

Tobacco White Paper Series

E-Cigarettes and Youth:

An examination of the public health and policy concerns over increased rates of youth use and exposure to e-cigarettes

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Electronic cigarettes (e-cigarettes) have grown dramatically in popularity over the last half-decade. As e-cigarette popularity has risen, so have rates of youth e-cigarette usage. A September, 2013 report by the U.S. Centers for Disease Control and Prevention reported that youth use of e-cigarettes doubled between 2011 and 2012. E-cigarettes are available in a large variety of sweet flavors, can be sold in youth-accessible locations, and can be widely advertised without running afoul of tobacco advertising restrictions. These factors have caused concern in the public health community that e-cigarettes may be a gateway for youth nicotine addiction and/or traditional tobacco use, and may act to "re-normalize" cigarette use as a social norm. While there is great concern over youth exposure to e-cigarettes, little is known about the long-term health effects of e-cigarette use. The U.S. Food and Drug Administration (FDA) is currently assessing the impact of ecigarettes and plans to announce proposed regulations in late 2013. Until the FDA proposals are announced, e-cigarette regulation will only exist at the state and local level. The purpose of this paper is to provide local health officials and policy makers a concise summary of the public health concerns and potential policy solutions regarding e-cigarettes. The public health issues highlighted by the paper include: increased youth use and exposure to e-cigarettes; the unknown health effects of long-term e-cigarette use; the lack of universal product standards; and the devices' unknown efficacy as a cessation tool. Finally, the paper examines the current state of e-cigarette regulation and outlines several potential local policy options.

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This paper has been written with a general audience in mind and is provided for educational purposes only and is not to be construed as legal opinion. Policy makers considering regulating youth exposure e-cigarettes in their municipalities should consult with their city law departments or other legal counsel.

I. INTRODUCTION

In September, 2013, the U.S. Centers for Disease Control and Prevention (CDC) reported that the percentage of U.S. middle and high school students who use electronic cigarettes doubled between 2011 and 2012. As of 2012, nearly two million middle and high school students reported using electronic cigarettes. 1

Electronic cigarettes are battery-powered devices that produce an inhalable vapor by heating an internal cartridge that is filled with a solution that usually contains nicotine and/or flavoring.^{2, 3, 4, 5} The devises can also be referred to as e-cigarettes, e-cigs, personal vaporizers, or electronic nicotine delivery systems (ENDS); the use of e-cigarettes is also known as "vaping."^{2, 3, 4} E-cigarettes physically resemble traditional cigarettes and the vapor they emit provides a similar flavor and sensation to that of inhaled tobacco smoke.^{2, 3, 4, 5} While some brands of e-cigarettes are disposable, many can be reused with refillable nicotine solution cartridges and batteries that can be recharged via wall outlet or USB cord.^{2, 3, 4, 5}

First produced in China, e-cigarettes entered the U.S. around 2006. Although they have only been available in the U.S. for less than a decade, the popularity of the devices has risen dramatically in the last few years. The current e-cigarette market is estimated to be approximately \$2 billion. While that is a small fraction of the market compared to traditional cigarettes (\$90 billion), the e-cigarette market is projected to reach \$10 billion by 2017. Presently, 21 percent of smokers have reported trying e-cigarettes, which is more than double the percentage reported in 2010.

As the availability of e-cigarettes has risen, so has the rate of youth usage. As highlighted by the Fall 2013 CDC report:

- the percentage of high school students who reported ever using electronic cigarettes rose from 4.7 percent in 2011 to 10 percent in 2012;
- the percentage of high school students who reported current e-cigarette use rose from 1.5 percent to 2.8 percent between 2011 and 2012, and;
- 76.3 percent of those students who reported current e-cigarette usage also reported current conventional cigarette usage.¹

The CDC report was not the first time that youth use of electronic cigarettes has been scrutinized. A 2012 focus group study found that young adults have positive perceptions of products such as electronic cigarettes. ¹⁰ In particular, young adults responded positively towards the choice of flavors. ¹⁰ Other young adult perceptions of the products included that they are less harmful than normal cigarettes and that they could be a gateway to cigarette smoking. ¹⁰ Finally, young adults reported that they would try the products if offered by a friend. ¹⁰

Many public health officials, including the director of the CDC, are concerned that the abundance of candy and dessert-like flavors of e-cigarettes may serve to lure youth to e-cigarettes, which in turn could result in youth eventually switching to regular tobacco. The same concerns regarding availability of flavored tobacco ultimately led Congress to prohibit the sale of flavored traditional cigarettes when it passed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) of 2009. Fe-cigarettes are currently available in such enticing flavors as: Cinnamon Toast Crunch, Fruit Loops, chocolate chip cookies, brownie, bubble gum, and gummi bear. Because e-cigarettes are largely unregulated, youth can be exposed to *and obtain* these products from easy sources such as specialty retail shops, mall kiosks, and even online. As of October 2013, only 25 states – Illinois included – prohibit the sale of e-cigarettes to minors.

Even in states where the sale of e-cigarettes to minors has been prohibited, youth are still being exposed to the products in large numbers – a phenomenon that public health officials warn may "renormalize" smoking-behaviors and cigarette use. 2,4 Because e-cigarettes can circumvent the otherwise strict restrictions on advertising of traditional tobacco products, markets can be flooded with highly stylized e-cigarette ads featuring celebrity endorsements and "retro" imagery harkening back to the golden age of cigarette marketing. The content and accessibility of these marketing campaigns led several members of Congress and 40 state Attorneys General to urge the FDA to act quickly to regulate e-cigarettes, warning that e-cigarette manufacturers are exploiting the lack of marketing restrictions to "target young users . . . using many of the exact same advertising and promotion techniques used for decades by cigarette manufacturers to hook teenagers on their products." Decades where the products is a product of the exact same advertising and promotion techniques used for decades by cigarette manufacturers to hook teenagers on their products."

Despite concerns by health officials, relatively little is known about the impact electronic cigarettes, including the long-term health effects of breathing the vapor, their efficacy as cessation device, and whether they "re-normalize" traditional tobacco and cigarette use. The U.S. Food and Drug Association (FDA) plans to announce proposed regulations of e-cigarettes in the Fall of 2013. ¹⁹ Until adequate regulations are in effect, however, it is important that public health organizations to continue to educate policy makers and citizens alike on the issues surrounding electronic cigarettes. If youth exposure to e-cigarettes is to be limited, more public health and policy information needs to be made readily available. It is with that necessity in mind that Respiratory Health Association has published this white paper highlighting the important public health concerns and available local policy options regarding e-cigarettes. Respiratory Health Association hopes that this paper will enable policy makers to make well-informed decisions on e-cigarettes, as well as give public health educators a more thorough understanding of both sides of the e-cigarette debate.

II. PUBLIC HEALTH CONCERNS

Unknown Health Effects

While e-cigarette vapor almost certainly contains fewer toxins and carcinogens than the 7000 found in traditional tobacco smoke, ²⁰ that fact alone does not mean that breathing e-cigarette vapor is "safe." No one contends that e-cigarette vapor is chemical-free, and there is not enough evidence to allow anyone to conclude there are no *long-term* effects of breathing e-cigarette vapor. Only recently have research efforts begun to identify the chemicals found in e-cigarette vapor and examine the *short-term* health effects of e-cigarette use.

- E-cigarette vapor contains detectable levels of known carcinogens and toxins, both in mainstream²¹ and in sidestream (secondhand/passive) vapor.²² However, one study found, that the levels of the toxins common between e-cigarette vapor and cigarette smoke were between 9 and 450 times lower in the e-cigarette vapor than in traditional cigarette smoke.²¹
- The compounds found in mainstream (MS) and sidesteam (SS) e-cigarette vapor include: Acetaldehyde (MS); Benzene (SS); Cadmium (MS); Formaldehyde (MS,SS); Isoprene (SS); Lead (MS); Nickel (MS); Nicotine (MS, SS); N-Nitrosonornicotine (MS, SS); and Toluene (MS, SS). ²³
- Limited preliminary research conducted by the FDA in 2009 found that among the e-cigarette cartridges tested, a majority contained diethylene glycol, a chemical used in antifreeze that is toxic to humans. Several other samples were found to contain tobacco-specific nitrosamines, which are human carcinogens. In addition, harmful tobacco-specific impurities anabasine, myosmine and B-nicotyrine were also found in a majority of the samples tested by the FDA.
- A 2012 study from Greece on the short-term effects of e-cigarette usage found that use of e-cigarettes, "caused an instant increase in airway resistance that lasted for over 10 minutes."
- A 2012 German study found that use of e-cigarettes causes detectable levels of volatile organic compounds to be emitted into indoor air, leading the authors to conclude that "passive vaping' must be expected from consumption of e-cigarettes."²²

Lack of Product Standards

Equally troubling to public health officials as the lack of health information on e-cigarettes use is the lack of uniform e-cigarette product standards. Because e-cigarettes are currently unregulated at the federal level, consumers do not have access to accurate information on e-cigarette ingredients, product quality, and safe product usage. Several studies, including preliminary FDA research, have found potentially dangerous inconsistencies in the manufacturing of e-cigarettes. These inconsistencies led the FDA to conclude that "quality control processes used to manufacture these products are substandard or nonexistent."

- In a limited lab study, the FDA found that certain cartridges labeled as 'no nicotine' actually
 contained nicotine and that other cartridges labeled as containing identical amounts of nicotine
 contained "markedly different" amounts of nicotine.²⁶
- E-cigarette nicotine cartridges are advertised to typically contain between 6 and 24mg of nicotine. However, some have been found to contain more than 100 mg.³ Excessive doses (0.5-1.0 mg per kg of weight of the person) of nicotine can be fatal.²⁷ The estimated lethal dose of nicotine for a child is 10mg.²⁸ Separate incidents of nicotine poisoning have resulted from children consuming bottles of e-cigarette nicotine solution; one such incident lead to the death of a child.^{29,30}
- Upwards of a dozen explosions caused by e-cigarette batteries were reported in 2013. 32 According to fire officials, the lithium-ion battery in an e-cigarette does not contain a built-in default setting (like in cell phones) to switch off when the battery is full; this can cause the coil to continue to draw heat until the lithium-ion inside explodes. 33 These explosions pose a danger especially to children; at least one such incident caused a child to sustain severe burns. 34

Unproven as a cessation tool

E-cigarettes have not been approved by the FDA as safe and effective for the purpose of smoking cessation. Limited studies that tested the effectiveness of e-cigarettes as a cessation device led to mixed results. Some studies found that using e-cigarettes, with or without nicotine, genuinely helped smokers reduce smoking or fully quit smoking; other studies found that e-cigarettes did not aid cessation and may actually prolong users' nicotine addictions. Because e-cigarettes are currently unregulated, individuals using e-cigarettes for cessation have no way of knowing with confidence whether e-cigarettes are safe for that specific use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or what, if any, objective benefits are associated with using the products. While certain studies have shown positive results, the efficacy of e-cigarettes as an aid for sustained smoking cessation has not been proven conclusively.³⁵

 A randomized clinical trial published in *Lancet* found that e-cigarettes, either with or without nicotine, were modestly effective at helping smokers quit, as compared to nicotine patches.³⁶

- In a recent study of e-cigarette users across four countries, 75 percent of respondents said that they used e-cigarettes to help reduce smoking and 85 percent said they were using e-cigarettes to help them quit smoking.³⁷ However, one commentator noted that the e-cigarette users were no more likely to have quit conventional cigarettes than non e-cigarette users.³⁸
- While some studies have posited that e-cigarettes may be an effective cessation aid, the
 University of California San Francisco Center for Tobacco Control and Research Education has
 noted that based on available research, e-cigarettes may deliver "14 times as much
 formaldehyde, 7 times as much actaldehyde, 6 times as much o-methylbenzene, 3 times as
 much cadmium and twice as much lead as . . . nicotine inhaler[s]," which are devices actually
 approved for use in smoking cessation.³⁹
- A 2013 study of e-cigarettes use among cessation quitline callers found that the callers who
 used e-cigarettes were, "significantly less likely to be tobacco abstinent" than the callers who
 had never tried e-cigarettes.⁴⁰
- One study examining the delivery of nicotine by e-cigarettes found that compared to approved cessation aids such as nicotine gum or patches, e-cigarettes did not deliver nicotine effectively and were less effective at suppressing users' cravings.⁴¹ This study led other commentators in the New England Journal of Medicine to warn that "[s]mokers attempting to use e-cigarettes for smoking cessation will most likely find them ineffective; indeed, their use may instead perpetuate smokers' addiction."²⁸

III. REGULATION OF E-CIGARETTES

Current Regulation

The FDA is planning to announce proposed regulations of e-cigarettes in the Fall of 2013.¹⁹ Federal regulation of e-cigarettes has been contemplated almost as long as the products have been in the U.S. In 2009, the FDA voiced numerous concerns over e-cigarettes, including: the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes; the products may contain ingredients that are known to be toxic to humans; the risks of increased nicotine addiction and initiation to traditional tobacco use among young people; and the lack of health and safety information available to consumers.¹² That same year, the FDA attempted to ban e-cigarettes as unapproved drug delivery devices; however, the U.S. Courts of Appeals for the District of Columbia ruled that e-cigarettes were properly regulated as tobacco products.⁴² In 2010, the FDA issued warning letters to several e-cigarette distributors regarding alleged violations of the Food, Drug, and Cosmetic Act, including, "violations of good manufacturing practices, making unsubstantiated drug claims, and using the devices as delivery mechanisms for active pharmaceutical ingredients."⁴³

Other countries have also struggled with the appropriate scope of regulation for e-cigarettes. In July, 2013, the World Health Organization issued a warning to consumers regarding e-cigarettes and

encouraged governments to regulate the sale of the devices.⁴⁴ A few months later, the European Parliament opted not to regulate the products as pharmaceuticals.⁴⁵ Instead, the European Union announced it will establish 18 as the minimum age to purchase e-cigarettes and will impose strict advertising and marketing restrictions, similar to those on traditional cigarettes.⁴⁵

In the U.S., until the FDA announces its proposed regulations, e-cigarette regulation will be left to the states. As of October, 2013, three states (North Dakota, New Jersey, Utah) and more than 100 municipalities across the U.S. have added e-cigarettes to their smoke-free venue laws. In addition, nine states have prohibited the use of e-cigarettes in other venues such as schools, government offices, correctional facilities, and public transportation.

Policy Options

Given the novelty of e-cigarettes, policy makers have had to search for equally innovative policy solutions to limit youth use and exposure to the products. The struggle with regulating e-cigarettes has derived not just from uncertainty of viable policy options, but also how to correctly *define* the products.

As mentioned above, both the FDA and EU were unsuccessful in attempting to regulate e-cigarettes as medical devices. Even with that option curbed for now, there has been significant debate whether e-cigarettes should be defined as "tobacco products," "alternative tobacco products," "alternative nicotine products," "nicotine delivery devices," "vapor products," or something else entirely. Tobacco control advocates argue that defining e-cigarettes as "tobacco products" will enable the strongest level of regulation and will prevent certain regulatory loopholes that could result from defining them as "alternative tobacco products," "alternative nicotine products," "vapor products," or "nicotine delivery devices." In July, 2013, the governor of Rhode Island vetoed legislation to ban the sale of e-cigarettes to minors that would have defined e-cigarettes as "vapor products." According to Governor Lincoln Chafee, by defining e-cigarettes as "vapor products" as opposed to "tobacco products," the legislation would have enabled e-cigarettes to evade existing ID, signage and licensing requirements, as well as tobacco taxes. Finally, by defining e-cigarettes as anything other than a "tobacco product," it is possible that states and municipalities could be subject to legal challenge for essentially defining a new class of tobacco products, which is a power exclusively reserved for the FDA and would, therefore, be preempted by the FSPTCA.

As of October, 2013, nine states, including Vermont, Minnesota and New Hampshire, have included ecigarettes in their respective definitions of "tobacco products." Illinois currently defines e-cigarettes as "alternative nicotine products" in its law prohibiting the sale of e-cigarettes to minors.⁴⁹

The issue of accurate definitions aside, the following list represents several of the leading policy options that states and local governments could explore to reduce youth exposure to e-cigarettes:

- Adding e-cigarettes to existing smoke-free laws. Three states and over 100 municipalities (including Evanston and Mundelein in Illinois) have either added e-cigarettes to their existing smoke-free laws or have created new smoke-free laws including e-cigarettes. ⁴⁶ The primary justification of this policy option is to "minimize the use of products that pose unknown health risks." ⁵⁰ In addition, adding e-cigarettes to smoke-free laws is believed to assist with enforcement of smoke-free laws. Since e-cigarettes physically resemble traditional cigarettes and e-cigarette vapor resembles tobacco smoke, it can be confusing for enforcement officials to identify whether or not the product being used is legal. Adding e-cigarettes to existing smoke-free laws would eliminate that confusion and enable equal enforcement against e-cigarettes and traditional tobacco products. Finally, by restricting exposure to e-cigarettes in public places, this policy option helps reinforce smoke-free lifestyles as a social norm with youth and young adults. As previously discussed, the primary difficulty with this policy option is in accurately defining e-cigarettes so as to enable the strongest level of cross-regulation.
- Minimum sales age. Another popular policy option for states and municipalities is to limit the sale of e-cigarettes by the age of the purchaser. So far, 25 states (including Illinois) and the District of Columbia have enacted laws establishing 18 as the minimum age to purchase e-cigarettes.⁷
- **Limiting youth access.** In addition to establishing a minimum sales age, municipalities could consider other options to limit youth access to e-cigarettes, such as restricting sales of the products to adult-only retailers or requiring e-cigarettes to be kept behind the counter.⁵⁰
- **Licensing.** If a municipality is able to successfully define e-cigarettes as tobacco products, then it may be possible to add e-cigarettes into existing tobacco licensing schemes. By requiring businesses to have a tobacco retail license to sell e-cigarettes, cities could limit the number of total sellers in the jurisdictions, as well as limit the location of e-cigarette retailers, such as around schools or other areas frequented by youth.
- Marketing regulation. Potential policy options around e-cigarette marketing include restricting point-of-sale advertising, requiring the posting of health warnings at point-of-sale locations, or imposing a total prohibition on the sale of the products. These options, however, do not come without significant obstacles. While governments have an interest in shielding consumers from false or misleading claims, commercial speech, including truthful advertising, is protected free speech under the First Amendment. The enactment of such options would undoubtedly result in litigation. For that reason, the regulation of e-cigarette marketing, perhaps more than any of the other policy options, would require a municipality to conduct a thorough legal analysis into the viability of such a policy within their jurisdiction.

- **Taxation**. While taxing e-cigarettes at the levels of traditional cigarettes is a politically popular idea, the ability of a state or municipality to tax e-cigarettes also hinges on how the products are defined in the statute. Federal law reserves for states and local governments the power to tax tobacco products; however, unless e-cigarettes are defined as tobacco products, then they may not be able to be taxed.
- Limiting Free Samples, Rebates, Discounts, and Coupons. The FSPTCA prohibited tobacco companies from engaging in certain pricing discounting activities, including: free samples of cigarettes, mail-order coupon redemption, and giving away free non-tobacco products with the purchase of tobacco products. The FSPTCA does not, however, restrict pricing discounts through the use of coupons or rebates. In addition, the FSPTCA allows the sampling of smokeless tobacco products in qualified adult-only locations. Nevertheless, the FSPTCA does preserve state authority to further restrict the sale and distribution of tobacco products. The U.S. Court of Appeals for the First Circuit recently upheld a local ordinance (Providence, RI) prohibiting licensed tobacco retailers from selling discounted tobacco products via multi-pack offers and coupon redemption. Regarding e-cigarettes, while any regulation would hinge upon defining e-cigarettes as tobacco products, if a state or municipality were to define e-cigarettes as tobacco products, then they could potentially be able to restrict the redemption of coupons for e-cigarettes, as well as rebates, free samples and pricing discounts.
- Restricting the sale of flavors. E-cigarettes are available in a wide array of flavors, including in an abundance candy, dessert and alcohol-themed options. The FDA has exclusive authority, via the FSPTCA, to regulate product standards, ⁵⁵ which includes product flavoring; however, states are preserved the right to regulate the sale and distribution of tobacco products. While a state or local government could not ban e-cigarette flavoring itself, they could potentially prohibit the sale or distribution of flavored e-cigarettes. New York, NY⁵⁶ and Providence, RI⁵⁷ both recently enacted ordinances prohibiting the sale of flavored non-cigarette tobacco products, except in tobacco bars. These ordinances were challenged on federal preemption and First Amendment grounds, but each was ultimately upheld in federal court. ⁵⁸ While no state or municipality has attempted to prohibit the sale of flavored e-cigarettes, these two rulings could potentially be supportive of more expansive regulation of flavored tobacco products. ¹

For more information on the implications of these cases, *see*, Fraley T, Sheridan A, Africk J, Maloney M. (November 2013). Reducing Youth Exposure to Flavored Tobacco: An analysis of <u>U.S. Smokeless Tobacco Mfg. Co. v. City of New York</u> and <u>Nat'l Ass'n of Tobacco Outlets v. City of Providence</u> and what they mean for the future of youth tobacco prevention. Respiratory Health Association. Available at: http://www.lungchicago.org/library/

IV. ADDITIONAL E-CIGARETTE RESOURCES:

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http://www.who.int/tobacco/communications/statements/eletronic cigarettes/en/

http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173430.pdf

http://www.tobaccofreekids.org/tobacco_unfiltered/post/2013_10_31_halloween

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