

MEMORANDUM

January 27, 2015

TO: Heath and Human Services Committee

FROM: Amanda Mihill, Legislative Attorney *A. Mihill*

SUBJECT: **Worksession:** Bill 56-14, Health and Sanitation – Smoking – Electronic Cigarettes

Bill 56-14, Health and Sanitation – Smoking – Electronic Cigarettes, sponsored by Councilmember Floreen, then Council Vice President Leventhal, and Councilmembers Branson, Navarro, Rice, Elrich, Riemer, Katz, Hucker and Berliner, was introduced on November 25, 2014. A public hearing was held on January 20 at which testimony was both in support and opposition to Bill 56-14.

Bill 56-14 would:

- prohibit the use of electronic cigarettes in public places where traditional tobacco smoking is prohibited;
- restrict the sale of certain liquid nicotine or liquid nicotine containers in retail outlets unless the nicotine is in a container considered child resistant packaging;
- prohibit the sale of electronic cigarettes in any place that is accessible to buyers of the product without the intervention of the seller (similar to tobacco products); and
- generally amend County law regarding smoking, electronic cigarettes, and health and sanitation.

Background

Before the introduction of Bill 56-14, the Health and Human Services Committee met twice on the issue of electronic cigarettes. All the materials from those worksessions are not reproduced in this packet, but can be found at the following links:

- July 21: http://www.montgomerycountymd.gov/council/Resources/Files/agenda/cm/2014/140721/20140721_HHS1.pdf
- September 18: http://www.montgomerycountymd.gov/council/Resources/Files/agenda/cm/2014/140918/20140918_HHS1.pdf

At the July 21 worksession, the Committee received briefings from the National Institutes of Health and the Legal Resource Center for Public Health Policy on electronic cigarettes. These briefings included a discussion of the current medical understanding of the health risks and public

policy concerns with electronic cigarette usage. The presentation from Dr. Walton and Dr. Boone from the National Institute on Drug Abuse is on ©10.

After the briefings, Committee members expressed specific concerns about the use of electronic cigarettes by minors and directed staff to provide options to restricting youth access to electronic smoking devices. Committee members discussed these options, including a prior draft of Councilmember Floreen's bill, at its September 18 worksession. Also at its September 18 worksession, Committee members received a briefing from the Department of Liquor Control's Licensing and Regulatory Enforcement staff on its program to identify entities that are selling tobacco to minors.

Health concerns of electronic cigarettes. Many individuals that oppose the prohibition of using electronic cigarettes in places where traditional cigarettes are prohibited argued that electronic cigarettes are less harmful than traditional tobacco products. Less harmful does not mean harmless. In prior worksessions, the Committee discussed the health concerns regarding electronic cigarettes. Some items noted in the attached presentation from the National Institute on Drug Abuse (©10-35) include:

- 90% of smokers begin while in their teens or earlier.
- Electronic cigarette use by high school students increased from less than 5% to almost 10% from 2011 to 2012.
- 1 in 5 middle school students that reported ever using electronic cigarettes have never tried conventional cigarettes.
- Reasons students gave for using electronic cigarettes include: curiosity, attraction of flavors, use by friends and family, desire to quit smoking, availability, and it is a sign of independence.
- Adult use is primarily by current smokers who give health reasons as the primary motivator for use (less harmful than conventional cigarettes, desire to cut down or quit conventional cigarettes, prevent relapse to conventional cigarettes, don't want to disturb others, use in smoke free places.)
- Concerns about electronic cigarettes include:
 - They are in general use but risks and benefits are not fully evaluated.
 - Lack of standards over design and contents.
 - May renormalize smoking or encourage poly-use.
 - Marketing that may attract kids (kid-friendly flavors, characters or famous actors, ads in media). The presentation noted that ads during the 2013 Super Bowl reached 10 million viewers and that from 2011 to 2013, electronic cigarette ads that reach children increased by 256%.

With regard to Secondhand and Thirdhand Exposure, the NIDA presentation noted:

- Electronic cigarettes have no sidestream emissions like a conventional cigarette.
- 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.

A 2014 World Health Report (©70-82) stated that “bystanders are to the aerosol exhaled by ENDS users, which increases the background level of some toxicants, nicotine as well as fine and ultrafine particles in the air” and acknowledged that the levels were lower than that of traditional cigarettes. The report noted, however, that “it is not clear if these lower levels in exhaled aerosol translate into lower exposure, as demonstrated in the case of nicotine.” The report further stated that “It is unknown if the increased exposure to toxicants and particles in exhaled aerosol will lead to an increased risk of disease and death among bystanders as does the exposure to tobacco smoke. However, epidemiological evidence from environmental studies shows adverse effects of particulate matter from any source following both short-term and long-term exposures.” The report further noted that existing evidence shows that e-cigarette aerosol is not merely water vapor.

Food and Drug Administration regulation. The Committee has heard in prior worksessions on this topic about the FDA’s pending regulation. The Family Smoking Prevention and Tobacco Control Act gives the 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). The docket is no longer open on this deeming regulation.

Legal status of electronic cigarettes in Maryland. At the public hearing, Bruce Bereano, on behalf of the Maryland Association for Tobacco and Candy Wholesalers, argued that the County did not have the authority to regulate electronic cigarettes and in prior correspondence cited 2 Court of Appeal cases as the basis for that statement. Council staff has reviewed the legal status of electronic cigarettes with the Committee in prior worksessions. In short, the FDA does not currently regulate electronic cigarettes (see discussion immediately below). And, of the 3 state regulatory schemes that are relevant to tobacco control (the Clean Indoor Air Act, Title 16 of the Business Regulation Article (cigarettes), and Title 16.5 of the Business Regulation Article (other tobacco products)), none regulate electronic cigarettes. Of particular relevance, (s)16.5-101(i) of the Business Regulation Article defines “other tobacco products” to include “any other tobacco or product made primary from tobacco, other than a cigarette, that is intended for consumption by smoking or chewing or as snuff.” This definition does not include electronic 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.

In support of his contention that the County does not have authority to regulate electronic cigarettes, Mr. Bereano cites *Atladis U.S.A., Inc. v. Prince George's County*¹ and *Allied Vending v. City of Bowie*². Neither of these cases support the conclusion that the County is preempted from regulating electronic cigarettes. In *Atladis*, the Court of Appeals held that state law occupies the field of regulating the packaging and sale of tobacco. In *Allied Vending*, the Court held that the state occupied the field of cigarette sales through vending machines.

The County Attorneys Office has similarly concluded that the County is not preempted from regulating electronic cigarettes (©42).

Action in Maryland jurisdictions. In November 2014, the Baltimore City Council enacted, and the mayor later signed into law, a bill that includes electronic smoking devices in its tobacco smoking prohibitions. Using an electronic smoking device is not prohibited in a restaurant or tavern (or in a designated area of a restaurant or tavern) if the restaurant or tavern notifies customers that the use of electronic devices is not allowed on its premises. Using an electronic smoking device is also not prohibited in a facility that was awarded a video operation license.

Issues for Committee Discussion

Should the Council wait until the Food and Drug Administration regulates electronic cigarettes? Debra Robins, on behalf of Century Distributors urged the Council not to regulate electronic cigarettes until the FDA regulates cigarettes (©51). As noted in the background section of this memorandum, although the FDA has proposed a regulatory framework for electronic cigarettes, it is unclear when (or whether) the FDA will adopt a final rule, what the contents of that rule will be, and when that rule will take effect. The County has a history of protecting the public health by taking action before other agencies with concurrent jurisdiction do so. As a recent example, the FDA recently (2014) finalized a rule to implement menu labeling throughout the country; the County has had this requirement since 2010. Council staff sees no need to wait until the FDA regulates electronic cigarettes to do so locally.

Should using an electronic cigarette be prohibited in public spaces? Bill 56-14 would prohibit using an electronic cigarette in any public place where smoking a traditional cigarette is also prohibited. Places in which smoking a traditional cigarette is prohibited generally include:

- Elevators
- Health care facilities
- County-owned or County leased facilities or property, including bus stop areas and bus shelters
- Theaters
- Businesses or organizations open to the public

Places in which smoking a cigarette is not prohibited include:

- In a tobacco shop

¹ 431 Md. 307 (2013).

² 332 Md. 279 (1993).

- When smoking is necessary to conduct certain research
- Up to 40% of sleeping rooms in a hotel or motel
- In the bar and dining area of a restaurant (subject to certain restrictions)
- On a golf course

Several individuals supported certain portions of the bill (banning sales to minors and/or requirement of child resistant packaging), but opposed the prohibition of using an electronic cigarette in these public places. Many of these individuals related their personal experiences using electronic cigarettes as a smoking cessation device. Chris Webber encouraged the Council to amend Bill 56-14 to follow the exemptions for restaurants and taverns in the Baltimore City law. Several other individuals supported the Bill as introduced on this issue and specifically opposed additional exemptions such as what was enacted in Baltimore.

Council staff first notes that Bill 56-14 would not ban the use of e-cigarettes entirely, as some individuals may believe. Rather, as mentioned above, Bill 56-14 would prohibit the use of electronic cigarettes only in places in which traditional smoking is prohibited. **Council staff does not recommend** amending Bill 56-14 to allow using an electronic cigarette in public places where smoking traditional cigarettes is prohibited. In Staff's view, the health concerns of electronic cigarettes outweigh the inconvenience of an individual needing to retreat to an area where smoking is permitted (i.e., outdoors).

Should FDA-approved devices be prohibited? As introduced, Bill 56-14 would exclude from the definition of electronic cigarette (and therefore the prohibitions of Bill 56-14) "any product approved by the Food and Drug Administration for sale as a drug or medical device." The ACS CAN recommended that this language be removed (©49). **Council staff recommendation:** Although Council staff understands the concerns expressed by the ACS CAN, we believe that if the FDA has determined that something is a medical device or drug, then residents should be allowed to use them. If the FDA determines an e-product is a medical device or drug in the future and it becomes a significant issue in the County, the Council could amend the law to remove this exemption.

Should the definition of electronic device be broadened? As introduced, Bill 56-14 would define an electronic cigarette in part as "an electronic device that delivers vapor for inhalation, including any refill, cartridge, or any other component of an electronic cigarette." The ACS CAN recommends the following definition:

any product containing or delivering nicotine or any other substance intended for human consumption that can be used by a person to simulate smoking through inhalation of vapor or aerosol from the product. The term includes any such device, whether manufactured, distributed, marketed, or sold as an e-cigarette, e-cigar, e-pipe, e-hookah, or vape pen, or under any other product name or descriptor. (©49)

Council staff recommendation: Council staff is comfortable with this expanded definition, although as noted in the issue above, we recommend that the FDA-approved medical devices and drugs are excluded from the definition.

Should electronic cigarettes be included in the definition of smoking or tobacco product? In several recommendations, the ACS CAN recommends that the definition of smoking or tobacco product include e-cigarettes (©49-50). Although this would simplify parts of the bill, Council staff reminds Committee members that e-cigarettes is not a tobacco cigarette or an “other tobacco product”, which are both regulated by the State. Rather, as explained above, electronic cigarettes are a nicotine product and the County has broad authority to regulate them.

Should Bill 56-14 prohibit the sale to, or purchase by, minors? As introduced, Bill 56-14 would prohibit the use of electronic cigarettes by minors. The ACS CAN recommends the bill be amended to prohibit the sale of electronic cigarettes by minors. Bill 56-14 does not address the sale of electronic cigarettes because state law already prohibits this (see ©50).

Should tobacco stores and vape stores prohibit minors from entering? The ACS CAN recommended that Bill 56-14 be amended to restrict minors from entering tobacco stores and vape stores (©50). Council staff does not have any concerns with this recommendation.

Should the child resistant packaging of liquid nicotine requirement sunset when FDA regulations are promulgated? In an e-mail to Councilmember Floreen, Ashlie Bagwell, on behalf of Lorillard Tobacco Company, urged that Bill 56-14 be amended to sunset the child resistant packaging requirement once FDA regulation mandates packaging requirements for liquid nicotine containers. Ms. Bagwell recommended the following language, which in her view would “simply allow for a standardized approach once the FDA comes out with their guidance/rules”:

The provisions of subdivision A 2 shall sunset upon the effective date of final regulations issued by the U.S. Food and Drug Administration or by any other federal agency where such regulations mandate packaging and labeling requirements for liquid nicotine containers.

Council staff recommendation: Council staff understands the desire for standardized approaches rather than having piecemeal requirements. Although Council staff is not opposed to this provision, Council staff would redraft it to ensure that there is no lapse in time between when the Council provision would sunset and the FDA regulation would take effect

County Attorney amendments. The County Attorneys Office recommends several clarifying amendments to prevent perceived enforcement difficulties (©43). These are detailed below and Council staff recommends the Committee adopt these amendments:

- amend Section 24-9(e)(2) to permit the use of “vaping” on signage;
- replace the phrase “using an electronic cigarette” with “vaping” throughout the bill;
- add a definition of vaping;
- amend Section 24-9(f) to add “vaping” after “who smokes” on line 76 and after “to smoke” on line 78; and
- cross reference the federal regulations for special packaging in Section 24-14.

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Bill No. 56-14
Concerning: Health and Sanitation –
Smoking – Electronic Cigarettes
Revised: 9/9/2014 Draft No. 4
Introduced: November 25, 2014
Expires: May 25, 2016
Enacted: _____
Executive: _____
Effective: _____
Sunset Date: None
Ch. _____, Laws of Mont. Co. _____

COUNTY COUNCIL FOR MONTGOMERY COUNTY, MARYLAND

By: Councilmember Floreen, Council Vice President Leventhal, and
Councilmembers Branson, Navarro, Rice, Elrich, Riemer, Katz, Hucker and Berliner

AN ACT to:

- (1) prohibit the use of electronic cigarettes in certain public places;
- (2) restrict the sale of certain liquid nicotine or liquid nicotine containers in retail outlets unless the nicotine is in a container considered child resistant packaging;
- (3) restrict the accessibility of certain tobacco products in retail settings, and require retail sellers of those products to take certain actions;
- (4) prohibit the use of electronic cigarettes by minors; and
- (5) generally amend County law regarding smoking, electronic cigarettes, and health and sanitation.

By amending

Montgomery County Code
Chapter 24, Health and Sanitation
Section 24-9

By adding

Chapter 24, Health and Sanitation
Sections 24-13 and 24-14

By renumbering

Chapter 24, Health and Sanitation
Sections 24-2, 24-3, 24-4, 24-5, 24-6, 24-7, 24-8, 24-9B, 24-9C, 24-9D, 24-10, 24-11,
24-11A

By repealing

Chapter 24, Health and Sanitation
Section 24-9A

By renaming

Chapter 24, Health and Sanitation
Article II

Boldface	<i>Heading or defined term.</i>
<u>Underlining</u>	<i>Added to existing law by original bill.</i>
[Single boldface brackets]	<i>Deleted from existing law by original bill.</i>
<u>Double underlining</u>	<i>Added by amendment.</i>
[[Double boldface brackets]]	<i>Deleted from existing law or the bill by amendment.</i>
* * *	<i>Existing law unaffected by bill.</i>

The County Council for Montgomery County, Maryland approves the following Act:

Sec. 1. Sections 24-2, 24-3, 24-4, 24-5, 24-6, 24-7, 24-8, 24-10, 24-11, and 24-11A are renumbered as follows:

24-2, 24-3. [Reserved.]

24-[4]2. Communicable diseases generally — Warning signs.

* * *

24-[5]3. [Same] Communicable diseases — Unauthorized removal of warning signs.

* * *

24-[6]4. [Same] Communicable diseases — Control in food establishments.

* * *

24-[7]5. Use of certain shoe-fitting devices or machines prohibited.

* * *

24-[8]6. Commitment of chronic alcoholics.

* * *

24-[10]7. Catastrophic health insurance plan.

* * *

24-[11]8. Massage.

* * *

24-[11A]8A. Fitness centers — defibrillators.

* * *

Sec. 2. Article II is renamed; Section 24-9 is amended; Section 24-9A is repealed; Sections 24-9B, 24-9C, and 24-9D are renumbered; and Section 24-13 is added as follows:

Article II. [Reserved] Smoking, Tobacco, and Nicotine.

24-9. Smoking and using electronic cigarettes in public places.

(a) Definitions. In this [Section] Article, the following words and phrases have the meanings indicated:

* * *

Electronic cigarette means an electronic device that delivers vapor for inhalation, including any refill, cartridge, or any other component of an electronic cigarette. Electronic cigarette does not include any product approved by the Food and Drug Administration for sale as a drug or medical device.

* * *

Smoking or smoke means the act of lighting, smoking, or carrying a lighted or smoldering cigar, cigarette, or pipe, of any kind.

* * *

Vape shop means any store that primarily sells electronic cigarettes. Vape shop does not include an area of a larger store in which electronic cigarettes are sold.

- (b) Smoking and using an electronic cigarette are prohibited in certain public places. A person must not smoke or use any electronic cigarette in or on any:

* * *

- (c) Exceptions. Smoking or using an electronic cigarette is not prohibited by this Section:

- (1) In a tobacco shop or a vape shop;

* * *

- (3) When smoking or using an electronic cigarette is necessary to the conduct of scientific research into the health effects of tobacco smoke and is conducted at an analytical or educational laboratory;

* * *

- (d) Notwithstanding paragraph (b)(11), the Director of the Department of Health and Human Services may designate an outside area on

property that is owned or leased by the County where smoking or using an electronic cigarette is allowed if the Director finds that a complete prohibition on that property would impede a program's mission or effective delivery of services.

(e) *Posting signs.*

(1) Except as provided in paragraph (e)(4), signs prohibiting or permitting smoking or using an electronic cigarette, as the case may be, must be posted conspicuously at each entrance to a public place covered by this Section.

(2) Where smoking or using an electronic cigarette is prohibited by this Section, the sign either must read "No smoking or using an electronic cigarette by order of Montgomery County Code § 24-9. Enforced by (department designated by the County Executive)" or be a performance-oriented sign such as "No Smoking or Using an Electronic Cigarette" or "This is a Smoke Free Establishment." The international no-smoking symbol may replace the words "No smoking."

* * *

(f) *Duty to prevent smoking in certain areas.* The owner or person in control of a building or area covered by this Section must refuse to serve or seat any person who smokes where smoking or using an electronic cigarette is prohibited, and must ask the person to leave the building or area if the person continues to smoke after proper warning.

* * *

(k) *Enforcement and penalties.*

(1) Any violation of this [Section] Article is a class C civil violation. Each day a violation exists is a separate offense.

(2) The County Attorney or any affected party may file an action in a court with jurisdiction to enjoin repeated violations of the Section.

(3) The County Executive must designate by Executive order one or more County departments or agencies to enforce this Article.

(4) The Director of the Department of Health and Human Services may suspend a license issued under Chapter 15 for up to 3 days if the Director finds, under the procedures of Section 15-16, that the operator of an eating and drinking establishment has knowingly and repeatedly violated any provision of this Section.

[24-9A. Reserved.]

24-[9B]10. Availability of tobacco products to minors.

* * *

24-[9C]11. Distribution of tobacco products to minors.

* * *

24-[9D]12. Tobacco and electronic cigarette [Products – Placement] products = placement.

(a) Placement. A retail seller of any tobacco or electronic cigarette product must not display or store the product in any place that is accessible to buyers of the product without the intervention of the seller or an employee of the seller.

(b) Definitions. *Tobacco product* means any substance containing tobacco, including cigarette, cigars, smoking tobacco, snuff, or smokeless tobacco.

(c) Applicability. This Section does not apply to:

(1) the sale of any tobacco or electronic cigarette product from a vending machine that complies with all requirements of state law; and

(2) any store where only or primarily tobacco or electronic cigarette products are sold.

[(d) Enforcement. The County Executive must designate by Executive order one or more County departments or agencies to enforce this Section.]

[24-12. Reserved.]

24-13. [Reserved] Use of electronic cigarettes by minors prohibited.

A person under 18 years old must not use an electronic cigarette.

24-14. Child Resistant Packaging of Liquid Nicotine Container Required.

(a) Definitions. In this Section, the following words have the meanings indicated:

Child resistant packaging means packaging that is:

(1) designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time; and

(2) not difficult for normal adults to use properly.

Child resistant packaging does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

Liquid nicotine container means a container that is used to hold liquid containing nicotine in any concentration.

(b) Child resistant packaging required. A retail seller of any liquid nicotine or liquid nicotine container must not sell, resell, distribute, dispense, or give away:

(1) any liquid or gel substance containing nicotine unless the substance is in child resistant packaging; or

(2) any nicotine liquid container unless the container constitutes child resistant packaging.

(c) Exceptions. This Section does not apply to a liquid nicotine container that is sold, marketed, or intended for use in an electronic cigarette if the container is prefilled and sealed by the manufacturer and not intended to be opened by the consumer.

24-[12]15-24-21. Reserved.

Approved:

Craig L. Rice, President, County Council

Date

Approved:

Isiah Leggett, County Executive

Date

This is a correct copy of Council action.

Linda M. Lauer, Clerk of the Council

Date

LEGISLATIVE REQUEST REPORT

Bill 56-14

Health and Sanitation – Smoking – Electronic Cigarettes

DESCRIPTION:	Bill 56-14 would prohibit the use of electronic cigarettes in public places where traditional tobacco smoking is prohibited; restrict the sale of certain liquid nicotine or liquid nicotine containers in retail outlets unless the nicotine is in a container considered child resistant packaging; prohibit the sale of electronic cigarettes in any place that is accessible to buyers of the product without the intervention of the seller (similar to tobacco products); and prohibit the use of electronic cigarettes by minors.
PROBLEM:	Electronic cigarettes are not currently regulated by the FDA or the state. Many youth could perceive electronic cigarettes as less harmful than traditional tobacco smoking. Current statistics show that e-Cigarette use by high school students increased from less than 5% to almost 10% from 2011 to 2012 and that reasons students gave for using e-Cigarettes include: curiosity, attraction of flavors, use by friends and family, desire to quit smoking, availability, and it is a sign of independence.
GOALS AND OBJECTIVES:	In part, to protect the health of minors by restricting the use and availability of electronic cigarettes to minors.
COORDINATION:	Health and Human Services
FISCAL IMPACT:	To be requested.
ECONOMIC IMPACT:	To be requested.
EVALUATION:	To be requested.
EXPERIENCE ELSEWHERE:	To be researched.
SOURCE OF INFORMATION:	Amanda Mihill, Legislative Attorney, 240-777-7815
APPLICATION WITHIN MUNICIPALITIES:	To be researched.
PENALTIES:	Class C violation.

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



National Institute
on Drug Abuse

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



National Institute
on Drug Abuse

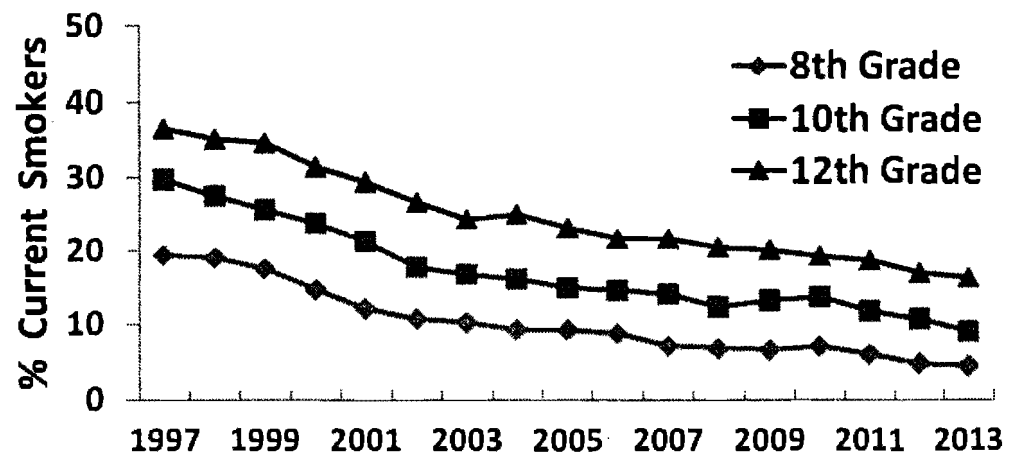
Source: HHS, The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.

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



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



National Institute
on Drug Abuse

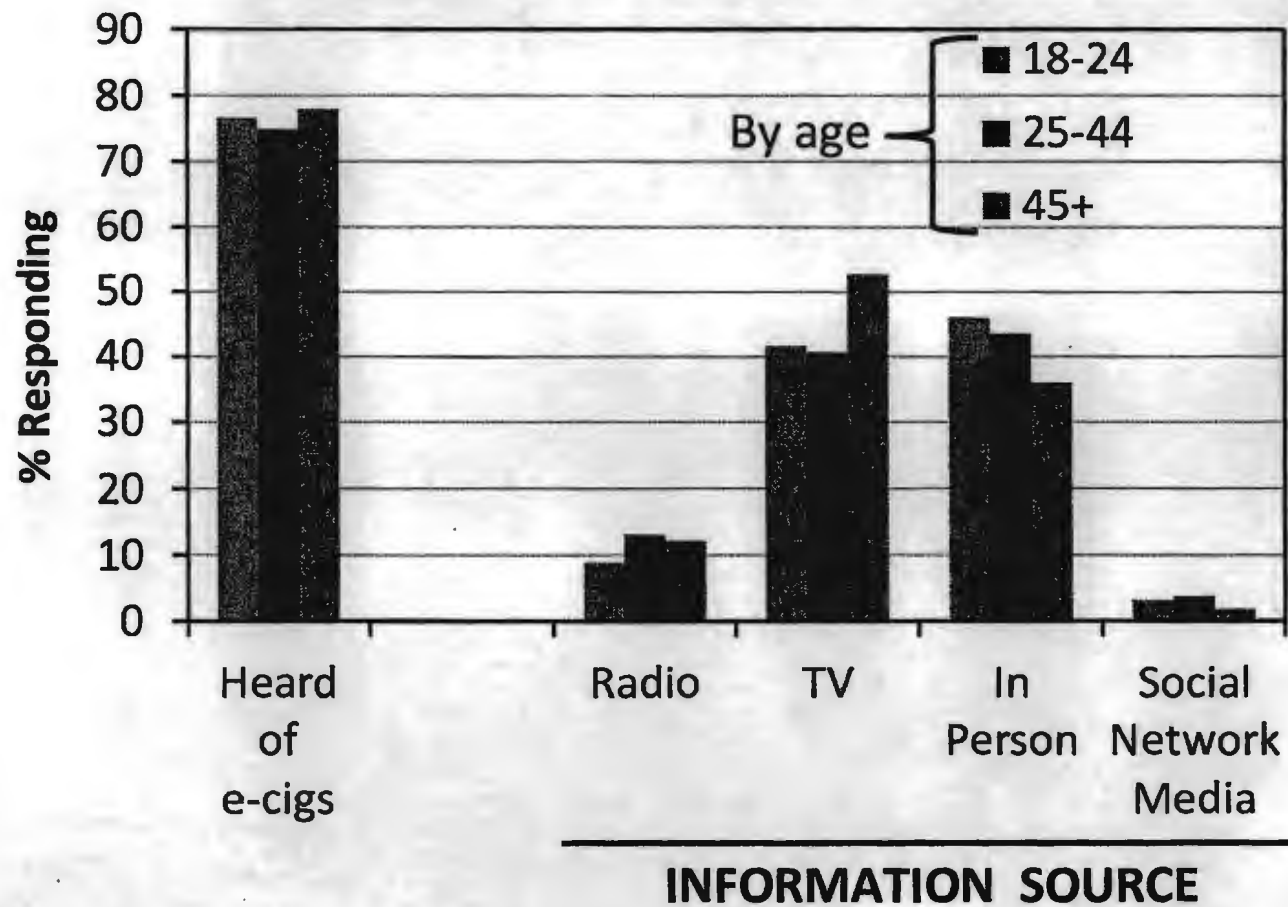
Electronic Cigarette (E-cigarette) History

- 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**

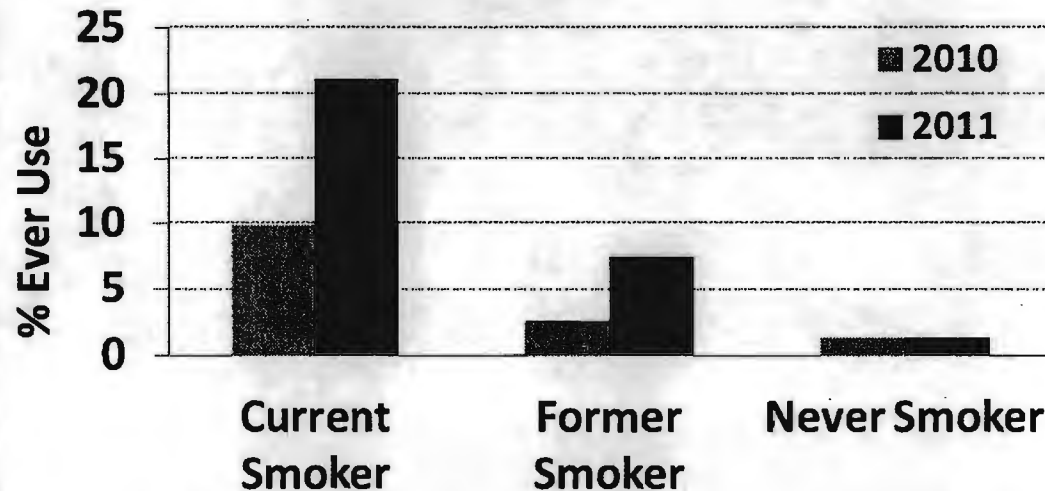


National Institute
on Drug Abuse

Most People Are Aware of Electronic Cigarettes



Adult Use of Electronic Cigarettes Primarily by Current Smokers



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

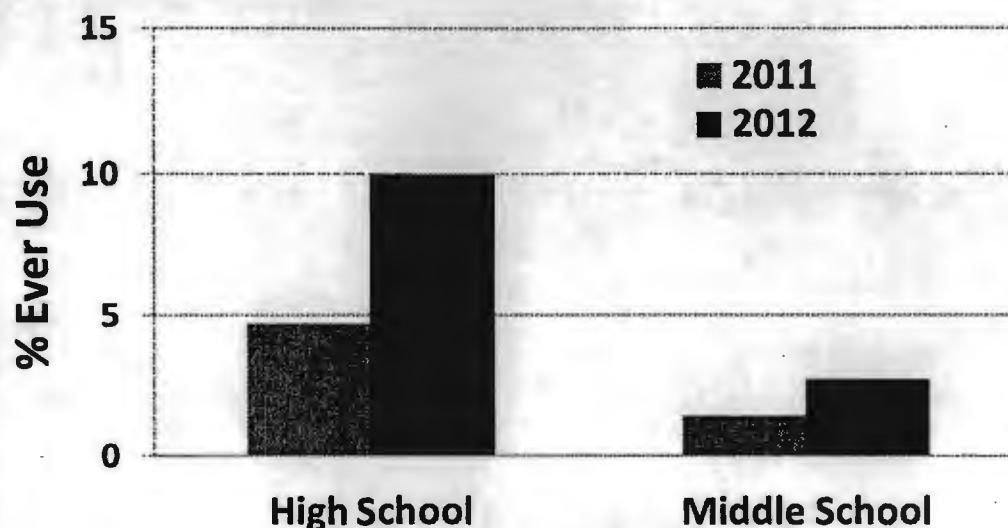
- **Health reasons primary motivator for e-cigarette use**
 - Believe less harmful than conventional cigarettes
 - Desire to cut down and/or quit conventional cigarettes
 - Help with reducing cravings and withdrawal symptoms
 - Want to prevent relapse to conventional cigarettes
 - Don't want to disturb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

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



National Institute
on Drug Abuse

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



National Institute
on Drug Abuse

Source: CDC, MMWR 62:893-97, 2013; Camenga, et al, 2014; Kong et al, 2014

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

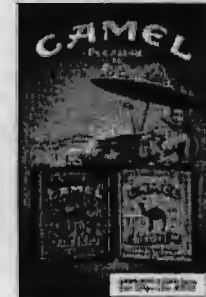
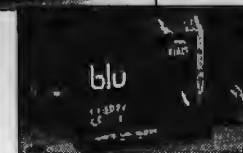


National Institute
on Drug Abuse

Source: http://tobacconomics.org/wp-content/uploads/2014/06/EcigStateLaws_SCTCENDS.pdf

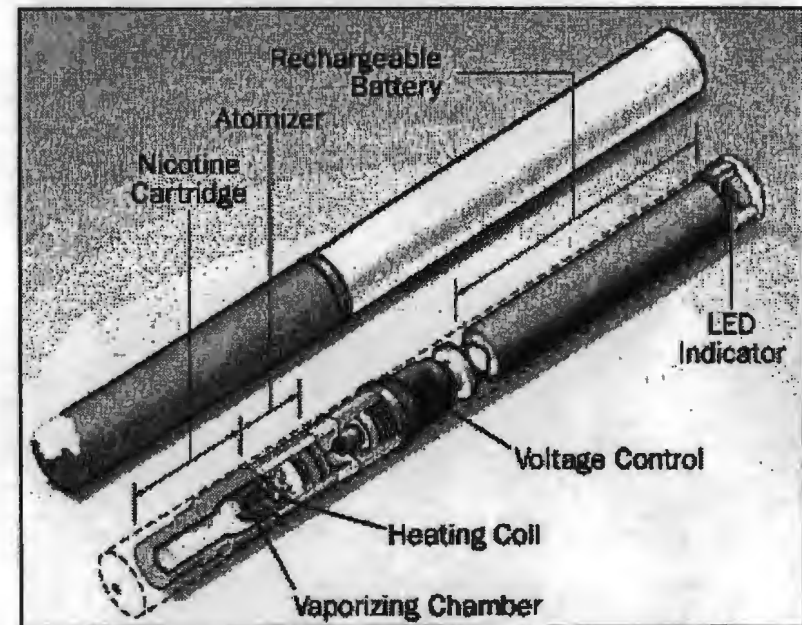
What are the Concerns About Electronic Cigarettes??

- 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



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

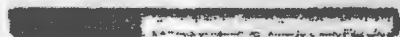


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Source: <http://science.howstuffworks.com/innovation/everyday-innovations/electronic-cigarette1.htm>

Types of Electronic Cigarettes

Disposable e-cigarette



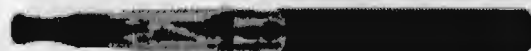
NJOY, White Cloud,
Greensmoke

Rechargeable e-cigarette



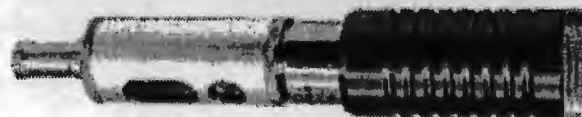
Markten, Mystic,
blu, VUSE

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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Source: Grana, et al, 2014

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	



100+ FLAVORS

- 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



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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



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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

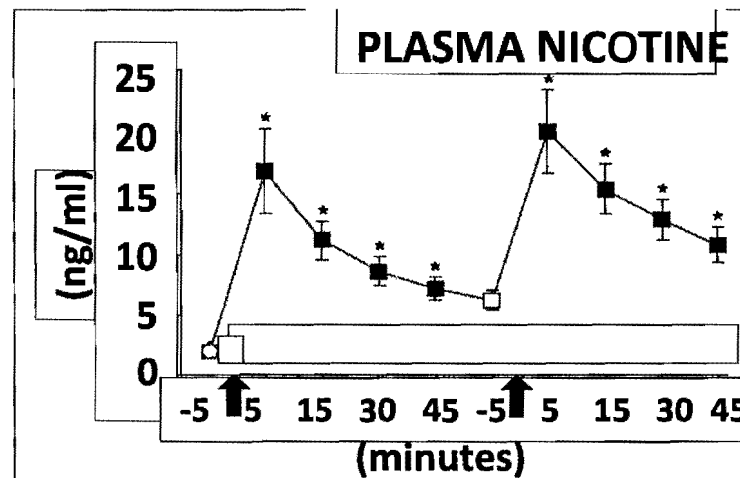


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Goniewicz et al, 2014; Kosmider et al, 2014

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



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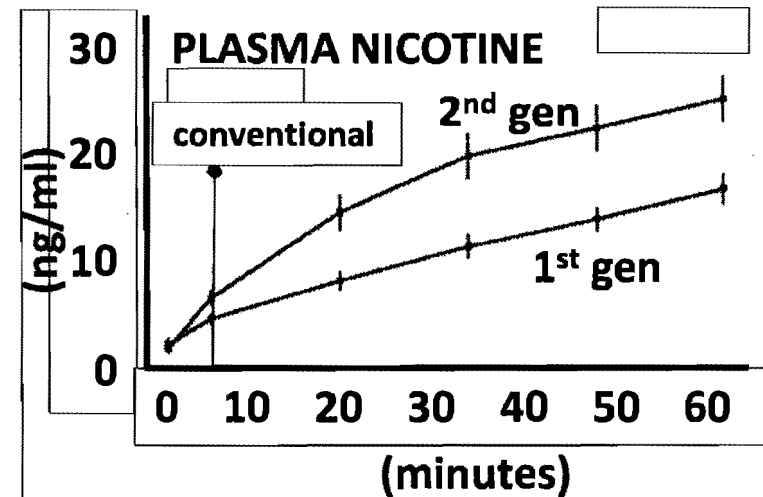
Source: Vansickel, et al, 2010

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 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

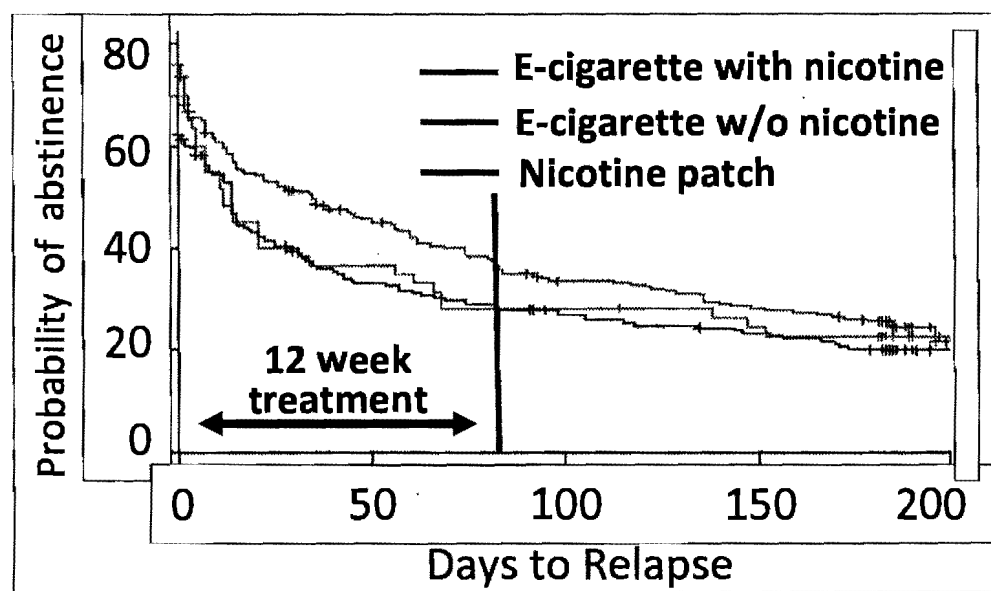
- E-cigarettes have no sidestream emissions like a conventional cigarette (generates smoke while holding)
- Exhaled aerosol may be inhaled by nearby individuals (secondhand exposure)
- Surfaces can be coated with the nicotine-containing aerosol as it settles (thirdhand exposure)
- Health effects of indirect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



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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



Source: Bullen et al, 2013

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



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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



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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?



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Additional slides



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on Drug Abuse

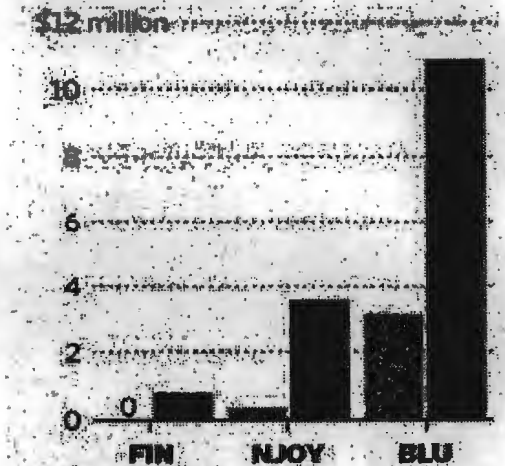
Electronic Cigarette Advertising

- 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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on Drug Abuse

Source: Wall Street Journal (online) - Dec 2013; Duke, et al (2013) - http://pediatricsde.aap.org/pediatrics/july_2014?pg=59#pg59

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.



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on Drug Abuse



ROCKVILLE, MARYLAND

MEMORANDUM

January 12, 2015

TO: George Leventhal, President, County Council

FROM: Jennifer A. Hughes, Director, Office of Management and Budget
Joseph F. Beach, Director, Department of Finance

SUBJECT: FEIS for Bill 56-14, Health and Sanitation - Smoking - Electronic Cigarettes

Please find attached the fiscal and economic impact statements for the above-referenced legislation.

JAH:fz

cc: Bonnie Kirkland, Assistant Chief Administrative Officer
Lisa Austin, Offices of the County Executive
Joy Nurmi, Special Assistant to the County Executive
Patrick Lacefield, Director, Public Information Office
Joseph F. Beach, Director, Department of Finance
Uma Ahluwalia, Director, Department of Human Health Service
David Platt, Department of Finance
Pofen Salem, Office of Management and Budget
Alex Espinosa, Office of Management and Budget
Nacem Mia, Office of Management and Budget

Fiscal Impact Statement
Council Bill 56-14
Health and Sanitation – Smoking – Electronic Cigarettes

1. Legislative Summary.

Bill 56-14 would:

- prohibit the use of electronic cigarettes in public places where traditional tobacco smoking is prohibited;
- restrict the sale of certain liquid nicotine or liquid nicotine containers in retail outlets unless the nicotine is in a container considered child resistant packaging;
- prohibit the sale of electronic cigarettes in any place that is accessible to buyers of the product without the intervention of the seller (similar to tobacco products); and
- generally amend County law regarding smoking, electronic cigarettes, and health and sanitation.

2. An estimate of changes in County revenues and expenditures regardless of whether the revenues or expenditures are assumed in the recommended or approved budget. Includes source of information, assumptions, and methodologies used.

There will be no increase in revenues.

Based on experience from other smoking related legislation, response to complaints is minimal.

Enforcement of child resistant packaging will have a fiscal impact if the Department of Health and Human Services (HHS) is charged with enforcement through inspection.

Expenditures based on 857 markets requiring bi-annual inspection is 428 inspections annually. Checking for child resistant packaging would add approximately 15 minutes to each inspection which results in an additional 107 hours of inspection or .05 FTE. At \$50 per hour, the additional county expenditure would be approximately \$5,350 annually.

The Department of General Services (DGS) estimates expenditures of \$18,220 for 400 signs to be posted conspicuously at each entrance to a public place covered under the legislation. Costs are for new sign fabrication (\$8,000), installation (\$10,000) and hardware (\$220).

The Department of Transportation (DOT) estimates expenditures of \$341,000 are needed to redesign and install Ride-On signs reflecting proper No Smoking or E-Smoking symbols and enforcement language in order to fully implement the law.

3. Revenue and expenditure estimates covering at least the next 6 fiscal years.

The expenditure identified in Question 2 would remain the same for each subsequent fiscal year.

DGS estimated costs would cover the next six fiscal years.

4. An actuarial analysis through the entire amortization period for each bill that would affect retiree pension or group insurance costs.

Not applicable.

5. An estimate of expenditures related to County's information technology (IT) systems, including Enterprise Resource Planning (ERP) systems.

Not applicable.

6. **Later actions that may affect future revenue and expenditures if the bill authorizes future spending.**

Not applicable.

7. **An estimate of the staff time needed to implement the bill.**

It would require 20 hours training based on one hour for 20 Environmental Health Specialists.

DGS estimates 672 staff hours for sign installation, inspection, and contractor oversight. Hours deployed for this effort are assumed during normal working hours. However, this will reallocate staff from other facility repairs and emergencies, such that backfill overtime may be incurred. The average overtime cost for DGS staff (Public Service Craftworker, G15) is \$36.4 per hour.

8. **An explanation of how the addition of new staff responsibilities would affect other duties.**

Overall average time to inspect a food service facility is two hours. Based on an additional 107 hours of time to inspect for child resistant packaging, it would result in approximately 53 fewer food service inspections completed annually.

9. **An estimate of costs when an additional appropriation is needed.**

Not applicable.

10. **A description of any variable that could affect revenue and cost estimates.**

If enforcement of child resistant packaging is moved from HHS to Liquor Control there would be little or no fiscal impact on HHS.

11. **Ranges of revenue or expenditures that are uncertain or difficult to project.**

Not applicable.

12. **If a bill is likely to have no fiscal impact, why that is the case.**

Not applicable.

13. **Other fiscal impacts or comments.**

None.

14. **The following contributed to and concurred with this analysis:**

Clark Beil, Sr. Administrator, Licensure and Regulatory Services, DHHS
Kenneth Welch, Environmental Health Manager, Licensure and Regulatory Services, DHHS
Patricia Stromberg, Budget Team Manager, DHHS
Beryl L. Feinberg, Deputy Director, Department of General Services
Richard Jackson, Division Chief, Department of General Services
Darlene Flynn, Chief of Management Services for Transit, Department of Transportation
Pofen Salem, Senior Management and Budget Analyst, Office of Management and Budget



Jennifer A. Hughes, Director
Office of Management and Budget

1/13/15
Date

Economic Impact Statement
Bill 56-14, Health and Sanitation – Smoking – Electronic Cigarettes

Background:

This legislation would:

- prohibit the use of electronic cigarettes in public places where traditional tobacco smoking is prohibited,
- restrict the sale of certain liquid nicotine or liquid nicotine containers in retail outlets unless the nicotine is in a container considered child resistant packaging, and
- prohibit the sale of electronic cigarettes in any place that is accessible to buyers of the product without the intervention of the seller.

1. The sources of information, assumptions, and methodologies used.

Sources of information include the Montgomery County Department of Health and Human Services (HHS) and the U.S. Center for Disease Control and Prevention (CDC).

The methodology used in the preparation of the economic impact statement is a review of various documents from the CDC related to the use of the products prohibited and restricted under Bill 56-14 and information provided by HHS. Included in the review is a description of the products, the results of a study conducted by the journal entitled *Nicotine & Tobacco Research*, and information provided by HHS.

According to the latest issue of *Morbidity and Mortality Weekly Report* from the CDC dated December 12, 2014, “electronic nicotine delivery systems (ENDS), including electronic cigarettes (e-cigarettes) and other devices such as electronic hookahs, electronic cigars, and vape pens, are battery-powered devices capable of delivering aerosolized nicotine and additives to the user.” According to the article, experimentation with and current use of e-cigarettes has risen sharply among youths and adults.

A new study published in *Nicotine & Tobacco Research* focused on middle and high school students who never smoked cigarettes but who used e-cigarettes. According to researchers from CDC, Food and Drug Administration (FDA), and Georgia State University, the number of youths who had never smoked a cigarette but had used e-cigarettes at least once increase three-fold. That is, the number of “never-smoking youth” who used e-cigarettes increased from 79,000 in 2011 to more than 263,000 in 2013.

The study also focused on the impacts of advertising on students. The findings reveal that ninety percent of “never-smoking youth” reported some level of exposure to advertising or promotions for cigarettes or other tobacco products. Researchers

Economic Impact Statement
Bill 56-14, Health and Sanitation – Smoking – Electronic Cigarettes

concluded that the greater number of advertising sources to which young people were exposed, the greater their rate of intention to smoke cigarettes.

According to data collect from websites, there are 52 e-cigarette and vapor stores in Maryland and eight stores are located in Montgomery County. According to information provided by HHS, there are no data on the number of e-cigarettes or vapor devices sold in the County. However, there are 847 licensed markets in the County including grocery stores, mini-marts, and gas stations that could sell e-cigarettes but currently may not. Therefore data on the sale and consumption of e-cigarettes and vapor devices in the County are not available to estimate with any degree of certainty the economic impact of Bill 56-14.

2. A description of any variable that could affect the economic impact estimates.

The variables the could affect the economic impact estimates are the number of e-cigarettes and vapor devices sold in the County and the consumption of such products by minors as defined by the CDC study.

3. The Bill's positive or negative effect, if any on employment, spending, saving, investment, incomes, and property values in the County.

Without specific data on the sales, businesses that sell e-cigarettes and vapor devices, and on consumption, it is difficult to determine the Bill's effect on employment, spending, savings, investment, incomes, and property values in the County. Such data could be obtained through a survey of establishments that are likely to sell such products.

4. If a Bill is likely to have no economic impact, why is that the case?

It is difficult without specific data as noted in paragraph #3 to determine the Bill's economic impact.

5. The following contributed to or concurred with this analysis: Mary Casciotti, David Platt and Rob Hagedoorn, Finance; Patricia Stromberg, HHS



Joseph F. Beach, Director
Department of Finance

11/12/15
Date

**Testimony on behalf of County Executive Isiah Leggett
Bill 56-14, Health and Sanitation—Smoking—Electronic Cigarettes
January 22, 2015**

Good evening Council President Leventhal and Councilmembers. I am Dr. Ulder Tillman. I am here tonight to testify on behalf of County Executive Leggett in support of Bill 56-14, which would place limits on the sale and use of e-cigarettes. The County Executive offers his enthusiastic support for this bill as it addresses a serious potential threat to the health of our residents.

Use of this product has grown dramatically since its introduction to the U.S. market in 2007, with sales doubling every year since 2010. E-cigarettes are being aggressively marketed by manufacturers even though risks are not fully understood and there are no real standards for their contents or design.

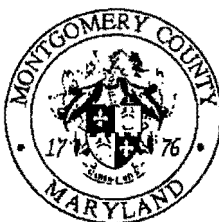
While the FDA is moving to regulate e-cigarettes, the Rulemaking process is a lengthy one and it is likely to be years before a final Rule is adopted. We are pleased that the State of Maryland has banned the sale of e-cigarettes to minors, but further action is needed to discourage the easy availability and increased use of this product. Montgomery County should not wait for the federal or State government to enact needed protections. While there is much we do not know about e-cigarettes, what we do know is very concerning: Use among youth is growing, stimulated by aggressive marketing and the use of flavorings in e-cigarettes that appeal to younger consumers.

Health advocates fear that the use of e-cigarettes by minors will normalize smoking-like behavior and that these youth may move on to use traditional tobacco products. Young children are at particular risk of harm caused by accidental ingestion of nicotine in e-cigarettes. Nationwide poison control centers report an alarming increase in calls related to ingestion of liquid nicotine by young children ages 0-5. Bill 56-14 will further limit youth access to e-cigarettes and will require nicotine refills to be in child resistant packaging—a measure that helps to insure the safety of children in homes where refillable e-cigarettes are being used.

Montgomery County has a long history of being out in front of efforts to limit the use of tobacco in our community, including bans on smoking tobacco products in county buildings, restaurants, and other public spaces. We have had remarkable success in reducing smoking rates across all segments of the population. The County Executive has been a strong supporter of these measures, including legislation adopted unanimously by the County Council in 2013 that prohibits smoking in all county-owned or leased property. The County Executive believes that wherever possible county law should treat e-cigarettes as if they were a traditional tobacco product and urges passage of this legislation.

The County Attorney has offered some suggestions for minor technical changes in the bill. A copy of that memorandum is also being submitted for the record. Executive staff will work with Councilmembers and their staff to address those suggestions.

Thank you for the opportunity to testify in support of the bill.



Isiah Leggett
County Executive

Marc P. Hansen
County Attorney

OFFICE OF THE COUNTY ATTORNEY

MEMORANDUM

TO: Uma Ahluwalia, Director
Department of Health and Human Services

VIA: Marc P. Hansen
County Attorney

Marc Hansen (initials)

FROM: Kristen M.K. Kaloria
Associate County Attorney

Kristen M.K. Kaloria

CC: Bonnie Kirkland
Assistant Chief Administrative Officer

DATE: December 8, 2014

RE: Review of Bill No. 56-14

Summary

Bill No. 56-14 ("the Bill") is designed to address public health concerns raised by the increasing popularity of electronic cigarettes. E-cigarettes consist of a power source, a heating device, and a liquid-filled cartridge. The devices deliver a smokeless vapor, which is usually flavored and often, but not always, contains nicotine. The cartridges used in e-cigarettes do not contain tobacco.

The Bill would prohibit the use of e-cigarettes in public places where traditional smoking is already banned, require that certain nicotine-containing liquids be sold in child-resistant packaging, place restrictions on the display and sale of electronic cigarettes, and prohibit use of electronic cigarettes by minors. Although tobacco products are heavily regulated by the state and federal government, e-cigarettes are not covered by the existing regulatory scheme. State law prohibits sale of e-cigarettes to minors, but is otherwise silent on the subject. The FDA recently announced its intention to regulate e-cigarettes, but there are no regulations currently in effect. Therefore, Bill 56-14 is unlikely to be preempted by the existing state or federal regulatory

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scheme. There are some concerns about ambiguities found in the language of the proposed Bill, which are detailed below. These ambiguities are likely to result in confusion and enforcement difficulties.

Legal Implications

I. Ambiguities

Section 24-9(e) Posting Signs

Section 24-9(e)(2) requires specific wording on no smoking signs. As amended, it would give several options, including "No smoking or using an electronic cigarette by order of the Montgomery County Code § 24-9. Enforced by (department designated by the County Executive)." The statute goes on to allow that "the international no-smoking symbol may replace the words 'No smoking.'" It is unclear if the international no-smoking symbol can also be used to indicate "no using an electronic cigarette" or if signs using the symbol would still need to contain those words. For the sake of brevity, it may also make sense to permit the use of the term "vaping" rather than "using an electronic cigarette" on signage. In that case, "vaping" should be added to the definitions in Section 24-9(a) and defined simply as "using an electronic cigarette." The term could then be used to simplify language throughout the Bill.

Section 24-9(f) Duty to prevent smoking in certain areas

As amended, section 24-9(f) requires the owner of a building or area covered by the statute to "refuse to serve or seat any person who smokes where smoking or using an electronic cigarette is prohibited...." Presumably, the statute also intends to prohibit serving or seating a person who is using an electronic cigarette in these areas. The term "smoke" is defined in 24-9(a) and does not include using an electronic cigarette. Likewise, the section goes on to state that the owner "must ask the person to leave the building or area if the person continues to smoke after proper warning." This provision is presumably meant to apply to persons using electronic cigarettes as well. Both of these provisions are easily clarified by adding "or using an electronic cigarette" after the word "smoke." Again, use of the term "vaping" would make these provisions less wordy.

Section 24-14 Child Resistant Packaging of Liquid Nicotine Container Required

The proposed section 24-14(b) would prohibit retail sales of any liquid or gel substance containing nicotine or any nicotine liquid container unless the product is in child resistant packaging. Section 24-14(a) defines "child resistant packaging" as packaging "(1) designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time; and (2) not difficult for normal adults to use properly." It goes on to state that "child resistant packaging

does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.” Although there is no reference to the federal regulation, this language is taken almost verbatim from the definition of “special packaging” found in 16 CFR §1700.1. The federal regulations are promulgated by the Consumer Products Safety Commission, which is charged with administering the Poison Prevention Packaging Act of 1970, 15 U.S.C §§ 1471-1476.

There is no indication how the County would evaluate compliance with this provision. While the CPSC does not approve or endorse certain packaging, it has promulgated regulations that provide for standardized package testing procedures, 16 CFR §1700.20, and specific requirements for child-resistant packaging based on the results of that testing, 16 CFR §1700.15. The County adopted the definition of special packaging from 16 CFR §1700.1, but doesn’t address the specific requirements or testing procedures found in the federal regulation. As a result, the Bill as proposed would likely result in significant confusion and would be difficult to enforce. This could be resolved by simply requiring compliance with the federal regulations for special packaging and cross referencing the federal regulations. At least one other state has taken this approach. Minnesota recently enacted a state law requiring child-resistant packaging for e-cigarette cartridges that provided: “For purposes of this section, ‘child-resistant packaging’ is defined as set forth in Code of Federal Regulations, title 16, section 1700.15(b)(1), as in effect on January 1, 2015, when tested in accordance with the method described in Code of Federal Regulations, title 16, section 1700.20, as in effect on January 1, 2015.” Minnesota Statute 461.20 (effective Jan 1, 2015).

II. Preemption

As tobacco is heavily regulated by the state, it is necessary to consider the possibility that local regulation in the area may be preempted. Generally speaking, state and federal tobacco regulations fall into two categories: regulation of sales and regulation of smoking in public places. There is no express preemption of electronic cigarette regulation in either state or federal law. Preemption may also be implied, either by conflict or because the state or federal government has regulated a field so forcibly that its intent to occupy the entire field must be inferred. *Mayor and City Council of Baltimore v. Sitnick*, 254 Md. 303, 323 (1969). For the reasons described below, implied preemption of Bill 56-14 is not a concern at this time.

Tobacco Sales

Maryland regulates the sale and manufacture of cigarettes and other tobacco products, imposing license requirements and other restrictions on vendors. Title 16 of the Business Regulation Article governs sale and manufacture of cigarettes, defined as “any size or shaped roll for smoking that is made of tobacco or tobacco mixed with another ingredient and wrapped in paper or in any other material except tobacco.” Md. Code, Business Regulation §16-101(b).

Title 16.5 governs sale of “other tobacco products,” defined as “(1) any cigar or roll for smoking, other than a cigarette, made in whole or in part of tobacco; or (2) 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.” Md. Code, Business Regulation §16.5-101(i). The tobacco tax regulation relies on a substantially similar definition. *See* Md. Code, Tax-General §12-101. The Criminal Law Article prohibits sale of tobacco products to minors. Md. Code Criminal Law §10-107. “Tobacco product” is defined simply as a substance containing tobacco, “includ[ing] cigarettes, cigars, smoking tobacco, snuff, smokeless tobacco, and candylike tobacco products.” Md. Code Criminal Law §10-101(d). Possession by a minor is also prohibited. Md. Code Criminal Law §10-108 (civil offense only).

None of the above statutes apply to electronic cigarettes. The detailed definitions of “cigarette” and “tobacco product” exclude e-cigarettes entirely, as e-cigarettes do not contain tobacco. Presumably recognizing this, the legislature enacted a new statute in 2012 prohibiting sale of “electronic nicotine devices” to minors. Md. Code, Health-General, §24-305. The 2012 statute represents the only state regulation of e-cigarettes at this time. As Bill 56-14 does not conflict with the state law prohibiting sales to minors, there is no existing conflict between the Bill and state law.

Local e-cigarette regulation is also easily distinguishable from the local regulation of cigarette vending machines, which was invalidated by the Court of Appeals in *Allied Vending Inc. v. City of Bowie*, 332 Md. 279 (1993). In *Allied Vending*, the local regulation imposed restrictions on the placement of cigarette vending machines and required an additional municipal license for the location of each vending machine. *Id.* at 282-83. The Court found that the regulations were preempted because the State had exercised exclusive control over regulation of cigarette sales dating back to 1890, and the current state regulatory scheme included extensive regulation of sales via cigarette vending machines, requiring two different licenses for owners of such machines. *Id.* at 302. In contrast, electronic cigarettes are subject to exactly one state regulation dating back to 2012. It is possible that state regulation will expand in the near future. In the meantime, however, there is no concern that the state has regulated so forcibly in the area as to impliedly preempt local regulation on the matter.

Smoking in Public Places

The state also regulates smoking in certain public areas. *See* Md. Code, Health-General, §§24-501—511 (“Maryland Clean Indoor Air Act”). In that context, smoking is defined as “the burning of a lighted cigarette, cigar, pipe, or any other matter or substance that contains tobacco.” Md. Code, Health-General, §24-501(g). Again, use of electronic cigarettes is undoubtedly excluded from this definition, as e-cigarettes do not contain tobacco. Thus, for the same reasons described above, Bill 56-14’s restrictions on e-cigarette use in public is distinguishable from the cigarette vending machine regulations struck down in *Allied Vending*

and is not preempted by existing state laws.

It is worth noting that a bill was proposed in the 2014 session that would have included "vaping" in Maryland Clean Indoor Air Act's definition of "smoking." *See* H.B. 1291 (Introduced February 7, 2014). The bill had 19 co-sponsors, but never got out of committee. Even if it had passed, the state law would not have preempted Bill 56-14, but it does suggest at least some support for further state regulation of e-cigarettes.

Federal Laws

Cigarettes and other tobacco products are also subject to various federal laws and regulations, including regulation of labeling, marketing, internet sales, and sales to minors. None of these laws appear to apply to e-cigarettes. The Food and Drug Administration recently announced its intention to develop regulations for e-cigarettes, which it considers to be tobacco products. Federal law gives the FDA broad authority to regulate "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary[of Health and Human Services] by regulation deems to be subject to [the Tobacco Products subchapter of the Food Drug and Cosmetic Act]." 21 U.S.C. 387a (b). It's anticipated that the rulemaking process will take years, but any regulations developed by the FDA will supersede conflicting local laws.

The federal government also regulates product packaging, as described above in the discussion of child-resistant packaging (See Section I, above). There is legislation currently pending before Congress that would require the Consumer Products Safety Commission to promulgate rules for liquid nicotine containers. *See* Child Nicotine Poisoning Prevention Act of 2014 S. 2581/H.R. 5486 (113th Congress). If passed, the resulting regulations would preempt Section 24-14, to the extent of any conflict.

If you have any concerns or questions concerning this memorandum please call me.

kmkk

Enclosure (bill)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Isiah Leggett
County Executive

Uma S. Ahluwalia
Director

January 22, 2015

George Leventhal, President
Montgomery County Council
100 Maryland Avenue
Rockville, Maryland 20850

Dear Council President Leventhal:

The Commission on Health (COH) thanks the County Council for addressing the issue of e-cigarettes. The COH recommends passage of Bill 56-14 prohibiting the use of e-cigarettes in public spaces where tobacco smoking is prohibited, requiring child resistant packaging of nicotine containers, prohibiting the use of e-cigarettes by minors, prohibiting the purchase of nicotine refills without the intervention of a seller, and amending County laws to treat e-cigarettes as conventional cigarettes.

The COH has deep reservations about claims that e-cigarettes are safe. According to the U.S. Food and Drug Administration (FDA), "e-cigarettes have not been fully studied so consumer do not know: 1) the potential risks of e-cigarettes when used as intended, 2) how much nicotine or potentially harmful chemicals are being inhaled during use, and 3) whether there are any benefits associated with using these products. Further, it is not known whether e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death."¹ While some consumer groups support e-cigarettes, the reports by FDA and U. S. Centers for Disease Control and Prevention (CDC), the limited scientific data, and the rapid rise in poison control reports give us great concern about the safety of these products and their potential danger to children.

The Consumer Advocates for Smoke-free Alternatives Association (CASAA)² claims the e-cigarette vapor contains no second hand smoke. CASAA points to a literature review article³, which they funded, that concluded that e-cigarettes vapors "do not warrant concerns." However in the review, Burstyn conceded that the data are poor. We question drawing such a strong conclusion from poor data. CASAA builds a case that e-cigarettes are safer than conventional cigarettes and smokeless tobacco. However, the COH believes that cigarettes and smokeless tobacco should not be held as the safety threshold.

A recent review of e-cigarette toxicological profiles⁴ pointed out that the publicly available data are insufficient to evaluate the safety of e-cigarette vapor. Studies within the review show the presence of

¹ <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>

² www.casaa.org

³ Burstyn, I. *BMC Public Health*, 14:18

⁴ Orr MS. *Tob Control* 2014;23:ii18-ii22.

low levels of tobacco-specific nitrosamines, which are known to be carcinogenic. The study authors of the review noted that toxicity varied with type and level of flavor additives; however, without an adequate characterization of exposure and safety margins, we remain concerned about long-term health effects.

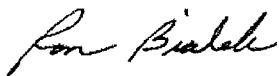
Unlike the demographic suggested by CASAA, CDC reported that e-cigarette use is growing rapidly among high school students⁵. The percent of high school students who used an e-cigarette rose from 4.7% to 10.0% between 2011 and 2012. Over 76% of students who used an e-cigarette also reported smoking a conventional cigarette. According to CDC, cigarette smoking remains the leading preventable cause of disease, disability, and death in the United States. We know of no scientific study that assesses the effect of dual cigarette and e-cigarette use.

Exposure to e-cigarette vapors residues deposited on surfaces has not been studied. However, in a small study of homes with hookah smokers, researchers measured the levels of nicotine and nitrosamines in children, and the levels of nicotine on surfaces in living rooms and children's bedrooms⁶. Although nitrosamine and nicotine levels are much lower in e-cigarette vapors than in hookah smoke, the deposition pattern of vapor may be similar. High levels of nicotine may accumulate on surfaces due to repeated deposition of e-cigarette vapors. Also referred to as third hand smoke, this deposition can expose non-smokers to potentially high levels of nicotine. This is especially concerning in the pediatric population.

The COH is also concerned about the growing number of calls to U.S. poison control centers due to exposure to e-cigarettes or their liquids. As e-cigarette use increased, the number of calls to poison control centers also increased from 1 call in September 2010 to 215 calls in February 2014. More than half of the calls to poison centers due to e-cigarettes involved children under age 5. In contrast, the number of calls due to cigarette exposure remained constant during this time frame, except for annual peaks in the summer. Tim McAfee, M.D., M.P.H., Director of CDC's Office on Smoking and Health noted that this finding is echoed by the National Youth Tobacco Survey showing that e-cigarette use is growing fast, as is the incidence of e-cigarette related poisonings⁷. Common complaints included vomiting, nausea and eye irritation. At least one suicide from intravenous injection of nicotine liquid was reported⁸. ABC News reported that in Fort Plain, New York, a 1-year old child died after ingesting liquid nicotine⁹.

For these reasons, the Commission on Health recommends passage of Bill 56-14 by the County Council.

Sincerely,



Ron Bialek, MPP, CQIA
Chair, Commission on Health

RB:dk

Cc: Isiah Leggett, County Executive
Uma Ahluwalia, Director Montgomery County DHHS
Dr. Ulder J. Tillman, County Health Officer

⁵ <http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html>

⁶ Kassem, N.O.F., et.al., *Nicotine Tob Res*, 2014 Jul;7:961-975

⁷ <http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html>

⁸ Chatham-Stevens, K, et.al. *Morbidity and Mortality Weekly Report*, 63:13, Apr. 4, 2014, p292

⁹ <http://abcnews.go.com/Health/childs-death-liquid-nicotine-reported-vaping-gains-popularity/story?id=27563788>



American Cancer Society 9
Cancer Action Network
801 Roeder Road, Suite 800
Silver Spring, MD 20910
301.758.1255
www.acscan.org

January 22, 2015

TO: George Leventhal, President
Members Montgomery County Council
FROM: Bonita M. Pennino, MS, Government Relations Director
RE: Bill 56-14, Health and Sanitation Smoking -Electronic Cigarettes
Position: Support with amendments

The American Cancer Society Cancer Action Network (ACS CAN) strongly supports prohibiting the use of electronic smoking devices in restricted areas in parity with traditional tobacco products, as well as prohibiting the sale of E-cigarettes to minors.

The American Cancer Society Cancer Action Network has significant concerns about the potential public health effects of electronic smoking devices such as electronic-cigarettes. There are concerns that they may create new tobacco users, keep people smoking rather than quit, and reverse efforts that have made smoking socially unacceptable. There is still no scientific evidence that electronic smoking devices can help smokers quit. Much more research is needed to determine what ingredients these products contain, how they are being used and what health effects they have on both users and those around the user.

Although ACS CAN supports the inclusion of electronic smoking devices in smoke-free laws, caution must be exercised when opening an existing law to ensure that it is not weakened in any way. In addition, to eliminate any confusion and strengthen the bill, ACS CAN makes the following recommendations:

1. Remove the exemptions for FDA approved electronic cigarettes. If the FDA approves electronic cigarettes as cessation product, allowing their use in public places due to social norming issues, involuntary exposure to aerosol emitted by product, and inability of business owners and public to distinguish between products approved by FDA and those that are not.
2. Amend the definition of smoking devices as follows:
"Electronic Smoking Device" means any product containing or delivering nicotine or any other substance intended for human consumption that can be used by a person to simulate smoking through inhalation of vapor or aerosol from the product. The term includes any such device, whether manufactured, distributed, marketed, or sold as an e-cigarette, e-cigar, e-pipe, e-hookah, or vape pen, or under any other product name or descriptor.
3. Amend the definition of smoking as follows:
"Smoking" means inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, or pipe, or any other lighted or heated tobacco or plant product intended for inhalation, including hookahs and marijuana, whether natural or synthetic, in any manner or in any form. "Smoking" also includes the use of an electronic smoking device which creates an aerosol or vapor, in any manner or in any form, or the use of any oral smoking device for the purpose of circumventing the prohibition of smoking in this Article.
4. Amend the section regarding product placement to include a broad definition of tobacco products. We recommend amending the definition for tobacco products for inclusion in youth access laws is as follows:
"Tobacco product" means:

- *(a) Any product containing, made, or derived from tobacco or nicotine that is intended for human consumption, whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, including, but not limited to cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, snuff, snus; and*
 - *(b) Any electronic device that delivers nicotine or other substances to the person inhaling from the device, including, but not limited to an electronic cigarette, cigar, pipe, or hookah.*
 - *(c) Notwithstanding any provision of subsections (a) and (b) to the contrary, "tobacco product" includes any component, part, or accessory of a tobacco product, whether or not sold separately. "Tobacco product" does not include any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where such product is marketed and sold solely for such an approved purpose.*
5. Amend the section referring to vending machine sales to limit vending machine sales to establishments allowed in places open only to adults.
 6. Include terms "tobacco shop" and "vape shop" in the section referring to "any store where only or primarily tobacco or electronic cigarette products are sold" and restrict minors from entering these establishments, or if minors is allowed require all tobacco products to be placed out of reach and require clerk intervention.
 7. As drafted, section 24-13 page 9 line 118-119 only prohibits use of e-cigarettes by minors and does not prohibit sale to or purchase by minors. Prohibiting sales to minors should be included in the bill language.

Until more research has been done regarding the potential health consequences caused by electronic smoking devices, ACS CAN supports restricting their use in parity with traditional tobacco products. Comprehensive smoke-free laws, along with regularly and significantly increasing the price of all tobacco products, and adequately funding tobacco prevention and cessation programs, are proven, effective ways to reduce tobacco's toll.



Century Distributors, Inc.

15710 Crabbs Branch Way

Rockville, MD 20855-2620

www.centurydist.com

Tel: 301-212-9100 • Fax 301-212-9681

Council Members:

I am here today not to talk about the effects of smoking and whether or not nicotine is an addictive substance.

Today I am here to tell you about a family business right in Montgomery County that I am president of, Century Distributors. What make us unique, we are the only wholesaler of our kind in Montgomery County, with the three owners living and educated in the County. Currently we have 183 employees, a fleet of 45 vehicles, and work out of 100,000 square feet of warehouse space. Most of our employees reside in Montgomery County.

Century's product mix is 82% Tobacco and 18% other consumer goods to retail. Our revenue is dependent on tobacco and now included in that category e-cigarettes. Without the tobacco revenue, I am certain Century would struggle to maintain our current level of viability as a business in Montgomery County.

In addition to the revenue Century derives from tobacco, we are the collecting agent for a significant portion of tax revenue for the State. Century is responsible for affixing the Maryland Tax stamp on each pack of cigarettes, currently at a price of \$2.00 per stamp. In 2014, Century stamped a total of 20,850,000 cigarette packs just for the state of Maryland representing almost \$41 million in revenue which trickles right down to Montgomery County and its residents. That number only represents what Century was responsible for in 2014, not what other wholesalers who provide cigarettes into Maryland.

Why, at this time, do we need another bill to limit where consumers can smoke or vape? Why is this even a discussion? I believe that most adult smokers are aware of where they can, and cannot, smoke. When was the last time someone received a citation for smoking at a bus stop or a public park? I know it is still legal to smoke on a public golf course because of the Montgomery County resident's interest in enjoying a cigar while playing golf. Will this also include vaping?

The FDA has stated on their web site

“it is not known whether e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes,...”

Until the FDA regulates e-cigarettes, it is too soon for Montgomery County to make any regulations.

Having an age restriction is and should be required, for any item with nicotine. Century and all manufactures want all Vaping products to be used only by adults. Vaping products should not be sold to minors.

There are so many vaping devices, but your concern is around open tank systems and all disposable units are closed systems. Are any of you aware of the differences?

Just this past Friday, Gov. Rick Snyder from Michigan vetoed a package of bills seeking to regulate electronic cigarettes because it would not regulate and tax the devices like tobacco products. “We are fully supportive of sensible regulation. We believe it’s an adult product,” McCormick said. “(But) it is not a tobacco product,...” Until the FDA regulates e-cigarettes, it is too soon for Montgomery County to make any regulations.

Debbie Robins
President



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☎ (301) 212-9681

✉ drobins@centurydist.com

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MARYLAND ENVIRONMENTAL HEALTH NETWORK

**Testimony in Support of: Montgomery County Council Bill #56-14
January 22, 2015**

Council President and Members of the Council,

My name is Rebecca Rehr and I am the Public Health Advocacy Coordinator for the Maryland Environmental Health Network. Our work focuses on energy and toxics policy as health policy, with asthma as a particular health outcome of concern. While tobacco policy is slightly outside the scope of our work, we are compelled to submit testimony supporting this bill, as mounting evidence shows the danger of electronic cigarettes to human health and the environment.

Last July, I attended the National Association of City and County Health Officials' (NACCHO) conference, where I learned that although companies producing e-cigarettes claim them as cessation products, none of these companies have actually applied to the FDA to be labeled as such. The entire e-cigarette industry, from production to point-of-sale, is completely bypassing the existing regulatory framework for traditional combustible cigarettes. With no regulation on sales or labeling, teens have started smoking e-cigarettes at astonishing rates. Recent research from the University of Michigan found that twice as many 8th and 10th graders reported smoking an electronic cigarette as a traditional cigarette and 17% of 12th graders had used an electronic cigarette in the previous 30 days, where 14% had smoked a traditional cigarette. E-cigs are now the nicotine delivery method of choice for teens. In addition, without regulations prohibiting smoking e-cigs inside, adults trying to stop smoking traditional cigarettes are just replacing them with e-cigs and are actually getting higher doses of nicotine as they can just take a puff whenever they like, instead of having to go outside to take a smoke break. Most egregious is the increase in the number of calls to poison control centers reporting children's consumption of the liquid nicotine in e-cigarette cartridges. The packaging looks appealing because the nicotine comes in flavors like bubble gum and cherry bomb and the packaging is not always childproof. The nicotine in these cartridges is highly concentrated and wreaks havoc on children's vulnerable systems when they are exposed.

In addition to the health outcomes of concern, there are also a number of unknowns about the environmental impact of e-cigarettes. Nicotine residue and heavy metals may be discarded when the e-cigarette and cartridges get thrown away. If they end up in landfills, they may leach into waterways and poison wildlife. There is no comprehensive recycling program for e-waste and packaging is not required to have proper disposal instructions.

Finally, we are learning more about the ingredients added to the electronic cigarette liquids, including diacetyl and acetyl propionyl. Diacetyl is used in food flavouring (most commonly in the butter flavouring on popcorn) and is safe to be eaten, but when inhaled has adverse effects on the lung. We know this because manufacturers of diacetyl have high rates of a rare lung disease that has come to be known as "popcorn lung." We are now putting products on the market that contain diacetyl in the form in which it is most toxic.

Since e-cigarettes are not regulated on the federal level, it is up to state and local jurisdictions to protect public health and safety. Provisions in this bill would protect children from the harmful effects of e-cigarettes and nicotine cartridges and protect patrons of restaurants and businesses. We applaud the Montgomery County Council for taking up this measure and appreciate this opportunity to provide comment.



Maryland GASP



2

Testimony in support of

Bill 56-14, Health and Sanitation - Smoking - Electronic Cigarettes.

First I would like to thank Council Member Floreen and the other sponsors of this bill for your concern about the health and well being of your constituents.

On behalf of the more than 100 members of the Maryland Group Against Smoker's Pollution who reside in Montgomery County, I ask you to vote for passage of Bill 56-14 as currently drafted for the following reasons. The bill is meant to:

- * Protect people who do not use E-cigarettes from the potential harmful ingredients found in the vapor
- * Protect our children from the misuse of these deadly devices
- * Keep our youth from becoming prematurely addicted to nicotine and possibly even illegal and hallucinogenic drugs like DMT.

Harry Shapiro, from the British charity Drugscope, recently stated that, "e-cigarettes are an ideal tool for consuming a wide spectrum of drugs". He states

"You can adapt those e-cigs to smoke just about anything. Not just what you're supposed to."

Many people believe that E- Cigarettes are harmless. How can anybody reach such a conclusion about a product that is totally unregulated and is primarily manufactured in foreign countries? As a scientist, who has measured the respirable suspended air particulates and the ionization radiation in tobacco smoke, I find this belief to be groundless. Even if some brands of E-cigarettes are less harmful than combustible cigarettes, what is true for one brand is not necessarily true for any other brand.

This legislation does not impose any new restrictions on smokers of normal cigarettes. It simply restricts the use of E-cigarettes to places where normal cigarettes can be used.

Please pass **Bill 56-14** as it is currently written.

Respectfully,

John O' Hara; Ph. D

President

Maryland Group Against Smoker's Pollution

Box 863, Bowie, MD 20718

(P) 301-262-3434

MDGASP@aol.com

**Testimony in Support of Bill 56-14
Health and Sanitation – Smoking – Electronic Cigarettes
January 22, 2015**

Presented by Anne Marie O’Keefe, PhD, JD
Chair, MdPHA Advocacy Committee

Thank you for this hearing today. I am Anne Marie O’Keefe. It is my privilege to teach in the graduate Public Health Program at Morgan State University. I am also very proud to say that I live in Silver Spring, recently selected the *Most Caring Suburb in America*. My family and I have long known that Silver Spring is the best place in the world to live. Thank you for all you have done to preserve and protect the health of Montgomery County residents, and for making it such a privilege to live here.

I am here today representing the Maryland Public Health Association as its Advocacy Committee Chair. MdPHA is the state affiliate of the American Public Health Association, a 142-year-old professional organization with more than 50,000 members. I will testify today only about the pending Bill 56-14 to regulate e-cigarettes. But I want every member of this august body to know that MdPHA believes very strongly in *Health in All Policies*, and we stand ready to assist you in every way that we can to continue your excellent record of protecting the public’s health.

Montgomery County leads the state in many important ways. It ensured the right of its residents to breathe clean indoor air – everywhere – in 2003 – four years before the Maryland General Assembly caught up and did so for the entire state. Hopefully, this Council’s actions on the issue of e-cigarettes will also lead the state to do the right thing.

The manufacturers and sellers of e-cigs – i.e., the Big Tobacco Companies who bring you the conventional cigarettes that kill 440,000 Americans every year – want you to believe that e-cigs are “harmless,” “safe alternatives” to tobacco, and can even help addicted smokers quit.

As was true with tobacco, the promotion of e-cigs is way ahead of reports on the research that honestly examines the health effects of these products. But from all that we know so far, e-cigarettes are certainly *not* safe. Rather:

- E-cigs are designed to deliver nicotine – as former Surgeon General Koop told us long ago, the most addictive drug we know.
- The vapor exhaled by e-cigarette smokers is *not* “pure” or “water.” Rather, it contains nicotine and other toxic and carcinogenic metals and chemicals including tobacco-specific nitrosamines.
- Even short-term exposure to propylene glycol, one of the primary components of the aerosol emitted by e-cigarettes, causes eye, throat and airway irritation. Long-term exposure can result in children developing asthma.

- The secondhand “vapor” from e-cigarettes may not be as dangerous as the secondhand smoke from conventional cigarettes which is estimated to kill 50,000 people every year in this country alone. But that does not make it “safe.” And it does not justify allowing it to pollute our indoor air.

Tobacco companies also want people to believe that e-cigs are really “cessation devices” that will help people kick their tobacco cigarette addictions. This assertion is also ludicrous. Why would tobacco companies manufacture, promote and sell a product designed to put them out of business? And why would their stockholders allow them to do so?

As CNN reported on December 31st, at least 2 million teens have tried or are using e-cigs. They are not doing so to kick conventional cigarette addictions. Teens who might never try conventional cigarettes are being attracted to e-cigs with flavors including “cotton candy,” “cherry crush” and “Gumi Bearz.” In fact, the Centers for Disease Control and Prevention reported that e-cigarette use doubled among middle and high school students between 2011 and 2012. This is not surprising considering that between 2011 and 2013, the number of youths exposed to television ads for e-cigarettes increased 321%.

Because e-cigarettes are not yet regulated by FDA – or any health agency – their quality, their ingredients, and even their levels of nicotine are largely unknown. One of the few things we know for sure is that e-cigs have brought a huge surge in nicotine poisoning. CDC reported in April of last year that e-cigarette related calls to poison centers went from an average of one per month in 2010 to 215 per month in February 2014. More than half of these were about children under the age of five who had been poisoned through ingestion, inhalation and absorption through the skin and eyes.

For all of these reasons, the World Health Organization’s Framework Convention on Tobacco Control recommends regulating e-cigarettes just like conventional cigarettes, including bans on indoor use, advertising restrictions, bans on sales to kids, health warnings, etc. Several jurisdictions across this country have already done so. Thank you again for Montgomery County being in the vanguard of this effort.

There is simply no reason to expose people to airborne toxins, and lead our kids to lifelong addictions, when there are no counterbalancing benefits except profits for the drug dealers who manufacture and sell this product.

Thank you.

Judy E. Ackerman
9305 Friars Road
Bethesda, MD 20817
Jeackerman18@gmail.com

January 16, 2015

The Honorable Nancy Floreen
Montgomery County Council
100 Maryland Avenue
Rockville, MD 20850

Dear Councilmember Floreen,

Thank you for introducing Bill 56-14, legislation that contains a number of provisions related to electronic cigarettes. I am particularly appreciative of the portion that would prohibit the use of electronic cigarettes in public places where traditional tobacco smoking is prohibited. Quite simply, e-cigarettes do give off vapors that many, including me, do not wish to be exposed to. Since there is no regulation of these products, the chemicals and fragrances in these products vary significantly. This makes doing research on the effects of these products on the user and bystanders difficult. Additionally, the use of e-cigarettes makes enforcing existing policies that prohibit smoking very challenging.

Although I am writing this as an individual citizen, I was very involved in the development and implementation of Montgomery College's tobacco-free policy and procedures. There was a dramatic difference in the air quality and cleanliness of our campuses when tobacco-free went into effect at the College. Today, when we see someone who appears to be smoking on campus, we have to go over to that person to determine whether they are smoking or vaping. Currently I can only "suggest" to them that it is inappropriate to vap, since e-cigarettes did not exist when our policy and procedures were approved. Some individuals on our campus challenge us by vaping in buildings. Once again, when they do this, we can only "suggest" that vaping is inappropriate since it resembles smoking, but we really don't have policy, procedure or law to back us.

Once our tobacco-free policy and procedure was in place, I did not receive a single letter or email from students, employees or visitors to the campus that said that they could no longer continue coming to the campus because their medical condition was worsened by going through cigarette smoke to get into buildings. I fear that without

adding e-cigarettes to policies and laws that prohibit or substantially limit smoking, we will once again disenfranchise students, employees and campus visitors who are impacted by e-cigarette vapors. Since September my office has received a number of complaints about e-cigarette use on campus.

A bill such as 56-14 covers public spaces and does not require that policies and procedures for each public space be changed. Thank you for initiating this bill.

Sincerely,

Judy E. Ackerman, Ph.D.

cc: Councilmember Leventhal, President Montgomery County Council

From: de Bari, Heather (NIH/NHLBI) [F]
Sent: Thursday, January 22, 2015 4:40:28 PM
To: County Council
Subject: e-cigarette bill testimony

Heather Kusnetz, PhD

debarih@mail.nih.gov<<mailto:debarih@mail.nih.gov>>

11800 Old Georgetown Rd

Rockville, MD 20852

Bill 56-14 – Nancy Floreen E-Cigarette Bill

Ruthann Eiser or applicable person:

I've been a postdoctoral fellow at the National Institutes of Health for a little over 2 years now, and I have 11 years of experience in the biological sciences. Thank you for the opportunity to put my ideas to written word on the Maryland E-Cigarette Bill (56-14). I wanted to draw your attention to the fact that research on the long-term effects of E-Cigarettes is unavailable and that my statements are based on research to-date.

It's obvious that there's a growing curiosity towards E-Cigarettes among youth. Not surprisingly, E-Cig manufacturers target youth by offering flavorings into e-juices. While flavorings and solvents can be safe when ingested, they can change chemically when heated, resulting in breakdown products that are unsafe to the user.

In this case, a minor or child can self-deliver toxic chemicals through use of an E-Cigarette. Would I want my child or teen to get a hold of E-Cigarettes and use them in an unlimited fashion? Absolutely not, and I think other parents and caregivers would stand beside me in my assertion. Minors should not be allowed to purchase E-Cigs because some E-Cigs do in fact contain nicotine even though they are labeled as nicotine-free. Just to put this into perspective, I wanted to point out that YOUR teen can go to an E-Cigarette kiosk (not in-store) located in the center isle at a mall in Rockville, MD.

I read peer-reviewed, scientific publications, and it is my current understanding that there is no evidence pointing towards e-cigarettes as a viable smoking cessation method. If you are allowed to use E-Cigarettes in public places, why would you have to quit traditional cigarettes? The answer is that you wouldn't have to. In fact, E-Cigarettes are rarely used exclusively; in other words, E-Cigs are often used along with traditional cigarettes, which have been proven to cause cancer.

I boast to friends back in New York State how wonderful Maryland is—how many awesome cultural restaurants you can eat at, and the availability of technology resources, among countless others. I would personally stop going to my favorite restaurant if I saw a sign outside that somehow intimated that E-Cigarettes could be used by customers.

(60)

Let's think about workers for a moment. Workers in restaurants and other public places would be exposed to an unknown amount of secondary nicotine, in addition to fine and ultra-fine particles that can deposit in the lungs. Nicotine has been shown to cause birth defects. Maryland would be taking a step back by allowing E-Cig use in public places because (1) it weakens smoke-free air legislation that lawmakers have worked so hard to enact, and (2) it gives the precedence that we are willing to take a public health risk without explicit ruling from the FDA.

Most people I know DO NOT know that E-Cigarettes are NOT regulated by the FDA. Furthermore, they have been misinformed that E-Cigarette aerosol is simply water vapor. They are confused as to why something resembling a conventional cigarette isn't regulated. All we can do is wait for the official FDA ruling. Until then, we need to protect Maryland Youth and to maintain the highest standards that we can for smoke-free air in the workplace, restaurants, and other public places where our fellow Marylanders frequent.

Thank you for taking the time to read my input on the matter. If you want to see actual numbers, 2 national surveys (one from the CDC and the other from the University of Michigan) have recently posted findings of E-Cigarette use among youth:

<http://www.cdc.gov/tobacco/youth/e-cigarettes/>

<http://www.drugabuse.gov/related-topics/trends-statistics/monitoring-future/monitoring-future-survey-overview-findings-2014>

(look at 'Areas of Concern')

With great concern,

Heather Kusnetz, PhD

*LAW OFFICES
OF
CHARLES FREDERICK CHESTER*

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Charles Frederick Chester (Md., D.C.)

January 22, 2015

BALTIMORE OFFICE

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Hon. George Leventhal, President
Montgomery County Council
50 Maryland Avenue
Rockville, Maryland 20850

Re: Bill No. 56-14 E Cigarettes

Dear President Leventhal:

I Chair the Governor's Council on Fitness, which has a statutory focus on Youth, Schools and Student Health. In addition, I attended Woodward High School in Montgomery County and partially as a result of the emphasis on health and fitness, eventually competed nationally in triathlon and served as a legal counsel to USA Triathlon.


As part of my legal career, I have also served as Counsel to the Montgomery County Senators and former Administrative Assistant to its Chair, former Senator Victor Crawford from District 20. Vic became a national figure in the fight against youth smoking, nicotine addiction and the struggle against The Tobacco Institute, a former law firm client.

The bill sponsored by Councilwoman Nancy Floreen deserves passage, along with any necessary amendments to broaden the definition of "e-cigarette, e-cigar, e-pipe, e-hookah or vape pen" and most importantly, to place an emphasis on what the device really is: a nicotine delivery system.

My reasons are as follows. First, there is already a ban in public places for cigarette smoking. Second, there already is a ban in place against cigarette sales to minors. Thirdly, the device in question is still burning nicotine, an addictive chemical that maintains or attracts a new dependency. As the NIH report to the Council highlighted, 90% of smokers start in their youth and can be lured by these flavored devices into the wrong direction through targeted marketing.

Thank you for your attention. Please continue with the existing public policy that bans sales to minors and any exposure of second hand smoke in public places.

Respectfully Submitted:


Charles F. Chester

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I started smoking when I was 9 years old. 30 years later I had a heart attack and was faced with the choice of life or death. Needless to say it was an easy choice, I chose life. After my heart attack I tried to go cold turkey. I found myself still drawn by the smell of cigarettes and after 5 years of fighting the urge I fell off the wagon, knowing by doing so I was risking my life.

Then I found vaping.

After two weeks of vaping I went to visit my cardiologist. He asked me if I was still smoking. I triumphantly said "No, I am vaping". He told me that's ok. I was surprised by his response and asked him why. He explained to me that nicotine was not the problem, and that it was the combustion of the tobacco that was the problem. I see my cardiologist every 6 months and I've been vaping for over 3 years now, every visit he comes back from my tests saying that I am looking good and doing well. I feel great and the urge to smoke is completely gone.

As an owner of a local vape shop I am rewarded everyday with opportunities to help those in my community to quit smoking. Although my store is new in the area, our company has been able to help thousands of people over the years to find a healthier alternative to cigarettes. I hear stories daily like mine.

To ban vaping in public would be detrimental to public health. When people see me vape they are able to see that there is another way to quit. That there is still hope of a healthier life. Second hand vapor has been proven to be harmless. Studies from Boston University and there is a study in progress at the University of Maryland studying just this subject. I urge you to please consider the stories of the ex-smokers here this evening and use resources like CASAA to learn more.

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Written Testimony to the Montgomery County Council
Bill 56-14
January 22nd, 2015

Dear Councilmembers:

My name is Ronald Ward and I am a life-time resident of Maryland. I am also an electronic cigarette or "e-cigarette" user for the past 5 years and a volunteer, unpaid activist for electronic cigarettes, serving as Director with the non-profit group The Consumer Advocates for Smoke-Free Alternatives Association (CASAA). For the last year I have owned an electronic cigarette retail store in Maryland. I am also a practicing attorney in the State of Maryland.

E-cigarette activists fully support reasonable regulation such as keeping these devices out of the hands of minors and setting e-liquid safety standards but this proposed bill goes too far. I ask that you amend Bill 56-14 to allow for the use of electronic cigarettes in public places.

I. What we know so far

Numerous studies point to electronic cigarettes being up to 99% less harmful than smoking traditional cigarettes. Even the FDA's own study of obsolete vaping devices found no more of particular carcinogens than other FDA-approved nicotine products.

There seems to be no issue with "second hand vape" as there is with cigarettes since 99% of nicotine is absorbed by primary user. Additionally, the vapor leaves no odor on your body, hair or clothes, and the smell does not linger in a room.

Recently, Dr. Igor Burstyn of Drexel University conducted a comprehensive study entitled "Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks". In this study, he compiled the existing data on the subject of electronic cigarettes and concluded that "Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. However, the aerosol generated during vaping as a whole (contaminants plus declared ingredients) creates personal exposures that would justify surveillance of health among exposed persons in

conjunction with investigation of means to keep any adverse health effects as low as reasonably achievable. Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern." <http://www.biomedcentral.com/1471-2458/14/18/>

II. Maryland Legislative History Regarding Electronic Cigarettes

As you are probably aware, the FDA has announced its intent to regulate e-cigarettes as tobacco products. Furthermore, Dr. Pamela Clarke is conducting a study on second hand vapor at the University of Maryland. Dr. Clarke even testified last year against a similar bill proposed in Prince Georges County. In her testimony, she asked the legislature to table the legislation until she has completed her study. The Prince Georges' County Council followed her recommendation and tabled the bill. <http://www.nbcwashington.com/news/local/Md-County-Holds-Off-on-E-Cigarette-Ban-230732221.html>

The State of Maryland has also introduced legislation that would ban the indoor use of these products in 2010 and in 2014. The bill in 2010 died in committee and the bill in 2014 was voted down handily in committee. (http://mgaleg.maryland.gov/2014RS/votes_comm/hb1291_ecm.pdf).

The first bill introduced at the state level was HB 720 which constituted an outright ban of the sale of electronic cigarettes in the State of Maryland (<http://mgaleg.maryland.gov/webmga/frmMain.aspx?tab=subject3&ys=2010rs/billfile/hb0720.htm>). That Bill received an unfavorable report in committee. The second bill in 2010 was SB 989 (<http://mgaleg.maryland.gov/2010rs/bills/sb/sb0989f.pdf>). This bill, for purposes of the Clean Indoor Air Act defined "Smoking" as "the burning of a lighted cigarette, cigar, pipe, or any other matter or substance that contains tobacco OR THE USE OF AN ELECTRONIC SMOKING DEVICE". No action was taken on this bill as it never got past a first reading.

Another relevant piece of legislation that passed in 2012 was HB 1272 which banned the sale of e-cigarettes to minors in the State of Maryland (<http://mgaleg.maryland.gov/webmga/frmMain.aspx?tab=subject3&ys=2012rs/billfile/hb1272.htm>). This bill was passed and became state law.

This 2014 legislative session, one bill was proposed that directly affected e-cigarettes and two that dealt with smokeless tobacco. The Bill was HB 1291 (<http://mgaleg.maryland.gov/webmga/frmMain.aspx?id=hb1291&stab=01&pid=billpage&tab=subject3&ys=2014RS>) (<http://blog.casaa.org/2014/02/call-to-action-maryland-e-cigarette.html>) which would have redefined vaping as smoking for purposes of the Clean Indoor Air Act. The Maryland House Economic Matters Committee, with a large majority, gave the bill an unfavorable report.

In late 2014, the Baltimore City Council introduced Bill 14-0371 <http://legistar.baltimorecitycouncil.com/attachments/11532.pdf>. The Baltimore City Council passed the bill with one major compromise (amongst other compromises). That is, the bill as passed banned the indoor use of electronic cigarettes with exceptions. Those areas

included retail establishments that derive most of their revenue from the sale of electronic cigarettes, bars, restaurants, taverns and casinos. These areas were exempt from the indoor use ban if they prominently displayed signs alerting their patrons that the use of electronic cigarettes is allowed in their establishments.

As you can see, over 5 years of proposed indoor use bans of electronic cigarettes were handily rejected or tabled pending further research by multiple legislatures at the State and local levels. Baltimore City even came to a compromise allowing the use of electronic cigarettes in places where adults congregate.

When the State of Maryland and its municipalities banned smoking in public places, it was based upon real evidence of the harm of second-hand smoke. Bills proposing bans of the indoor use of electronic cigarettes are based on no such evidence. They are predicated upon the mere possibility that second-hand vapor is harmful to bystanders. That is not sufficient evidence to support such a law.

III. Proposed bill

I believe that you should amend Bill 56-14 because it treats electronic cigarettes as if they were a traditional cigarette. This would be, in my humble opinion, a mistake in many ways. Most importantly, it would discourage the use of a product that is allowing smokers to switch to a better alternative. It is in the interests of public health to allow for their availability and use both indoors and outdoors. For the above-mentioned reason, I humbly suggest that the County Council strike the indoor use portion of the bill or, at the least, provide exceptions for places where adults congregate.

If the Committee were to decide to issue a favorable report for this bill, at the minimum, it should allow vaping in establishments that are "adult-only" venues. At the least it should be left to the decision of the owners of the establishment. Many private companies and state agencies in Maryland including schools, hospitals, government buildings have already prohibited the use of electronic cigarettes.

IV. Conclusion

I recommend that the Montgomery County Council amend Bill 56-14 to allow for the use of electronic cigarettes in public places. In the alternative, I recommend that the Committee table this bill until there is proof that second hand vapor, produced by e-cigarettes, is actually harmful to bystanders. If this Council was to adopt this bill, I would ask for exceptions to the law that allows vaping in places where adults congregate.

Sincerely,

Ronald A. Ward Jr., Esq.

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My name is Chris Webber, and I am a lifelong Montgomery County resident; I'd like to first thank you for your time, and, tell you that I greatly appreciate you making the effort to objectively listen to how your constituents feel about bill 56-14. We are all here today because we are interested in protecting and promoting the public health, however, though we share this common goal, it is unclear even from the research provided to the Council by the NIDA how this piece of legislation would improve the public health; it is easy to see however, how it could harm it.

When considering this bill, you must accept a simple fact that is widely agreed upon by experts on both sides of the debate; electronic cigarettes are healthier than tobacco cigarettes. This simple fact has been certified as true by organizations such as the FDA, and most recently by the American Heart Association.

As stated in the Overview from the NIDA, the primary consumer of electronic cigarettes are smokers, and the primary motivations for use is a desire to improve health, and remain indoors without negatively impacting others.

Equating vapor and smoke therefore, not only represents a dangerous moral hazard, but it directly and negatively impacts the public health by removing a primary motivation in making a healthier choice. I can tell you from personal experience, the ability to satisfy my cravings indoors was a major factor in switching from smoke to vapor, and has helped me be tobacco free for 2 years after a 10 year pack a day tobacco habit.

Even though public use bans discourage current smokers from switching to a healthier alternative, proponents of these bans argue that they're warranted because "e-cigarettes re-normalize smoking, and the effects of 2nd hand vapor are unknown. These concerns however, are completely unfounded, and crafting legislation that will do real harm to based off these erroneous assumptions is an abdication of your responsibility to govern based on evidence.

With regards to Renormalizing smoking; In the data provided to you by NIDA it is clear that the vast majority of the population is aware of vapor devices, and common sense will tell you that a device like this, which bears no resemblance to a tobacco cigarette, does nothing to renormalize tobacco use; it only normalizes vaping, which again, is widely agreed upon as a healthier alternative to tobacco use.

With regards to 2nd hand exposure, study after study have been conducted since 2007 looking for a smoking gun, however the only results have been ideologically driven conclusions not supported by the actual data. Of the experiments done, many which were unable to detect anything by propylene glycol and vegetable glycerin, there were a few that found scary sounding compounds such as formaldehyde acrolein, and other Volatile Organic Compound. These studies, which were conducted by researchers who have made careers out of vilifying anything that resembled smoke, conveniently leave out of the headlines however, is that they found these compounds at about the same concentrations you would expect from simply walking around downtown DC or any urban environment.

It is my strong belief that this legislation is based primarily in irrational and unwarranted fear, and it will do more harm than good to the public health by discouraging smokers from adopting a healthier alternative. If the Council does decide to move forward however, I recommend that they take the same sensible approach Baltimore City recently took by amending the bill to allow establishments to opt out of the ban by conspicuously posting signs indicating vapor products are permitted. In this way, Establishments with smoking patrons who wish to promote a healthier lifestyle are free to do so, and patrons with unwarranted fears are equally free to make their own decisions.

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**TESTIMONY OF STEVEN C. WEISS,
Montgomery County Resident**

**Montgomery County Council Public Hearing on Electronic Cigarettes
January 22, 2015**

I'm Steven Weiss, a resident of Kensington since 2001. I work for and volunteer with the American Cancer Society Cancer Action Network, which is formally represented by other speakers at this hearing. I am appearing tonight in my capacity as a private citizen.

I first want to thank the Council for holding this important hearing and inviting residents of the community to speak. I also want to thank Councilmember Floreen for her efforts to address the unregulated use of electronic cigarettes in Montgomery County.

Like many parents, I've seen first-hand how savvy marketing by the e-cigarette industry is misleading kids about electronic tobacco products. I've heard my 11-year-old son assert that e-cigarettes are safer than regular cigarettes. I've seen advertisements for e-cigarettes gain prominence in popular publications such as Sports Illustrated, which arrives at my house each week. And I've witnessed the industry's aggressive marketing tactics in crowded venues right here in Montgomery County.

I was with my family at the busy Westfield Wheaton shopping mall over the holidays and passed a kiosk selling e-cigarettes, apparently to all comers. What really caught my attention was an e-cigarette salesperson taking deep drags from one of his devices and blowing large plumes of aerosol vapor toward the ceiling. This salesperson was clearly trying to be seen by as many holiday shoppers as possible, and he was quite effective, judging from the number of kids and adults who looked over at him as they walked by.

Some people say it's good to expose smokers and would-be smokers to products that could be safer than traditional cigarettes. But science hasn't determined just how dangerous e-cigs are. The fact is we don't know the short-term or long-term health effects of using e-cigarettes. We don't know whether or not they are effective at getting large numbers of people to stop smoking traditional cigarettes, or if they are instead used by most smokers as a convenience in places where they can't light up. We don't know the health impact of e-cigarette vapor on the children and families of people who use these devices.

Here's what is known:

- E-cigarette vapor contains toxic compounds including formaldehyde, which is found in traditional cigarette smoke and is commonly used as an industrial fungicide, germicide, and disinfectant. (Source: National Cancer Institute, <http://1.usa.gov/1hpBunE>)
- More than three-quarters of middle and high school students who report using e-cigarettes also report using conventional cigarettes. (Source: NIH)

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- E-cigarette manufacturers are under no requirement to reveal the ingredients in their products – yet they currently market their products in more than 100 flavors, such as chocolate, fruit, gummi bear, and cotton candy, that appeal to kids.

More studies must be done to determine whether e-cigarettes are less harmful than traditional cigarettes. With scientific evidence lacking, e-cigarette companies have taken full advantage of their deep pockets to market their products in ways that deliberately mislead the public about their health impact. Perhaps worse, e-cigarette companies have gone to great lengths to make smoking “cool” again after years of efforts by the public health community to stigmatize tobacco use. That shouldn’t be a surprise, given that some of the world’s largest tobacco companies, including Philip Morris’ corporate parent Altria and R.J. Reynolds, own e-cigarette brands.

Until now, e-cigarette companies have enjoyed virtually no restrictions on the sale and marketing of their products. As a result, the use of e-cigarettes among youth has more than doubled in a few short years. But in the absence of federal regulation of e-cigarettes, states and communities nationwide are taking action to protect public health by passing e-cig regulations.

Now is the time for Montgomery County to enact its own strong prohibitions on the use, sale, and marketing of e-cigarettes. Councilmember Floreen’s bill could go a long way toward protecting kids from these potentially harmful products. But it needs to be strengthened to achieve its desired result. For example:

- E-cigarettes must be treated like other tobacco products so they are covered by smoke-free workplace laws that protect the health of workers.
- The prohibition on minors using e-cigarettes must be accompanied by a ban on the sale of e-cigarettes to minors.
- Businesses that sell e-cigarettes and similar products must be required to place them out of the reach of kids.

My colleagues from the American Cancer Society Cancer Action Network have detailed these and other important amendments that will ensure the bill is effective and achieves its intended purpose.

I encourage the Council to adopt these amendments and a pass strong bill that will protect my kids and children throughout Montgomery County from the potential dangers of e-cigarettes.

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WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

**Conference of the Parties to the
WHO Framework Convention
on Tobacco Control**

Sixth session
Moscow, Russian Federation, 13–18 October 2014
Provisional agenda item 4.4.2

FCTC/COP/6/10
21 July 2014

Electronic nicotine delivery systems

Report by WHO

INTRODUCTION

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fifth session (Seoul, Republic of Korea, 12–17 November 2012) to the Convention Secretariat to invite WHO to examine emerging evidence on the health impacts of electronic nicotine delivery systems (ENDS) use and to identify options for their prevention and control, for consideration at the sixth session of the COP.¹ This report incorporates the December 2013 deliberations and scientific recommendations on ENDS by the WHO Study Group on Tobacco Product Regulation (TobReg), and analysis from a recent WHO survey on tobacco products.²

2. ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased. Whereas some experts welcome ENDS as a pathway to the reduction of tobacco smoking, others characterize them as products that could undermine efforts to denormalize tobacco use. ENDS, therefore, represent an evolving frontier, filled

¹ See decision FCTC/COP5(10).

² The WHO tobacco products survey on smokeless, electronic nicotine delivery systems, reduced ignition propensity cigarettes, and novel tobacco products was sent to all WHO Member States. A total of 90 WHO Member States, including 86 Parties to the WHO FCTC, had responded to the survey as at 9 April 2014. These countries are: Australia, Austria, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Bhutan, Bolivia (Plurinational State of), Botswana, Brazil, Brunei Darussalam, Cambodia, Canada, Chile, China, Colombia, Congo, Costa Rica, Croatia, Czech Republic, Djibouti, Dominica, Ecuador, Egypt, Estonia, Fiji, Finland, France, Gabon, Georgia, Ghana, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Japan, Jordan, Kenya, Kuwait, Lao People's Democratic Republic, Latvia, Lebanon, Lithuania, Malaysia, Maldives, Mali, Mauritania, Mongolia, Morocco, Myanmar, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Philippines, Poland, Qatar, Republic of Korea, Russian Federation, Slovakia, South Sudan, Spain, Sudan, Suriname, Sweden, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, Tuvalu, United Arab Emirates, United States of America, Uruguay, Uzbekistan, Viet Nam, and Zambia.

with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates. The evidence and recommendations presented in this report are therefore subject to rapid change.

PRODUCT DESIGN AND CONTENTS

3. ENDS, of which electronic cigarettes are the most common prototype, deliver an aerosol by heating a solution that users inhale. The main constituents of the solution by volume, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents.

4. Although some ENDS are shaped to look like their conventional tobacco counterparts (e.g. cigarettes, cigars, cigarillos, pipes, or hookahs), they also take the form of everyday items such as pens, USB memory sticks, and larger cylindrical or rectangular devices.

5. Battery voltage and unit circuitry differences can result in considerable variability in the products' ability to heat the solution to an aerosol and, consequently, may affect delivery of nicotine and other constituents, and may contribute to the formation of toxicants in the emissions.

6. User behaviour may affect nicotine absorption – length of puffs, depth of inhalation and frequency of use may be factors. However, while a faster, deeper puff increases nicotine delivery from a conventional cigarette, it might diminish it from ENDS due to cooling of the heating element.

7. In addition to manufacturer differences, some users modify products at home to alter delivery of nicotine and/or other drugs. Products vary widely in the ease with which they can be modified and the ease with which they can be filled with substances other than nicotine solutions.

THE ENDS MARKET

8. The use of ENDS is apparently booming. It is estimated that in 2014 there were 466 brands¹ and that in 2013 US\$ 3 billion was spent on ENDS globally. Sales are forecasted to increase by a factor of 17 by 2030.² Despite this projection, transnational tobacco companies are divided about the prospects of the growth of ENDS sales and some companies have reported a slowdown in sales in some markets.^{3,4,5} There are no data on ENDS use at the global level and for many countries. However, data mainly from North America, the European Union (EU) and Republic of Korea indicate that ENDS use at least doubled among both adults and adolescents from 2008 to 2012.⁶ In 2012, 7% of EU citizens aged 15 years and over had tried electronic cigarettes. However, only 1% of the total population used them regularly.⁷ In 2013, 47% of smokers and ex-smokers in the United States of

¹ Zhu S-H, Sun JY, Bonnevie E, Cummins SE, Gamst A, Yin L, Lee M. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control*. 2014;23:iii3–iii9. doi:10.1136/tobaccocontrol-2014-051670.

² The tobacco industry at a crossroads: cigarettes growth falters as focus falls on alternatives. Euromonitor international. July 2013

³ Evans P. E-cigarettes are the future? Not so fast, says BAT's boss. *Wall Street Journal*. 30 July 2014 (<http://blogs.wsj.com/corporate-intelligence/2014/07/30/e-cigs-are-the-future-not-so-fast-says-bats-boss/>)

⁴ Prior A. Lorillard profit down as e-cigarette sales drop: electronic cigarette sales tumble 35%, offsetting slight increase in traditional cigarettes. *Wall Street Journal*. 30 July 2014 (<http://online.wsj.com/articles/lorillard-profit-down-as-e-cigarette-sales-drop-1406720447>).

⁵ Wile R. Citi e-cigarettes: the e-cigarette boom is over. *Business Insider*. 15 May 2014 (<http://www.businessinsider.com/citi-ecigarette-growth-slows-2014-5>).

⁶ Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

⁷ Attitudes of Europeans towards tobacco (Special Eurobarometer 385). European Commission, May 2012.

America had tried e-cigarettes, but prevalence of established use was 4% in this group.¹ Users report that the main reasons for using ENDS are to reduce or stop smoking and because they can be used in smoke-free places.²

9. According to the recent WHO survey, ENDS availability is widespread. Slightly over half of the world's population live in 62 countries that report the availability of ENDS in their jurisdictions, 4% live in countries reporting that ENDS are not available, while the rest live in countries that did not respond concerning the availability of ENDS.

10. Recently, the transnational tobacco companies have entered the ENDS market. Some of them are aggressively competing with the independent companies to gain market share. Given the economic power of the tobacco industry, recent moves to sue other companies alleging patent infringement may be an indicator of how difficult it will be for ENDS to remain a business niche dominated by independent companies.

QUESTIONS RELATED THE USE OF ENDS

11. Questions have been articulated in three groups:

- (a) health risks to users and non-users;
- (b) efficacy in helping smokers to quit smoking and ultimately nicotine dependence; and
- (c) interference with existing tobacco-control efforts and implementation of the WHO FCTC.

Health risks to users and non-users

12. Most ENDS products have not been tested by independent scientists but the limited testing has revealed wide variations in the nature of the toxicity of contents and emissions.

13. Health risks from nicotine inhalation are affected by several factors.

- (a) The capacity of ENDS to deliver nicotine to the user varies widely, ranging from very low to levels similar to that of cigarettes, depending on product characteristics, user puffing behaviour and nicotine solution concentration.
- (b) Nicotine is the addictive component of tobacco. It can have adverse effects during pregnancy and may contribute to cardiovascular disease. Although nicotine itself is not a carcinogen, it may function as a "tumour promoter".³ Nicotine seems involved in fundamental aspects of the biology of malignant diseases, as well as of neurodegeneration.

¹ Giovenco DP, Lewis MJ, Delnevo CD. Factors associated with e-cigarette use. *American Journal of Preventive Medicine*. Published online, 27 May 2014. doi: <http://dx.doi.org/10.1016/j.amepre.2014.04.009>.

² Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

³ Nicotine alters essential biological processes like regulation of cell proliferation, apoptosis, migration, invasion, angiogenesis, inflammation and cell-mediated immunity in a wide variety of cells including fetal, embryonic and adult stem cells, adult tissues as well as cancer cells.

- (c) The evidence is sufficient to caution children and adolescents, pregnant women, and women of reproductive age about ENDS use because of the potential for fetal and adolescent nicotine exposure to have long-term consequences for brain development.¹

14. The main health risk from nicotine exposure other than through inhalation is nicotine overdose by ingestion or through dermal contact. Since most countries do not monitor these incidents the information is very scarce. Reports from the United States and the United Kingdom nonetheless indicate that the number of reported incidents involving nicotine poisoning has risen substantially as the use of ENDS has increased. The actual number of cases is probably much higher than those reported.

15. Evidence concerning the health risks resulting from chronic inhalation of toxicants in aerosol to ENDS users are described below.

- (a) Short-term effects of ENDS use include eye and respiratory irritation caused by exposure to propylene glycol. Serious short-term health problems may occur but are very rare.
- (b) Given the relatively recent entry of ENDS into the market and the lengthy lag time for onset of many diseases of interest,² such as cancer, conclusive evidence about the association of ENDS use with such diseases will not be available for years or even decades.
- (c) However, evidence based on the assessment of the chemical compounds in the liquids used in and aerosol produced by ENDS indicate:
- (i) potential cytotoxicity of some solutions that have raised concerns about pregnant women who use ENDS or are exposed to second-hand ENDS aerosol.³ Cytotoxicity was related to the concentration and number of flavourings used in the e-liquid;
 - (ii) the aerosol usually contains some carcinogenic compounds and other toxicants found in tobacco smoke at average levels of 1–2 orders of magnitude lower than in tobacco smoke, but higher than in a nicotine inhaler. For some brands, the level of some of these cancer causing agents, such as formaldehyde and other toxicants like acrolein have been found to be as high as in the smoke produced by some cigarettes;⁴
 - (iii) the range of size of particles delivered by ENDS is similar to that of conventional cigarettes, with most particles in the ultrafine range (modes around 100–200 nm) compared to the bigger size found in cigarette smoke. However, ENDS generate lower level of particles than cigarettes.⁵
- (d) Therefore, it is very likely that average ENDS use produces lower exposures to toxicants than combustible products.

16. Evidence concerning the health risks resulting from inhalation of second-hand ENDS aerosol by non-users are described below.

¹ The health consequences of smoking – 50 years of progress. A report of the Surgeon General. Rockville (MD); US Department of Health and Human Services: 2014 (p.126).

² Including the lack of agreed early biomarker changes to assess potential harms.

³ Bahl V, Lin S, Xu N, Davis B, Wang Y. Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. *Reproductive Toxicology*. 2012;34:529–37.

⁴ Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control*. 2014;23(2):133–139. doi:10.1136/tobaccocontrol-2012-050859.

⁵ Schripp T., D. Markewitz, E. Uhde, and T. Salthammer. Does e-cigarette consumption cause passive vaping? *Indoor Air*. 2013;23(1):25–31.

(a) Bystanders are exposed to the aerosol exhaled by ENDS users, which increases the background level of some toxicants,^{1,2} nicotine³ as well as fine and ultrafine particles in the air. Nevertheless the level of toxicants, nicotine and particles emitted from one ENDS is lower than that of conventional cigarette emissions.⁴ It is not clear if these lower levels in exhaled aerosol translate into lower exposure, as demonstrated in the case of nicotine. Despite having a lower levels of nicotine than in second-hand smoke, the exhaled ENDS aerosol results in similar uptake as shown by similar serum cotinine levels.⁵

(b) It is unknown if the increased exposure to toxicants and particles in exhaled aerosol will lead to an increased risk of disease and death among bystanders as does the exposure to tobacco smoke. However, epidemiological evidence from environmental studies shows adverse effects of particulate matter from any source following both short-term and long-term exposures. The low end of the range of concentrations at which adverse health effects has been demonstrated is not greatly above the background concentration, which for particles smaller than 2.5 µm has been estimated to be 3–5 µg/m³ and increases with dose, which means that there is no threshold for harm and that public health measures should aim at achieving the lowest concentrations possible.⁶

17. In summary, the existing evidence shows that ENDS aerosol is not merely “water vapour” as is often claimed in the marketing for these products. ENDS use poses serious threats to adolescents and fetuses. In addition, it increases exposure of non-smokers and bystanders to nicotine and a number of toxicants. Nevertheless, the reduced exposure to toxicants of well-regulated ENDS used by established adult smokers as a complete substitution for cigarettes is likely to be less toxic for the smoker than conventional cigarettes or other combusted tobacco products. The amount of risk reduction, however, is presently unknown. The 2014 Surgeon General’s Report concluded that non-combustible products such as ENDS are much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced.

Efficacy in helping smokers to quit smoking and ultimately nicotine dependence

18. Although anecdotal reports indicate that an undetermined proportion of ENDS users have quit smoking using these products their efficacy has not been systematically evaluated yet. Only a few studies have examined whether the use of ENDS is an effective method for quitting tobacco smoking.

¹ Under near real-use conditions, e-cigarettes increased indoor air levels of polycyclic aromatic hydrocarbons, 1,2-propanediol, 1,2,3-propanetriol, glycerine, and aluminium.

² Schober W, Szendrei K, Matzen W, Osiander-Fuchs H, Heitmann D, Schettgen T et al. Use of electronic cigarettes (e-cigarettes) impairs indoor air quality and increases FeNO levels of e-cigarette consumers. *International Journal of Hygiene and Environmental Health*. 2014;217(6):628–37. doi:10.1016/j.ijheh.2013.11.003.

³ Czogala JI, Goniewicz ML, Fidelus B, Zielinska-Danch W, Travers MJ, Sobczak A. Secondhand exposure to vapors from electronic cigarettes. *Nicotine and Tobacco Research*. 2014;16(6):655–62. doi: 10.1093/ntr/ntt203.

⁴ McAuley TR, Hopke PK, Zhao J, Babaian S. Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhalation Toxicology*. 2012;24(12):850-7.

⁵ Flouris AD, Chorti MS, Poulianiti KP, Jamurtas AZ, Kostikas K, Tzatzarakis MN et al. Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function. *Inhalation Toxicology*. 2013;25(2):91–101. doi: 10.3109/08958378.2012.758197.

⁶ WHO air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide: summary of risk assessment. Geneva: World Health Organization; 2006.

⁷ The health consequences of smoking – 50 years of progress: a report of the Surgeon General. Atlanta (GA): US Department of Health and Human Services; 2014 (p. 874).

19. The evidence for the effectiveness of ENDS as a method for quitting tobacco smoking is limited and does not allow conclusions to be reached. However, the results of the only randomized control trial that compared use of ENDS, with or without nicotine, to use of nicotine patches without medical assistance in the general population, showed similar, although low, efficacy for quitting smoking.¹ A recent study also shows some, although limited, effectiveness in real-world conditions.²

20. At this level of efficacy, the use of ENDS is likely to help some smokers to switch completely from cigarettes to ENDS. However, for a sizeable number of smokers ENDS use will result in the reduction of cigarette use rather than in quitting. This will lead to dual use of ENDS and cigarettes. Given the likely greater importance of duration of smoking (number of years smoking) over intensity (number of cigarettes smoked per day) in generating negative health consequences, dual use will have much smaller beneficial effects on overall survival compared with quitting smoking completely.³

21. No ENDS product has yet been evaluated and approved for smoking cessation by a governmental agency, although the United Kingdom's Medicines and Healthcare Products Regulatory Agency is in the process of reviewing some of these products.

22. In considering ENDS as a potential cessation aid, smokers should first be encouraged to quit smoking and nicotine addiction using a combination of already approved treatments. However, at the individual level, experts suggest that in some smokers who have failed treatment, have been intolerant to it or who refuse to use conventional smoking cessation medication, the use of appropriately-regulated ENDS may have a role to play in supporting attempts to quit.^{4,5}

Impact on existing tobacco-control efforts

23. Although ENDS present a range of potential benefits to smokers, there is an extensive and often heated debate about whether ENDS will prove to have a positive or negative impact on population health and particularly tobacco control. Areas of legitimate concern include avoiding nicotine initiation among non-smokers and particularly youth while maximizing potential benefits for smokers. Such concerns are referred to as the gateway and renormalization effects.

24. Gateway and renormalization concerns.

(a) The gateway effect refers to two potential circumstances:

- (i) the possibility that children (and generally non-smokers) will initiate nicotine use with ENDS at a rate greater than expected if ENDS did not exist;⁶ and
- (ii) the possibility that once addicted to nicotine through ENDS children will switch to cigarette smoking.

¹ Bullen CB, Howe C, Laugesen M, McRobbie H, Parag V, Williman J et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*. 2013;382(9905):1629–37.

² Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction*. Published online, 20 May 2014. doi:10.1111/add.12623.

³ The health consequences of smoking – 50 years of progress: a report of the Surgeon General. Atlanta (GA): US Department of Health and Human Services; 2014.

⁴ Fiore MC, Schroeder SA, Baker TB. Smoke, the chief killer – strategies for targeting combustible tobacco use. *New England Journal of Medicine*. 2014;370(4):297–9. doi: 10.1056/NEJMp1314942.

⁵ Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

⁶ this This does not mean that use of ENDS by children is not a concern in itself.

(b) The renormalization effect refers to the possibility that everything that makes ENDS attractive to smokers may enhance the attractiveness of smoking itself and perpetuate the smoking epidemic. ENDS mimic the personal experience and public performance of smoking and their market growth requires marketing that is challenging commercial communication barriers erected to prevent the promotion of tobacco products.

(c) The likelihood and significance of these two effects occurring will be the result of a complex interplay of individual, market and regulatory factors and is difficult to predict. They can only be assessed with empirical data, which at present are virtually non-existent.

(d) The limited existing survey data from a handful of countries show that experimentation with ENDS is increasing rapidly among adolescents and that in itself is of great concern even if most of the young ENDS users also smoke. In fact, except in one case, the surveys show that there are few exclusive ENDS users who have never smoked (mostly around 1% of the population).^{1,2,3} These data do not allow the conclusions to be drawn as to whether this is a sign of adolescent smokers switching to ENDS, an established pattern of dual use, or a temporary experimentation fashion. Therefore, in the absence of longitudinal data, existing evidence does not allow an affirmation or rejection of the role of ENDS in increasing nicotine addiction among adolescents above existing uptake rates, much less as to whether ENDS lead to smoking in these countries. Among adults the pattern of dual use seems also the predominant one, resulting in a reduction of smoked cigarettes and with few never smokers starting to use ENDS (below 1% of the population).^{4,5}

(e) There are also very limited data from very few countries about the evolution of the smoking epidemic in the presence of the ENDS boom. In one country (United Kingdom), where tobacco-control measures are very strong and ENDS use is popular and growing, it seems that smoking prevalence, cigarette consumption as well as overall nicotine use continues to decrease gradually.⁶ Whether these contrasting trends are causally related cannot be concluded from these data. At least for the United Kingdom, renormalization as measured by prevalence of smoking is not occurring currently. Whether this would be the case for other countries cannot be generalized from the existing data and needs to be proven empirically.

25. More specific public health questions related to the interaction between ENDS and tobacco-control efforts are discussed below.

26. Positioning the tobacco-control message: The entry of ENDS in the market has created challenges to the core message of tobacco control, which until now has been that tobacco use should

¹ Calculations based on Centers for Disease Control and Prevention reported data from the United States National Youth Tobacco Survey, contained in: Corey C, Wang B, Johnson SE, Apelberg B, Husten C, King BA et al. Notes from the field: electronic cigarette use among middle and high school students – United States, 2011–2012. *Morbidity and Mortality Weekly Report*;62(35):729–30.

² Lee S, Grana RA, Glantz SA. Electronic cigarette use among Korean adolescents: a cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking. *Journal of Adolescent Health*. Published online, 22 November 2013. doi: <http://dx.doi.org/10.1016/j.jadohealth.2013.11.003>.

³ Lukasz Goniewicz M, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. *Pediatrics*. Published online, 17 September 2012. doi:10.1542/peds.2011-3448.

⁴ Sutkina EL, McCoy TP, Morrell HER, Hoepfner BB, Wolfson M. Electronic cigarette use by college students. *Drug and Alcohol Dependence*. 2013;131(3):214–221. <http://dx.doi.org/10.1016/j.drugalcdep.2013.05.001>.

⁵ ASH UK fact sheet. Use of electronic cigarettes in Great Britain. April 2014. Available from: http://www.ash.org.uk/files/documents/ASH_891.pdf.

⁶ West R, Brown J, Beard E. Smoking toolkit study. Trends in electronic cigarette use in England. Updated 4th April 2014. Available from: <http://www.smokinginengland.info/latest-statistics/>.

not be started and if started it should be stopped.¹ The promotion of ENDS comes with at least one of the following messages or a combination of them: (a) try to quit smoking and if everything fails use ENDS as the last resort; (b) you do not need to quit nicotine addiction, just smoking; and (c) you do not need to quit smoking, use ENDS where you cannot smoke. Some of these messages are difficult to harmonize with the core tobacco-control message and others are simply incompatible.

27. The role of the tobacco industry: The future role of ENDS is strongly determined by the commercial interests of the industry that manufactures and sells ENDS. While there are “independent” ENDS companies that have reported no interest in perpetuating tobacco use, the tobacco industry involved in the production and sale of ENDS certainly is.

(a) The ENDS market, initially dominated by companies with no links to the tobacco industry, is increasingly owned by the tobacco industry. All main transnational tobacco companies sell ENDS and one of them is launching legal proceedings over patents against its rivals as they become increasingly aggressive in the battle for the fast-growing e-cigarette market. The increasing concentration of the ENDS market in the hands of the transnational tobacco companies is of grave concern in light of the history of the corporations that dominate that industry.

(b) It is unclear yet what this means for the ENDS market. However, if prior interest of the tobacco industry in reduced-risk products serves as a precedent, their interest lies in maintaining the status quo in favour of cigarettes for as long as possible, while simultaneously providing a longer-term source of profit should the cigarette model prove unsustainable. In addition, selling these products is intended to bring reputational benefits to these companies, as they can pretend to be part of the solution to the smoking epidemic.² ENDS may follow the trend of smokeless tobacco wherein the industry’s historic interest in smokeless tobacco products outside some Nordic countries was both because they could be used in smoke-free environments and because they could be promoted to young, non-tobacco users to create a new form of tobacco use.³

28. Potential interference with smoke-free policies.

(a) Smoke-free policies are designed not only to protect non-smokers from second-hand smoke, but also to provide incentives to quit smoking and to denormalize smoking as adolescents are particularly vulnerable to visual cues and social norms.⁴

(b) The use of ENDS in places where smoking is not allowed

- (i) increases the exposure to exhaled aerosol toxicants of potential harm to bystanders,
- (ii) reduces quitting incentives, and
- (iii) may conflict with the smoking denormalizing effect.

(c) Many ENDS look like smoking products and even if they do not resemble them, the exhaled vapour looks like tobacco smoke. ENDS are marketed to be used where smoking is

¹ de Andrade M, Hastings G, Angus K, Dixon D, Purves R. The marketing of electronic cigarettes in the UK. London: Cancer Research UK; November 2013.

² Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry’s use of the term tobacco harm reduction in order to inform public health policy. Tobacco Control. Published online, 22 January 2014. doi:10.1136/tobaccocontrol-2013-051502.

³ Mejia AB, Ling PM. Tobacco industry consumer research on smokeless tobacco users and product development. American Journal of Public Health. 2010;100(1):78–87. doi: 10.2105/AJPH.2008.152603.

⁴ Preventing tobacco use among youth and young adults. A report of the Surgeon General. Rockville (MD); US Department of Health and Human Services: 2012.

prohibited and given the resemblance to tobacco products it is likely that their use where smoking is banned will make enforcing smoke-free policies more difficult.

(d) The fact that ENDS exhaled aerosol contains on average lower levels of toxicants than the emissions from combusted tobacco does not mean that these levels are acceptable to involuntarily exposed bystanders. In fact, exhaled aerosol is likely to increase above background levels the risk of disease to bystanders, especially in the case of some ENDS that produce toxicant levels in the range of that produced by some cigarettes.

29. The role of ENDS marketing (which falls into two categories: consumer marketing aimed at the general public, and stakeholder marketing aimed at policy-makers and public health bodies):

(a) ENDS are being marketed to consumers in many media and forms, including television commercials, sports and cultural sponsorship, celebrity endorsement, social networking, online advertising, point-of-sale displays, pricing strategies, and product innovation. Some marketing clearly emulates the very successful tobacco advertising asserting an independent identity and a lifestyle choice, aligning oneself with celebrities, fashionable and youthful places and activities. Some ENDS are marketed not only as socially acceptable but as socially superior. Unsubstantiated or overstated claims of safety and cessation are frequent marketing themes aimed at smokers. Some ENDS marketing also promotes long-term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned. ENDS marketing activities have the potential to glamorize smoking and attracting children and non-smokers even if those are unintentional results. However, no empirical studies have been conducted to show whether the negative prospects of ENDS marketing are actually directly associated with attitudinal and behavioural changes among children and non-smokers consistent with the realization of such potential. Concerns have also been raised over the use of flavours in the marketing of ENDS. One recent study indicates that ENDS are marketed in 7764 unique flavours.³ Although the role of ENDS flavours potential attractiveness has not been studied yet, expert opinion indicates that candy-like flavours could entice youths to experiment with ENDS and could also facilitate the development of tobacco dependence by enhancing the sensory rewards of ENDS use.¹ The tobacco industry's internal documents suggest that flavouring agents have played an important role in the industry's targeting of children and youth, and there is a concern that they could play the same role in the uptake of ENDS in these age groups.

(b) The marketing message to tobacco-control stakeholders is one of alignment of industry and public health interests based on the harm reduction potential of ENDS. This leads to a proposal of partnership between government and industry because industry claims a meaningful seat at the table in the so-called harm reduction debate.

CURRENT REGULATION AND POLICY: RESULTS OF THE WHO SURVEY

30. Table 1 reflects the results of the 2014 WHO survey, showing the distribution of countries according to the regulatory approach taken to ENDS.

Type of ENDS	ENDS regulated as					Not regulated or unknown
	consumer product	therapeutic product	tobacco product	other	total	
With nicotine	14 (27%)*	12 (6%)	22 (10%)	11 (6%)	59 (49%)	135 (51%)
Without nicotine	23 (35%)	0 (0%)	18 (7%)	12 (2%)	53 (44%)	141 (56%)

¹ The scientific basis of tobacco product regulation: a WHO Study Group on Tobacco Product Regulation report. Candy-flavoured tobacco products: research needs and regulatory recommendations. Geneva; World Health Organization: 2007 (WHO Technical Report Series 945).

* The figure in parentheses after the number of countries indicates the percentage of the world population living in these countries.

31. The sale of ENDS with nicotine is banned in 13 of the 59 countries that regulate them. However, the majority of these 13 countries report that ENDS are available to the public, probably through illicit trade and cross-border Internet sales.

32. The survey also shows that:

- (a) comprehensive advertising, promotion and sponsorship bans on ENDS are in place in 39 countries (in which 31% of the world's population live);
- (b) use of ENDS in enclosed public places is banned in 30 countries (35%);
- (c) premarket review is required by 19 countries (5%);
- (d) vendor licences are required by nine countries (4%);
- (e) policies on ENDS sales to minors were confirmed by 29 countries (8%). Where specified, minimum required age for purchase ranged from 18 to 21 years.

GENERAL CONSIDERATIONS

33. Smokers will obtain the maximum health benefit if they completely quit both tobacco and nicotine use. In fact, Article 5.2(b) of the Convention commits Parties not only to preventing and reducing tobacco consumption and exposure to tobacco smoke but also to preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not.

34. The rapid growth of ENDS use globally can neither be dismissed nor accepted without efforts to appropriately regulate these products, so as to minimize consequences that may contribute to the tobacco epidemic and to optimize the potential benefits to public health. Thus it is important to identify public health concerns and to consider these concerns when undertaking regulation and surveillance.

35. Regulation of ENDS is a necessary precondition for establishing a scientific basis on which to judge the effects of their use, and for ensuring that adequate research is conducted, that the public has current, reliable information as to the potential risks and benefits of ENDS, and that the health of the public is protected. Public health authorities need to prioritize research and invest adequately to elucidate evidentiary uncertainties as soon as possible. However, the greater responsibility to prove claims about ENDS scientifically should remain with the industry.

36. When designing a regulatory strategy for ENDS, governments should bear in mind the following general regulatory objectives:

- (a) impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;
- (b) minimize potential health risks to ENDS users and non-users;
- (c) prohibit unproven health claims from being made about ENDS; and
- (d) protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.

37. Because the product, the market and the associated scientific evidence surrounding ENDS are all evolving rapidly, all legislation and regulations related to ENDS should be adaptable in response to

new scientific evidence, including evaluation of different models for ENDS regulation, as evidence accumulates.

38. Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of ENDS will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realized.

SPECIFIC REGULATORY OPTIONS

39. In order to achieve the general regulatory objectives mentioned above, Parties that have not banned the sale of ENDS could consider the following non-exhaustive list of regulatory options, on the understanding that the advisability and feasibility at country level of each of these options will depend on a complex set of country-specific factors, including the existing regulatory frameworks and the legal exigencies of the regulatory process.

40. **Health claims.** Prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids, until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval. The regulatory standard for cessation claims and approval as cessation aids should remain an appropriate body of evidence, based on well-controlled clinical trials. For ENDS products to be approved for smoking cessation by the suitable regulatory agency, the appropriate balance should be reached between providing accurate scientific information to the public about the risks of ENDS use and its potential benefits as compared with smoking. This balance can only be determined through scientifically tested audience messaging.

41. **Use of ENDS in public places.** Since the reasonable expectation of bystanders is not a diminished risk in comparison to exposure to second-hand smoke but no risk increase from any product in the air they breathe, ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapour is proven to be not harmful to bystanders and reasonable evidence exists that smoke-free policy enforcement is not undermined. If smoke-free legislation is not fully developed according to Article 8 of the WHO FCTC and the guidelines for its implementation, this should be done as soon as possible.

42. **Advertising, promotion and sponsorship.** Given that the same promotional elements that make ENDS attractive to adult smokers could also make them attractive to children and non-smokers, Parties should contemplate putting in place an effective restriction on ENDS advertising, promotion and sponsorship. Some forms of ENDS promotion, however, may be considered acceptable by Parties if empirical evidence shows that ENDS might play a role in helping some smokers to quit without leading to increased ENDS use by minors and non-smokers who otherwise would not have used nicotine.

43. Any form of ENDS advertising, promotion and sponsorship must be regulated by an appropriate governmental body. If this is not possible, an outright ban on ENDS advertising, promotion and sponsorship is preferable to the implementation of voluntary codes on ENDS marketing, given the overwhelming evidence that similar codes for tobacco and alcohol products have failed to protect young people from such advertising.

44. Advertising, promotion and sponsorship of ENDS with or without nicotine, must, at a minimum:

- (a) state clearly whether the product contains nicotine or may be used with nicotine solutions;
- (b) not make them appealing to or target, either explicitly or implicitly, non-smokers or non-nicotine users, and must therefore indicate that ENDS are not suitable for use by people who do not currently consume tobacco products;

- (c) not make them appealing to or target, either explicitly or implicitly, minors, including through the selection of media, location or the context in which they appear or through imagery that promotes sexual or sporting prowess;
- (d) never promote ENDS for non-smokers, and their use should not be portrayed as a desirable activity in its own right;
- (e) encourage smoking cessation and provide a quitline number if one exists;
- (f) contain nothing that could reasonably be expected to promote the use of tobacco products, such as:
 - (i) the appearance or/and use of tobacco products;
 - (ii) the use of any brand name, design, colour, emblem, trademark, logo or trade insignia or any other distinctive feature that might be associated by the audience with a tobacco product;
 - (iii) the use of the words e-cigarette, electronic cigarette, or any other descriptor that might reasonably be expected to create confusion with the promotion of cigarettes and other combustible tobacco products;
 - (iv) showing ENDS products in ways that could reasonably be expected to promote tobacco products, including images of tobacco-like products;
- (g) not contain health or medicinal claims, unless the product is licensed for those purposes by the appropriate regulatory agency. Electronic cigarettes and other nicotine-containing products should be presented only as an alternative to tobacco, and should include warnings that dual use will not substantially reduce the dangers of smoking;
- (h) not undermine any tobacco-control measure, including by not promoting the use of ENDS in places where smoking is banned;
- (i) include factual information about product ingredients other than nicotine and in a way that does not distort evidence of risks;
- (j) not link these products with gambling, alcohol, illicit drugs or with activities or locations in which using them would be unsafe or unwise.

45. Advertising, promotion and sponsorship of ENDS that contain nicotine or may be used with nicotine solutions must:

- (a) clearly state the addictive nature of nicotine and that these products are intended to deliver nicotine;
- (b) Prohibit suggestions that ENDS have positive qualities as a consequence of the addictive nature of the product.

46. All authorized forms of ENDS advertising, promotion and sponsorship must be cleared by the appropriate authority prior to publication/transmission in order to proactively prevent inappropriate marketing, and then be monitored to assess compliance.

47. **Protection from vested commercial interests.** Transparency should be required from ENDS and tobacco companies advocating for and against legislation and regulation, both directly and through third parties. No matter what role the tobacco industry plays in the production, distribution and sale of ENDS, this industry, its allies and front-groups can never be considered to be a legitimate public health partner or stakeholder while it continues to profit from tobacco and its products or represents the interests of the industry. Article 5.3 of the WHO FCTC should be respected when developing and implementing ENDS legislation and regulations.

48. **Product design and information.** ENDS should be regulated to:
- (a) minimize content and emissions of toxicants;
 - (b) ensure use of nicotine of pharmacological quality, when nicotine use is intended;
 - (c) standardize nicotine delivery at levels known to the consumers;
 - (d) minimize acute nicotine toxicity;
 - (e) impede product alteration to use of other drugs;
 - (f) ban ENDS solutions with fruit, candy-like and alcohol-drinks flavours until empirical evidence shows that they are not attractive to minors;
 - (g) require manufacturers and importers to disclose to governmental authorities information about the contents and emissions of ENDS; and
 - (h) require registration of manufacturers and importers with governmental authorities.
49. **Health warnings.** ENDS health warnings should be commensurate with proven health risks. In this regard, the following risk warnings could be considered: potential nicotine addiction; potential respiratory, eyes, nose and throat irritant effect; potential adverse effect on pregnancy (due to nicotine exposure).
50. **Surveillance and monitoring.** Governments are recommended to use or strengthen their existing tobacco surveillance and monitoring systems to assess developments in ENDS and nicotine use by sex and age.
51. **Sale to minors.** Retailers should be prohibited from selling ENDS products to minors, and vending machines should be eliminated in almost all locations.

REGULATORY FRAMEWORK

52. In order to implement the suggested general regulatory objectives as well as the specific regulatory options, Parties will need to consider the available national regulatory frameworks that could best provide solid regulatory grounds. Nevertheless, it is likely that a two-pronged regulatory strategy – regulating ENDS as both a tobacco product, in accordance with the provisions of the WHO FCTC, and as a medical product – would be necessary.

53. The applicability of many of the WHO FCTC provisions to the regulation of ENDS was reviewed in a report by the Convention Secretariat on this topic¹ presented at the fifth session of the COP.

ACTION BY THE CONFERENCE OF THE PARTIES

54. The COP is invited to note this report and to provide further guidance.

¹ Document FCTC/COP/5/13 (available at www.who.int/fctc/publications).

Effective: October 1, 2012

West's Annotated Code of Maryland Currentness

Health--General

■ Title 24. Miscellaneous Provisions

■ Subtitle 3. Limitations on Manufacture or Sale

→→ **§ 24-305. Sale, distribution, or offer for sale of electronic nicotine devices to minors prohibited**

Application of section

(a) This section does not apply to a tobacco product that is regulated under Title 16 of the Business Regulation Article.

Sale, distribution, or offer of sale of **electronic** nicotine devices

(b)(1) Except as provided in paragraph (2) of this subsection, a person may not sell, distribute, or offer for sale to a minor an **electronic** device that can be used to deliver nicotine to the individual inhaling from the device, including an **electronic cigarette**, cigar, cigarillo, or pipe.

(2) This subsection does not apply to a nicotine device that contains or delivers nicotine intended for human consumption if the device has been approved by the United States Food and Drug Administration.

Fines and penalties

(c) A person that violates this section is guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$1,000 for each violation.

Defenses

(d) In a prosecution for a violation of this section, it is a defense that the defendant examined the purchaser's or recipient's driver's license or other valid identification issued by an employer, government unit, or institution of higher education that positively identified the purchaser or recipient as at least 18 years of age.

CREDIT(S)

Added by Acts 2012, c. 714, § 1, eff. Oct. 1, 2012.

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MD Code, Health - General, § 24-305, MD HEALTH GEN § 24-305

Current through the 2014 Regular Session of the General Assembly.

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