

HHS COMMITTEE #1
July 21, 2014

MEMORANDUM

July 17, 2014

TO: Health and Human Services Committee

FROM: Linda McMillan, Senior Legislative Analyst 
Amanda Mihill, Legislative Attorney

SUBJECT: **Briefings and Discussion – E Cigarettes**

Expected for this session:

Dr. Kevin Walton, Ph.D.
Program Officer, Medications Research Grants Branch
Division of Pharmacotherapies and Medical Consequences of Drug Abuse
National Institute on Drug Abuse
National Institutes of Health

Dr. Ericka M. Boone, Ph.D.
Office of Science Policy and Communications
National Institute on Drug Abuse
National Institutes of Health

William C. Tilburg, JD
Deputy Director, Legal Resource Center for Public Health Policy
University of Maryland Carey School of Law

Also attending will be Dr. Ulder Tillman, Montgomery County Health Officer, and Dr. Donald Shell, Director, Cancer and Chronic Disease Bureau, Maryland Department of Health and Mental Hygiene.

At this session, the HHS Committee will first be provided with a briefing from Dr. Walton and Dr. Boone that will describe what e-cigarettes are and what is known and unknown about the possible health implications. Attached at © 1-2 is a NIDA Drug Facts briefing on Electronic Cigarettes. The brief notes:

- E Cigarettes have a cartridge that holds a liquid solution containing varying amounts of nicotine, flavoring, and other chemicals; a heating device; and a rechargeable battery.
- Generally, puffing action activates the heating device and vaporizes the liquid in the cartridge.
- Although they do not produce tobacco smoke, e-cigarettes still contain nicotine and other potentially harmful chemicals.
- It is unclear whether e-cigarettes may be effective as a smoking cessation tool or whether they could perpetuate nicotine addiction.
- There is concern that e-cigarette use may serve as a “gateway” or introductory product for youth to try other tobacco products.

Attached at © 3-5 is the first of two briefs from the University of Maryland School of Law. Its conclusion sections says, “While ESDs continue to gain popularity, not enough is currently known about their short-term and long-term health risks, their effectiveness as smoking cessation tools, or even contents. However, the scant information that is available suggests the need for comprehensive regulation.” This brief also notes that the language of most states’ existing clean indoor air laws (including Maryland) do not restrict the use of electronic cigarettes because the tobacco does not burn.”

The second brief from the University of Maryland School of Law (© 7-9) provides recommendations on restrictions and regulations that should be put in place such as:

- The licensing of electronic smoking device (ESD) retailers.
- Prohibiting the use of ESDs on school grounds.
- Prohibiting flavored ESD nicotine to make the product less appealing to youth.
- Limiting the placement of sale to areas inaccessible to the consumer.
- Restricting the sale to places where only adults are allowed to enter.

Attached at © 10-14 is a letter from the National Association of Attorneys General urging the Food and Drug Administration to meet its deadline to issue proposed regulations for the advertising, ingredients, and sales to minors of electronic cigarettes.

Attached at © 15-18 is information sent to the Council from Mr. Bruce Bereano, on behalf of the Maryland Association of Tobacco and Candy Distributors. It also includes information from The Consumer Advocates for Smoke-free Alternatives Association. Mr. Bereano says that the health effects of electronic cigarettes are currently unknown, that the Association of Tobacco and Candy Distributors supports the current law prohibiting minors from selling, purchasing, or using e-cigarettes, that local government has no authority to legislate or regulate any cigarette or tobacco product, and e-cigarettes do not possibly have any secondary hand effects on others.

Summary of Current Federal, Maryland State, and Montgomery County Law and Regulation (provided by Council Legislative Attorney)

Federal Law

The FDA does not currently regulation e-cigarettes. However, that could soon change. The Family Smoking Prevention and Tobacco Control Act gives the U.S. Food and Drug Administration (FDA) the authority to regulate the manufacturing, marketing, and sale of tobacco products. The law applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products, and to any other tobacco product “deemed” by regulation to be subject to the law. The FDA has issued a “deeming” regulation that would, among other actions, subject e-cigarettes to regulations already applicable to cigarettes, including:

- minimum age of purchase;
- prohibition on free samples;
- health warnings;
- prohibition of certain vending machine sales; and
- report to the FDA product and ingredient listings.

The “deeming” regulation would not address flavorings (which may be attractive to youth smokers), but the FDA is seeking comment on this topic as well as how noncombustible products (such as e-cigarettes) should be regulated. The deadline to comment on this proposed regulation was July 9.

Under the Act, state and local governments retain considerable authority in the area of tobacco regulation. Federal law specifically states that the Family Smoking Prevention and Tobacco Control Act cannot be construed to “limit the authority of a . . . State or political subdivision of a state . . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than” the requirements of the Act, including laws “relating to or prohibiting the sale, distribution, possession, exposure to, access, to advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.”¹

The Act does expressly preempt a state or political subdivision from having, for a tobacco product, “a requirement that is different from, or in addition to, any requirement . . . relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.”² However, this preemption provision “does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.”³

¹ 21 U.S.C. §387p(a)(1).

² 21 U.S.C. §387p(a)(2)(A).

³ 21 U.S.C. §387p(a)(2)(B).

The Act grants state and local governments additional authority in the area of advertising. Prior to this Act, state and local governments were preempted from enacting laws restricting cigarette advertising and promotion for health reasons. The Act loosened these preemptions and authorizes a state or local government “enact statutes and promulgate regulations, based on smoking and health . . . imposing specific bans or restrictions on the time, place, and manner, but not content of, the advertising or promotion of any cigarettes.”⁴

To summarize, generally speaking, federal law grants state and local governments wide authority to enact or adopt tobacco control actions that are more stringent than federal law, but preempts them from regulating the tobacco product itself.

State Law

In addition to other miscellaneous provisions in state law, there are three regulatory schemes that are important regarding tobacco control: the Clean Indoor Air Act, Title 16 of the *Business Regulation* Article of the Maryland Code (cigarettes), and Title 16.5 of the *Business Regulation* Article (other tobacco products). At present time, none of these laws regulate e-cigarettes. In relevant part, §16.5-101(i) of the *Business Regulation* Article defines “other tobacco products” to include “any other tobacco or product made primarily from tobacco, other than a cigarette, that is intended for consumption by smoking or chewing or as snuff.” It is Council staff’s understanding that the state does not interpret this definition to include e-cigarettes. The only state law on point to Council staff’s knowledge is §24-305 of the Health-General Article of the Maryland Code, which prohibits distribution of electronic cigarettes to a minor.

County Law

County law does not prohibit smoking e-cigarettes.

⁴ 15 U.S.C. §1334(c).

Drug Facts

www.drugabuse.gov

Electronic Cigarettes (e-Cigarettes)

Electronic cigarettes (also called e-cigarettes or electronic nicotine delivery systems) are smokeless, battery operated devices designed to deliver nicotine with flavorings or other chemicals to the lungs of users without burning tobacco (the usual source of nicotine). They are typically manufactured to resemble regular tobacco cigarettes, cigars, pipes, or even everyday items like pens or USB memory sticks. More than 250 different e-cigarette brands are currently on the market.

While e-cigarettes are often promoted as safer alternatives to traditional cigarettes, little is actually known yet about the public health implications of using these devices.

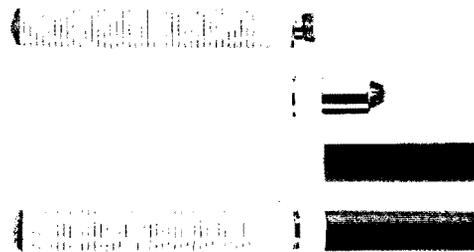
How Do e-Cigarettes Work?

Most e-cigarettes consist of three different components, including:

- A cartridge, which holds a liquid solution containing varying amounts of nicotine, flavorings, and other chemicals
- A heating device (vaporizer)
- A rechargeable battery

In most e-cigarette, puffing activates the battery-powered heating device, which vaporizes the liquid in the cartridge. The

resulting aerosol or vapor is then inhaled (called “vaping”).



Are e-Cigarettes Safer than Conventional Cigarettes?

Unfortunately, this question is difficult to answer because insufficient information is available on these new products.

Cigarette smoking remains the leading preventable cause of sickness and mortality, responsible for over 400,000 deaths in the United States each year. The worst health consequences associated with smoking (e.g., cancer and heart disease) are linked to inhalation of tar and other chemicals produced by tobacco combustion; the pleasurable, reinforcing, and addictive properties of smoking are produced mostly by the nicotine contained in tobacco.

E-cigarettes are designed to simulate the act of tobacco smoking by producing an appealingly flavored aerosol that looks

and feels like tobacco smoke and delivers nicotine but without the toxic chemicals produced by burning tobacco leaves. Because they deliver nicotine without burning tobacco, e-cigarettes appear as if they are a safer, less toxic alternative to conventional cigarettes.

Although they do not produce tobacco smoke, e-cigarettes still contain nicotine and other potentially harmful chemicals. Nicotine is a highly addictive drug, and recent research suggests nicotine exposure may also prime the brain to become addicted to other substances. Also, testing of some e-cigarette products found the vapor to contain known carcinogens and toxic chemicals (such as diethylene glycol and nitrosamines), as well as potentially toxic metal nanoparticles from the vaporizing mechanism. The health consequences of repeated exposure to these chemicals are not yet clear.

Another worry is the refillable cartridges used by some e-cigarettes. Users may expose themselves to potentially toxic levels of nicotine when refilling them. Cartridges could also be filled with substances other than nicotine, thus possibly serving as a new and potentially dangerous way to deliver other drugs.

Can e-Cigarettes Help a Person Quit Smoking?

Some people believe e-cigarette products may help smokers lower nicotine cravings while they are trying to discontinue their tobacco use. However, at this point it is unclear whether e-cigarettes may be effective as smoking-cessation aids. There is also the possibility that they could perpetuate the nicotine addiction and thus interfere with quitting.

Because e-cigarettes are not currently marketed either as tobacco products or as devices having a therapeutic purpose, they are not regulated by the FDA. In ad-

E-Cigarette Use by Youth

E-Cigarettes are increasingly popular among adolescents. Although they contain nicotine derived from tobacco, they are not yet subject to regulation as tobacco products, including the requirement that purchasers be a certain age. Some states have banned sale of e-cigarettes to minors, but they can get around that by ordering online. Their easy availability (online or via mall kiosks), in addition to their wide array of cartridge flavors (such as coffee, mint, candy, and fruit flavors), may make them particularly appealing this age group.

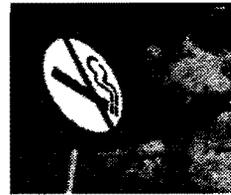
There is a concern that e-cigarette use may serve as a “gateway” or introductory product for youth to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.

In addition, there is currently no regulation of the liquids that are used in e-cigarettes. So, there are no accepted measures to confirm their purity or safety.

These products have not been thoroughly evaluated in scientific studies. This may change in the near future, but for now, very little data exists on the safety of e-cigarettes, and consumers have no way of knowing whether their purported therapeutic benefits or advantages over conventional cigarettes are real.

Learn More

For additional information on e-cigarettes, please see <http://www.fda.gov/forconsumers/consumerupdates/ucm225210.htm> and our NIDA TV Spotlight: <http://www.youtube.com/watch?v=Iz67IqkLwYs&feature=youtu.be>



Overview

Electronic Smoking Devices

I. Introduction

Commonly referred to as electronic cigarettes or “e-cigs,” Electronic Smoking Devices (“ESDs”) are battery-powered nicotine delivery devices. Designed to look and feel like traditional tobacco products (such as cigarettes, cigars, cigarillos and pipes), ESDs deliver nicotine to the bloodstream through vapor, rather than smoke. Often, the devices are enhanced with candy, fruit or alcohol flavorings.

ESD use is on the rise. Sale revenues eclipsed \$1 billion worldwide in 2013 and are projected to surpass cigarette sales by 2047.¹ Likewise, ESD use has increased among youth; according to the Centers for Disease Control and Prevention (“CDC”), between 2011 and 2012, electronic cigarette use doubled among teens.² In 2012, more than 10 percent of high school students reported trying ESDs, up from 4.7% in 2011.³

Despite this increase in popularity, at present, the health risks associated with ESD use have not been sufficiently studied, their ingredients are largely unknown, and they remain unregulated at the federal level. However, state and local governments may regulate the distribution and use of ESDs, and commercial and residential property owners may restrict the use of ESDs on their property.

The following sections provide an overview of the health effects and regulatory status of ESDs. Specifically, Part II discusses the health risks of ESDs, their contents, and their use as smoking cessation aids. Part III describes the status of federal regulations. Finally, Part IV outlines existing state regulations as well as property owners' legal ability to restrict ESD use.

II. Health Effects

The health effects of ESDs are still not very well understood, as there are few comprehensive studies on the subject. However, the information that is available reveals some troubling aspects of these devices. For instance, ESDs have been shown to cause an immediate increase in airway resistance after only 10 minutes of use.⁴ Additionally, in 2009, the Food and Drug Administration (“FDA”) evaluated a small sample of electronic cigarette cartridges and determined that they contained detectable levels of carcinogens and toxins.⁵ ESD vapors have also been found to contain toxins (although the detected levels were lower than in cigarette smoke).⁶

Perhaps most notably, ESDs contain nicotine—a highly addictive substance that can lead to other addiction disorders, particularly in youth. Studies have shown that compared to high school students who had never smoked, high school students who were nicotine-dependent smokers were almost 18 times as likely to have an alcohol or other drug use disorder.⁷

While it is known that ESDs contain nicotine and toxic substances, there is still a lack of adequate data to properly determine the health risks of ESDs—both for the users and bystanders. Long-term studies, for example, still need to be conducted.⁸ Additionally, the “quality control” system for ESD manufacturing is “questionable.”⁹ ESD companies are not subject to any manufacturing standards, so ingredients and their concentrations (like nicotine levels) vary for each brand.¹⁰

Finally, despite popular belief that ESDs can be used to help people quit smoking, the effectiveness of these products as smoking cessation aids has not been conclusively proven. In one recent study, e-cigarettes were found to be “modestly effective” in helping smokers quit, with the efficacy level “similar” to that of nicotine patches.¹¹ However, the study also noted the continued “uncertainty... about the place of e-cigarettes in tobacco control,” and emphasized that “more research is urgently needed to clearly establish their overall benefits and harms at both individual and population levels.”¹²

Therefore, until more comprehensive studies and data are available, the public health community largely advocates the use of the “precautionary principle”—implementing regulations now while the health risks of ESDs are more effectively determined.¹³

III. Federal Regulation

Currently, there is no federal regulation of ESDs. While traditional cigarettes are subject to several federal restrictions, including flavoring and advertising regulations,¹⁴ ESD manufacturers have none of these constraints. Therefore, ESDs are available in a variety of youth-appealing flavors that can be advertised on a variety of platforms, including television and social media.¹⁵

The Food and Drug Administration initially tried to regulate ESDs as "drug/device" combination products under the Federal Food, Drug, and Cosmetic Act ("FDCA"). However, in *Sottera, Inc. v. Food & Drug Admin.*, the U.S. Court of Appeals for the D.C. Circuit ruled that the FDA could not regulate ESDs as "drug/device" combination products unless the products were being marketed as therapeutic devices (i.e., smoking-cessation tools).¹⁶ However, the court did rule that the FDA could regulate ESDs as "tobacco products" under the broad language of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA").¹⁷ The FSPTCA provides the FDA regulatory power over "tobacco products," and this specifically includes products "derived from tobacco."¹⁸ According to the court, since the nicotine in the ESDs was "derived from" tobacco, the FDA could exert its regulatory authority over the ESDs as "tobacco products."¹⁹

On April 24, 2014, the U.S. Food and Drug Administration ("FDA") issued its long-awaited Proposed Rule which would deem electronic cigarettes and other "tobacco products" (i.e., cigars, hookah, dissolvable tobacco, and pipe tobacco) subject to the FDA's regulatory authority under the Federal Food, Drug, and Cosmetic Act (as amended by the Family Smoking Prevention and Tobacco Control Act). Under this Proposed Rule, electronic cigarettes would be subject to several requirements already in place for cigarettes, roll-your-own tobacco and smokeless tobacco, such as a minimum age of purchase, mandatory ingredient disclosures and health warning requirements. While the proposed regulations do not address flavorings, advertising, or marketing restrictions, the FDA is seeking comment from the public on these and other areas which may be addressed in future regulations. The public has until July 9, 2014 to submit comments to the FDA about its current proposed regulations.²⁰ The FDA must review all of these comments and draft its Final Rule, which will then be published in the Federal Register; however, these final regulations may not have an implementation date until years after publication.²¹

IV. State, Local, and Private Property Regulation

Absent federal regulation, state and local authorities have begun to regulate the sale and distribution of ESDs. For example, 24 states, including Maryland, currently prohibit the sale of ESDs to minors.²² In order to further curb youth access, Indiana, North Carolina and South Carolina also regulate the sale of ESDs through vending machines.²³

Other approaches to ESD regulation include treating ESDs as "tobacco products" for tax purposes—Minnesota, for example, already applies its tobacco products tax to ESDs.²⁴ Other states, including Massachusetts, Delaware and Maine, have attempted to do the same.²⁵

While at least 30 states have comprehensive clean indoor air laws restricting the use of lighted tobacco products in indoor public places such as bars, restaurants and office buildings, only a few have extended these provisions to include the use of ESDs. For example, New Jersey, North Dakota, and Utah have specifically amended their clean indoor air laws to prohibit the use of electronic cigarettes in public places and workplaces.²⁶ However, the language of most states' existing clean indoor air laws (including Maryland's) does not restrict the use of ESDs because ESDs do not "burn" as defined in these statutes.²⁷

State officials, however, do recognize the risks of ESDs and the need for government oversight. In September 2013, the National Association of Attorneys General sent a letter to the FDA urging the FDA to issue proposed regulations on electronic cigarette advertising, ingredients, and sales to minors; 41 Attorneys General signed the letter.²⁸ Additionally, the Attorneys General of California and Oregon sued a leading electronic cigarette manufacturer in separate lawsuits, alleging that the manufacturers were making false health claims and targeting their products to minors. Both states were successful: In California, the manufacturer agreed to follow certain marketing and sales restrictions, and in Oregon, the manufacturer was permanently banned from doing business in the state.²⁹

Despite the lack of federal and comprehensive state regulation on ESD use, public housing authorities and private property owners do have the ability to restrict the use of ESDs on their property. While smoking is a legal activity, courts have repeatedly held that there is no constitutional or fundamental right to smoke, and that the act of smoking is subject to only a minimal level of protection under the Equal Protection Clause of the U.S. Constitution.³⁰ Therefore, local housing authorities and private property owners have the legal ability to restrict smoking (including ESD use), on their properties, just as they may restrict several other legal activities (e.g., prohibiting pets on the premises). Any private property owner can implement these restrictions, including those who own businesses, restaurants/bars, and other private property open to the public.

However, if housing authorities and private property owners wish to restrict the use of ESDs, they should explicitly include ESDs in their smoke-free policies and also provide a clear definition of ESDs. Specifically including and defining these devices in smoke-free policies is the best way to regulate their use, given the current ambiguous and rather fluid nature of state and federal regulation (e.g., the definition of "tobacco products").

When drafting or amending smoke-free policies, the Legal Resource Center recommends the following ESD definition: "**Electronic Smoking Device**" means any device that heats a liquid, gel, or other substance to produce a vapor that is intended to be inhaled by the user. Such devices include, but are not limited to, e-cigarettes, e-cigars, and e-pipes.

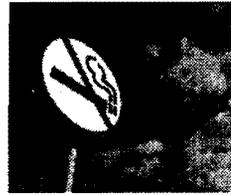
V. Conclusion

While ESDs continue to gain popularity, not enough is currently known about their short-term and long-term health risks, their effectiveness as smoking cessation tools, or even their contents. However, the scant information that is available suggests the need for comprehensive regulation. In the absence of federal regulations, states and local authorities can continue to take the lead in restricting the availability and appeal of ESDs to minors. Property owners can also restrict the use of ESDs on their premises. Such regulations can help protect the public from the unknown, potentially harmful effects of these new devices.

If you have any questions or are interested in further information regarding ESDs, including assistance in drafting ESD policies, ordinances, or similar materials, please feel free to contact the Legal Resource Center through email at tobacco@law.umaryland.edu, or by phone at 410-706-0842.

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- ¹ Natalie Robehmed, *E-cigarette Sales Surpass \$1 Billion As Big Tobacco Moves In*, Forbes (Sept. 17, 2013), <http://www.forbes.com/sites/natalierobehmed/2013/09/17/e-cigarette-sales-surpass-1-billion-as-big-tobacco-moves-in/>
- ² CDC, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012*, Morbidity and Mortality Weekly Report (Sept. 6, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w
- ³ *Id.*
- ⁴ *Experts warn that e-cigarettes can damage the lungs*, European Respiratory Society (Sept. 2, 2012), <http://www.erscongress2012.org/mediacenter/news-release/item/428-experts-warn-that-e-cigarettes-can-damage-the-lungs.html>
- ⁵ FDA, *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted By FDA* (July 22, 2009), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>
- ⁶ Maciej Goniewicz, et al., *Levels of selected carcinogens and toxicants in vapour from electronic cigarettes*. *TOB. CONTROL* (March 6, 2013), <http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.abstract>
- ⁷ National Center on Addiction and Substance Abuse, *Adolescent Substance Use: America's #1 Public Health Problem* (June 2011), <http://www.casacolumbia.org/upload/2011/20110629adolescentsubstanceuse.pdf>
- ⁸ *Experts warn that e-cigarettes can damage the lungs*, European Respiratory Society (Sept. 2, 2012), <http://www.erscongress2012.org/mediacenter/news-release/item/428-experts-warn-that-e-cigarettes-can-damage-the-lungs.html>
- ⁹ Neal L Benowitz and Maciej Goniewicz, *The Regulatory Challenge of Electronic Cigarettes*, *J. OF AM. MED. ASSOC.* (March 2013), http://www.tobacco.ucsf.edu/sites/default/files/u795/Benowitz_Gona%20E-cig%20JAMA%202013.pdf
- ¹⁰ Tobacco Control Legal Consortium, *Regulating E-Cigarettes: Tips and Tools* (May 2011), <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regecigs-2011.pdf>
- ¹¹ Christopher Bullen, et al., *Electronic cigarettes for smoking cessation: a randomised controlled trial*, *The Lancet* (Sept. 7, 2013), <http://download.thelancet.com/flatcontentassets/pdfs/S0140673613618425.pdf>
- ¹² *Id.*
- ¹³ *See, e.g.*, Tobacco Control Legal Consortium, *Regulating E-Cigarettes: Tips and Tools* (May 2011) <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regecigs-2011.pdf> ; National Association of Attorneys General, *Letter to FDA Urging Regulation of E-Cigarettes* (Sept. 24, 2013), <http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20%285%29%281%29.pdf>
- ¹⁴ *See* Family Smoking Prevention and Tobacco Control Act ("FSPTCA"), P.L. 111-31 (2009), <http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>
- ¹⁵ *See, e.g.*, Jolie Lee, *E-cigarette ads model big tobacco ads of old*, USA Today (Nov. 11, 2013), <http://www.usatoday.com/story/news/nation/2013/11/11/e-cigarettes-kids-advertising/3467475/>
- ¹⁶ 627 F.3d 891 (D.C. Cir. 2010).
- ¹⁷ *Id.*
- ¹⁸ FSPTCA § 101, <http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>
- ¹⁹ *Sottera*, 627 F.3d at 897-99.
- ²⁰ U.S. Food and Drug Administration, *Proposed Rule 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* (April 24, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-0001>
- ²¹ Tobacco Control Legal Consortium, *A Deeming Regulation: What is Possible Under the Law* (2014), <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-deeming-reg-what-is-possible-2014.pdf>
- ²² Legal Resource Center, *Laws Restricting Electronic Smoking Device Sales to Minors* (2014), http://www.law.umaryland.edu/programs/publichealth/documents/LRC_ESD_Legislation.pdf
- ²³ Legal Resource Center, *Laws Restricting Electronic Smoking Device Sales to Minors* (2014), http://www.law.umaryland.edu/programs/publichealth/documents/LRC_ESD_Legislation.pdf
- ²⁴ Minnesota Dept. of Revenue, *Revenue Notice #12-10: Tobacco Products Tax—Taxability—E-Cigarettes*, (Oct. 22, 2012), http://www.revenue.state.mn.us/law_policy/revenue_notices/RN_12-10.pdf
- ²⁵ Legal Resource Center, *Laws Restricting Electronic Smoking Device Sales to Minors* (2014), http://www.law.umaryland.edu/programs/publichealth/documents/LRC_ESD_Legislation.pdf
- ²⁶ Legal Resource Center, *Laws Restricting Electronic Smoking Device Sales to Minors* (2014), http://www.law.umaryland.edu/programs/publichealth/documents/LRC_ESD_Legislation.pdf
- ²⁷ *See, for example*, MD Health-Gen. § 24-501(g) (defining "smoking" as the "burning of a lighted...matter or substance that contains tobacco").
- ²⁸ National Association of Attorneys General, *Letter to FDA Urging Regulation of E-Cigarettes* (September 24, 2013), <http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20%285%29%281%29.pdf>
- ²⁹ State of California Dept. of Justice, Office of the Attorney General, *Electronic Cigarette Maker Agrees to Stop Marketing to Minors* (Oct. 29, 2010), <http://oag.ca.gov/news/press-releases/electronic-cigarette-maker-agrees-stop-marketing-minors> ; Oregon Dept. of Justice, Office of the Attorney General, *Oregon Attorney General Ousts Electronic Cigarette Company from State* (Aug. 9, 2010), <http://www.doj.state.or.us/releases/pages/2010/re1080910.aspx>
- ³⁰ *Brashear v. Simms*, 138 F. Supp. 2d 693 (D. Md. 2001) ; *McGinnis v. Royster*, 410 U.S. 263 (1973).



State and Local Policy Options

Electronic Smoking Devices

Electronic Smoking Devices ("ESDs") are battery operated devices designed to heat a liquid nicotine solution to the point of vapor in order to deliver vapor the user for inhalation, mimicking the act of smoking. ESDs first began appearing widely in the United States in about 2006, and use and availability have significantly increased since.¹ ESD sales have doubled every year since 2008, and are projected to approach \$2 billion in 2013.² At the same time, the Centers for Disease Control and Prevention ("CDC") reported that ESD use among students in grades 6-12 more than doubled between 2011 and 2012 – the first years for which data is available – to an estimated 1.8 million students.³

These trends are concerning due to unanswered questions about the health risks arising from ESD use, including both negative health risks resulting from inhaling ESD vapor and broader negative health consequences at the population level. With respect to individual negative biological risks from inhaling vapor, studies have indicated that ESDs cause airway constriction in users and that inhaled and exhaled aerosol contain a number of the same carcinogens found in cigarettes.⁴ At the population level, ESDs complicate enforcement of existing prohibitions on smoking indoors, diminish those prohibitions' secondary impact of cessation of tobacco use, and impede progress in social norm change related to smoking.⁵ These concerning trends are compounded by a lack of accurate data on ESDs due to their short time on the market and the lack of any meaningful quality control or product standards.

Due to the lack of accurate information on ESDs and their potential health risks, jurisdictions have proposed a variety of policy options to address ESDs. This document provides information on some of those approaches, including approaches to regulating use, regulating price point, and regulating youth access.

Regulating ESD Use

Licensure

Requiring licensure of ESD retailers should be a prerequisite to enforcement of any prohibitions on the sale or distribution of ESDs. Under Maryland law, the sale of ESDs to youth less than 18 years old is prohibited.⁶ However, there is no existing mechanism to enforce these restrictions. In order to effectively enforce this prohibition, and any additional prohibitions, state and local governments could consider requiring that ESD retailers be licensed similarly to how sellers of cigarettes and other tobacco products are already licensed. As a secondary benefit, licensing ESD retailers would make tracking retail sales easier and could allow a comprehensive database from which the jurisdiction could select retailers to conduct inspections for compliance.

Applying Clean Indoor Air Laws

State and local governments could consider legislation to prohibit individuals from utilizing ESDs in public spaces or work places, typically by including them in the jurisdiction's Clean Indoor Air Act. As discussed above, due to the novelty and short length of time these products have been widely marketed, there is a lack of scientific consensus for or against regulation of ESDs indoors. However, ESD use may create confusion in enforcement of existing clean indoor air laws, impede progress made in changing social norms around smoking, and encourage dual-use of ESDs in conjunction with traditional cigarettes.⁷ In order to prevent dual use of these products, and to avoid the confusion of enforcing existing clean indoor air laws, state and local governments could consider prohibiting ESD use in places where smoking is already prohibited. As of 2014, three states and 108 municipalities include ESDs in their clean indoor air smoking prohibitions.⁸

Restrict Use on School Grounds

State and local governments could also consider prohibiting the use of ESDs on school property. Although, as discussed above, Maryland law prohibits the sale of ESDs to minors, it does not prohibit ESD use or possession by minors. And, Maryland's statewide tobacco-free schools' policy only prohibits the use or possession of products derived from the tobacco plant that are smoked, chewed, sniffed, or otherwise consumed.⁹ Because ESD are not expressly included in the statewide tobacco-free schools policy's definition of tobacco products, it is unclear whether possession or use of electronic smoking devices by minors is prohibited in all public schools. In order to prevent youth from using ESDs during school, and to provide school personnel with a mechanism to discipline students for using these products, state and local governments should consider expressly including ESDs in their tobacco-free school policies. In Maryland, at least Anne Arundel, Calvert, Garrett, and Prince George's Counties have expressly included ESDs in their policies.¹⁰

Restricting Youth Access to ESDs

Flavors

In order to make the products less appealing to youth users, state and local governments could consider prohibiting flavored ESD nicotine. Under the federal Tobacco Act, traditional cigarettes may not be flavored.¹¹ But ESDs are not included in the federal law, and flavors make nicotine use less harsh and more appealing to youth.¹² Providence, RI, and New York, NY, currently prohibit the sale of flavored tobacco products, including flavored electronic cigarette cartridges, in their jurisdictions except at retail stores whose primary revenue source is the sale of tobacco products.¹³ The laws in both Providence and New York were challenged by manufacturers and upheld as valid local sales restrictions not preempted under the Tobacco Control Act.¹⁴

Point of Sale

State and local governments could also consider legislation that limits the placement of ESDs to areas inaccessible by the consumer. Certain jurisdictions in Maryland require tobacco products to be kept in an area inaccessible to the consumer.¹⁵ In addition, cigarettes may only be sold in vending machines in Maryland if the machine is located in an 18 and over establishment.¹⁶ However, although ESDs may not be sold to minors, the products may remain easily accessible by underage consumers. Legislation that prohibits the sale of ESDs in areas accessible to minors would provide retailers with a clear, easily understandable rule and bring ESD product placement in line with that of traditional tobacco products.

"18 And Over" Stores

Similarly, state and local governments could consider requiring ESDs to be sold in places only where adults over 18 are allowed to enter. As discussed above, federal law allows state and local governments to enact sales restrictions on all tobacco products. In addition, as discussed above, state law allows cigarette vending machines only in 18 and over establishments.¹⁷ Legislation which would limit the sale of ESDs to specific locations would be a valid sales restriction under the Tobacco Control Act to limit youth exposure to ESDs.

Regulating ESD Pricing

Taxation

To reduce the price advantage over traditional tobacco products that ESDs currently enjoy, and to impact youth use, states could consider reclassifying ESDs into a category of tobacco products already taxed or create a special tax category for ESDs. The Tobacco Control Act expressly preserves the authority of state and local governments to levy taxes on tobacco products.¹⁸ Underage youth are particularly sensitive to price, as seen from declining rates correlated with tax increases with combustible products in many different jurisdictions. And, in general, ESDs are around 1/2 the cost per use compared to combustible tobacco.¹⁹ At least 7 states have tried to implement a tax specifically on e-cigarettes; Minnesota is the only state to do so currently - equal to 95% of the wholesale price.²⁰

This document was developed by the Legal Resource Center for Public Health Policy at the University of Maryland Francis King Carey School of Law, with funding and support provided in part by the Centers for Disease Control and Prevention. The Legal Resource Center for Public Health Policy provides information and technical assistance on issues related to public health in Maryland. The legal information and assistance does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

- ¹ Barbara Demick, *A high-tech approach to getting a nicotine fix*, L.A. Times (April 25, 2009), <http://articles.latimes.com/2009/apr/25/world/fg-china-cigarettes25>
- ² Bonnie Herzog, *Equity research*. (June 12, 2013), <http://www.smallcapfinancialwire.com/wp-content/uploads/2013/11/E-Cigs-Revolutionizing-the-Tobacco-Industry-Interactive-Model.pdf>.
- Natalie Robehmed, *E-cigarette Sales Surpass \$1 Billion As Big Tobacco Moves In*, Forbes (Sept. 17, 2013), <http://www.forbes.com/sites/natalierobehmed/2013/09/17/e-cigarette-sales-surpass-1-billion-as-big-tobacco-moves-in/>
- ³ CDC, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012*, Morbidity and Mortality Weekly Report (Sept. 6, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w
- ⁴ *Experts warn that e-cigarettes can damage the lungs*, European Respiratory Society (Sept. 2, 2012), <http://www.erscongress2012.org/mediacenter/news-release/item/428-experts-warn-that-e-cigarettes-can-damage-the-lungs.html>
- FDA, *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted By FDA* (July 22, 2009), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>
- ⁵ Neal L Benowitz and Maciej Goniewicz, *The Regulatory Challenge of Electronic Cigarettes*, J. OF AM. MED. ASSOC. (March 2013), http://www.tobacco.ucsf.edu/sites/default/files/u795/Benowitz_Gona%20E-cig%20JAMA%202013.pdf
- ⁶ MD. CODE ANN., HEALTH GEN. § 24-305 (2012).
- ⁷ Neal L Benowitz and Maciej Goniewicz, *The Regulatory Challenge of Electronic Cigarettes*, J. OF AM. MED. ASSOC. (March 2013), http://www.tobacco.ucsf.edu/sites/default/files/u795/Benowitz_Gona%20E-cig%20JAMA%202013.pdf
- ⁸ American Nonsmokers' Rights Foundation, *U.S. State and Local Laws Regulating Use of Electronic Cigarettes* (January 2, 2014), <http://www.no-smoke.org/pdf/ecigslaws.pdf>
- ⁹ Code Md. Regs. 13A.0204.03
- ¹⁰ Legal Resource Center for Public Health Policy, *Maryland School System Tobacco-Free Policies* (January 2014), <http://www.npr.org/blogs/health/2014/02/17/276558592/candy-flavors-put-e-cigarettes-on-kids-menu>
- ¹¹ 21 U.S.C.A. § 387g (West)
- ¹² Jenny Lei Bolaroi, *Candy Flavors Put E-Cigarettes on Kid' Menu*, National Public Radio (Feb. 17, 2014),
- ¹³ Providence, R.I., Code of Ordinances § 14–309; New York City Administrative Code § 17–715
- ¹⁴ See Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I., 731 F.3d 71 (1st Cir. 2013); see also U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428 (2d Cir. 2013)
- ¹⁵ Md. Code, Local Gov't. Art. §1-1202
- ¹⁶ Md. Code, Bus. Reg. § 16-3A-02
- ¹⁷ *id.*
- ¹⁸ 21 USCA § 387p
- ¹⁹ bluBlog, *How Much Do E-Cigs Cost*, <http://blog.blucigs.com/how-much-do-e-cigs-cost/> (accessed Feb. 27, 2014).
- ²⁰ Minnesota Dept. of Revenue, *Revenue Notice #12-10: Tobacco Products Tax—Taxability—E-Cigarettes*, (Oct. 22, 2012), http://www.revenue.state.mn.us/law_policy/revenue_notices/RN_12-10.pdf



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September 24, 2013

The Honorable Margaret Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDA Regulation of E-Cigarettes

Dear Commissioner Hamburg,

The undersigned Attorneys General write to urge the Food and Drug Administration (FDA) to take all available measures to meet the FDA's stated deadline of October 31, 2013, to issue proposed regulations that will address the advertising, ingredients, and sale to minors of electronic cigarettes (also known as e-cigarettes).

State Attorneys General have long fought to protect their States' citizens, particularly youth, from the dangers of tobacco products. For example, every State Attorney General sued the major cigarette companies for the harm their products caused. With the protection of our States' citizens again in mind, the undersigned Attorneys General write to highlight the need for immediate regulatory oversight of e-cigarettes, an increasingly widespread, addictive product.

As you know, e-cigarettes are battery-operated products designed to deliver nicotine to the user by heating liquid nicotine, derived from tobacco plants, along with flavors and other chemicals, into a vapor that the user inhales. The nicotine found in e-cigarettes is highly addictive, has immediate bio-chemical effects on the brain and body at any dosage, and is toxic in high doses.¹

E-Cigarette Sales are Growing Exponentially Using Marketing that Includes Television

Sales of e-cigarettes have grown rapidly in the United States, and after doubling every year since 2008, sales in 2013 are now accelerating even faster and projected to reach \$1.7 billion.² The cost of e-cigarettes has fallen

¹ U.S. Surgeon General, U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction* (1988); Emergency Response Safety and Health Database, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, http://www.cdc.gov/niosh/ershdb/EmergencyResponseCard_29750028.html

² Compare Josh Sanburn, *Can Electronic Cigarettes Challenge Big Tobacco?*, Time.com, Jan. 8, 2013, available at <http://business.time.com/2013/01/08/can-electronic-cigarettes-challenge-big-tobacco/>, (estimating 2013 sales at \$1 billion), with Stuart Elliot, *E-Cigarette Makers' Ads Echo Tobacco's Heyday*, New York Times, Aug. 29, 2013, available at <http://www.nytimes.com/2013/08/30/business/media/e-cigarette-makers-ads-echo-tobaccos-heyday.html>, (estimating 2013 sales at \$1.7 billion).

dramatically, as well, making them more affordable, and thus more attractive to young people. Unlike traditional tobacco products, there are no federal age restrictions that would prevent children from obtaining e-cigarettes, nor are there any advertising restrictions.

Along with the growth of e-cigarette sales, there has also been a growth of e-cigarette advertising over the past year. For example, in this year's Super Bowl broadcast, NJOY e-cigarettes purchased a 30-second television advertisement slot which reached at least 10 million viewers in certain markets and reportedly translated into a dramatic 30-40% increase in sales.³ The advertisement depicted an attractive man smoking an e-cigarette that looked just like a real cigarette. Since then, advertisements for e-cigarettes have regularly appeared on primetime television, making it easier for those advertisements to reach children. Moreover, e-cigarettes are not being marketed as smoking cessation devices, but rather as recreational alternatives to real cigarettes. Consumers are led to believe that e-cigarettes are a safe alternative to cigarettes, despite the fact that they are addictive, and there is no regulatory oversight ensuring the safety of the ingredients in e-cigarettes.

E-Cigarettes Appeal to Youth

E-cigarettes contain fruit and candy flavors -- such as cherry, chocolate, gummy bear, and bubble gum -- that are appealing to youth. The FDA has banned such flavors from cigarettes and should take the same action regarding e-cigarettes. E-cigarettes and refills of the liquid nicotine solution used with e-cigarettes can easily be ordered online without age verification. By intentional use or mistaken ingestion from the non-child resistant containers, e-cigarettes and liquid nicotine refills can deliver dangerously high doses of liquid nicotine to youth.

In addition to flavors, e-cigarette manufacturers, such as eJuiceMonkeys.com and Magic Puff City E-cigarettes, use cartoon monkeys to sell e-cigarettes,⁴ even though for many years, the major manufacturers of traditional cigarettes have been banned from using cartoons to advertise. Finally, e-cigarette manufacturers, such as White Cloud Cigarettes, offer reusable e-cigarette "skins" -- known as Vapor Jackets -- that are intended to make the e-cigarette desirable or fashionable and are available in a variety of patterns that appeal to children, one of which uses images from the popular video game, Angry Birds.⁵

Further, data from the 2011 and 2012 National Youth Tobacco Surveys (conducted by the Centers for Disease Control and Prevention) show that e-cigarette use among students doubled in the last year. Specifically, one in 10 high school students reported that they had tried an e-cigarette in the last year -- up from one in 20 in 2011, and 1.8 million middle and high school students said they had tried e-cigarettes in 2012.⁶ The increased usage among young people

³ Benjamin Wallace, *Smoke Without Fire*, New York Magazine, April 28, 2013, available at <http://nymag.com/news/features/e-cigarettes-2013-5/>.

⁴ See <http://ejuicemonkeys.com/> and <http://cityecigarettes.com/>

⁵ See <http://www.whitecloudelectroniccigarettes.com/accessories/vapor-jackets/>

⁶ Catherine Corey, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012*, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, September 6, 2013, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w

echoes the growth among adult users, and researchers indicated that aggressive marketing campaigns, in part, drove the increase.⁷

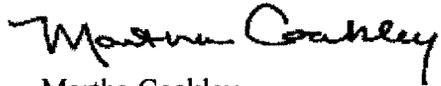
The FDA has Authority to Regulate E-cigarettes and Protect the Public

In the Tobacco Control Act, Congress recognized that nicotine is an addictive drug, and virtually all new users of tobacco products are under the age of eighteen and are therefore too young to legally purchase such products. Congress further found that tobacco advertising and marketing contributes significantly to the teenage use of nicotine-containing tobacco products. To help prevent children from using tobacco products, the Tobacco Control Act imposed restrictions on advertising and marketing to youth. These restrictions should be applied to e-cigarettes, as well, to safeguard children from nicotine addiction and other potential health effects of e-cigarettes.

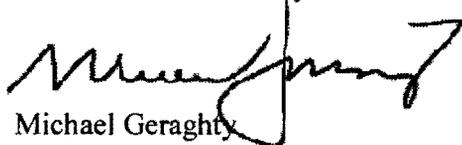
The FDA has authority to regulate electronic cigarettes as “tobacco products” under the Tobacco Control Act, as they are products “made or derived from tobacco” that are not a “drug,” “device,” or combination product. Case law, such as *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010), further supports the contention that e-cigarettes are “made or derived from tobacco” and can be regulated as “tobacco products” under the Tobacco Control Act.

We ask the FDA to move quickly to ensure that all tobacco products are tested and regulated to ensure that companies do not continue to sell or advertise to our nation’s youth.

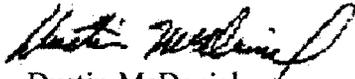
Very respectfully yours,



Martha Coakley
Massachusetts Attorney General



Michael Geraghty
Alaska Attorney General



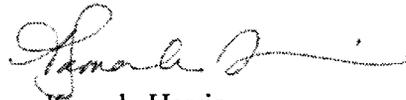
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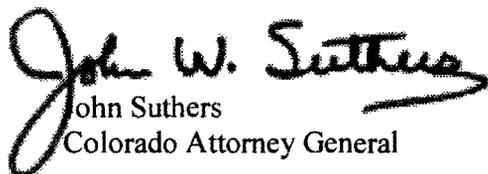


Tom Horne
Arizona Attorney General



Kamala Harris
California Attorney General

⁷ Sabrina Tavernise, *Rise Is Seen in Students Who Use E-Cigarettes*, New York Times, September 5, 2013, available at <http://www.nytimes.com/2013/09/06/health/e-cigarette-use-doubles-among-students-survey-shows.html>

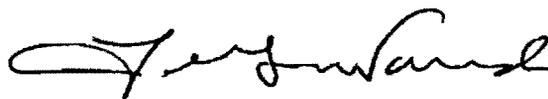

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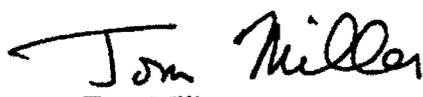

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Guam Attorney General

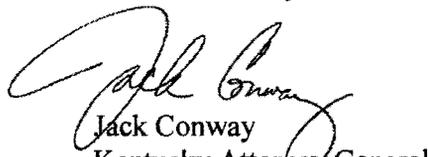

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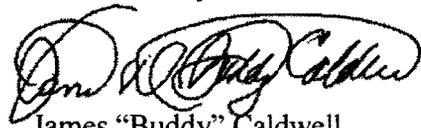

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Lisa Madigan
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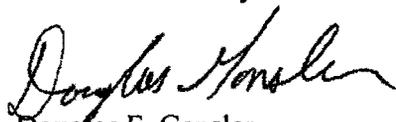

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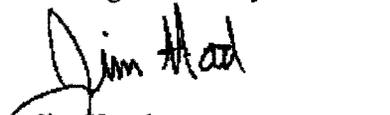

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Lori Swanson
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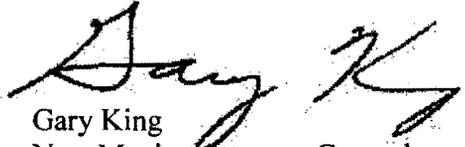

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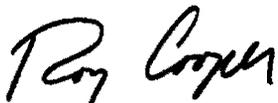

Tim Fox
Montana Attorney General



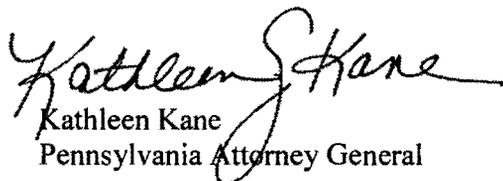
Catherine Cortez Masto
Nevada Attorney General



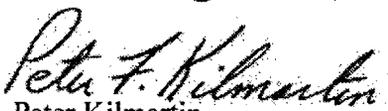
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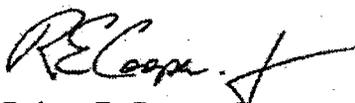
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North Carolina Attorney General



Kathleen Kane
Pennsylvania Attorney General



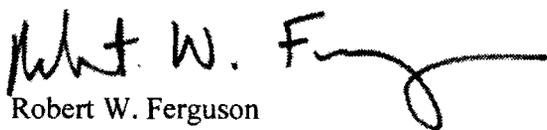
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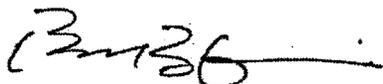
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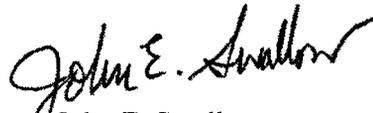
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Peter K. Michael
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From: Rice's Office, Councilmember
Sent: Tuesday, July 15, 2014 9:24:55 AM
To: Montgomery County Council
Subject: FW: E-Cigarette Briefing

From: lobbyannapolis@comcast.net [mailto:lobbyannapolis@comcast.net]
Sent: Tuesday, July 15, 2014 9:24 AM
To: Andrews's Office, Councilmember; Berliner's Office, Councilmember; Elrich's Office, Councilmember; Branson's Office, Councilmember; Floreen's Office, Councilmember; Leventhal's Office, Councilmember; Navarro's Office, Councilmember; Rice's Office, Councilmember; Riemer's Office, Councilmember
Subject: E-Cigarette Briefing

I understand that this Thursday, July 17th the Montgomery County Council is holding a briefing on e-cigarette usage. Regretfully, I will be out of town and cannot attend to participate. On behalf of my client, the Maryland Association of Tobacco and Candy Distributors, I submit the following comments and information for the record.

1. The health effects of using electronic cigarettes scientifically and reliably are currently unknown, the FDA's recent announcement and proposed regulations clearly reflect that in that while the FDA is seeking standards in the industry there are no proposed regulations attempting to ban or restrict their usage by adults.
2. Since 2012 Maryland has had a statute on the books, which my client fully supported and helped enact, which forbids and prohibits minors from selling or purchasing or using e-cigarettes. See Health General Article Section 24-305.
3. Recent decisions by the Court of Appeals, Altadis U.S.A., Inc. vs. Prince George's County in April 2013 and Allied Vending vs. City of Bowie in 1993 make clear that local governments have no authority to legislate or regulate any cigarette or tobacco products in terms of the sale or placement thereof and that would include in my view e-cigarettes which contain nicotine product as to cigarettes and are likened to cigarettes to when government bodies try to regulate or restrict them.
4. The attached document gives information and explains the contents and parts of an e-cigarette. E-cigarettes only produce a vapor comprised of only of water, propylene glycol, and do not smell or contain any order and do not unlike cigarettes possibly have any secondary hand effects on others.
5. Propylene glycol is approved by the FDA for use in a large number of consumer products and it is not associated with any adverse health effects.
6. Respectfully, I do not feel that the Montgomery County Council has the authority to legislate concerning the sale or placement of e-cigarettes and for the Council to consider or classify e-cigarettes in the same category of cigarettes would be scientifically wrong and without proper foundation and this subject matter should be left to the FDA for further study and regulation in a consistent and uniform fashion.

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CASAA

**Electronic Cigarettes
(E-Cigarettes): The
Facts**



**The Consumer Advocates
for Smoke-free
Alternatives Association**

CASAA.org
board@casaa.org
blog.casaa.org
join.casaa.org



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Diagram of an electronic cigarette

What is an e-cigarette?

An electronic cigarette (e-cigarette) consists of a battery; an atomizer; and a cartridge that contains propylene glycol (PG) or vegetable glycerin (VG), water, flavoring, and optional strengths of nicotine. When the user activates the unit, the battery supplies heat to the atomizer, which vaporizes some of the liquid in the cartridge.

Is there more than one type?

Some models resemble a real cigarette, a real cigar, or a real pipe. Many are odd shapes and cannot be mistaken for the real thing. Some models have a button that must be depressed when inhaling to activate the vaporization. These models are called "manual." Some models combine the atomizer and cartridge into a single piece, called a "cartomizer."

Are there other names for it?

"Electronic cigarette" is often shortened to e-cigarette or e-cig. Another name for this type of product is Personal Vaporizer (PV).

Are they a smoking cessation product?

No. FDA-approved "smoking cessation" products are intended to be used as treatment for nicotine addiction. E-cigarettes are intended to be used as a replacement for smoking tobacco cigarettes, supplying a less harmful source of nicotine.

Are they safe?

While nothing is ever 100% "safe," due to the fact that nothing is burned, e-cigarettes don't deliver the things that cause smoking-related disease and death. Vapor contains no tar, no carbon monoxide, no solid particles, and none of the thousands of chemicals that are created by combustion. Nicotine does not cause lung disease, heart disease, or cancer. Reports of *minor* adverse health effects appear to be far more rare than more serious reports involving FDA-approved pharmaceutical nicotine products.

What about the FDA's tests?

The FDA's press release of July 2009 left out important information. A day's supply of liquid contains no more nitrosamines ("carcinogens") than FDA-approved nicotine products. (See box at right.) The quantity of diethylene glycol detected in the liquid was well below toxic levels and has never been

detected in the vapor. In short, the FDA did not find harmful quantities of any substance.

Who uses them?

The Etter & Bullen survey found that 99.7% were current daily, occasional, or former smokers; and 70.2% no longer smoke. (See links on back panel.)

Why are flavors offered?

Most consumers start out wanting a unit that looks like and vapor that tastes like their brand of cigarette. As they move away from smoking tobacco cigarettes, they begin to find the tobacco flavors distasteful. Over 80% of 2,168 survey respondents said they have used non-tobacco flavored liquid, with 51.9% using fruit or candy flavors on a regular basis.

Nanograms of Tobacco-Specific Nitrosamines in a one-day supply of products containing nicotine:

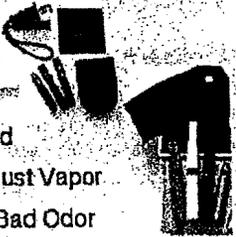
Quantity	Product	Ng.
1 gram	16 mg. e-cigarette liquid	8
1 each	21 mg. nicotine patch	8
10 pieces	4 mg. nicotine gum	20
1 pack	Marlboro full-flavor cigarettes	126,000



Nicotine without smoke

Electronic Cigarettes

- ✓ Nicotine
- ✗ No Ashes
- ✗ No Butts
- ✗ No Fire Hazard
- ✗ No Smoke – Just Vapor
- ✗ No Lingering Bad Odor



Nothing is burned, so there are no ashes, no butts to dispose of and no second-hand smoke. The vapor dissipates quickly and has no lingering odor. No study has found harmful levels of any chemical or carcinogen in e-cigarette vapor.

How effective are they?

Surveys of e-cigarette users, who have access to educational information about e-cigarettes and a diversity of products, show that up to 79% completely replace smoking with using e-cigarettes.

What are the health effects?

In multiple surveys, over 90% of users report that their health has improved since they completely or even partially switched from inhaling smoke to inhaling vapor. The most frequently reported health improvement is in lung function, with coughing and wheezing reduced or eliminated.

Research

Burstyn, I. Peering through the mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks? Drexel University. 2013
<http://publichealth.drexel.edu/SiteData/docs/ms08/f90349264250e603/ms08.pdf>

Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, Walker N. Electronic cigarettes for smoking cessation: a randomised controlled trial. Lancet. 2013 Sep 9.
<http://www.ncbi.nlm.nih.gov/pubmed/24029165>

Caponnetto P, Campagna D, Cibella F, Morjaria JB, Caruso M, Russo C, Polosa R. Efficiency and Safety of an electronic cigarette (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. PLoS One. 2013 Jun 24;8(6):e66317.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0066317>

Dawkins L, Turner J, Crowe E. Nicotine derived from the electronic cigarette improves time-based prospective memory in abstinent smokers. Psychopharmacology (Berl). 2013 Jun;227(3):377-84.
<http://www.ncbi.nlm.nih.gov/pubmed/23344557>

Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. Addiction. 2011 Nov;106(11):2017-28.
<http://www.ncbi.nlm.nih.gov/pubmed/21592253>

Siegel MB, Tanwar KL, Wood KS. Electronic cigarettes as smoking cessation tool: Results from an Online Survey. American Journal of Preventive Medicine 2011 Apr; 40(4):472-5.
http://www.stop-tabac.ch/fra/images/stories/documents_stop_tabac/seigel%20e%20cigs%20am%20i%20prev%20med%202011.pdf

CASAA Lab Reports Collection:

http://casaa.org/Lab_Reports__ecigarettes.html

Electronic Cigarettes: An Overview

**Presentation to
Montgomery County Council**

July 21, 2014

Kevin Walton, PhD

Division of Pharmacotherapies and Medical Consequences of Drug Abuse

Ericka Boone, PhD

Office of Science Policy and Communications

National Institute on Drug Abuse, NIH



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Conventional Tobacco Use in the U.S.

- Associated morbidity and mortality
 - 480,000 Americans die each year from smoking (\approx 1 in 5 deaths)
 - 16 million suffer from tobacco-related illnesses
- Economic cost: nearly **\$300B** annually
 - \$133B in direct medical care
 - \$156B in lost productivity
- 18.1% of all U.S. adults smoke (42% in 1965)

However, in the past year

- 68.9% of adult smokers wanted to stop smoking
- 42.7% of adult smokers made a quit attempt



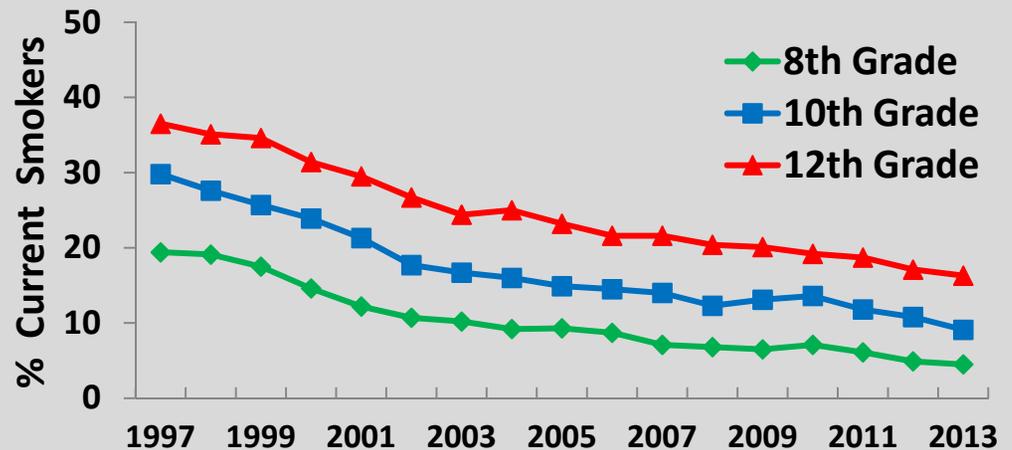
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Youth Smoking Continues as a Concern

- 90% of smokers begin while in their teens or earlier
- 14% of high school students (grades 9–12) smoke
- Use of multiple tobacco products is common
- With current trends, 6 million teens alive today will die from smoking-related diseases

However...

- The percent of teens who are current smokers* has been declining for more than a decade



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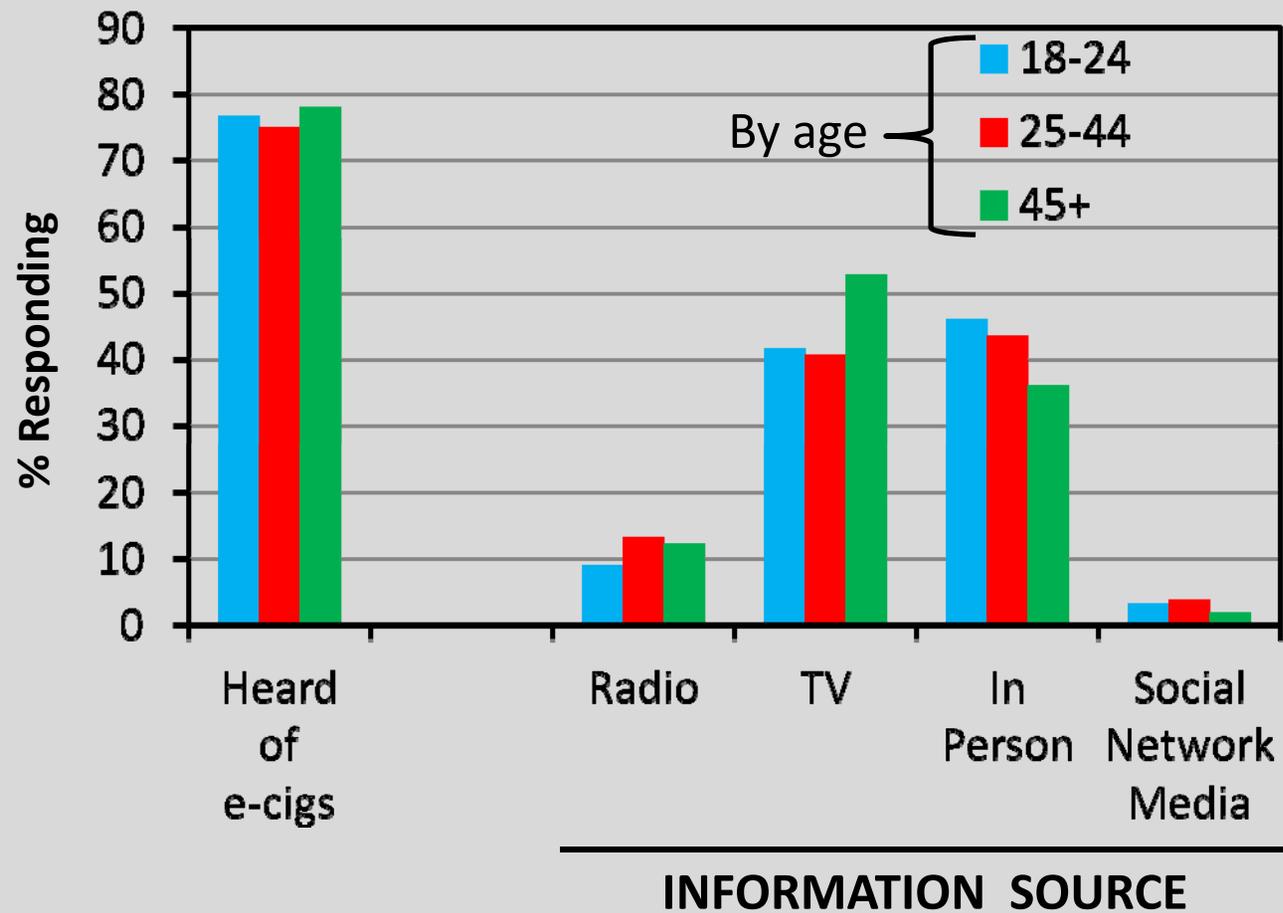
Source: HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012
CDC, MMWR 62(No. 45), November 15, 2013; Johnston, MTF National Results on Drug Use:1975-2013

Electronic Cigarette (E-cigarette) History

- An e-cigarette is a smokeless nicotine delivery device
 - E-cigarettes can also contain no nicotine, just producing a flavored aerosol (vapor)
- First introduced in China in 2003
- Available in the U.S. since 2007
- Made by U.S. tobacco companies and independent non-conventional-tobacco companies
 - Lorillard (blu), Reynolds American (Vuse), Altria (MarkTen)
 - Independent large players include NJOY and Logic
- Over 250 e-cigarette brands in the U.S.
- E-cigarette use has doubled every year since 2010
- Estimated to be **greater than \$1.5B industry**



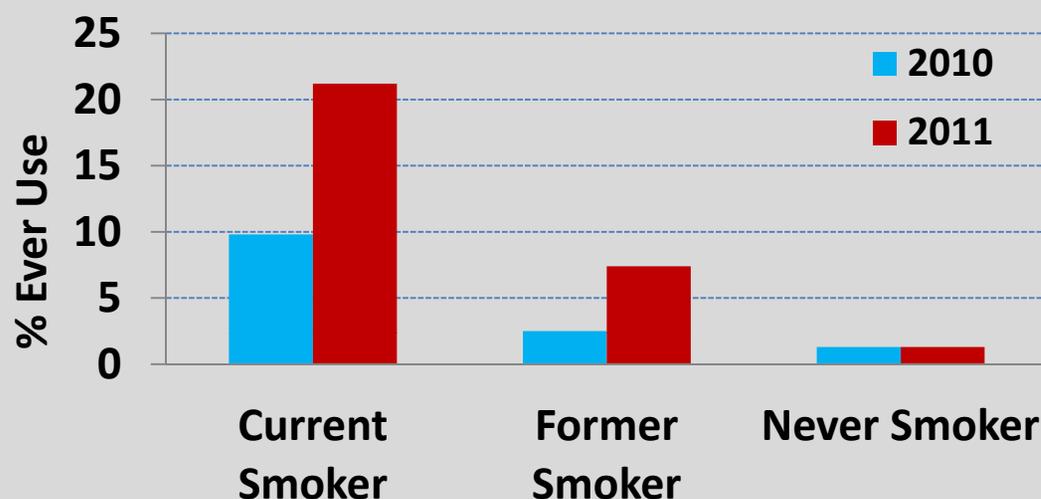
Most People Are Aware of Electronic Cigarettes



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Source: Zhu et al, 2013

Adult Use of Electronic Cigarettes Primarily by Current Smokers



≈80% of current users
report dual use with
conventional cigarettes

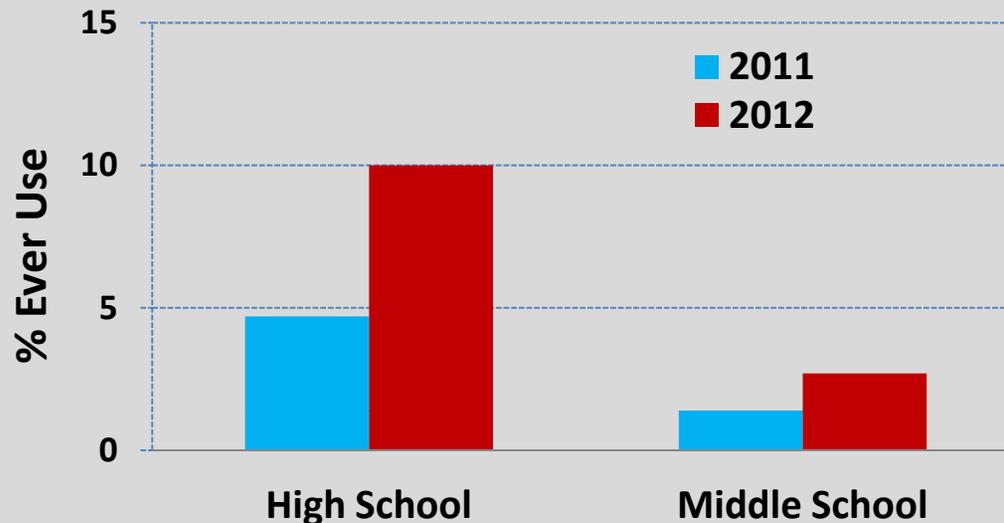
- **Health reasons primary motivator for e-cigarette use**
 - Believe less harmful than conventional cigarettes
 - Desire to cut down and/or quit conventional cigarettes
 - Help with reducing cravings and withdrawal symptoms
 - Want to prevent relapse to conventional cigarettes
 - Don't want to disturb others with smoke or for use in smoke-free places



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Source: King et al, 2013; Pearson et al, 2012; Lee et al, 2014; Brown et al, 2014; Etter, 2010; Kralikova et al, 2013; Pearson et al, 2012; Vickerman et al, 2013

Electronic Cigarette Use by Youth Increasing



76.3% of students who used in the past month also smoked conventional cigarettes

- 1 in 5 middle school students that reported ever using e-cigarettes have **never** tried conventional cigarettes
- Reasons given for using e-cigarettes
 - Curiosity
 - Attraction of flavors
 - Use by friends and family
 - Desire to quit smoking
 - Availability
 - Sign of independence



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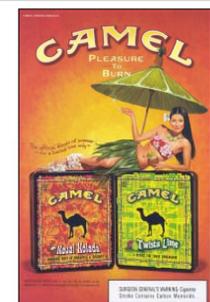
Current E-Cigarette Regulation is Limited

- E-cigarettes mostly unregulated under federal law
 - FDA currently seeking to regulate the sale, manufacture, and distribution of e-cigarettes
 - Unknown when regulations will be finalized
- There are no official standards of design or contents
- There is no requirement to provide public information on the contents of e-cigarettes
- Many states, [including Maryland](#), regulate the sale of e-cigarettes to minors



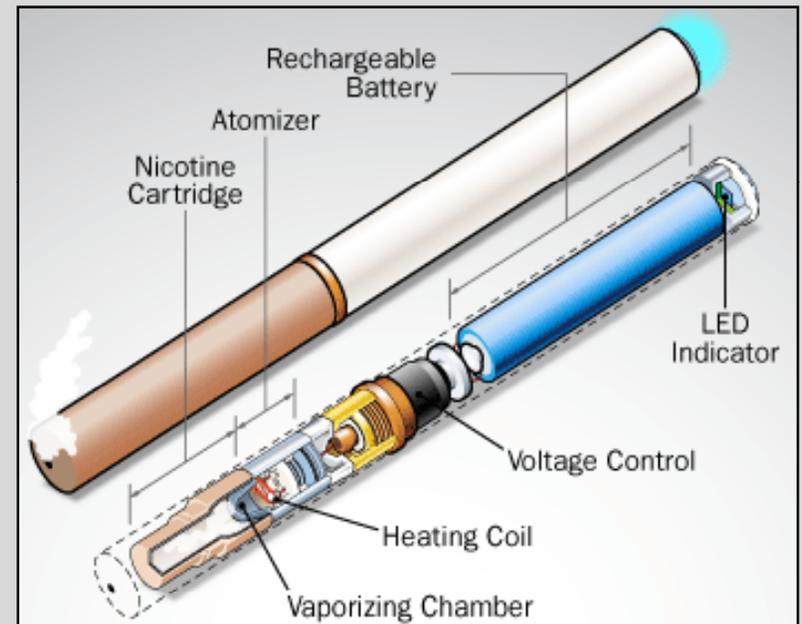
What are the Concerns About Electronic Cigarettes??

- In general use but risks and benefits not fully evaluated
- Lack of standards over design and contents
- Potential relapse for former smokers or use by never smokers
- May renormalize smoking or encourage poly-use
- Potential for use with controlled substances
- Marketing that may attract kids
 - Kid-friendly flavors (e.g., chocolate, fruit, gummi bear, cotton candy, etc) and characters or famous actors; ads in media sources with large youth reach



Anatomy of an Electronic Cigarette

- Consists of a power source, heating device (aerosolizer/vaporizer), and liquid-containing cartridge
- Puffing activates the battery-powered heating device, which heats the nicotine solution into an aerosol (vapor), which is then inhaled
- Early devices designed to resemble conventional tobacco cigarettes



Types of Electronic Cigarettes

Disposable e-cigarette



NJOY, White Cloud,
Greensmoke

Rechargeable e-cigarette



Markten, Mystic,
blu, VUSE

**Pen-style, medium-sized
rechargeable e-cigarette**



eGo, Vaporking,
Totally Wicked

**Tank-style, large-sized
rechargeable e-cigarette**



Volcano Lavatube

Sealed device
or cartridge

User adds liquid
to device



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Tank Systems and Liquid Refills

- Tank systems give users access to an extensive assortment of flavors and nicotine concentrations

	Strength					
Red Label	0.0%	0.6%	1.0%	1.4%	1.8%	3.0%
Herbal e-liquid	0.0%					
Titan Fluid	11mg/ml		18mg/ml		36mg/ml	
Patriot Range	6mg/ml	10mg/ml	14mg/ml	18mg/ml	30mg/ml	
Original e-liquid	8mg/ml	11mg/ml	18mg/ml	24mg/ml	36mg/ml	



- These devices are gaining in popularity
- Can have larger, more powerful batteries
- Concerns about accidental liquid nicotine poisoning
 - CDC reports increase in poison control center calls regarding e-cigarettes: 1 call/month in 2010, 214 calls/month in 2014
 - Regulatory efforts discussed to require child-safe packaging



Electronic Cigarette Liquid Contents

1. Nicotine (0% to 3.6%)
 2. Propylene Glycol (PG)
 3. Vegetable Glycerin (VG)
(Glycerol)
 4. Water
 5. Flavorings
- Experience with PG and VG
 - The Food and Drug Administration classifies PG and VG as “Generally Recognized As Safe” (GRAS)
 - PG/VG used in medicines, cosmetics, and food products
 - PG for inhalation (e.g., asthma inhalers) at concentrations much lower than in e-cigarettes
 - VG does not have a history of use for inhalation
 - PG and VG used to create artificial theatrical fog



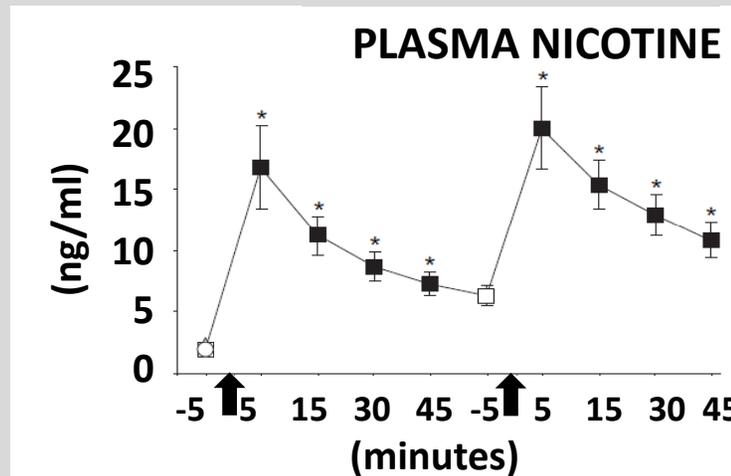
Electronic Cigarette Aerosol Contents

- Long-term safety of aerosol inhalation is unknown
 - It is not just water vapor; little experience with some constituents
 - Some compounds same as in tobacco smoke: acrolein, acetaldehyde
 - Generally lower levels of toxins (9-450x) than in tobacco smoke
- Variable voltage devices can alter the aerosol
 - Higher voltage produces higher temps, more nicotine in aerosol
 - This can increase levels of toxic compounds: e.g., formaldehyde
 - Levels can approach those measured in conventional cigarettes
- E-cigarette aerosol is less complex than tobacco smoke
 - There are an estimated 5000 compounds in tobacco smoke
 - Tobacco smoke includes 70 known carcinogens
 - Many fewer compounds in e-cigarette aerosol



Addiction Potential: Conventional vs. Electronic Cigarette

- Conventional cigarette delivers nicotine rapidly



Arrow indicates
smoking initiation:
10 puffs/30 seconds

- Other compounds in smoke may enhance addiction
- Association of smoking with specific behaviors
 - Social interactions, drinking, stress
- Children and teenagers may be highly susceptible to nicotine addiction

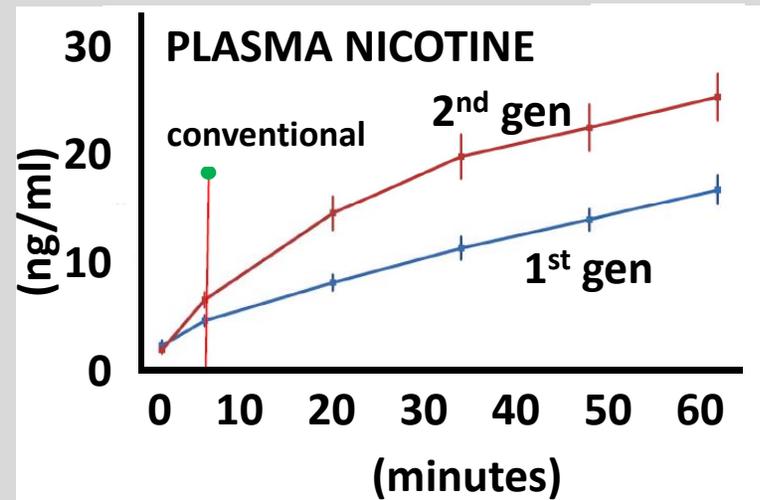


Addiction Potential: Conventional vs. Electronic Cigarette

- E-cigarettes have been less effective at nicotine delivery

However

- Newer devices can deliver more nicotine
- Nicotine delivery can be modified by puffing behavior



- Unknown effects of flavors and additives
- Situational use is similar – social, drinking, stress
- Use by children and teenagers is a significant concern



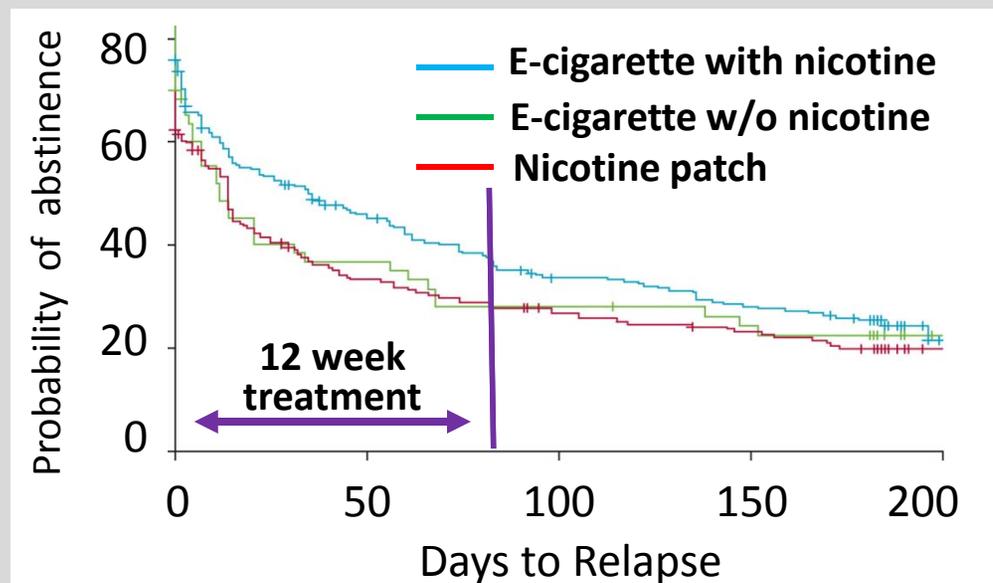
Secondhand and Thirdhand Exposure

- E-cigarettes have no sidestream emissions like a conventional cigarette (generates smoke while holding)
- Exhaled aerosol may be inhaled by nearby individuals (secondhand exposure)
- Surfaces can be coated with the nicotine-containing aerosol as it settles (thirdhand exposure)
- Health effects of indirect aerosol exposure are unclear
- Extensive experience with conventional cigarettes is being used as a guide to investigate these questions



Electronic Cigarettes: Nicotine Cessation

- Nicotine replacement therapy (NRT) is an approved cessation treatment
- E-cigarettes may be a uniquely effective NRT due to their potential to mimic conventional cigarettes
 - More rapid nicotine delivery than approved NRT
 - Behavioral aspects: mouth feel, exhaling aerosol, touch
- Only a few peer-reviewed clinical studies
 - Limited effect
 - Little nicotine delivered



Electronic Cigarettes: Harm Reduction

- “People smoke for the nicotine but they die from the tar”
Prof Michael Russell, 1976
- In a harm reduction model, smokers would replace conventional cigarettes with e-cigarettes
- There is active debate on the proper approach
 - Some advocates support the immediate routine use of e-cigarettes to replace conventional cigarettes
 - A more cautious view seeks a better understanding on safety and their impact on conventional cigarette use
- No peer-reviewed harm reduction studies



NIH Supported Research into Electronic Cigarettes

- Device design and function
- Health effects of aerosol constituents
- Biomarkers (physiological measures of exposure)
- How does marketing influence use
- What are the effect of flavorings on preferences
- Longitudinal surveys of use by youth and adults
- Potential for cessation and harm reduction



There are More Questions than Answers for Electronic Cigarettes

- How safe are e-cigarettes for long term use?
- Will conventional cigarette smokers who use e-cigarettes completely switch or become dual users?
- Will e-cigarettes alter a smoker's intentions to quit?
- Can e-cigarettes be an effective tool in cessation?
- Will non-smoking youth routinely use e-cigarettes?
- How will e-cigarettes affect youth smoking of conventional cigarettes?



Additional slides



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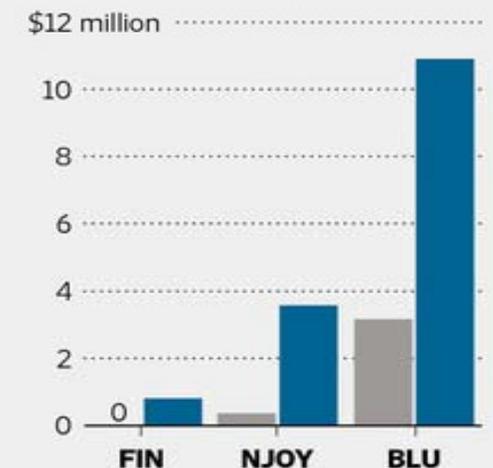
Electronic Cigarette Advertising

- Advertising of traditional cigarettes TV ads banned since 1971
- Increased youth exposure to e-cig ads
 - Between 2011-2013, e-cig TV ads that reach children increased by 256% and young adults by 321%
- Ads during 2013 Super Bowl reached more than 10 million viewers
- In 2013, \$30 million spent on ads in for 'blu' e-Cig brand (increase planned for 2014)
- In 2014, \$30 million budgeted to promote NJOY e-Cigs in the US (spending triple that of 2013)

Ramping Up

TV ad spending for e-cigarettes

■ 2012 ■ JAN. TO SEPT. 2013



Source: Kantar Media
The Wall Street Journal



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Regulatory Options Enacted by States

- Taxing e-cigs similar to tobacco products
- Restrict or prohibit redemption of coupons for tobacco products, including e-cig products
- Prohibit distribution of free samples
- Regulate sale and distribution of flavored non-cigarette tobacco products with characterizing flavors (similar to New York)
- Comprehensive youth access laws prohibiting sale to minors, requirement to be kept behind counters, sold only in places where adults permitted to enter and raise minimum age to purchase
- Include e-cigs in smoke and tobacco-free restrictions
- Regulate the sale and marketing of e-cigs, health warnings at point-of-sale



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Source: <http://publichealthlawcenter.org/sites/default/files/pdf/tclc-fs-regulatory-options-e-cigarettes-2013.pdf>

Current State Regulations

United States 100% Smokefree Air Laws

American Nonsmokers' Rights Foundation

As of July 3, 2014

Note: American Indian and Alaska Native sovereign tribal laws are not reflected on this map.

Territories and Commonwealths

Commonwealth of Northern Mariana Islands

Guam

American Samoa

Puerto Rico

U.S. Virgin Islands

Locality Type with a 100% Smokefree Law

▲ City

● County



U.S. State and Local Laws Regulating Use of Electronic Cigarettes

American Nonsmokers' Rights Foundation

As of July 3, 2014

Note: American Indian and Alaska Native sovereign tribal laws are not reflected on this map.

Territories and Commonwealths

Commonwealth of Northern Mariana Islands

Guam

American Samoa

Puerto Rico

U.S. Virgin Islands

Locality Type

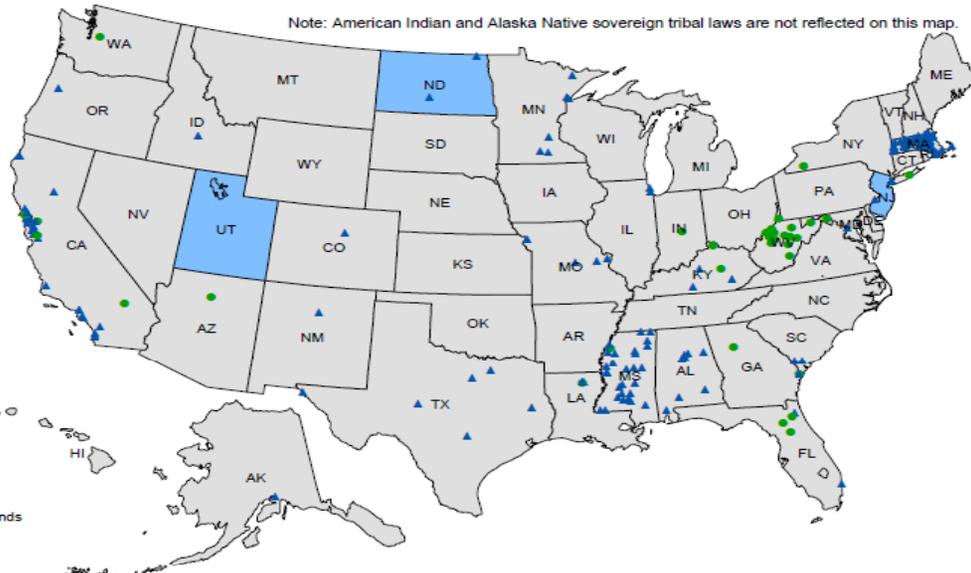
▲ City

● County

State and Commonwealth/Territory Law Type

■ Law Restricts E-cigarette Use in 100% Smokefree Venues

■ No E-cigarette Restriction in 100% Smokefree Venues



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Physiological Effects of Nicotine

- Nicotine is rapidly delivered to the bloodstream via conventional cigarettes.
- Nicotine stimulates the adrenal glands to release the hormone epinephrine (adrenaline), increasing blood pressure, respiration, and heart rate.
- Nicotine increases release of the neurotransmitter dopamine, affecting brain pathways controlling reward and pleasure.
- Long-term brain changes induced by continued nicotine exposure result in addiction—a condition of compulsive drug seeking and use, even in the face of negative consequences.

