that other toxic chemicals may be present in these products.[33] There is also not enough evidence to establish that e-cigarettes do not lead to dual-use, do not reduce cessation and do not increase initiation. The potential for e-cigarettes to lead to dual and poly-use is particularly concerning as e-cigarettes may serve as a bridge to fulfill nicotine cravings while a smoker is in a smoke-free environment. This creates a potential to negate public health gains from the enactment of smoke-free policies.

Reports of adverse events related to e-cigarettes also raise concerns about the health effects of these unregulated products. Of the 102 adverse event reports on tobacco products that have been submitted to the FDA from the 1980s through the first quarter of 2012, 47 reports concern e-cigarettes starting in 2008.[34] These reports have included eight adverse events that the FDA has characterized as serious, including:

> Hospitalization for illnesses such as pneumonia, congestive heart failure, disorientation, seizure, hypotension, possible aspiration pneumonia, second-degree burns to the face (product exploded in consumer's mouth while driving and during routine use), chest pain and rapid heartbeat, possible infant death secondary to choking on e-cig cartridge, and loss of vision requiring surgery.[35]

The less serious events reported to the FDA included complaints of "headache/migraine, chest pain, cough/sputum, nausea/vomiting, dizziness, feeling sick, confusion/stupor, sore throat, shortness of breath, abdominal pain, pleurisy, blurry vision, and sleepy/tired."[36] Previously it was assumed that these adverse events are not necessarily causally connected to e-cigarette use since they could be related to underlying conditions or other factors.[37]

However, the growing evidence of adverse events are indicative of the relationship between e-cigarette use and negative health effects. Adverse events reported to the FDA between October 2013 and March 2014 included increased numbers of reports of chest pain, dizziness, headache, nausea, respiratory and auditory problems, irritated sinus, asthma like syndromes, anxiety and loss of reality, persistent cough, bronchitis, burning sensation around mouth/ lips, and loss of appetite.[38] Symptoms mentioned were experienced by smokers as well as adult and young/children bystanders and in one case, a domestic animal. In most cases symptoms ceased when removed from the environment causing the symptoms. Among the more severe adverse events reported are seizure (verified through MRI) resulting in a 2-day hospitalization, chest tightening and tingling in jaw and anxiety attack.[39] One adverse event reported to the FDA stated

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including formaldehyde, acetaldehyde, acrolein, tobacco-specific nitrosamines, cadmium, nickel, and lead – but at lower levels than reported for cigarette smoke).

[33] Tests conducted by the FDA found small amounts of diethylene glycol in e-cigarette aerosol, along with small amounts of nitrosamines. Westenberger Memorandum, *supra* note 7.

[34] 113 Ii-Lun Chen, *FDA Summary of Adverse Events on Electronic Cigarettes*, 15(2) NICOTINE & TOBACCO RES. 615, 615 (2013). The first adverse report related to e-cigarettes was submitted to the FDA in 2008. *Id.*

[35] *Id.*

[36] *Id*

[37] *Id.*

[38] FDA E-Cigarette Adverse events -10/5/13 to 3/12/14 http://www.fda.gov/downloads/TobaccoProducts/AboutCTP/UCM393323.pdf (last visited Jun.29,2015)

[39] *Id.*

that an individual who purchased liquid nicotine for her electronic cigarette inhaled aerosol or drank the liquid until she became and was admitted to an emergency room in a psychotic condition.[40] These numbers and seriousness of the reports related to e-cigarettes emphasize the need for regulation and further assessment of these products.

While the potential harm to users of e-cigarettes is worrisome, the potential poisoning risk for toddlers and young children is alarming also. A CDC study analyzing calls to poison control centers found a dramatic increase in e-cigarette-related calls each month and the proportion of calls related to e-cigarette exposure versus conventional cigarette exposure increased from 0.3% to 41.7%.[41] The prevalence of poisonings and potential danger prompted the American Association of Poison Control Centers and its fifty-five member centers to issue a statement urging e-cigarette users to keep the devices and liquids away from children.[42] While there is little record of the severity of the poisoning events, there is evidence that the liquid found in e-cigarettes contains amounts of nicotine that could be toxic or even lethal – especially to children - if ingested or absorbed transdermally.[43] The risk to children is particularly concerning given the fact that e-cigarettes are frequently sold in flavors attractive to children.[44] There has been one report of a fatality due to ingestion of liquid nicotine.[45] Based on the data and statistics alone the FDA is obligated to act to protect the public health. The dangers posed by e-cigarettes warrants far more stringent action than the FDA has proposed thus far.

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

While proponents of e-cigarettes portray nicotine as a harmless drug with effects on the body similar to that of caffeine, a growing body of scientific evidence paints a different picture. The most recent report of the U.S. Surgeon General, The Health Consequences of Smoking – 50 Years of Progress, devotes an entire chapter to the health effects of nicotine.[46] In addition to the significant risk of addiction, the report warns of the potential risk of poisoning due to ingestion of nicotine, the effect on the rates of various types of cancer, the role in cardiovascular disease, the effect on the immune system, the various negative reproductive outcomes, the impact on lung

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[40]FDA E-Cigarette Adverse events -10/5/13 to 3/12/14 http://www.fda.gov/downloads/TobaccoProducts/AboutCTP/UCM393323.pdf (last visited Jun.29, 2015).

[41] Samira Asma, et al., *CDC Grand Rounds: Global Tobacco Control* 63(13) MORBIDITY & MORTALITY WKLY. REP. 277 (2014), http://www.cdc.gov/mmwr/pdf/wk/mm6313.pdf.

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

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

[44] *Id*. at 2

[45] Gillian Mohney, First Child's Death From Liquid Nicotine Reported as 'Vaping' Gains Popularity, Dec. 12, 2014, http://abcnews.go.com/Health/childs-death-liquid-nicotine-reported-vaping-gains-popularity/story?id=27563788.

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

development, as well as nicotine's long-term detrimental effects on fetus and adolescents, especially on cognitive development.[47]

As explained above, the number of calls to poison control centers related to exposure to e-cigarettes and their refill liquid is growing at an alarming rate. The Surgeon General's report notes that although the acute toxicity of nicotine is known, there are very few studies to determine the effects of poisoning or the threshold for lethality.[48] What is known is that symptoms of poisoning include nausea, vomiting, diarrhea, increased salivation, increased respiratory secretions, bradycardia, seizures and respiratory depression.

Exposure to non-lethal doses of nicotine is also linked to several adverse health outcomes, some of them severe. The Surgeon General's report concludes that while there is "insufficient data to conclude that nicotine causes or contributes to cancer in humans, but there is evidence showing possible oral, esophageal, or pancreatic cancer risks."[49] Nicotine exposure is also linked to several reproductive health issues. Nicotine may play a role in fetal growth restriction.[50] There is also evidence that nicotine increases the risk of preterm delivery, stillbirth, and Sudden Infant Death Syndrome.[51] The report also concludes that nicotine may have significant adverse effects on fetal lung development.

There is a significant and worrisome risk of harm related to the exposure of nicotine during important and vulnerable stages of brain development, notably during fetal and adolescent growth.[52] The Surgeon General's report finds that nicotine has an adverse impact on fetal development because nicotine is a developmental toxicant, vasoconstrictor and is "known to cross the placenta and concentrate in the fetus at levels slightly higher than those in the mother."[53] In smokers, "the combination of exposure to nicotine and hypoxia could decrease the supply of nutrients and oxygen to the embryonic tissues through a vasoconstrictive impact, resulting in congenital defects."[54] Adolescents are also particularly "vulnerable to the adverse effects of nicotine on the central nervous system" including "long-term structural and functional changes in the brain."[55] With the rising rates of use among youth and young adults, it is clear that the FDA must take action that will reduce the number of youth whose brains are being rewired for nicotine addiction by these unregulated products. The significant role that e-cigarettes are playing in youth initiation warrants significant action by the FDA.

b. Given all of the unknowns regarding e-cigarettes, the way in which the FDA has proposed to regulate the products thus far, fails to sufficiently protect public health.

[47] *Id*. at 126-127
[48] *Id*. at 111-112
[49] *Id*. at 116.
[50] Id. at 118.
[51] *Id*. at 118-119.
[52] *Id*. at 120
[53] *Id*. at 471.
[54] *Id*. at 472
[55] *Id*. at 122.

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

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

Initially it was assumed that it would take decades to understand the long-term public health effects of e-cigarettes but the body of evidence is sufficient for FDA act boldly. The devices represent technological "gadgets" that appeal to young people, and the advertising and marketing of the products preys on this appeal. The products are marketed in youth-attractive flavors that are prohibited for cigarettes. There is no question that unchecked, this exploited attractiveness will continue to result in skyrocketing rates of use among youth and young adults. Those who try the products will eventually become addicted to nicotine and some will likely experiment with other products to satisfy that addiction. Even if the rates of switching from e-cigarettes to highly toxic and carcinogenic combustible products are low, there is more than enough evidence for the FDA to do more than it has proposed to do. The FDA is tasked with protecting public health *now*, not with waiting to find the outer limits of the resulting harm and then attempting to remediate that harm.

i. The proposed deeming regulation's failure to regulate all of the different variations and types of e-cigarette devices will have dire consequences.

Given the vastly different outcomes of subjecting a given product and its manufacturer to: 1) only the statutory requirements of the Tobacco Control Act, 2) the Act and the FDA's regulations promulgated under the Act, or 3) neither source of law, it is imperative that the FDA clearly outline what sources of law apply to which products. The proposed deeming regulation falls short of that clarity. This lack of clarity regarding which restrictions apply to which products results in several significant problems with the proposed regulation of e-cigarettes. One

issue is the use of the terms "component," "part," and "accessory," without clear, established definitions. A trip to any convenience store or e-cigarette specialty store across the country reveals the need for the FDA to set firm, clear boundaries for its regulatory reach and to develop infrastructure to ensure that the products that are outside of its authority are genuinely free of tobacco-derived nicotine. The proposed regulation also, perplexingly, does not address the issue of whether or not certain e-cigarette retail stores are tobacco product manufacturers according to the Food, Drug, and Cosmetic Act. Any establishment that is repackaging or relabeling tobacco products must register with the FDA and abide by the other requirements established for manufacturers. If FDA doesn't amend the proposed rule and provide clear and concise direction regarding which restrictions apply to which products then unauthorized entities will continue to manufacture, market and distribute products. The availability of any unregulated products in the marketplace will undermine the potential public health gains from FDA regulation. Therefore, FDA must act promptly to protect the public health by amending the proposed regulation.

ii. The FDA must do more than the bare minimum in its regulation of "components," "parts," and "accessories."

The proposed regulation would allow the FDA to begin regulating any product that meets the Tobacco Control Act's broad definition of the term, "tobacco product." That definition allows the FDA to regulate the components, parts, and accessories of tobacco products as well. However, in its proposal, the FDA has declined to assert its jurisdiction over all tobacco product accessories. Moreover, while it has proposed to subject all components and parts to the statutory provisions of the Tobacco Control Act, only those components and parts that contain nicotine will be subject to regulations promulgated by the FDA under its regulatory authority.
It is difficult to foresee the precise implications of these regulatory distinctions as the FDA has not provided definitions for the terms "component," "part," or "accessory." However, it is clear that implementation of this regulation will be quite difficult due to this approach. Without clear, precise definitions, analysis of the regulatory impact is impossible.

E-cigarettes can be separated into two categories, those that are intended to be disposable and those that are intended to be reusable. So-called disposable e-cigarettes are typically sold individually or in very small packs which come with everything a user needs to begin using the device immediately. The device is sold with a charged battery and is prefilled with nicotine liquid. Once either the battery has died of the device has run out of nicotine liquid, a user discards the entire device and must purchase another. These devices are marketed in many different flavors and are often sold with varying levels of nicotine, including some devices which are falsely advertised as not containing nicotine.

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

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

The FDA's Preliminary Regulatory Impact Assessment identifies many of the costs associated with complying with this proposed regulation. As can be expected, the transition from a truly free market to one that is regulated can create significant costs for regulated entities, although this is a sliding scale. Because of the potential costs associated with compliance with the Tobacco Control Act, a manufacturer that is looking to make a profit has a monetary incentive to ensure that as many of its products as possible are not tobacco products and thus outside of FDA regulation. Doing so preserves the status quo where manufacturers are essentially free to do as they please in the manufacturing, distribution, advertising and marketing of their products. The FDA draws its regulatory distinctions in a way that will likely prove to be unwise, resulting in a change to the market such that the sale of nicotine liquid will be entirely separated from the sale of e-cigarette devices. This sales practice already exists to a degree but the regulation, as proposed, would likely drastically shift the market in this direction. This will create a regulatory scheme in which the FDA will be unable to collect adequate information on dosage and other aspects of how the devices are used in practice. This is particularly concerning given that some products that are advertised as not containing nicotine actually contain nicotine.

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

The problem is compounded by the fact that liquid nicotine can be purchased in very large quantities, much more than an individual user needs for a single device. If youth can easily acquire a device, they need only find a way to procure the liquid nicotine and given the fact that many users will have more than they can consume, black and gray markets will likely spring up. Because there is such a fine line between a tobacco product component or part and a non-tobacco product, the FDA need not draw the lines in favor of the least amount of regulation, as it appears to have done. It is well within the FDA's power to ensure that all e-cigarettes are subject to the statutory and regulatory schemes for tobacco products. The FDA also has a responsibility to the public to test all liquids that claim to be non-nicotine to confirm that manufacturers and retailers are making truthful claims. If they are not, the FDA also has a responsibility to take enforcement action against these products as misbranded tobacco products.

Allowing any version of these products to escape regulation creates a missed opportunity to protect public health and with the tremendous public health impact that e-cigarettes will have, the FDA must do more than it has proposed to do. The agency ought to deem all e-cigarette-like devices as components or parts of a tobacco product subject to the statutory requirements and restrictions in the Tobacco Control Act. Additionally, FDA should also extend all of the regulatory provisions of the current propose rule to all deemed products, components and parts regardless of whether or not they contain nicotine. Such an action is justified under the broad reach of the public health standard.

iii. The FDA must more clearly define the terms "component," "part," and "accessory."

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

The most definitive statements made by the FDA in this proposal do not provide enough information to sort out the differences between the three terms.
FDA believes that components and parts of tobacco products are those items that are included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product. Components and parts that would be covered under this proposal include those items sold separately or as part of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product. Such examples would include air/smoke filters, tubes, papers, pouches, or flavorings used for any of the proposed deemed tobacco products (such as flavored hookah charcoals and hookah flavor enhancers) or cartridges for e-cigarettes. In addition, FDA considers accessories to be those items that are not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product, but may be used, for example, in the storage or personal possession of a proposed deemed product. Therefore, items such as hookah tongs, hookah bags and cases, hookah charcoal burners and holders, cigar foil cutters, humidors, or cigar carriers would be considered accessories and would not fall within the scope of this proposed rule.[56]

[56] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule, 79 Fed. Reg. 23,142, 23,153 (proposed April 25, 2014) (to be codified at 21 C.F.R. pt. 1100, 1140, and 1143) [hereinafter "Deeming Regulation"].

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

iv. The FDA should clarify that the scope of the term "manufacturer," covers many e-cigarette retail stores.

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

Under the Act, a tobacco product manufacturer is "any person, including any repacker or relabeler, who—manufactures, fabricates, assembles, process, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States.[57] As e-cigarettes have risen in popularity, thousands of new or existing retail stores have begun to sell e-cigarette liquid that is mixed on-site to the customer's specifications. Store employees mix various concentrations of nicotine with flavor additives and other chemicals and package the liquid for the consumer in the retail store. Even the most conservative reading of the Act would show that any store selling custom-made e-cigarette mixtures is a tobacco product manufacturer. A business that mixes custom nicotine liquid solutions is repackaging, assembling, and processing the nicotine solution. Furthermore, if the store puts its own labels on the products, this activity constitutes labeling or relabeling. In addition, many of these stores also sell items to modify devises and, thus, could be engaged in the manufacturing, fabricating, and assembling of tobacco products.

The growing number of these types of retailers, combined with the potential dangers of handling and mixing dangerous chemicals or modifying the devices, makes it necessary for the FDA to require that these establishments be treated as manufacturers under the Tobacco Control Act and § 900(20), 123 Stat. at 1786 (codified at 21 USC § 387), and abide by all of the requirements of

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

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

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

The Tobacco Control Act explicitly prohibits all characterizing flavors in cigarettes except menthol and tobacco.[58] While Congress focused its attention on the wide range of fruit- and candy-flavored cigarettes, it did not expressly extend the flavor prohibition to other tobacco products.[59] This is an obvious gap that could be closed by agency regulation.

The FDA can and should prohibit all flavors in all tobacco products, including menthol. There is no limitation in the Act that would prevent the FDA from prohibiting the use of mint and menthol flavoring in all tobacco products and there is no rational basis for excluding them from such a prohibition.[60] Rather, there is extensive evidence showing that menthol cigarettes are the source of addiction for nearly half of all teen smokers.[61] Menthol increases the palatability of smoking, especially among youth and members of racial and ethnic populations, and menthol increases the difficulty of quitting. There is also evidence that trying flavored non-cigarette tobacco products is related to increased rates of youth smoking. A recent study of flavored tobacco product sales concluded: "Ever trying flavored tobacco products were strongly

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

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

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

[61] Menthol Citizen Petition, *supra* note 60.

associated with current smoking among teens. The findings from this study suggest that regulations prohibiting sales of flavored tobacco products could decrease youth smoking."[62]

The reasons that support prohibiting the sale of sweet or candy-flavored cigarettes also apply to flavored non-cigarette tobacco products. As the FDA's own *Parental Advisory on Flavored Tobacco Products* states, flavored tobacco products:[63]

- Appeal to kids.
  Young people are much more likely to use flavored tobacco products than adults, and tobacco industry documents show that companies have designed flavored cigarettes with kids in mind. For example, one tobacco company suggested creating a honey-flavored cigarette to attract teenagers who like sweet products.
- Disguise the bad taste of tobacco.
  Candy and fruit flavors mask the bad taste of tobacco, making it easier for kids to start using tobacco products. Once they start using one tobacco product, however, they are more likely to experiment with others.
- Are just as addictive as regular tobacco products.
  Scientists have found that many kids think flavored tobacco products are safer and less addictive than regular tobacco products. This is not true. All tobacco products contain nicotine, the primary addictive chemical that makes it so hard to quit using tobacco.
- Have the same harmful health effects as regular tobacco products.
  Flavored cigarettes, cigars and pipes are not less dangerous than regular tobacco products. Smoking any kind of tobacco product increases your risk of developing serious health problems, including lung cancer, heart disease and emphysema. Tobacco products that you don't smoke, like snuff and chewing tobacco, have also been shown to cause gum disease and cancers of the mouth.

The FDA's advisory committee's conclusions regarding the appeal and harm of flavored tobacco products are strongly supported by scientific research.[64] While adults use flavored products as well, these products are clearly designed to appeal to youth. This intent is made more obvious by the marketing, which is designed to entice young people to try the product, and the flavors, which make it easier for youth to smoke or use smokeless products.[65] Internal tobacco industry documents have establish a long history of the use of flavored cigarettes to attract children.[66]

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[62] Shannon M. Farley, et al, *Teen Use of Flavored Tobacco Products in New York City* NICOTINE TOBACCO RES. 1 (published online ahead of print) doi:10.1093/ntr/ntu126 (2014).
[63] U.S. FOOD & DRUG ADMIN., FDA ADVISORY, FLAVORED TOBACCO PRODUCTS—WHAT YOU NEED TO KNOW, *available at* www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/UCM183262.pdf.
[64] Carrie M. Carpenter et al., *New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies*, 24 HEALTH AFF. 1601, 1608 (2005); *see also* Joseph A. Califano, Jr. & Louis W. Sullivan, Editorial, *The Flavor of Marketing to Kids*, WASH. POST, June 29, 2006, at A27 ("By masking the regular tobacco flavor and scent, flavored cigarettes make it even more appealing for a 12- or 13-year old to take that initial puff and keep smoking until he or she gets hooked.").
[65] Stacy M. Carter & Simon Chapman, *Smokers and Non-smokers Talk About Regulatory Options in Tobacco Control*, 15 TOBACCO CONTROL 398 (2006).
[66] Memorandum on New Flavors Sensations from A.B. Hudson to P.T. Sherman (July 3, 1978), *available at* http://legacy.library.ucsf.edu/tid/tlp76b00/pdf; Memorandum on Unique Flavored Cigarettes from Kenneth W.

Failing to extend a prohibition on flavors to other products ignores this blatant industry tactic to hook youth on tobacco products.

Flavorings also form the basis of youth-enticing marketing campaigns. For example, Apple Blend Skoal Chew promotions assert that the product will "combine rich, premium tobacco with the crisp flavor of juicy apples,"[67] available in a pouch similar to a tea bag. One manufacturer's little cigar is marketed as containing "a nice punch of 'wild raspberry' to tantalize the taste buds."[68] Advertisements and packaging employ stylish designs and bright colors that further emphasize the flavor and entice youth.[69] In fact, nearly every aspect of the marketing for these flavored tobacco products is strikingly similar to the marketing used for similarly flavored candies and sweetened beverages. That kids like flavored tobacco products is supported by the target audience itself. One teen described Cherry Skoal as "a beginner's product that helped me gradually go up the ladder."[70] "Cherry is like the kindergarten for Copenhagen," said another high school boy.[71]

In addition to flavored product use by youth, many adults and subpopulations of adults are also attracted to flavored products. The attractiveness of flavored tobacco products is supported by a recently published report from the Centers for Disease Control and Prevention (CDC), which found that a substantial proportion, 42.8%, of adult cigar smokers report using flavored cigars. Even more troubling is the CDC's findings that the prevalence of flavored cigar use among smokers increases with decreasing age, with 57.1% of 18-24 year old smokers reporting use of flavored cigars in comparison to 43.2% of smokers age 25-44, 28.9% of smokers age 45-64, and 13.4% of smokers over age 65.[72] It is clear that younger smokers who are in the early stages of developing addiction are the most attracted to flavored products. Moreover, the CDC report found that there are notable disparities in flavored cigar use across subpopulations of cigar smokers, with flavored cigar use higher among female than male cigar smokers (60.8% vs. 39.2%), higher among Hispanic than non-Hispanic white cigar smokers (61.7% vs. 37.9%), and higher among lesbian, gay, bisexual and transgendered individuals than heterosexual cigar

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Swicegood to Susan McReynolds (June 27, 1979), *available at* http://legacy.library.ucsf.edu/tid/htr76b00/pdf; Memorandum on New Products-Flavored Cigarettes from Tom H. Mau to Andrew H. Tisch (Sept. 6, 1972), *available at* http://legacy.library.ucsf.edu/tid/nes46b00/pdf; Memorandum from Marketing Innovations Corp. to Brown & Williamson Tobacco Corp. on Youth Cigarette – New Concepts (Sept. 1972), *available at* http://legacy.library.ucsf.edu/tid/xfq76b00/pdf.

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

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

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

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

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

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

smokers (67.0% vs. 41.8%).[73] Flavored cigars are used by populations with greater health disparities, making swift action on flavored cigars particularly important.

Additionally, there is evidence suggesting that flavors are contributing to the popularity and growth of the smokeless tobacco market. A study of smokeless tobacco users seeking cessation treatment found that a majority of the subjects currently used a mint-flavored smokeless tobacco product (58.7%) and had initiated smokeless tobacco use with a mint-flavored product (57.7%).[74] This study also observed that the likelihood of switching to a flavored smokeless tobacco product after initiating with a non-flavored product was higher than the likelihood of switching to a non-flavored product after initiating with a flavored product.[75] The importance of flavoring to the prevalence of smokeless tobacco product use is further supported by data indicating that sales of flavored moist snuff products not only increased 72.1% from 2005 to 2011, but also contributed to about 60% of growth in sales in the moist snuff category overall.[76] Each year from 2005 to 2011, flavored products comprised at least 54% of the overall moist snuff market share.[77] The market share of flavored products is even higher for the subcategory of snus – 79.6% in 2011.[78] Unchecked, the market for flavored tobacco products will continue to grow, leading to an increase in youth initiation and diminishing cessation.

Some state and local governments have taken action to prohibit the sale of flavored tobacco products. The only state that has passed legislation prohibiting the sale of flavored cigars is Maine; that statute is comprehensive and is currently being enforced by the Attorney General of Maine.[79] New York City passed an even more expansive bill restricting the sale of flavored non-cigarette tobacco products, but exempt menthol, mint and wintergreen.[80] The prohibited products include flavored cigars and smokeless tobacco products, but the law exempts sales in adult-only facilities.[81] The City Council's action was prompted by city officials' alarm at the wide array of cigar flavors, like cookie dough, chocolate chip and pink berry, which appeared to target minors.[82]

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[73] *Id.*

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

[75] *Id.*

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

[77] *Id.*

[78] *Id.*at 4.

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

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

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

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

Other jurisdictions, including Providence, Rhode Island, and Santa Clara County, California, have followed suit with even more comprehensive flavored tobacco product sales restrictions that protect youth.[83] Both Providence and New York City successfully defended their flavored product provisions against legal challenges brought on the grounds that only the federal government has this authority.[84] This developing case law provides helpful guidance to other communities considering a sales restriction on flavored tobacco products. However, a piecemeal approach cannot match the public health impact that a nationwide prohibition on flavored tobacco products would have both with respect to decreasing youth initiation and reducing adult tobacco use.

Each of the products that the FDA proposes to now regulate are available in flavors that are undeniably attractive to young people as well as adults and present all of the hazards of flavored cigarettes. The FDA must take action to prevent the attraction and addiction of young people to these products that contribute to chronic disease and premature death. Therefore, the agency must immediately prohibit the sale of all flavored tobacco products.

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

Such a prohibition is not only obviously within the FDA's authority to establish product standards[85] and to restrict the sale and distribution[86] of tobacco products, a prohibition on flavors would be a logical outgrowth of the FDA's current proposal. The proposed deeming regulation recognizes the youth appeal of flavors[87] and specifically solicits information regarding "what additional actions, if any, should FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults?"[88] The simplest action is a prohibition of all

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

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

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

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

[87] Deeming Regulation, 79 Fed. Reg. at 23,144-23,146

[88] Deeming Regulation, 79 Fed. Reg. at 23,147.

flavors in all tobacco products with the exception of the flavor of tobacco. Any flavor additive to a tobacco product serves only to mitigate the harsh flavor of tobacco, making tobacco product use easier and thus increasing initiation and decreasing cessation. The FDA has deferred meaningful action on flavors long enough. The time for a flavor prohibition is now.

vi. The FDA should restrict advertising and marketing of e-cigarettes.

The FDA should extend the following advertising and marketing restrictions that currently only apply to cigarettes and smokeless tobacco to all tobacco products: 1) prohibit tobacco product brand and trade names of non-tobacco products; [89] 2) prohibit brand and trade name sponsorship of sporting and cultural events; [90] 3) require notice of all advertising in any non-traditional medium.[91] Each of these marketing techniques is recognized as a tactic to increase youth initiation. In addition, the FDA must address the now-common practice of advertising e-cigarettes on television and radio. Cigarettes and smokeless tobacco product advertisements have been prohibited on television and radio for decades. The growing number of e-cigarette advertisements is renormalizing tobacco product advertisements in these mediums. The FDA cannot simply sit on the sidelines while e-cigarette advertisements are being broadcast to millions of people, many of whom are youth and young adults. There are a range of options available to the FDA. Given the ubiquitous and irresponsible marketing of tobacco products, and e-cigarettes in particular, it is important for the FDA to take the necessary steps to protect children from predatory marketing practices.[92]

The tobacco industry has a long history of marketing its products to young adults and children to get them addicted to nicotine at a young age.[93] These restrictions do not prevent the tobacco industry from communicating about its products to adult consumers but do restrain the industry

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[89] 57 Equivalent regulations related to cigarettes and smokeless tobacco can be found at 21 C.F.R. § 1140.16(a) (2013). The FDA has agreed not to enforce this regulation against some manufacturers until amendments are made to the regulation. The FDA has yet to promulgate a rule making any such amendments. See Stipulation of the Parties, Renegade Tobacco Co. v. U.S. Food & Drug Admin., No. 3:10-cv-00265-HEH (E.D. Va. May 19, 2010)(stipulating that the litigation should be stayed pending the FDA's consideration of amendments to 21 C.F.R. § 1140.16(a)).

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

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

[92] Letter from Henry Waxman et al., United States Congressman, to Kamala Harris et al., Attorneys General (Feb. 12, 2014), http://democrats.energycommerce.house.gov/sites/default/files/documents/Harris-MillerSorrell-Master-Settlement-Agreement-Tobacco-2014-2-12.pdf; Full Committee Hearing – Progress and Challenges: The State of Tobacco Use and Regulation in the U.S, 113th Cong. (2014), http://www.help.senate.gov/hearings/hearing/?id=a0a14829-5056-a032-526d-3bc1bfd96586; Aggressive E-cigarette Marketing and Potential Consequences for Youth, 113th Cong. (2014), http://www.commerce.senate.gov/public/index.cfm?p=Hearings&ContentRecord_id=42af91a8-6308-45b5-9842-74bc5833be73&ContentType_id=14f995b9-dfa5-407a-9d35-56cc7152a7ed&Group_id=b06c39af-e033-4cba-9221-de668ca1978a&MonthDisplay=6&YearDisplay=2014; Protecting Children from Electronic Cigarette Advertising Act of 2014, S. 2047, 113th Cong. (2014), http://www.gpo.gov/fdsys/pkg/BILLS- 113s2047is/pdf/BILLS-113s2047is.pdf; see also H.R. 4325, 113th Cong. (2014)(companion bill), http://www.gpo.gov/fdsys/pkg/BILLS-113hr4325ih/pdf/BILLS-113hr4325ih.pdf; Smoke Act, H.R. 5010, 113th Cong. (2014), http://www.gpo.gov/fdsys/pkg/BILLS-113hr5010ih/pdf/BILLS-113hr5010ih.pdf; Child Nicotine Poisoning Prevention Act of 2014, S. 2581, 113th Cong. (2014, http://www.gpo.gov/fdsys/pkg/BILLS-113s2581is/pdf/BILLS-113s2581is.pdf

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

from preying on children. Given the increasing appeal of these products to youth and young adults and the amount of experimentation that is already underway, there is clearly a need to implement these restrictions to curb youth initiation of tobacco use as is the FDA's charge from Congress. The restrictions proposed by the FDA represent a small step in the right direction. However, the FDA must extend all of the current advertising and marketing restrictions concerning cigarettes and smokeless to these newly-covered products.

vii. The FDA should strengthen warning labels on e-cigarettes.

Warning labels are one of the oldest and most basic public health measures to attempt to mitigate the negative health effects of smoking.[94] Since the first warning labels appeared on cigarette packages in 1965, warning labels have been an important source of information for tobacco users.[95] While there is evidence that warning labels can go stale, [96] and the need for large graphic warning labels is clear,[97] the newly-covered products are typically marketed with no warning labels whatsoever. This contributes to the state of confusion surrounding the health effects of these new products.[98] At the very least, these products must display textual warnings; but to use the full extent of its authority and to provide the strongest protection for public health, the FDA should require large graphic warnings for all tobacco products. The FDA must establish warning labels for e-cigarettes and recognize that dissolvable tobacco products are smokeless tobacco products for the purpose of warning label regulation.

Although the proposed regulation includes a warning label requirement, the proposed warning is anemic and likely to be ineffective. The proposed warning label for the deemed tobacco products is: "This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."[99] There are several problems with this label. First, a warning that focuses only on the possibility of addiction is meaningless to consumers. There are a variety of products perceived as harmless that

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[94] Ctrs. for Disease Control & Prevention, *Cigarette Package Health Warnings and Interest in Quitting Smoking—14 Countries*, 2008-2010, 60(20) MORBIDITY & MORTALITY WKLY. REP. 645 (2011), http://www.cdc.gov/mmwr/pdf/wk/mm6020.pdf; U.S. DEP'T. OF HEALTH & HUMAN SERVS., ORAL HEALTH IN AMERICA: A REPORT OF THE SURGEON GENERAL (2000) [hereinafter, SGR 2000], http://silk.nih.gov/public/hck1ocv.@www.surgeon.fullrpt.pdf; Heikki Hiilamo et al., *The Evolution of Health Warning Labels on Cigarette Packs: The Role of Precedents, and Tobacco Industry Strategies to Block Diffusion*, 23(2) TOBACCO CONTROL 1 (2014) (published online ahead of print), doi:10.1136/tobaccocontrol-2012-050541.

[95] SGR 2000, *supra* note 94, at 163.

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

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

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

[99] Deeming Regulation, 79 Fed. Reg. at 23,162. There are additional warning labels proposed for cigars.

are also addictive, such as caffeine, so a warning containing only this statement is unlikely to resonate with consumers.

The deeming regulation also fails to require multiple warnings for newly-covered tobacco products. Establishing multiple warnings will allow for rotation, maintaining the effectiveness of the warning labels. Effective warning labels are an important tool in the FDA's arsenal to protect public health. The agency's proposed warning label requirements for newly-covered tobacco products are underwhelming and must be improved in a final regulation. The public health standard requires the agency to establish warning labels that will reduce initiation and increase cessation. Stronger warning labels are needed to adequately protect public health.

viii. The FDA must prohibit self-service access to e-cigarettes and prohibit their sale online.

Self-service access can play a significant role in youth initiation and the FDA must act to limit this avenue for youth access to all tobacco products. Under the Tobacco Control Act, retailers cannot provide self-service access to cigarettes and smokeless tobacco or sell these products in vending machines, unless the retailer is an adults-only establishment.[100] The Supreme Court upheld a similar restriction implemented by the Massachusetts Attorney General, finding that self-service displays of cigarettes may be prohibited because "[u]nattended displays of tobacco products present an opportunity for access without the proper age verification required by law."[101] Similarly, when the FDA first proposed the prohibition on self-service access to cigarettes, it relied on evidence such as the Institute of Medicine (IOM) Report Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths (1994), which referred to surveys in two communities that found over 40% of daily smokers in grade school shoplifted cigarettes.[102] The public health rationale for this restriction extends to the newly-covered tobacco products: eliminating self-service access where youth are permitted reduces youth access to those products. There is no public health rationale for refusing to extend the prohibition on self-service access to the newly-covered tobacco products. While some state and local governments prohibit self-service access for all tobacco products, many are unable to do so because of a lack of local authority, state preemption of local authority, or other barriers. The FDA is the only government entity that can taking sweeping action to protect public health throughout the country and the agency must prohibit self-service access to e-cigarettes. The FDA should also prohibit the sale of e-cigarettes over the internet. Few websites implement any form of reliable age verification and there is no reason to allow this loophole to persist in the era of FDA regulation.

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

[100] 21 C.F.R. §§ 1140.14(c), 1140.16(c)(2)(ii) (2010).
[101] Lorillard Tobacco v. Reilly, 533 U.S. 525, 569 (2001).
[102] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,441 (Aug. 28, 1996).

The lack of e-cigarette packaging standards has led to product designs for the containers for liquid nicotine that may encourage children to ingest the product's poisonous content.[103] Some labels include cartoons, have colorful labeling, or depict edible ingredients indicating a bottle's particular flavor, such as cherry, chocolate, or bubble gum. The contents themselves can have the aroma of the edible ingredient pictured on the label.[104] Any of these factors could be enticing enough for a child to investigate, cumulatively they are a lethal combination.

As the use of e-cigarettes increases, so too does the risk of accidental poisoning. The CDC analyzed calls to U.S. poison centers from September 2010 to February 2014 regarding e-cigarette exposure related incidents. The results show that e-cigarettes accounted for 0.3% of the exposure calls in September 2010 and 41.7% of the calls in February 2014.[105] Just over half of the calls made regarding exposure were for incidents involving children ages 0–5.[106] The prevalence of poisonings and the potential danger to young children prompted the American Association of Poison Control Centers and its fifty-five member centers to issue a statement urging e-cigarette users to keep the devices and liquids away from children.[107] One teaspoon (5 ml) of a 1.8% nicotine solution could be lethal to a 200-pound person.[108] Most liquid nicotine levels vary in range from 1.8% to 2.4%.[109] Considering that most refill bottles contain between 10–30 milliliters, there are at least enough doses in each bottle to kill between two and six full-grown adults. There is an even greater danger to small children as it takes proportionally less nicotine to create a lethal dose as body weight decreases.

The American Association of Poison Control Centers data shows that human exposures to e-cigarettes and liquid nicotine reported to poison control centers has increased fourteen fold from 2011 to 2014. The number of cases reported jumped from 271 in 2011 to 3,783 in 2014. As of May 31, 2015, the number of cases reported in 2015 is 1,499.[110]

The effects of nicotine exposure can vary depending on the size of the person and the amount of nicotine ingested or absorbed. Common effects that have been reported include eye irritation, nausea, and vomiting.[111] As exposure increases, the effects worsen and can include seizures, neuromuscular blockade (muscle weakness or paralysis) and respiratory failure.[112] There are

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

[104] 3 Tony Leys, E-Cigarette Liquid Refill Warning, DES MOINES REGISTER Mar. 25, 2014 (included in Iowa Poison Center's Media Packet), http://www.iowapoison.org/news-and-recalls/e-cigarette-liquid-refillwarning/

[105] Kevin Chatham-Stephens, et al., Ctrs. for Disease Control & Prevention, *Notes from the field: Calls to Poison Centers for Exposures to Electronic Cigarettes* 63(13) MORBIDITY & MORTALITY WKLY. REP. 292, 292-93 (2014), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm

[106] *Id.*

[107] News Release, *supra* note 42.

[108] Bassett, *supra* note 103. ("[A]n estimated median lethal dose between 1 and 13 mg per kilogram of body weight, 1 teaspoon (5 ml) of a 1.8% nicotine solution could be lethal to a 90-kg person.").

[109] Matt Richtel, Selling a Poison by the Barrel: Liquid Nicotine for E—Cigarettes, N.Y. TIMES, Mar. 24, 2014, at A1, http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-ecigarettes.html.

[110] *Electronic Cigarettes and Liquid Nicotine Data*, American Association of Poison Control (May. 31, 2015) https://aapcc.s3.amazonaws.com/files/library/E-cig_ Nicotine_Web_Data_through_5.2015.pdf (last visited on Jun. 29, 2015)

[111] News Release, *supra* note 42.

[112] Bassett, *supra* note 103.

several means of accidental exposure. Nicotine can be inhaled, ingested, absorbed through the skin, lips, mouth or eyes.[113] Most reported exposure cases having been from ingestion.[114] At this point, there has been one fatality reported due to liquid nicotine ingestion.[115]

Due to the obvious danger and the alarming increase in calls to poison control centers, some state legislatures have already taken precautions. Legislators in Illinois, Indiana, Minnesota, New Mexico, North Carolina, New York, North Dakota, Ohio, Oregon, Rhode Island, Tennessee, Utah, Vermont, Virginia, and Wyoming have passed laws that require child-resistant packaging on all liquid nicotine refillable bottles. Some retailers have also voluntarily begun selling only those refills that have child-resistant caps.[116]

II. Conclusion

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

New regulations should be crafted to prevent a potential public health epidemic, rather than waiting for further evidence of harm. If future evidence shows that e-cigarettes are an effective tool to reduce the health harms of tobacco addiction, the FDA can adjust its regulatory approach accordingly. Until then, the agency must act decisively to regulate e-cigarettes. Evidence suggests that as the popularity and prevalence of e-cigarettes increase, so too will experimentation and regular use by youth. This fear is heightened by the public's knowledge of past tobacco industry behavior as we collectively experience déjà vu while witnessing e-cigarette companies using marketing tactics that are known to appeal to youth and are now forbidden for cigarettes. The FDA must do more to protect public health from the potential harms of e-cigarettes.

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[113] E.J. Mundell, Nicotine Poisoning of Infant highlights 'E-Cig' Dangers, Docs Report, HEALTHDAY, http://consumer.healthday.com/public-health-information-30/poisons-health-news-537/nicotine-poisoning-of-infanthighlights-new-e-cig-dangers-687620.html (last updated May 7, 2014).
[114] Chatham-Stephens et al., *supra* note 105, at 292-93.
[115] Mohney, *supra* note 45.
[116] Richtel, *supra* note 109, at A1.

Respectfully,

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