



1400 EYE STREET, N.W. • SUITE 1200 • WASHINGTON, DC 20005
PHONE (202) 296-5469 • FAX (202) 296-5427

July 2, 2015

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

RE: Docket No. FDA-2014-N-1936: Electronic Cigarettes and the Public Health Workshop

The Campaign for Tobacco-Free Kids submits these comments in response to the U.S. Food and Drug Administration’s (FDA) request for comments regarding e-cigarettes and the public health.¹ These comments incorporate by reference the comments we filed on August 8, 2014 in Docket No. FDA-2014-N-0189, RIN 0910-AG38, Proposed Rule on Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Tobacco Control Act to the extent those comments address e-cigarettes and their regulation. The current comments focus largely on research and data developed and published after August 2014, as well as drawing upon the presentations made to FDA during the agency’s three public workshops on Electronic Cigarettes and the Public Health.

Table of Contents

INTRODUCTION 2

I. EMERGING INFORMATION ABOUT E-CIGARETTES AND RELATED LIQUID NICOTINE PRODUCTS SUPPORTS THE NEED FOR STRONG FDA REGULATION TO ADDRESS ADVERSE POPULATION-WIDE EFFECTS OF THE CURRENT UNREGULATED MARKET 7

 A. Population-Wide Effects on Youth Tobacco Use 8

 1. Given the addictiveness of nicotine and its impact on adolescents, it is imperative that FDA attach high priority to curbing youth usage of the products..... 8

 2. The continued increase in youth usage of electronic cigarettes supports strong FDA action to prevent youth addiction to nicotine and the risk of migration to more hazardous tobacco products.... 9

 3. The increasing use of kid-friendly flavors in e-cigarettes supports strong FDA action to prohibit characterizing flavors in the products. 11

¹ 79 Fed. Reg. 71437 (December 2, 2014); *see also* 80 Fed. Reg. 15018 (March 20, 2015) (extending comment period to July 2, 2015).

4.	The continued marketing of the products to attract young people supports application of marketing restrictions on the products as restrictive as current FDA restraints on cigarettes and smokeless marketing.....	15
5.	The increase in incidents of young children being exposed to liquid nicotine supports immediate FDA action to mandate child resistant packaging for liquid nicotine products.....	20
B.	Population-Wide Effects on Adult Tobacco Use.....	21
1.	There is currently uncertainty about the potential for e-cigarettes to aid in smoking cessation and no e-cigarette has been approved by FDA’s Center for Drug Evaluation and Research (CDER) as a safe and effective smoking cessation device.....	21
2.	Based on current data, there is legitimate concern about widespread dual use of e-cigarettes and cigarettes, which does not yield meaningful health benefits unless it leads to a smoker no longer using cigarettes or serves as a pathway to that result.....	23
II.	EMERGING INFORMATION ABOUT E-CIGARETTES AND THEIR EFFECTS ON INDIVIDUAL USERS SUPPORTS STRONG FDA REGULATION OF THE CONTENT OF E-CIGARETTES.....	27
A.	Criterion for Considering the Appropriateness of Establishing Product Standards.....	27
B.	The variability and uncertainty respecting levels of toxicants delivered by e-cigarette products and their health effects on users supports strong FDA product standards, requirements for good manufacturing practices and other regulatory responses.....	28
1.	Evidence regarding hazardous constituents and other hazards in e-cigarettes.....	28
2.	Potential toxicity of flavorings.....	31
C.	The variability and uncertainty respecting nicotine and nicotine delivery supports strong FDA product standards, requirements for good manufacturing practices and other regulatory responses.....	32
III.	RECOMMENDATIONS FOR REGULATORY ACTION.....	35
	APPENDIX.....	37

INTRODUCTION

The challenge for FDA in regulating electronic cigarettes² is to develop a regulatory structure that takes proper account of the possibility that e-cigarettes might help a significant number of smokers to quit using cigarettes completely while still protecting the public health against the serious risk that the availability of e-cigarettes may increase the number of youth who use tobacco products, discourage quitting among smokers who would otherwise quit using tobacco altogether, encourage former smokers to relapse, and weaken current and future evidence-based tobacco control measures. What has taken place in the marketplace over the last several years has heightened these concerns. Sales of e-cigarettes have burgeoned and the

² The terms “electronic cigarettes,” or “e-cigarettes,” as used in these comments, refers to the full range of products in which a nicotine solution is heated and generates a nicotine aerosol to be inhaled by the user.

market is crowded with hundreds of brands and literally thousands of individual products. Yet in the absence of regulation neither the consumer nor the government can know all the components each of these products contains, how these products are manufactured, or what the long-term health consequences of their use will be. The science produced and presented since August 2014 continues to demonstrate that there is still much we do not know about these products and their impact on individual and public health.

The evidence presented in these workshops and elsewhere demonstrates the need for prompt, effective and comprehensive regulation of e-cigarettes by FDA. These basic principles must guide FDA's regulatory policy:

- Whatever potential electronic cigarettes may have for reducing the number of cigarette smokers, FDA must put in place policies that do everything possible to minimize the number of youth who use these products. Concern about youth usage of these products has grown with the release of data demonstrating dramatically increased use of these products by young people over the last three years.
- The ultimate goal of tobacco control is the elimination of the death and disease caused by tobacco. While cigarettes are by far the number-one cause of tobacco-related death in the U.S., complete abstinence from any tobacco product is the most certain method of achieving that overarching goal. Therefore, FDA's regulatory approach to electronic cigarettes must be carefully framed not to detract from or weaken policies established to reduce the use of cigarettes, cigars, smokeless tobacco and other tobacco products.
- Any strategy adopted by FDA that seeks to cause cigarette and cigar smokers to switch exclusively to a different tobacco product, such as electronic cigarettes, must take into account individual and population benefits and harms. As we noted in our August 8, 2014 submission to the deeming rule docket, FDA regulations must govern the safety, content, appeal, marketing and distribution of all tobacco products, including electronic cigarettes. In addition, FDA must consider whether in fact the use of such products will effectively eliminate the use of combusted tobacco products for a significant number of smokers.
- FDA must not delay making the necessary regulatory decisions to protect the public health while additional science is developed, but FDA must also take immediate steps to require e-cigarette manufacturers to develop and submit sound scientific studies to narrow the current gaps in our knowledge about these products. Only carefully done scientific studies can determine whether these products can be manufactured, marketed and sold in ways that do not increase youth usage and whether e-cigarettes are effective in assisting smokers to quit smoking.

The vacuum that currently exists in federal regulatory policy for e-cigarettes fails to serve any legitimate goal. It neither protects the public health by preventing initiation, particularly

among young people, nor facilitates cessation among smokers. It fails to require that the product be manufactured according to good manufacturing practices or according to any consistent product standards. It fails to provide adequate incentives for manufacturers to produce products designed to maximize smoking cessation and leaves both FDA and the public uninformed about the public health impact of the many different products on the market. It fails to require that toxic constituents be eliminated or reduced, or to require that manufacturers even know whether toxic constituents are present and, if so, in what concentration. It fails to require that consumers be informed of the content or the addictiveness of the product. It fails to restrict the manner in which the product is marketed. It fails to prevent or to discourage advertising and marketing practices that encourage young people to use the product. It fails to prevent or to discourage internet sales of the product that permit sellers to put the product into the hands of young people.

Evidence submitted at the FDA workshops has demonstrated that e-cigarette usage by young people is increasing nationwide. According to the National Youth Tobacco Survey (NYTS) released by both the U.S. Centers for Disease Control and Prevention (CDC) and FDA, prevalence of current e-cigarette usage (past 30 day use) among high school students increased from 1.5 percent in 2011 to 13.4 percent in 2014. Moreover, CDC figures show that the number of young people who have used e-cigarettes but have never smoked a combustible cigarette more than tripled between 2011 and 2013.

The rise in youth use of electronic cigarettes found in the recently released NYTS is consistent with the trend found in the December 2014 Monitoring the Future study. The data are not yet adequate to predict the long-term effect of the increase in youth use found in these studies, but the numbers are a cause for concern and action. Any use of nicotine-based products by youth is troubling.

The sharp increase in e-cigarette usage by young people is not surprising, given the marketing of these products directed at young people. More than 7,700 unique e-cigarette flavors are available online, many of them fruit, candy or dessert flavors and many with names obviously designed to be attractive to an underage market. The rapidity with which new flavors have been introduced makes clear that, at a minimum, manufacturers are introducing new flavors to encourage initiation, particularly among youth, and with no scientific evidence that these flavors significantly improve adult cessation. On the other hand, there is evidence that the attractiveness of such flavors is a leading reason why high school students try e-cigarettes.

Moreover, evidence submitted at the workshops identified numerous advertising, marketing and sales strategies designed to increase the appeal of e-cigarettes to children or to make it possible for sellers to put e-cigarettes in their hands. The evidence demonstrates extensive exposure of children to e-cigarette advertising. Indeed, marketing expenditures for e-cigarette companies increased dramatically between 2011 and 2014. The ability of e-cigarette manufacturers to advertise their products on television—a medium not open to cigarette advertisers for more than forty years—has subjected millions of young people to advertising

campaigns for these products. Evidence was submitted at the workshops showing the effectiveness of this advertising.

Evidence presented to FDA demonstrates the prevalence of e-cigarette event-based marketing (a practice prohibited for cigarettes) and marketing through online and social media.

Compilations of advertising copy for e-cigarettes show a concerted strategy by e-cigarette manufacturers to target youth in the marketing of their products, including many of the same tactics by which the major tobacco companies had so successfully targeted youth in the marketing of cigarettes. These practices—none of them currently subject to federal regulation as to e-cigarettes—call out for effective regulation.

Moreover, the evidence demonstrates that young people can and do obtain e-cigarettes on the internet with no effective age verification.

FDA has also received evidence demonstrating the sharp increases in nicotine exposure and poisoning incidents in which children—most of them under the age of five—ingested liquids after gaining access to the containers. There is an urgent need for effective requirements for child-resistant packaging.

Unless e-cigarettes are effective in helping cigarette smokers stop smoking completely, they confer no public health benefit. The available evidence is limited and inconclusive regarding the potential for e-cigarettes to contribute to smokers switching entirely to e-cigarettes or quitting all forms of tobacco, and non-existent on the long-term impact of e-cigarette use. Most studies of e-cigarette usage have not adequately differentiated between different e-cigarette products. It is impossible to draw valid conclusions without studies that do so.

The results of longitudinal studies, some of which are in progress, may make it possible to evaluate this potential more effectively in future years if the studies are carefully controlled.

The evidence submitted to FDA in its e-cigarette workshops and the most recent research support several general conclusions regarding the effects of e-cigarettes on individual users:

- In general, e-cigarettes deliver lower amounts of carcinogenic substances and other toxicants to their individual users who switch exclusively from cigarettes to electronic cigarettes.
- The degree to which e-cigarettes deliver carcinogenic substances and other toxicants to their users may vary considerably according to product design and use.
- E-cigarettes deliver nicotine, a highly addictive substance. The amount of nicotine delivered and the effectiveness with which it is delivered varies widely among various categories of products, and even within categories of products, according to the design and use of the products.

- Nicotine is not only addictive, but adolescent exposure to nicotine may have lasting adverse consequences for brain development.
- Some e-cigarettes that were tested contain carcinogenic substances that could and should be eliminated or greatly reduced by sound product standards and required good manufacturing practices.
- Some e-cigarettes that were tested contain substances that may increase the risk of cardio-pulmonary disease and that could and should be eliminated or greatly reduced by the establishment of sound product standards and required good manufacturing practices.
- The use of many flavorings in e-cigarettes presents a public health risk. Flavors may increase the attractiveness of these products to young people and are clearly being introduced into the marketplace without adequate testing or concern for their impact on youth. In addition, the chemicals in some of the flavorings may present a health hazard as a component of an e-cigarette aerosol.

The evidence submitted at the FDA workshops, and available generally to FDA, supports all of the following policy recommendations.

- FDA should promulgate the deeming rule as soon as possible. It is essential that FDA's regulation of e-cigarettes be as comprehensive as its regulation of other tobacco products and that FDA apply the same rigorous scientific scrutiny to these products. It is also essential that the application of FDA's authority over these products not be delayed, including the authority governing the introduction of new and modified products.
- To address the mounting evidence of youth exposure to e-cigarette advertising and the rise in use of e-cigarettes by youth,
 - FDA should exercise its regulatory authority, to impose effective restrictions on the sale and distribution, and, to the maximum extent permitted by the First Amendment, on the advertising, marketing and promotion, of e-cigarettes to prevent irresponsible industry marketing practices that are directed at young people, including the application of all the provisions of the 2010 rule on marketing cigarettes and smokeless products to youth.
 - FDA should prohibit the sale of e-cigarettes in remote transactions, including internet sales.
 - FDA should prohibit characterizing flavors in e-cigarettes (except tobacco flavor). As to any non-tobacco flavor that a manufacturer seeks to use, FDA should require that the manufacturer first submit valid scientific evidence prior to the addition of the flavor that it (1) makes it more likely that a significant number of

smokers will quit smoking completely, (2) does not pose a health hazard, (3) does not contribute to initiation of tobacco product use, including e-cigarette use, particularly among youth, or relapse into tobacco product use, and (4) does not result in continued use of tobacco products by those who otherwise would have quit.

- FDA should require e-cigarettes to be accompanied by a government-mandated warning of the addictiveness of nicotine.
- FDA should adopt rules requiring e-cigarettes to consistently meet strict product standards that eliminate or sharply reduce the presence of toxicants, control the level of nicotine being delivered, help cigarette smokers to quit using combustible products entirely, minimize the appeal of e-cigarettes to youth, and prohibit the sale of e-cigarettes unless they are made according to good manufacturing practices and in a manner that delivers consistent and measurable levels of the same constituents.
- FDA should immediately require child-resistant packaging of e-cigarettes and related liquid nicotine products.

I. EMERGING INFORMATION ABOUT E-CIGARETTES AND RELATED LIQUID NICOTINE PRODUCTS SUPPORTS THE NEED FOR STRONG FDA REGULATION TO ADDRESS ADVERSE POPULATION-WIDE EFFECTS OF THE CURRENT UNREGULATED MARKET

Proper regulation of e-cigarettes is essential both to reduce the number of people who use conventional cigarettes and become sick and die as a result and to protect the public health by preventing initiation, particularly among youth, discouraging continued use of combusted products, and preventing relapse of tobacco use by smokers who have quit. Products that are not responsibly manufactured and marketed pose a threat to the public health. As discussed more fully below, even apart from its addictive properties, nicotine adversely affects adolescent brain development. Moreover, there is a risk that e-cigarettes could serve as a gateway to nicotine addiction and use of regular cigarettes by kids and other non-users. These concerns are magnified by the prospect that irresponsible marketing campaigns, like those widely used by several of the major sellers of e-cigarettes, could undermine decades of work to reduce youth smoking. To prevent this result, FDA should use its authority, to the maximum extent permitted by the First Amendment, to prevent the advertising, marketing and promotion of e-cigarettes to children.

Although the availability of properly regulated e-cigarettes might contribute to adult cessation, the indiscriminate marketing of e-cigarettes could reduce the number of smokers who quit if smokers use them in addition to, and not instead of, regular cigarettes. Effective

regulation by the FDA is needed to minimize the potential harms of e-cigarettes and to ensure that any potential benefits of e-cigarettes are attained consistent with the protection of our youth and other tobacco nonusers.

A. Population-Wide Effects on Youth Tobacco Use

1. Given the addictiveness of nicotine and its impact on adolescents, it is imperative that FDA attach high priority to curbing youth usage of the products.

The National Institute on Drug Abuse considers tobacco/nicotine a “drug of abuse” and highlights the role of nicotine addiction in fueling dependence on tobacco.³ It is critical, therefore, that FDA take strong action to prevent youth uptake of e-cigarettes, including marketing restrictions, an effectively presented government-mandated warning of the addictiveness of nicotine, sales restrictions, and regulation of the content of e-cigarette products.

Adolescents are particularly susceptible to the addictive properties of nicotine.⁴ A March 2015 report by the Institute of Medicine (IOM), found that “adolescent brains are uniquely vulnerable to the effects of nicotine and nicotine addiction.”⁵ Adolescents exhibit symptoms of drug dependence at lower levels of cigarette consumption compared with adults.⁶ In addition, dependence develops over a relatively short duration of smoking. Among occasional adolescent smokers, a large proportion experienced at least one symptom of nicotine dependence upon quitting, even in the first four weeks after initiating monthly smoking (at least two cigarettes within a two-month period).⁷

The vulnerability of adolescents to nicotine addiction is one of the reasons they continue smoking. Research shows that about 80 percent of established adult smokers began smoking before the age of 18.⁸ As a result of nicotine addiction, about three out of four teen smokers end

³ National Institute on Drug Abuse, see: <http://www.drugabuse.gov/drugs-abuse>; <http://www.drugabuse.gov/publications/research-reports/tobacco/nicotine-addictive>.

⁴ U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, HHS, U.S. Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health (OSH), 2012, at 457.

⁵ Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015 at 2, http://www.iom.edu/~media/Files/Report%20Files/2015/TobaccoMinAge/tobacco_minimum_age_report_brief.pdf.

⁶ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, CDC OSH, 2010, pps 157 and 161. See also DiFranza F, *Nicotine Addiction and E-Cigarettes*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015, at 466-67.

⁷ HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Attorney General*, CDC OSH 2012, at 24 (citing DiFranza, et al.).

⁸ Data from the 2013 National Survey on Drug Use and Health, affirms <http://www.icpsr.umich.edu/icpsrweb/SAMHDA/>.

up smoking into adulthood, even if they intend to quit after a few years.⁹ Indeed, research has shown that adolescents have little understanding of the grip of nicotine. One study found that 60 percent of adolescents believed that they could smoke for a few years and then quit.¹⁰

Youth usage of e-cigarettes is particularly troubling because human brain development, including areas involved in higher cognitive functions, continues throughout adolescence and into the 20s.¹¹ Citing several studies, the 2012 Surgeon General's report concluded, "[E]xposing the developing brain to nicotine has been shown to alter its structure and function in a way that introduces long-lasting vulnerability for addiction to nicotine and other substances of abuse."¹² In addition, the 2014 Surgeon General's report concluded that "the evidence is suggestive that nicotine exposure during adolescence, a critical window for brain development, may have lasting adverse consequences for brain development."¹³ Indeed, the parts of the brain most responsible for decision making, impulse control, sensation seeking, and susceptibility to peer pressure continue to develop and change through young adulthood.¹⁴ A recently published review of the evidence on the impacts of nicotine on the developing brain concluded that "evidence is currently sufficient to warrant extreme caution regarding exposure of adolescents to exogenous nicotine."¹⁵

2. The continued increase in youth usage of electronic cigarettes supports strong FDA action to prevent youth addiction to nicotine and the risk of migration to more hazardous tobacco products.

Recent data show that large and rapidly growing numbers of young people are using e-cigarettes. National data released by CDC and FDA show that, for the first time, youth use of electronic cigarettes exceeds use of regular cigarettes.¹⁶ Current e-cigarette use among high school students increased from 4.5 percent in 2013 to 13.4 percent in 2014 (it was just 1.5 percent in 2011). A similar increase was seen among middle school students – current e-cigarette use increased from 1.1 percent in 2013 to 3.9 percent in 2014. According to the survey,

⁹ HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General: Fact Sheet*, 2012, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/factsheet.html>.

¹⁰ Institute of Medicine of the National Academies, *Ending the Tobacco Problem: A Blueprint for the Nation*, 2007, at 91.

¹¹ England, LJ, et al., "Nicotine and the Developing Human, A Neglected Element in the Electronic Cigarette Debate," *American Journal of Preventive Medicine*, [Epub ahead of print], pii: S0749-3797(15)00035-5. doi: 10.1016/j.amepre.2015.01.015, March 7 2015.

¹² HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Attorney General*, 2012, at 457 (citing Leslie, 2004; Deby and Tiffany, 2008, and Dao, 2011).

¹³ 2014 Surgeon General's Report at 126.

¹⁴ Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015.

¹⁵ England, LJ, et al., "Nicotine and the Developing Human, A Neglected Element in the Electronic Cigarette Debate," *American Journal of Preventive Medicine*, [Epub ahead of print], pii: S0749-3797(15)00035-5. doi: 10.1016/j.amepre.2015.01.015, March 7 2015, at 5.

¹⁶ The 2014 NYTS modified the question structure for e-cigarettes, including a new preamble to the e-cigarette section and changes to the question wording. Some of the increase in prevalence could be the result of these changes.

approximately two million high school students and 450,000 middle school students currently use e-cigarettes.¹⁷ Since the same study found that 1.6 million youth smoke cigarettes, this means that at least 800,000 e-cigarette users do not smoke cigarettes.

The data released by CDC and FDA follows the release of data from the Monitoring the Future survey in 2014,¹⁸ which found that past-month use of e-cigarettes was higher than regular cigarettes among 8th, 10th and 12th graders, and more than twice as many 8th and 10th graders reported using e-cigarettes compared to regular cigarettes.¹⁹

Data released previously from CDC show that the number of U.S. youth who have used e-cigarettes, *but have never smoked a regular cigarette*, more than tripled in three years, from 79,000 in 2011 to more than 263,000 in 2013.²⁰ Similar data for 2014 have not yet been released.

Limited evidence exists regarding the relationship between e-cigarette use and conventional smoking intentions.²¹ CDC data from 2013 indicate that the youth who have used e-cigarettes, but have never smoked a regular cigarette, were nearly twice as likely to express intention to smoke regular cigarettes as those who have never used e-cigarettes.²²

Another study, this one of young adults, examined the relationship between e-cigarette use and openness to cigarette smoking.²³ Openness to cigarette smoking was defined as the lack of a firm intention not to smoke soon or in the next year, a definition that draws on previous research. In the study, researchers analyzed data from the 2012-2013 National Adult Tobacco Survey, focusing their analysis on young adults who had never established cigarette smoking behavior. Among this group, 7.9 percent reported ever trying e-cigarettes. Nearly half (46.1 percent) of these young adults who had ever tried an e-cigarette reported being open to smoking cigarettes, compared to only 14.2 percent of those who had never tried an e-cigarette. Openness to smoke conventional cigarettes was also high among young adults who had ever tried other tobacco products.

¹⁷ U.S. Centers for Disease Control and Prevention (CDC), "Tobacco Use Among Middle and High School Students — United States, 2011-2014," *Morbidity and Mortality Weekly Report (MMWR)* 64(14):381-385, April 2015, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm?s_cid=mm6414a3_e. Current use is defined as use on at least one day in the past 30 days.

¹⁸ Monitoring the Future assessed e-cigarette use for the first time in 2014.

¹⁹ University of Michigan, Monitoring the Future Study, December 16, 2014, "E-cigarettes surpass tobacco cigarettes among teens." University of Michigan News Service: Ann Arbor, MI, <http://www.monitoringthefuture.org>.

²⁰ Bunnell, R, et al., "Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013," *Nicotine & Tobacco Research* 17(2):228-35, February 2015.

²¹ Coleman, B, et al., "Association Between Electronic Cigarette Use and Openness to Cigarette Smoking Among US Young Adults," *Nicotine & Tobacco Research* 17(2):212-8, 2015.

²² Bunnell, R, et al., "Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013," *Nicotine & Tobacco Research* 17(2):228-35, February 2015.

²³ Coleman, B, et al., "Association Between Electronic Cigarette Use and Openness to Cigarette Smoking Among US Young Adults," *Nicotine & Tobacco Research* 17(2):212-8, 2015.

The study indicates that ever use of e-cigarettes, along with ever use of other combustible products, is associated with being open to smoking cigarettes (although the direction of this association cannot be assessed). It is important to recognize that, due to the relatively recent introduction of e-cigarette products and the lack of data from prospective longitudinal studies, the study authors make clear that “a direct link between use of e-cigarettes and progression to use of cigarettes has not been shown.”

Still, measuring the openness to cigarette smoking is of particular interest. Although few studies have followed young adults over time to determine if those found to be at risk of smoking actually go on to smoke, the study authors note that “the few studies that have done so have found that a lack of a firm intention not to smoke is a powerful predictor of increased risk of progression to actual use.”

The trend in youth use of e-cigarettes is of great concern. It would be irresponsible to postpone regulatory action until we determine what percentage of youth e-cigarette users actually become cigarette smokers or become long-term e-cigarettes users. The latest data on the increasing use of e-cigarettes, and the associated openness to smoking cigarettes, supports strong FDA action —now— to prevent youth addiction to nicotine and the risk of migration to more hazardous tobacco products.

3. The increasing use of kid-friendly flavors in e-cigarettes supports strong FDA action to prohibit characterizing flavors in the products.

Though these products are relatively new to the market, the variety of flavors available for use in e-cigarettes has grown exponentially. In addition to the more traditional candy and fruit flavors like cherry and chocolate, e-cigarettes and refill liquids or cartridges are also being sold in such options as cotton candy, root beer float, and banana split. These fruit and candy flavorings have long been considered attractive to kids and are no longer permitted in regular cigarettes.

When it implemented the statute’s prohibition of characterizing flavors in cigarettes, FDA cited studies showing that 17-year-old smokers are three times as likely to use flavored cigarettes as are smokers over the age of 25.²⁴ There is every reason to believe that the use of sweet and fruity flavors in e-cigarettes, bolstered by advertising reaching kids, is having the same effect it has had for other tobacco products – making a highly addictive product more appealing to youth.

E-cigarette manufacturers contend that certain flavors may enhance the effectiveness of e-cigarettes in assisting smokers to quit. Before any non-tobacco flavor is permitted, these companies should be required to produce credible scientific evidence that specific flavors not

²⁴ FDA Guidance for Industry and FDA Staff, “General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) (“FDA Guidance on Characterizing Flavors”), at 2.

only aid in smoking cessation, but that they do not pose a health hazard, do not contribute to initiation of tobacco product use or relapse into tobacco product use, and do not function to deter smoking cessation by those who otherwise would have quit.

a. E-Cigarettes are available in an increasing number of flavors.

By January 2014, researchers were able to identify more than 7,700 unique e-cigarette flavors available online, with an average of more than 240 new flavors being added per month.²⁵ Among more than 400 available brands, 84 percent offered fruit flavors and 80 percent offered candy and dessert flavors.²⁶

In addition to the vast selection available online, thousands of “vape” shops have now opened throughout the country that allow consumers to sample and purchase refill liquids, including a combination of flavors chosen by the user.²⁷

The top three cigarette manufacturers now also have e-cigarettes that come in a variety of flavors other than tobacco. In February 2015, Altria announced that they were expanding the flavors in their MarkTen brand e-cigarettes, and later introduced MarkTen XL in “Fusion” and “Winter Mint” varieties.²⁸ Since December 2014, Reynolds American’s Vuse product comes in flavors such as Rich Mint, Crema and Chai, while Lorillard’s blu e-cigarette features such flavors as Cherry Crush, Vivid Vanilla and Pina Colada.²⁹

In November 2012, executive vice president of NJOY stated that, “We believe that e-cigs--or any tobacco products--that are chocolate or strawberry, a reasonable person could conclude it might appeal to an underage consumer. Because of that, we have no interest; we don’t want the risk of attracting the underage buyer. We don’t think it’s right for us and we don’t think it’s right for the category.”³⁰ Yet less than two years later, NJOY announced that the

²⁵ Zhu, S-H, et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation,” *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

²⁶ Zhu, S-H, et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation,” *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

²⁷ Johnson, A, “Up in smoke? Alamance e-cigarette store operators concerned about proposed regulations,” *Times-News*, April 30, 2014, <http://www.thetimesnews.com/news/top-news/up-in-smoke-alamance-e-cigarette-store-operators-concerned-about-proposed-regulations-1.313005>. The website for VapeRite ATL also notes that customers can “mix well over 100,000 possible flavor and mix type combinations” [<https://atlanta.vaperite.com/#vape-bar>, accessed May 30, 2014].

²⁸ “Altria’s MarkTen Getting Supersized,” *Convenience Store News*, February 19, 2015, <http://www.csnews.com/product-categories/tobacco/altrias-markten-getting-supersized>. See also: <http://www.trinketsandtrash.org/detail.php?artifactid=10081>.

²⁹ blu cigs, Flavor Cartridges, accessed June 10, 2014 from <http://www.blucigs.com/product/flavor-cartridges/>. Kress, M, “Innovation Defines RAI’s Investor Day,” *Convenience Store News*, November 17, 2014, <http://www.csnews.com/product-categories/tobacco/innovation-defines-rais-investor-day>. On June 12, 2014, Reynolds American, Inc. and Lorillard completed a merger, by which ownership of the blu brand was transferred to Imperial Tobacco Group PLC.

³⁰ Vonder Haar, M, “The Value of Self-Regulating E-Cigs: NJOY exec: Responsible practices now will ensure long-term survival,” *Tobacco E-News*, November 6, 2012, <http://www.cspnet.com/category-news/tobacco/articles/value-self-regulating-e-cigs>.

company was releasing flavors, such as “vanilla bean” and “black & blue berry” starting in August 2014.³¹ Even further, the company’s marketing for these flavors now include “recipes” to mix the flavored liquids to make new flavors such as “blueberry pie with whipped cream” and “peaches & cream.”³²

b. Impact of flavors on youth use of e-cigarettes

National data specifically on youth use of flavored e-cigarettes have yet to be reported, but the increase in the number of youth using e-cigarettes is an indication that they are attracted to these products.

Research presented to FDA at the June 1 workshop points to the availability of appealing flavors as well as the ability to customize flavors as a factor in use of e-cigarettes among young people.³³

One study of adolescents and young adults in Connecticut found that nearly 44 percent listed the availability of appealing flavors as one of the reasons they tried e-cigarettes. The other top reasons were curiosity (54 percent) and peer influence (32 percent). Researchers noted that appealing flavors are particularly important to high school students. Compared to college students, high school students were more likely to experiment with e-cigarettes because of appealing flavors (47 percent versus 33 percent).³⁴

Another study of Connecticut high school and middle school students found that among students who had ever used e-cigarettes, most reported that they had tried and preferred “sweet” flavors. Overall, 71 percent had tried sweet-flavored e-cigarettes, compared to 22 percent trying menthol and 14 trying tobacco flavors. When asked which flavors they preferred, 57 percent of those ever using e-cigarettes preferred sweet flavors, with far fewer preferring menthol (3.5 percent) or tobacco flavors (0.5 percent). The authors noted that menthol and tobacco flavors appeared to be used mostly by those who were also cigarette smokers, although at considerably lower rates than sweet flavors.³⁵

Although some have argued that certain flavors in e-cigarettes may enhance their appeal and effectiveness as devices to aid smoking cessation by adults, this assertion is unproven. Many

³¹ NJOY Blog, “NJOY E-Liquid Flavor Breakdown,” July 22, 2014, <https://www.njoy.com/blogs/ta-da-presenting-njoy-vape-e-liquids>. For examples of its marketing of its new flavors, see NJOY’s Facebook Photostream, July 23-24, 2014, https://www.facebook.com/NJOYecigs/photos_stream.

³² NJOY’s Facebook Photostream, September 26, 2014, https://www.facebook.com/NJOYecigs/photos_stream. See also, “Vape Mixology Recipe Book,” retail pamphlet obtained in New Jersey store, March 2015, <http://www.trinketsandtrash.org/detail.php?artifactid=9897&page=1>.

³³ Krishnan-Sarin, S, *Use, Appeal and Access to E-cigarettes among Youth*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 1, 2015.

³⁴ Kong, G, et al., “Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults,” *Nicotine & Tobacco Research* 17(7):847-54, July 2015.

³⁵ Krishnan-Sarin, S, et al., “E-Cigarette Use Among High School and Middle School Adolescents in Connecticut,” *Nicotine & Tobacco Research* 17(7):810-8, 2015.

of the existing studies on this issue have significant limitations, and ultimately contribute very little to our knowledge of the impact of flavors on cessation. Even if flavors in e-cigarettes were to aid some adult smokers in quitting smoking, if those flavors also induced many youth to try and become addicted to nicotine, then the risks have the potential to outweigh the benefits.

A 2013 survey that examined the impact of flavorings on the e-cigarette experience of dedicated e-cigarette users used a convenience sample of participants recruited from popular e-cigarette user forums and e-cigarette advocate websites.³⁶ In a convenience sample the respondents are not representative of the population, and in this study the authors acknowledge that participants were primarily dedicated e-cigarette users who had positive experiences with e-cigarettes. In addition, this internet-based survey just asked participants to rate the importance of flavor variability in reducing or quitting smoking but did not actually assess if having access to a variety of flavors leads to reduced consumption or quitting or if those who said they had quit stayed quit over time.

A study featured in the June 1 workshop presentation, *Flavors in E-cigarettes: Promise or Peril?*, examined interest in using flavored e-cigarettes among non-smoking teens compared to current smokers, many of whom also use e-cigarettes.³⁷ The study – funded by e-cigarette manufacturer NJOY – found that non-smoking teens’ interest in using flavored e-cigarettes was very low compared to that of an adult smoker. It is not surprising that the adult smokers in the study, many of whom had already used e-cigarettes, reported higher interest in e-cigarettes as compared to teen never-smokers—what is being measured is interest in flavors in a group predisposed to use of a product versus interest in flavors in a group predisposed *not* to use the product at all. Further, there is a difference between teens who are committed non-smokers and those teens who display some susceptibility to smoking or who use or have tried e-cigarettes or had used tobacco products more recently. To fully explore the potential impact of flavors, independent studies must also examine this broader group of teens. Finally, the data do not address the question of whether flavors themselves enhance the potential effectiveness of the e-cigarettes as a cessation device. The study does not provide the evidence to support claims that flavors (beyond tobacco) are necessary to promote full conversion among smokers and does not address the extent to which a prohibition on flavors would discourage smokers who otherwise would use e-cigarettes as a means of quitting smoking from doing so.

The increasing use of kid-friendly flavors in e-cigarettes raises a serious concern that the fruit and candy flavors serve to make a highly addictive product more appealing to youth. Indeed, emerging research points to the availability of appealing flavors as a factor in use of e-

³⁶ Farsalinos, K, et al., “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey,” *International Journal of Environmental Research and Public Health* 10:7272-7282, 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/pdf/ijerph-10-07272.pdf>.

³⁷ Shiffman, S, *Flavors in E-cigarettes: Promise or Peril?* Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 1, 2015. See also, Shiffman, S, et al., “The Impact of Flavor Descriptors on Nonsmoking Teens’ and Adult Smokers’ Interest in Electronic Cigarettes,” *Nicotine & Tobacco Research* Advance Access, doi:10.1093/ntr/ntu333, January 26, 2015.

cigarettes among young people. The increasing availability of flavors and experience with other flavored tobacco products supports a product standard prohibiting characterizing flavors (other than tobacco) in e-cigarettes. One thing is for certain; e-cigarette manufacturers are introducing new flavors without first testing them to ensure that they do not appeal to youth.

4. The continued marketing of the products to attract young people supports application of marketing restrictions on the products as restrictive as current FDA restraints on cigarettes and smokeless marketing.

E-cigarette manufacturers continue to promote their products in the absence of any marketing or advertising restrictions like those that apply to cigarettes under the Master Settlement Agreement (“MSA”) or regulations promulgated pursuant to the Tobacco Control Act that were designed to protect youth from cigarette marketing.³⁸ Failing to extend regulation and marketing restrictions of the Tobacco Control Act to include e-cigarettes would be a failure to protect millions of youth, and would undermine decades of tobacco prevention efforts to denormalize and deglamorize smoking.

Unlike cigarettes and smokeless tobacco, e-cigarette companies are not currently required to report their marketing and promotion expenditures to the U.S. Federal Trade Commission (FTC), so the exact amount spent to advertise and promote their products and details of how the money is spent are unknown and the current projections vary and likely underestimate total expenditures. A 2014 study shows that e-cigarette promotional expenditures³⁹ were minimal through mid-2010 but then jumped to \$12 million in 2011. One year later, in 2012, expenditures nearly doubled to \$22 million.⁴⁰ A survey of leading e-cigarette manufacturers, conducted by staff for 11 members of Congress, found that six of the nine surveyed companies spent a total of \$59.3 million on advertising and promotion in 2013.⁴¹ A study by Legacy estimates this number to be even higher, at \$82.1 million.⁴² At the FDA workshop on June 1, Dr. Lauren Dutra stated that by the end of 2014, annual marketing spending by e-cigarette companies in all media had exceeded \$100 million for the first time (\$112.9 million).⁴³

³⁸ Section III of the Master Settlement Agreement of 1998 (“MSA”) between the major tobacco companies and 52 States and territories contains numerous restrictions on the advertising, marketing, and promotion of cigarettes and roll-you-own tobacco, including a prohibition on targeting youth. The MSA applies to approximately 95 percent of cigarettes sold in the United States. Similar provisions apply to smokeless tobacco products under the Smokeless Tobacco Master Settlement Agreement.

³⁹ Promotional expenditures include TV, print, radio, outdoor and internet channels.

⁴⁰ Kornfield, R, et al., “Rapidly increasing promotional expenditures for e-cigarettes,” *Tobacco Control*, Published Online First: April 30, 2014.

⁴¹ See Durbin, RJ, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, April 14, 2014,

http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f.

⁴² Legacy, *Vaporized: E-Cigarettes, Advertising, and Youth*, April 2014,

http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf.

⁴³ Dutra, L, *Adolescent E-cigarette Use: What We Already Know*. 2014 data from Kantar Media. Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 1, 2015.

As the availability and marketing of e-cigarettes continues to increase, children’s exposure to and odds of experimenting with them will likely increase as well. Emerging research presented at the FDA workshops in June by Dr. Laura Gibson indicates that even among never users of both e-cigarettes and cigarettes, greater than weekly exposure to e-cigarette advertising is associated with greater intentions to use e-cigarettes in the next six months and the perception that more than half of peers are using e-cigarettes, reflecting an impact on social norms.⁴⁴

The following examination of the marketing and advertising of e-cigarettes leaves no doubt that the industry’s strategy includes targeting minors. Extensive examples of e-cigarette marketing were submitted as part of our August 8, 2014 submission to the deeming rule docket. The Appendix attached to these comments provides additional examples since those comments were filed of how e-cigarette manufacturers continue to execute this strategy. Many of the themes pervasive in today’s e-cigarette advertisements imitate those that made cigarettes popular decades ago.⁴⁵ Across these marketing avenues, e-cigarette companies promote and build the image of e-cigarettes by portraying e-cigarettes as symbols of glamour, sex appeal, maturity and rugged independence, implicitly associating the products with an adolescent’s idealized life style.⁴⁶

Echoing the marketing practices of tobacco companies from decades ago (many of which are now banned for cigarettes), e-cigarettes are being aggressively marketed in ways that appeal to youth. E-cigarette marketing tactics include:

Television. While cigarette advertising has been absent from TV and radio since 1971, TV advertising is the second highest tracked marketing expense among e-cigarette manufacturers.⁴⁷ According to the Legacy study, from June to November 2013, e-cigarette companies spent \$7.4 million on national TV ads and another \$3.3 million on local TV ads. These ads were strategically targeted to reach youth through network placement on Comedy Central, ABC Family, MTV and Spike.⁴⁸ NJOY, specifically, has aired ads on ESPN, during the Academy Awards, and during the Super Bowl—one of the most watched TV events of the

⁴⁴ Gibson, L, *E-Cigarette Use, Cognitions, and Ad Exposure: Interim Results from the UPenn Youth and Young Adult Survey*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 1, 2015.

⁴⁵ See *7 Ways E-Cigarette Companies Are Copying Big Tobacco’s Playbook*, http://www.tobaccofreekids.org/tobacco_unfiltered/post/2013_10_02_ecigarettes.

⁴⁶ The U.S. District Court for the District of Columbia concluded that the tobacco companies’ marketing of cigarettes was intended to “burnish. . .the image of their youth brands to convey rugged independence, rebelliousness, love of life, adventurousness, confidence, self-assurance and belonging to the ‘in’ crowd. *U.S. v. Philip Morris USA, Inc.*, 449 F.Supp.2d at 616.

⁴⁷ Kornfield, R, et al., “Rapidly increasing promotional expenditures for e-cigarettes,” *Tobacco Control* 24(2):110-1, March 2015; Kim, AE, et al., “E-cigarette Advertising Expenditures in the U.S., 2011-2012,” *American Journal of Preventive Medicine* 46(4):409-412, 2014; Legacy, *Vaporized: E-Cigarettes, Advertising, and Youth*, April 2014, http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf; Richardson, A, et al., “Noncombustible Tobacco Product Advertising: How Companies Are Selling the New Face of Tobacco,” *Nicotine & Tobacco Research* 16(5):606-14, 2014.

⁴⁸ Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics* 134(1):e29-36, July 2014.

year.⁴⁹ As noted in our previous comments, a study in *Pediatrics* found that from 2011 to 2013, exposure of youth aged 12-17 to e-cigarette advertisements on TV increased by 256 percent.⁵⁰ This same study estimates that e-cigarette advertisements may reach an audience of up to 24 million youth. Given the extent of television advertising, it is not a surprise that one study found that television is one of the most common ways that people hear about e-cigarettes.⁵¹ Alarmingly, research presented by Dr. Matthew Farrelly at the FDA Workshop on June 1 shows these ads are effective—a recent randomized trial exposing adolescent e-cigarette non-users to such ads showed that they led to 50 percent higher intentions to use e-cigarettes.⁵²

Event-based Marketing. E-cigarette companies sponsor and place tents or displays at a variety of events, many of which are popular with youth and young adults. These include music festivals and sporting events, such as racing, sailing, and poker tournaments.⁵³ A survey of local vape shops in Oklahoma found that one store sponsored the local high school football team, which allowed them to put up a banner for their store at games.⁵⁴ They also use these venues as opportunities to hand out free samples and branded promotional items.

Online and Social Media. E-cigarette companies market extensively on product websites and maintain a strong presence on social media sites popular among youth, like Facebook, YouTube, Instagram, and Twitter.⁵⁵ Twitter, for instance, can have very high exposure with very little expense for the promoter and, of more concern, youth can easily access tweets. One study found nearly 74,000 tweets about e-cigarettes in just a two month period, most of which were sent by a few commercial enterprises. These tweets included links to

⁴⁹ Legacy, *Vaporized: E-Cigarettes, Advertising, and Youth*, April 2014, http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf.

⁵⁰ Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics* 134(1):e29-36, July 2014.

⁵¹ Emery, SL, et al., “Wanna know about vaping? Patterns of message exposure, seeking and sharing information about e-cigarettes across media platforms,” *Tobacco Control* 23:iii17-iii25, 2014. Pepper, JK et al., “How U.S. Adults Find Out About Electronic Cigarettes: Implications for Public Health Messages,” *Nicotine & Tobacco Research* 16(8):1140-1144, August 2014.

⁵² Farrelly, M, *A Randomized Trial of the Effect of E-cigarette Television Ads on Intentions to Use E-Cigarettes*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 1, 2015.

⁵³ Durbin, RJ, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, April 14, 2014, http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f.

⁵⁴ Cheney, M, Gowin, M, & Wann, TF, “Marketing Practices of Vapor Store Owners,” *American Journal of Public Health*, online ahead of print, doi:10.2105/AJPH.2015.302610, April 16, 2015, <http://www.ncbi.nlm.nih.gov/pubmed/25880960>.

⁵⁵ Durbin, RJ, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, April 14, 2014, http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f. See also, Noel, JK, Rees, VW, & Connolly, GN, “Electronic cigarettes: a new ‘tobacco’ industry?” *Tobacco Control* 20:81, 2011.

websites promoting product deals and smoking cessation, despite the lack of evidence supporting such claims.⁵⁶

E-cigarette manufacturers also place ads on search engines and websites, including those that focus on music, entertainment, and sports and which often have substantial youth and young adult audiences.⁵⁷ The companies rarely take steps to effectively prevent access to these websites by minors, as evidenced by the Legacy study showing that 43 percent of teens (ages 13-17) had seen e-cigarette advertisements online always, most or some of the time.⁵⁸ Research has shown that youth with extensive exposure to pro-tobacco messages on the internet are 1.6 times more likely to experiment with e-cigarettes.⁵⁹ Without adequate restrictions in place to limit youth access to online and social media marketing, e-cigarette companies not only knowingly enable youth exposure to their marketing, they also provide youth an opportunity to purchase an addictive product with minimal obstacles.⁶⁰ Indeed, recently published research from North Carolina found that youth successfully purchased e-cigarettes over the internet in 93.7 percent of the attempts subverting age of sale restrictions in the state.⁶¹

Point-of-Sale Advertising and Promotions. E-cigarette manufacturers also invest in point-of-sale marketing in order to compete with other tobacco products and ensure their products are prominently displayed at retail checkouts. Sales of e-cigarettes continue to climb since their initial introduction in the U.S. While information on sales in vape shops and online is unavailable, Nielsen data on sales in traditional retail channels such as convenience stores, drug stores, grocery/food stores, and some mass merchandisers, show a more than doubling (132.5 percent) of sales in just one year, between 2012 and 2013.⁶²

Like traditional tobacco products, e-cigarettes are placed, promoted, and priced to be appealing to anyone—including youth—who go into these retail locations. In 2012, nearly one-third of retailers sold e-cigarettes, with availability greatest in convenience stores and drug stores.^{63,64} In contrast to cigarettes, e-cigarettes can be placed on store countertops and in self-

⁵⁶ Huang, J, et al., “A cross-sectional examination of marketing of electronic cigarettes on Twitter,” *Tobacco Control* 23:iii26-iii30, 2014.

⁵⁷ Richardson, A, et al., “Tobacco on the web: surveillance and characterization of online tobacco and e-cigarette advertising,” *Tobacco Control*, Published Online First: February 14, 2014.

⁵⁸ Legacy, *Vaporized: E-Cigarettes, Advertising, and Youth*, April 2014, http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf.

⁵⁹ Agaku, IT & Ayo-Yusuf, OA, “The Effect of Exposure to Pro-Tobacco Advertising on Experimentation With Emerging Tobacco Products Among U.S. Adolescents,” *Health Education & Behavior* 41(3):275-280, December 16, 2013.

⁶⁰ Durbin, RJ, et al., *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*, April 14, 2014, http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f.

⁶¹ Williams, RT, Derrick J, & Ribisl, KM, “Electronic cigarette sales to minors via the internet.” *JAMA Pediatrics* 169(3):e1563, doi: 10.1001/jamapediatrics.2015.63, Epub March 2, 2015.

⁶² Giovenco, DP, et al., “E-Cigarette Market Trends in Traditional U.S. Retail Channels, 2012–2013,” *Nicotine & Tobacco Research* advance access, doi:10.1093/ntr/ntu282, January 15, 2015.

⁶³ *Ibid.*

service displays, unless a state or locality has enacted a law to prohibit those practices for e-cigarettes. Indoor and outdoor signs advertising e-cigarettes are also placed throughout retail stores, including at kids' eye level (less than three feet above the ground).⁶⁵ A 2014 study reported that 60 percent of teens (ages 13-17) had seen e-cigarette ads at convenience stores, supermarkets and gas stations.⁶⁶ This extensive marketing and availability of e-cigarettes is troubling given that research from a 2011 national youth survey shows that students exposed to pro-tobacco messages most of the time or always in retail stores are 1.7 times more likely to experiment with e-cigarettes.⁶⁷

Other tactics that have been used to market e-cigarettes include magazine advertising with images and themes that appeal to young people, celebrity spokespersons who depict e-cigarette smoking as glamorous and cool, radio advertisements and even cartoon imagery. Taken as a whole, it is clear that e-cigarette manufacturers are marketing their products in ways that appeal to children.

In addition to alluring children, e-cigarette advertisements could be having adverse effects on cigarette smokers as well. One study found that portraying the use of e-cigarettes in commercials increased cigarette smoking urges among daily cigarette smokers and marginally significantly increased their cigarette smoking.⁶⁸

Because of the clear evidence of exposure to – and impact of – e-cigarette marketing on youth, the provisions in the 2010 rule pertaining to cigarettes and smokeless tobacco, including prohibiting sales to minors, vending machine sales, and free product sampling, prohibition of self-service displays of deemed products, the prohibition of tobacco brand names on non-tobacco merchandise, and the brand name sponsorship of musical and athletic events should be extended to e-cigarettes. However, taking such an action is not sufficient to protect the public health. Because of the inherent difficulty of enforcing effective age verification for on-line sales, FDA should prohibit sales of e-cigarettes over the internet. If the agency decides to permit internet sales, it should at least impose age-verification procedures on internet sellers of e-cigarettes analogous to those mandated for internet cigarette sales by the Prevent All-Cigarette Trafficking Act of 2009.

⁶⁴ Rose, SW, et al., “The availability of electronic cigarettes in US retail outlets, 2012: results of two national studies,” *Tobacco Control*, 23:iii10-iii16, 2014.

⁶⁵ Ganz, O, et al., “Electronic cigarette advertising at the point-of-sale: a gap in tobacco control research,” *Tobacco Control*, Published Online First, doi: 10.1136/tobaccocontrol-2013-051337, March 11, 2014.

⁶⁶ Khan, T, et al, *Changes in E-Cigarette Availability over Time in the United States: 2010 – 2012*, a Bridging the Gap Research Brief, 2014, http://www.bridgingthegapresearch.org/asset/48gsz7/btg_e-cigarette_brief_FINAL_March2014.pdf.

⁶⁷ Agaku, IT & Ayo-Yusuf, OA, “The Effect of Exposure to Pro-Tobacco Advertising on Experimentation With Emerging Tobacco Products Among U.S. Adolescents,” *Health Education & Behavior* 41(3):275-280, December 16, 2013.

⁶⁸ Maloney, EK & Cappella, JN, “Does Vaping in E-Cigarette Advertisements Affect Smoking Urge, Intentions, and Perceptions in Daily, Intermittent, and Former Smokers?” *Health Communication*, published online first, March 11, 2015.

5. The increase in incidents of young children being exposed to liquid nicotine supports immediate FDA action to mandate child resistant packaging for liquid nicotine products.

In his presentation at the FDA workshop on June 2, Dr. Kevin Chatham-Stephens from CDC noted that exposure to liquid nicotine found in e-cigarettes has caused a burgeoning number of calls to poison control centers.

There were 3,692 calls involving exposures to e-cigarette devices and liquid nicotine in 2014, a more than 1,400 percent increase over the number of calls in 2011 (238). More than half (58 percent) of these calls to poison hotlines were to report exposures among children five years old and younger.⁶⁹ Dr. Chatham-Stephens also noted that these figures are likely to be an underestimate of the true number of exposures, noting that it is estimated that half of all poisonings go unreported to poison control centers.⁷⁰

In addition to the above data for 2014, the American Association of Poison Control Centers (AAPCC) reports 1,499 calls involving exposures to e-cigarette devices and liquid nicotine in the first five months of 2015 alone (similar to 1,533 in the first five months of 2014).⁷¹

Prior data published by CDC found that e-cigarette calls were more likely than calls involving traditional cigarettes to include a report of an adverse health effect following exposure.⁷² Further, AAPCC states that, “Some children and toddlers who come in contact with e-cigarette devices or liquid nicotine have become very ill; some even requiring ER visits with nausea and vomiting being the most significant symptoms.”⁷³

The CDC analysis found that a large majority of the exposures (80 percent) were through ingestion, with other cases of exposure through inhalation or absorption through the skin or eyes.⁷⁴ In her presentation at the FDA workshop on June 2, Dr. Jeannie Limpert from the FDA

⁶⁹ Chatham-Stephens, K. *Calls to U.S Poison Centers Involving Exposure to Electronic Cigarettes*. Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 2, 2015.

⁷⁰ Chatham-Stephens, K. *Calls to U.S Poison Centers Involving Exposure to Electronic Cigarettes*. Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 2, 2015.

⁷¹ American Association of Poison Control Centers (AAPCC), E-Cigarette Devices and Liquid Nicotine, <http://www.aapcc.org/alerts/e-cigarettes/>, accessed June 9, 2015. Data from 2014-2015 are considered preliminary and the numbers may change as cases are closed and additional information is received.

⁷² CDC, “Calls to Poison Centers for Exposures to Electronic Cigarettes – United States, September 2010-February 2014,” *MMWR* 63(13):292-293, April 4, 2014, <http://www.cdc.gov/mmwr/pdf/wk/mm6313.pdf>.

⁷³ American Association of Poison Control Centers (AAPCC), E-Cigarette Devices and Liquid Nicotine, <http://www.aapcc.org/alerts/e-cigarettes/>, accessed June 6, 2015. Data from 2014-2015 are considered preliminary and the numbers may change as cases are closed and additional information is received.

⁷⁴ Chatham-Stephens, K. *Calls to U.S Poison Centers Involving Exposure to Electronic Cigarettes*. Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 2, 2015.

Center for Tobacco Products discussed a number of cases of adverse experiences of non-users, including a case of a toddler who ingested e-liquid containing nicotine and died.⁷⁵

The unregulated market for e-cigarettes is allowing indiscriminate availability of the dangerous and toxic chemical nicotine, with the appeal of fruit and candy flavors, in containers without child-resistant packaging. As Dr. Kyran Quinlan of the American Academy of Pediatrics told FDA, “The urgency on this issue cannot be overstated.”⁷⁶

The recent promulgation of an Advanced Notice of Proposed Rulemaking on this subject⁷⁷ is a first step toward meeting this immediate need but because of the special urgency of this threat, FDA should act swiftly to mandate child-resistant containers for liquid nicotine products.

B. Population-Wide Effects on Adult Tobacco Use

1. There is currently uncertainty about the potential for e-cigarettes to aid in smoking cessation and no e-cigarette has been approved by FDA’s Center for Drug Evaluation and Research (CDER) as a safe and effective smoking cessation device.

Some e-cigarette users report that they believe that e-cigarettes will help them quit or reduce the number of cigarettes they smoke and state that they often use e-cigarettes for this reason.⁷⁸ However, there is not enough evidence to conclude that e-cigarettes are a safe and effective smoking cessation device and no e-cigarette has been approved by FDA’s CDER as a cessation device.⁷⁹ The U.S. Preventive Services Task Force, which makes recommendations about the effectiveness of specific preventive care services after a thorough assessment of the available science, recently concluded that “the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation.”⁸⁰ According to researchers

⁷⁵ Limpert, J. *Electronic Nicotine Delivery Systems: Nonuser Adverse Experiences Reported to FDA/CTP*. Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” June 2, 2015.

⁷⁶ Dr. Kyran Quinlan, *Liquid Nicotine Poisoning: An Emerging Threat to Children*. Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 11, 2014.

⁷⁷ Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquids, and Other Tobacco Products, Request for Comments, Docket No. FDA-2015-N-1514, 80 F.Reg. 37555, July 1, 2015.

⁷⁸ Grana, R, et al., “E-Cigarettes: A Scientific Review,” *Circulation* 129(19):1972-86, May 13, 2014; Pepper, JK and Brewer, NT, “Electronic nicotine delivery systems (electronic cigarette) awareness, use, reaction and beliefs: a systematic review,” *Tobacco Control* 23:375-384, 2014; Adkison, S, et al. “Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey,” *American Journal of Preventive Medicine* 44(3):207-215, 2013.

⁷⁹ King, BA, et al., “Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011,” *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update, U.S. Public Health Service Clinical Practice Guideline*, May 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

⁸⁰ U.S. Preventive Services Task Force, *Draft Recommendation Statement Tobacco Smoking Cessation in Adults and Pregnant Women: Behavioral and Pharmacotherapy Interventions*, May 2015, <http://www.uspreventiveservicestaskforce.org/Announcements/News/Item/public-comment-on-draft->

from CDC, “There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service.”⁸¹

Overall, the current data are limited and provide mixed results about the effectiveness of e-cigarettes in helping current smokers successfully quit. Two randomized controlled trials found that e-cigarettes are moderately effective in helping smokers quit, with rates of cessation with e-cigarettes similar to rates of cessation with NRT.⁸² Some longitudinal studies with comparison groups have found that e-cigarette use is not associated with successful quitting, finding that e-cigarette users were not more likely to have quit smoking compared to non-users.⁸³ Some cross-sectional studies have found, based on user reports, that e-cigarettes can help adults quit⁸⁴ while others have found no association between e-cigarette use and quitting.⁸⁵

Several studies indicate that e-cigarette use by cigarette smokers can lead to reductions in cigarette consumption, but success in quitting completely is dependent on the type of products used and how they are used.⁸⁶ A 2014 longitudinal study of current smokers found that smokers

[recommendation-statement-and-draft-evidence-review-tobacco-smoking-cessation-in-adults-including-pregnant-women.](#)

⁸¹ King, BA, et al., “Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011,” *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update*, U.S. Public Health Service Clinical Practice Guideline, May 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

⁸² Bullen, C, et al., “Electronic cigarettes for smoking cessation: a randomised controlled trial,” *The Lancet* 382(9905):1629-37, November 16, 2013; Capanetto, P, et al. “Efficiency and Safety of an eElectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month pilot study,” *PloS One* 8(6):e66317, 2013; Polosa, R. et al., “Effectiveness and tolerability of electronic cigarette in real life: a 24 month prospective observational study,” *Internal and Emergency Medicine* 9(5):537-46, August 2014.

⁸³ Adkison, S, et al. “Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey,” *American Journal of Preventive Medicine* 44(3):207-215, 2013; Vickerman, KA, et al., “Use of Electronic Cigarettes Among State Tobacco Cessation Quitline Callers,” *Nicotine & Tobacco Research* 15(10):1787-91, October 2013.

⁸⁴ Etter, JF & Bullen, C, “A longitudinal study of electronic cigarette users,” *Addictive Behaviors* 39(2):491-4 2014; Goniewicz, M, Lingas, EO, & Hajek, P, “Patterns of electronic cigarette use and user beliefs about their safety and benefits: An Internet survey,” *Drug and Alcohol Review* 32(2):133-40, 2013.

⁸⁵ Popova, L & Ling, PM, “Alternative tobacco product use and smoking cessation: a national study,” *American Journal of Public Health* 103(5):923-930, 2013; Christensen, T, Welsh, E, & Faseru, B, “Profile of e-cigarette use and its relationship with cigarette quit attempts and abstinence in Kansas adults,” *Preventive Medicine* 69:90-94, 2014.

⁸⁶ McRobbie, H, et al., “Electronic cigarettes for smoking cessation and reduction (Review), *The Cochrane Database of Systematic Reviews* 12:CD010216, 2014; Bullen, C, et al., “Electronic cigarettes for smoking cessation: a randomised controlled trial,” *The Lancet* 382(9905):1629-37, November 16, 2013; Capanetto, P, et al. “Efficiency and Safety of an eElectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month pilot study,” *PloS One* 8(6):e66317, 2013; Polosa, R, et al. “Effect of an electronic nicotine delivery device (e-cigarette) on smoking reduction and cessation: a prospective 6 month pilot study,” *BMC Public Health* 11:786, 2011.

who used e-cigarettes daily for at least one month were more than six times as likely to have quit smoking than those who never used e-cigarettes or only used them once or twice.⁸⁷

While limited studies have examined the relationship between e-cigarette use and quitting, as discussed at the FDA workshop on June 1 by Dr. Jennifer Pearson, the quality of existing data varies considerably and suffers from several limitations, including small samples, imprecise measurement and selection bias.⁸⁸ In some cases, the products evaluated do not reflect what is available in the current marketplace. More high quality research with strong study designs, including randomized control trials, are needed to adequately assess the potential of e-cigarettes as a cessation aid. Importantly, while the FDA's CTP requires a public health standard for the regulation of tobacco products, any product that makes a therapeutic claim (i.e. smoking cessation) must meet CDER's safety and efficacy standard by undergoing an extensive development, testing, and review process.

2. Based on current data, there is legitimate concern about widespread dual use of e-cigarettes and cigarettes, which does not yield meaningful health benefits unless it leads to a smoker no longer using cigarettes or serves as a pathway to that result.

E-cigarettes could have a negative impact on public health if smokers use them in addition to, and not instead of, regular cigarettes. To date, there is insufficient evidence to indicate what percentage of smokers are switching to exclusive e-cigarette use. While some studies suggest that some smokers are able to quit cigarettes while using electronic cigarettes, the overall evidence indicates that many smokers use e-cigarettes in conjunction with smoking.

A 2015 study in Great Britain also found that smokers who used e-cigarettes daily were more likely to have achieved at least a 50 percent reduction in tobacco cigarette consumption at one-year follow-up. Non-daily use of e-cigarettes was not associated with a substantial reduction in cigarette consumption.⁸⁹ A third study, that examined study of current and former cigarette smokers in the U.S., United Kingdom, Canada and Australia, found that current e-cigarette users significantly reduced the number of cigarettes smoked per day compared to non-users.⁹⁰

National survey data show that the large majority of current e-cigarette users (both adults and youth) report using both e-cigarettes and conventional cigarettes. According to CDC

⁸⁷ Biener, L & Hargraves, JL, "A Longitudinal Study of Electronic Cigarette Use in a Population-based Sample of Adult Smokers: Association with Smoking Cessation and Motivation to Quit," *Nicotine & Tobacco Research* 17(2):127-33, February 2015.

⁸⁸ Pearson, J. *E-cigarettes and Smoking Cessation: Insights and Pitfalls from Observational Studies*. Presentation at the FDA "Electronic Cigarettes and the Public Health: A Public Workshop," June 1, 2015.

⁸⁹ Brose, LS, et al., "Is use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with a 1-year follow-up," *Addiction* doi: 10.1111/add.12917 [Epub ahead of print], 2015.

⁹⁰ Adkison, S, et al. "Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey," *American Journal of Preventive Medicine* 44(3):207-215, 2013.

researchers, more than three-quarters of adult (76.8 percent) and youth (76.3 percent) current e-cigarette users are current smokers.⁹¹ More than one in three (36.5 percent) current smokers report having ever used e-cigarettes, with 9.4 percent of smokers (approximately 4 million adults) reporting that they also currently use e-cigarettes.⁹² According to an online survey conducted by Legacy in 2014, 47 percent of current smokers ages 13-17 are current e-cigarette users and among young adults ages 18-21, 65 percent of current smokers are current e-cigarette users.⁹³ Numerous studies have also documented that e-cigarette users are using e-cigarettes in conjunction with cigarettes.⁹⁴

This high level of dual use is not surprising given that e-cigarette marketing urges smokers to use e-cigarettes at times and in places where they cannot smoke conventional cigarettes. This type of marketing encourages dual use of electronic and conventional cigarettes, thus promoting continued smoking. One study found that more than 80 percent of e-cigarette users pointed to use in smoke-free zones as a reason for using the product.⁹⁵

The question of whether smokers who use e-cigarettes switch completely and abstain from smoking entirely or whether they use both products concurrently (dual use) has important health consequences. Smokers who continue to smoke (even fewer cigarettes per day) but also use e-cigarettes will increase their individual risk if this delays or prevents cessation. Furthermore, there is strong evidence that merely reducing smoking, as opposed to completely abstaining from it, does not reduce the risk of many smoking-related harms. CDC has highlighted the importance of quitting cigarettes completely, not just cutting down. According to CDC, “if you only cut down the number of cigarettes you smoke by adding another tobacco product, like e-cigarettes, you still face serious health risks. Smokers must quit smoking completely to fully protect their health – even a few cigarettes a day are dangerous.”⁹⁶

⁹¹ CDC, “Electronic Cigarette Use Among Middle and High School Students — United States, 2011 – 2012,” *MMWR*, 62(35), September 6, 2013; King, BA, et al., “Trends in Awareness and Use of E-cigarettes Among US Adults, 2010-2013,” *Nicotine and Tobacco Research* 17(2):219-27, February 2015. Current use is past month use.

⁹² King, BA, et al., “Trends in Awareness and Use of E-cigarettes Among US Adults, 2010-2013,” *Nicotine and Tobacco Research* 17(2):219-27, February 2015. See also CDC, *Key Findings: Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013*, http://www.cdc.gov/tobacco/basic_information/e-cigarettes/adult-trends/index.htm.

⁹³ Legacy, *Vaporized: E-Cigarettes, Advertising, And Youth*, April 2014, http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf.

⁹⁴ Grana, R, et al., “E-Cigarettes: A Scientific Review,” *Circulation* 129(19):1972-86, May 13, 2014; Pepper, JK and Brewer, NT, “Electronic nicotine delivery systems (electronic cigarette) awareness, use, reaction and beliefs: a systematic review,” *Tobacco Control* 23:375-384, 2014; Adkison, S, et al. “Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey,” *American Journal of Preventive Medicine* 44(3):207-215, 2013; Bullen, C, et al., “Electronic cigarettes for smoking cessation: a randomised controlled trial,” *The Lancet* 382(9905):1629-37, November 16, 2013.

⁹⁵ Adkison, S, et al. “Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey,” *American Journal of Preventive Medicine* 44(3):207-215, 2013.

⁹⁶ CDC, “Powerful new Tips from Former Smokers” ads focus on living with vision loss and colorectal cancer,” CDC Press Release, March 26, 2015.

The risks of light and intermittent smoking are substantial. Research demonstrates that light and intermittent smokers continue to be at substantial risk for numerous life-threatening diseases. A longitudinal study of more than 50,000 men and women in Norway found that “compared with sustained heavy smokers, people with reduced cigarette consumption showed no reduced risk of all-cause mortality, or of premature deaths from ischemic heart disease, cardiovascular disease and smoking-related cancer.” There was a small but insignificant reduction in risk of death from lung cancer. After long-term follow-up, researchers concluded that there was no evidence that heavy smokers who decrease their cigarette consumption by as much as 50 percent significantly reduce their risk of premature death.⁹⁷

Other research, including several Surgeon General’s reports, shows that the risk of cardiovascular disease and other smoking-related diseases depends largely on the length of time a person smokes, not just the number of cigarettes smoked. Thus, prolonging smoking, despite smoking fewer cigarettes while concurrently using e-cigarettes, will continue to put a smoker’s health at great risk.⁹⁸ According to recent Surgeon General’s reports:

- “reducing the number of cigarettes smoked per day is much less effective than quitting entirely for avoiding the risks of premature death from all smoking-related causes of death.”⁹⁹
- “the strongest determinant of risk for many diseases (e.g., lung cancer) caused by tobacco use is the duration of smoking.”¹⁰⁰
- “In addition, an earlier age of initiation extends the potential duration of smoking throughout the lifespan. For the major chronic diseases caused by smoking, the epidemiologic evidence indicates that risk rises progressively with increasing duration of smoking; indeed, for lung cancer, the risk rises more steeply with duration of smoking than with number of cigarettes smoked per day.”¹⁰¹

An analysis of the American Cancer Society’s Cancer Prevention Study II, a prospective study on smoking and lung cancer, found that years of cigarette smoking was “far more

⁹⁷ Tverdal, A & Bjartveit, K, “Health consequences of reduced daily cigarette consumption,” *Tobacco Control* 15:472-480, 2006.

⁹⁸ U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, CDC, Office on Smoking and Health (OSH), 2010. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012; HHS, *The Health Consequences of Smoking: A Report of the Surgeon General*, CDC, OSH, 2004; HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, OSH, 2014, Schane, RE, Ling, PM, & Glantz, SA, “Health Effects of Light and Intermittent Smoking: A Review,” *Circulation* 121(3):1518-1522, 2010.

⁹⁹ HHS, *The Health Consequences of Smoking – 50 Years of Progress A Report of the Surgeon General*, 2014.

¹⁰⁰ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, CDC, OSH, 2010.

¹⁰¹ HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012.

important than the number of cigarettes smoked per day in predicting lung cancer risk” among men in the U.S. According to researchers, new evidence indicates that this may also be true for women.¹⁰²

A literature review of the health effects of light and intermittent smokers found that compared to non-smokers, light and intermittent smokers are at greater risk for cardiovascular diseases, lung cancer and lower respiratory tract infections, among other things. The study also found that light smokers face nearly the same risk for cardiovascular disease as daily smokers. According to the authors, “Light and intermittent smoking carry nearly the same risk for cardiovascular disease as daily smoking. The dose-response relationship between tobacco exposure and cardiovascular mortality is highly nonlinear.”¹⁰³

This review makes clear that the risks of light and intermittent smoking are considerable. The authors found “a dose-response relationship for cigarette smoking and lung cancer, with no evidence of a threshold. For daily smokers (20 cigarettes per day), the risk of dying of lung cancer is 23 times higher in men and 13 times higher in women than in nonsmokers. The risks for light smokers, although lower, are still substantial. Women between the ages of 35 and 49 years who smoke 1 to 4 cigarettes per day have 5 times the risk of developing lung cancer and men have 3 times the risk as nonsmokers.”¹⁰⁴

The evidence clearly shows that the benefits of reduced smoking that does not lead to cessation are modest and outweighed by the danger of prolonged smoking.

In summary, based on current data, the impact of e-cigarette use on smoking cessation outcomes is still inconclusive and no e-cigarette has been approved by CDER as safe and effective as a smoking cessation aid. While multiple studies suggest that e-cigarettes lead to reductions in cigarette consumption, it is yet unknown whether this reduction leads to complete smoking cessation. Existing research suggests that rather than promoting cessation, smokers are using e-cigarettes in conjunction with cigarette smoking. This pattern of use could have an adverse impact on public health. It is critical that FDA regulate e-cigarettes to protect the public health against the risks posed by an increasingly dynamic and diverse marketplace in tobacco products and ensuring continued, and accelerated, progress toward eliminating tobacco-related disease and death. In addition, effective regulation is necessary to ensure that any potential e-cigarettes may have to assist in smoking cessation is realized.

¹⁰² Flanders, WD, et al., “Lung Cancer Mortality in Relation to Age, Duration and Smoking, and Daily Cigarette Consumption: Results from Cancer Prevention Study II,” *Cancer Research* 63:6556, October 1, 2003.

¹⁰³ Schane, RE, Ling, PM, & Glantz, SA, “Health Effects of Light and Intermittent Smoking: A Review,” *Circulation* 121(3):1518-1522, 2010.

¹⁰⁴ Schane, RE, Ling, PM, & Glantz, SA, “Health Effects of Light and Intermittent Smoking: A Review,” *Circulation* 121(3):1518-1522, 2010.

II. EMERGING INFORMATION ABOUT E-CIGARETTES AND THEIR EFFECTS ON INDIVIDUAL USERS SUPPORTS STRONG FDA REGULATION OF THE CONTENT OF E-CIGARETTES

As a product category, e-cigarettes are so rapidly evolving, and even now are so varied in design and operation, that it is difficult to make a comprehensive assessment of their health risks to individual users. Nevertheless, what we have learned about these products to this point underscores the need for prompt FDA regulation to set standards to protect the consumer.

The common element in this product category is that they are battery-operated devices that function to heat a liquid nicotine solution into a nicotine aerosol¹⁰⁵ inhaled by the user. Their evolution has been so rapid in recent years that they often are spoken of as consisting of three generations of designs. The first generation products are designed to look and feel like tobacco cigarettes. Often referred to as “cigalikes,” some models are disposable and some are rechargeable. The first generation devices come in various nicotine concentrations and with different flavorings. The second generation devices – often referred to as “tank systems” are larger and do not typically resemble a cigarette, but rather look more like pens or small screwdrivers. These have removable “tanks” that the user can refill with different e-liquids, thus varying the nicotine content and flavorings. They also typically have larger-capacity batteries and larger atomizers and electronic circuits which enhance nicotine delivery. Third generation devices, often termed “mods,” generally are larger than second generation devices and allow the user to make a variety of customized modifications, including different cartridge, atomizer and battery options that can greatly increase aerosol production.¹⁰⁶

A. Criterion for Considering the Appropriateness of Establishing Product Standards

The Tobacco Control Act gives FDA authority to establish product standards if it finds that such standards are “appropriate for the protection of the public health” and authority to establish good manufacturing practices “to assure that the public health is protected and that ...tobacco product[s are] in compliance with” the Act.

In considering the appropriateness of establishing strict requirements for good manufacturing practices and product standards, the criterion that should be applied is whether the product is more hazardous than a properly manufactured e-cigarette. An e-cigarette that does not

¹⁰⁵ We will use the term “aerosol” throughout to refer to what is inhaled by the e-cigarette user, although the term “vapor” also is commonly used. Aerosols are solid or liquid particles suspended in a gas, whereas “vapor” more accurately refers to the gas itself. Based on research completed to date on e-cigarettes, it would appear more accurate to use the term “aerosol” in reference to e-cigarettes. See Thornburg, J, *Measurement Methods for Electronic Cigarette Aerosol Emissions*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014; Cheng, T, “Chemical evaluation of electronic cigarettes,” *Tobacco Control* 23:ii11-ii17.

¹⁰⁶ See generally, Bhatnagar, A, et al., “Electronic Cigarettes: A Policy Statement from the American Heart Association,” *Circulation*, 130(16):1418-36, October 14, 2014; Zhu, S-H, et al, “Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation,” *Tobacco Control* 23:iii3-iii9, 2014.

meet that criterion should not be marketed regardless of whether it is any more or less hazardous than a combusted tobacco product. We should not tolerate e-cigarettes that contain constituents that can, with proper product standards and good manufacturing practices, be eliminated or sharply reduced.

Although the level of toxicants in e-cigarettes usually does not approach the level of those same toxicants in cigarettes, the presence of dangerous toxicants, and their variability in various e-cigarette designs, is a reason for action. As Dr. Maciej Goniewicz, who has led some of the principal studies in this area, told FDA, “. . . if there is any risk and if there are possibilities to reduce the risk, why not implement a proper strategy to minimize the risk to protect consumers?”¹⁰⁷ Such a strategy should be considered an essential component of FDA’s future regulation of e-cigarettes.

- B. The variability and uncertainty respecting levels of toxicants delivered by e-cigarette products and their health effects on users supports strong FDA product standards, requirements for good manufacturing practices and other regulatory responses.

- 1. Evidence regarding hazardous constituents and other hazards in e-cigarettes

E-cigarettes present a risk that a variety of toxicants will be delivered to the user. In its December 2014 workshop, FDA heard a discussion of one study¹⁰⁸ of aerosol generated from 12 models of “first generation” e-cigarettes, which found the following categories of toxicants in the aerosol: (1) carbonyl compounds, including formaldehyde, classified by IARC as carcinogenic to humans; acetaldehyde, classified by IARC as possibly carcinogenic to humans; and acrolein, which causes irritation to the nasal cavity, and damage to the lining of the lungs and is thought to contribute to cardiovascular disease in cigarette smokers; (2) two volatile organic compounds, toluene and m,p-xylene; (3) three toxic metals, cadmium, nickel and lead; and (4) traces of the carcinogenic nitrosamines NNN and NNK. However, this study also found that levels of these toxicants in the smoke of a conventional cigarette were from nine to 450-fold higher than levels in the aerosol of an e-cigarette. For example, exposure to acrolein, a major contributor to cardiovascular disease from smoking, was found to be 15 times lower on average in e-cigarette aerosol compared to cigarette smoke. An FDA survey of research on the chemistry of e-cigarettes through September 2013 also found various studies identifying harmful or potentially harmful constituents in the cartridges, refill solutions and aerosols of e-cigarettes, including TSNAs, aldehydes, metals and volatile organic compounds.¹⁰⁹ Another review of studies investigating the health effects of e-cigarettes indicated that, although many of the harmful

¹⁰⁷ Goniewicz, M, *Toxicants in E-Cigarette Refill Solutions and Vapor*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014.

¹⁰⁸ Goniewicz, M, *Toxicants in E-Cigarette Refill Solutions and Vapor*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014; Goniewicz, ML, et al., “Levels of selected carcinogens and toxicants in vapour from electronic cigarettes,” *Tobacco Control* 23(2):133-9, March 2014.

¹⁰⁹ Cheng, T, “Chemical evaluation of electronic cigarettes,” *Tobacco Control* 23:ii11-ii17.

substances detected in e-cigarette liquid and aerosol were identified in very low concentrations, we do not know the effect of intense and chronic exposure – with 200-300 daily inhalations – over decades of use.¹¹⁰ In addition, the safety of the combination of harmful substances has yet to be evaluated.¹¹¹

Although the levels of toxicants in e-cigarette liquids and aerosol appear generally lower than in cigarette smoke, the degree of health risk to individual e-cigarette users is unknown. FDA was presented with one study¹¹² of 22 new e-cigarette cartomizers (a single unit combining the heating function of an atomizer with the cartridge holding the nicotine liquid) from one manufacturer purchased over a two-year period. The study found nanoparticles of metals which appear on FDA’s Harmful and Potentially Harmful Constituents (HPHC) list. Indeed, lead and chromium concentrations in the aerosols were within the range of conventional cigarettes, while nickel was about two to 100 times higher in concentration in the e-cigarette aerosol than in Marlboro cigarettes. The study also found that cartomizer fluid with tin particles was more cytotoxic than fluid that lacked particles. It observed that nanoparticles tend to penetrate deep into the respiratory system and reach the alveolar sacs, as well as being transported to other organs, including the liver, kidney, heart and brain. It found that poor solder joints likely contributed to the presence of tin in the aerosol.

The variability in toxicants also is suggested by a study of 28 e-liquids, from seven manufacturers, purchased from German retailers or ordered on-line.¹¹³ Although glycerol and propylene glycol are commonly used as solvents for nicotine in e-liquids, this study found highly toxic ethylene glycol, a compound found in antifreeze, in 13 of the 28 liquids, in varying amounts. Analysis of e-cigarette aerosols revealed a significant formation of carbonyls, especially formaldehyde, acetaldehyde, as well as acrolein and propionaldehyde, in one brand widely distributed by German retailers. Indeed, this study found exposure to formaldehyde can be comparable to conventional cigarettes. FDA also was presented with evidence that levels of acrolein vary significantly among brands of e-cigarettes, with some having levels within the

¹¹⁰ Pisinger, C & Dossing, M, “A systematic review of health effects of electronic cigarettes,” *Preventive Medicine* 69:248-260, 2014.

¹¹¹ *Id.*

¹¹² Williams M, *Metals and Silicates Identified in Electronic Cigarette Fluid and Aerosol*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014; Williams, M, et al., “Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol,” *PlosOne*, 8(3), March 2013.

¹¹³ Hutzler, C, “Chemical hazards present in liquids and vapors of electronic cigarettes,” *Archives of Toxicology* 88(7):1295-308, July 2014.

range of conventional cigarettes.¹¹⁴ Acrolein accounts for 88 percent of the non-cancer risk of smoking; even low levels of acrolein can be particularly toxic.¹¹⁵

Researchers also have determined that the levels of carcinogens in e-cigarettes appear to vary significantly with changes in the content of e-liquids and design of the e-cigarette. For example, levels of the carcinogens formaldehyde and acetaldehyde in aerosol appear to be significantly impacted by the type of nicotine solvent used and, especially, by the voltage of the battery. One study¹¹⁶ of the most popular device available on the Polish market as of January, 2013 – a “second generation” tank system that permits different kinds of e-liquids to be placed in the “tank” and changes in the voltages of the battery – found that the highest levels of these carcinogens were found in aerosol generated from propylene glycol-based aerosol.¹¹⁷ In addition, the levels of these carcinogens rapidly increased with increased battery output voltage. The higher voltage leads to higher temperature in the heating element inside the device, resulting in more e-liquid consumed per puff. Increasing voltage from 3.2 to 4.8 V resulting in four to over 200 times increase in formaldehyde, acetaldehyde, and acetone levels. Indeed, the levels of formaldehyde in aerosol from high-voltage devices were in the range of levels reported in tobacco smoke. The study authors wrote, “[t]his finding suggests that in certain conditions [electronic cigarettes] might expose their users to the same or even higher levels of carcinogenic formaldehyde than tobacco smoke.”¹¹⁸ This study suggests that the second and third generation e-cigarettes may present additional risks by allowing the user to make adjustments that affect the functioning of the device and the delivery of toxic constituents.¹¹⁹

In its December 2014 Workshop, FDA also received testimony illustrating the need for basic manufacturing quality standards for e-cigarettes, and their components.¹²⁰ These risks include (1) leakage of e-liquid through the mouthpiece, (2) leaching of compounds from the materials used to construct the e-cigarette (e.g., metals, polymers, silica and ceramics) into the e-liquid; (3) material degradation over time, and (4) leaking, overheating or exploding batteries.

¹¹⁴ Bhatnagar, A, *Cardiovascular Effects and Potential Cardiovascular Disease Risk Associated with Electronic Cigarette Use*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015 (citing Bekki K. et al., “Carbonyl Compounds Generated from Electronic Cigarettes,” *International Journal of Environmental Research and Public Health* 11(11):11192-11200, 2014).

¹¹⁵ *Id.*

¹¹⁶ Kosminder, L, et al., “Carbonyl Compounds in Electronic Cigarette Vapors – Effects of Nicotine Solvent and Battery Output Voltage,” *Nicotine & Tobacco Research* 16(10):1319-1326, October 2014.

¹¹⁷ In addition, although propylene glycol generally is considered non-toxic, prolonged exposure can cause eye and respiratory irritation and some individuals, including asthmatics, may be particularly susceptible. See Bhatnagar, A, *Cardiovascular Effects and Potential Cardiovascular Disease Risk Associated with Electronic Cigarette Use*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015.

¹¹⁸ Kosminder, *supra* at 1324.

¹¹⁹ See Drummond, B, *Health Effects of E-Cigarettes: An Overview*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015; Bhatnagar, A, *Cardiovascular Effects and Potential Cardiovascular Disease Risk Association with Electronic Cigarette Use*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015.

¹²⁰ Gad, SE, *Material Hazards Associated with E-Cigarettes*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014.

As chemical engineer Samantha Gad-McDonald told FDA, with respect to batteries alone, lack of care in manufacturing can present “a fairly high possibility for risk.”¹²¹ Thus, it is important for FDA to use its authority to establish good manufacturing practices for these products to reduce the risk of malfunction and the health and safety risks that could result.

In light of these concerns, FDA should move promptly to establish product standards to ensure that hazardous or potentially hazardous constituents that can be eliminated or sharply reduced are in fact eliminated or sharply reduced and that require the implementation of rigorous product specifications to ensure that standards are consistently met. In addition, it is important for FDA to establish good manufacturing practices that would ensure that the processes used to manufacture these products are adequate to produce products that are free from hazards.

2. Potential toxicity of flavorings

Even apart from their role in making e-cigarettes attractive to young people, flavoring chemicals added to e-liquids may pose additional health risks to users. As one study has observed, the variety of flavorings used in e-cigarettes is “staggering.”¹²² As stated earlier, as of January 2014, there were over 7,700 unique flavors in these products. The number of flavors is growing dramatically; between August 2012 and January 2014, an average of 242 new flavors were added per month.¹²³ Flavorings that may be generally recognized as safe in human food may not be safe as constituents in an inhaled aerosol. Indeed, the Flavor and Extract Manufacturers Association of the United States (FEMA), which conducts a safety assessment program for flavors, has issued a statement warning e-cigarette and flavor manufacturers and marketers against representing that flavor ingredients used in e-cigarettes are safe just because FEMA has given them the status as “generally recognized as safe” (GRAS) in food products.¹²⁴ As Ann Hubbs of CDC’s National Institute for Occupational Safety and Health told FDA, “safe enough to eat does not mean you can breathe it.”¹²⁵

According to Dr. Jessica Barrington-Trimis, in her presentation to FDA, with respect to e-cigarettes, “the potential toxicity for different flavoring components and the potential respiratory toxicity is quite high.”¹²⁶ One example is the chemical diacetyl, used to give food a buttery or creamy flavor. High doses of diacetyl, deemed safe for ingestion by FEMA, have been shown to cause severe and irreversible obstructive lung disease, when inhaled by workers

¹²¹ *Id.*

¹²² Zhu, S-H, et al., “Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation,” *Tobacco Control* 23: iii3-iii9, 2014.

¹²³ *Id.* at iii5.

¹²⁴ FEMA, “The Safety Assessment and Regulatory to Use Flavors – Focus on E-Cigarettes,” revised March 3, 2015.

¹²⁵ Hubbs, A, *Toxicology of Inhaled Diacetyl and 2,3-Pentanedione*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 9, 2015.

¹²⁶ Barrington-Tremis, JL, *Considerations Regarding the Impact of Flavorings*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 9, 2015.

exposed to particulate aerosolized flavorings containing diacetyl.¹²⁷ A recent evaluation of 159 sweet-flavored e-nicotine solutions found diacetyl in 69.2 percent of samples and in at least one sample from 91.6 percent of manufacturers.¹²⁸

In one study of 125 e-liquids manufactured by seven European manufacturers, benzaldehyde was found in 70 percent of the products and its concentration in aerosol generated from cherry-flavored samples was significantly higher than in products of other flavors. Exposure to benzaldehyde vapors has been shown to cause eye pain, conjunctiva redness, burning sensations in the nose and throat, cough and breathing difficulty.¹²⁹

FDA also was presented with evidence of the elevated cytotoxicity of cinnamon-flavored e-liquid.¹³⁰

Thus, in addition to the population-wide risk that flavors will attract young people to e-cigarettes and introduce them to nicotine addiction and tobacco products, there is great uncertainty about the risk to individual health of inhaling the chemicals used to produce various flavorings. The generation of dangerous toxicants through the heating of flavorings may well be an independent reason to prohibit characterizing flavors in e-cigarettes.

- C. The variability and uncertainty respecting nicotine and nicotine delivery supports strong FDA product standards, requirements for good manufacturing practices and other regulatory responses.

The vast majority of electronic cigarettes deliver nicotine to the user. Indeed, the potential for e-cigarettes to help smokers quit using cigarettes depends, in part, on the extent to which e-cigarettes actually offer a less hazardous alternative source of nicotine that enables cigarette smokers who otherwise are unable to quit smoking to switch to use e-cigarettes exclusively. However, the capacity of these products to efficiently deliver addictive levels of nicotine to users also poses a set of potential risks to public health; namely, that they will introduce young people to nicotine addiction, potentially leading to smoking cigarettes or using other dangerous tobacco products. There is also a risk that the perception of e-cigarettes as a safer product than cigarettes could lead former smokers back to the world of nicotine addiction and, perhaps, escalation to more dangerous products.

¹²⁷ Barrington-Tremis, JL, Samet, JM, & McConnell, R, "Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?," *Journal of the American Medical Association*, doi:10.1001/jama.2014.14830, published online November 10, 2014.

¹²⁸ Farsalinos, KE, et al., "Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins," *Nicotine & Tobacco Research* 17(2):168-174, February 2015.

¹²⁹ Goniewicz, M, *Toxicants in E-Cigarette Refill Solutions and Vapor*, Presentation at the FDA "Electronic Cigarettes and the Public Health: A Public Workshop," December 10, 2014.

¹³⁰ *Id.* (citing Bahl. V. et al., "Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models," *Reproductive Toxicology* 34:529-537, 2012.)

In addition to its addictiveness, nicotine is far from harmless in adults. Nicotine contributes to increased risk for cardiovascular disease among smokers.¹³¹ In his presentation to FDA, Dr. M. Brad Drummond of Johns Hopkins University catalogued some of the health effects of nicotine, including a transient increase in heart rate and blood pressure, a risk of a reduction in coronary blood flow, a change in thrombosis risk, an increased risk of low birth weight babies and impact on fetal brain development.¹³²

The risk of e-cigarette use by pregnant women is of special concern. As Dr. Melissa Suter told FDA, “if a mother does use an e-cigarette with nicotine, her fetus is going to immediately see that nicotine . . . [and] no amount of nicotine is known to be safe in pregnancy.”¹³³ The 2014 Surgeon General’s Report found the evidence sufficient to infer that nicotine exposure during fetal development has lasting adverse consequences for brain development, and that it adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes, including preterm delivery and stillbirth.¹³⁴ Moreover, as discussed previously, nicotine adversely affects brain development in adolescents and therefore has the potential to cause lasting harm even apart from the creation of addiction.

FDA’s own review of the research literature on nicotine levels found in e-cigarette cartridges, refill solutions, aerosols and environmental emissions found that “[t]he data indicate that the nicotine levels in e-cigarettes vary considerably. E-cigarette brands and models differ in the efficacy and consistency of nicotine yields, and the delivery of nicotine is not uniform either from puff-to-puff or across products of the same brand.”¹³⁵ One quantitative analysis of nicotine in e-cigarette aerosols generated from 15 popular e-cigarette brands found that total nicotine in aerosol varied by brand from 0.5 to 15.4 mg per 300 puffs.¹³⁶ It appears that nicotine yield to the user may vary according to the nicotine concentration in the liquid, the design of the product (and particularly may be a function of electrical power), and puff topography.¹³⁷ Some designs of e-cigarettes may provide the same or more nicotine than a single cigarette, and some far

¹³¹ HHS, *The Health Consequences of Smoking: 50 Years of Progress: A Report of the Surgeon General*, CDC OSH, 2014 (2014 Surgeon General’s Report).

¹³² Drummond, B, *Health Effects of E-Cigarettes: An Overview*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015, at 388. See also Bhatnagar, A, *Cardiovascular Effects and Potential Cardiovascular Disease Risk Association with Electronic Cigarette Use*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015, at 402-03.

¹³³ Suter, M, *Electronic Cigarette Use in Pregnancy: Potential Effects on Fetal Health and Development*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 10, 2015, at 455, 460.

¹³⁴ 2014 Surgeon General’s Report at 8.

¹³⁵ Cheng, T, “Chemical evaluation of electronic cigarettes,” *Tobacco Control* 23:ii11-ii17, 2014, at ii12.

¹³⁶ *Id.* (citing Goniewicz, ML, et al., “Levels of selected carcinogens and toxicants in vapour from electronic cigarettes,” *Tobacco Control* 23(2):133-9, March 2014).

¹³⁷ Talih, S, et al., “Effects of User Puff Topography, Device Voltage, and Liquid Nicotine Concentration on Electronic Cigarette Nicotine Yield: Measurements and Model Predictions,” *Nicotine & Tobacco Research* [Advance Access], doi:10.1093/ntr/ntu174, September 3, 2014.

less.¹³⁸ Exposure to nicotine by the user may depend on experience and use behaviors. Although early studies showed that e-cigarettes did not significantly increase nicotine levels in inexperienced users, recent studies indicate that current users, particularly experienced users, are able to achieve similar nicotine exposures as from traditional cigarettes.¹³⁹

There also is substantial evidence that the level of concentration of nicotine in e-liquids may vary considerably from the level put on the label. FDA’s literature review found “the level of nicotine listed on the labels of e-cigarette cartridges and refill solutions is often significantly different from measured values and labelling may not adequately convey the amount or concentration of nicotine.”¹⁴⁰ One study of e-liquid found in cartridges and refill solutions of four e-cigarette manufacturers found measured nicotine levels all significantly lower than the labeled concentrations.¹⁴¹ Another study of 71 electronic cigarette refill products and one related do-it-yourself product found that 35 of the 54 nicotine-containing fluids had quantified nicotine concentrations that deviated by more than 10 percent from the manufacturer labels, with 46 of 50 being in excess of labeled values.¹⁴² Many were more than 20 percent higher than indicated on the label; quantified nicotine concentrations varied from as little 1.1 percent to as much 89.7 percent from the labeled value.¹⁴³ Even duplicate samples of the same product varied in nicotine concentration.¹⁴⁴ The Salt Lake City Health Department did an analysis of 153 e-liquids obtained from 14 vape shops and 16 tobacco specialty stores in Salt Lake County, UT, and found that 61 percent of the e-liquids tested differed by at least 10 percent from the labeled nicotine content, with discrepancies that ranged from 88 percent less to 840 percent more than stated.¹⁴⁵ Forty-two percent of the vape shop samples contained levels of nicotine that were higher than stated on the labels, and 25 percent had lower levels of nicotine than stated on the label.¹⁴⁶

¹³⁸ St. Helen, G, *Nicotine Pharmacokinetics and Systemic Uptake from Different E-cigarette Devices*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 9, 2015, at 183; Goniewicz, M, *Exposure to Nicotine and Toxicants among Exclusive Users of Electronic and Tobacco Cigarettes*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” March 9, 2015, at 192; Talih, S, et al., “Effects of User Puff Topography, Device Voltage, and Liquid Nicotine Concentration on Electronic Cigarette Nicotine Yield: Measurements and Model Predictions,” *Nicotine & Tobacco Research* [Advance Access], doi: 10.1093/ntr/ntu 174, September 3, 2014.

¹³⁹ Schroeder, MJ & Hoffman, AC, “Electronic cigarettes and nicotine clinical pharmacology,” *Tobacco Control* 23:ii30-ii35, 2014.

¹⁴⁰ Cheng, *Tobacco Control* at ii12.

¹⁴¹ Lisko, JG, et al., “Chemical Composition and Evaluation of Nicotine, Tobacco Alkaloids, pH, and Selected Flavors in E-Cigarette Cartridges and Refill Solutions,” *Nicotine & Tobacco Research* [Advance Access], doi:10.1093/ntr/ntu279, 2015.

¹⁴² Davis B, et al., “Nicotine Concentrations in Electronic Cigarette Refill and Do-It-Yourself Fluids,” *Nicotine & Tobacco Research* 17(2):134-41, February 2015.

¹⁴³ *Id.* at 139.

¹⁴⁴ *Id.*

¹⁴⁵ Salt Lake City Health Department, *Analysis of Nicotine Content in E-Liquid Samples*, December 2014.

¹⁴⁶ *Id.*

Finally, nicotine-related impurities have been found in e-liquids far in excess of those in FDA-approved nicotine replacement therapies (NRTs).¹⁴⁷

There is no question that, in the current unregulated market, there is no nicotine standardization, either in concentration in e-liquids or in the delivery of nicotine to the user. The consumer also has no reason to be confident that accurate information about nicotine levels is being communicated through proper labelling. As Dr. Michael Trehy of FDA's Center for Drug Evaluation and Research commented in the first FDA workshop, "There are product quality issues in the marketplace, which the consumer would have difficulty identifying."¹⁴⁸ Essentially, with respect to many of these products, the e-cigarette consumer has no idea how much nicotine he/she is getting.

It therefore is essential for FDA to complete its deeming rule and proceed to issue product standards, good manufacturing practices and labeling standards to enhance whatever possibility may exist that e-cigarettes can assist smokers to quit the use of combusted products entirely and to protect consumers against individual and population-wide risks posed by the indiscriminate distribution of tobacco products to the general public.

III. RECOMMENDATIONS FOR REGULATORY ACTION

Based on research currently available to FDA, there is a sufficient scientific basis to implement the following regulatory actions:

- FDA should promulgate the deeming rule as soon as possible.
- FDA should immediately apply to e-cigarettes all the provisions of the 2010 rule on marketing to youth.
- FDA should exercise its regulatory authority, to the maximum extent permitted by the First Amendment, to prohibit or restrict the advertising, marketing and promotion of e-cigarettes to children.
- FDA should prohibit the sale of e-cigarettes in remote transactions, including internet sales.
- FDA should require e-cigarettes to be accompanied by a government-mandated warning of the addictiveness of nicotine.

¹⁴⁷ Trehy, ML, *Nicotine, Nicotine Related Impurities and Additives in E-Cigarette Cartridges and Refills*, Presentation at the FDA "Electronic Cigarettes and the Public Health: A Public Workshop," December 10, 2014.

¹⁴⁸ *Id.*

- FDA should prohibit characterizing flavors in e-cigarettes (except tobacco flavor). The use of any non-tobacco flavor should be permitted by FDA only upon a showing by the manufacturer that the flavor makes it more likely that a significant number of smokers will quit smoking completely, does not pose a health hazard, does not contribute to tobacco product initiation, particularly by youth, and does not sustain smoking among those who otherwise would have quit.
- FDA should adopt rules requiring e-cigarettes to consistently meet strict product standards and product specifications in order to eliminate or sharply reduce the presence of toxicants and to prohibit the sale of e-cigarettes unless they are manufactured according to good manufacturing practices.
- FDA should immediately require child-resistant packaging of e-cigarettes.

Respectfully submitted,

A handwritten signature in black ink that reads "Matthew L. Myers". The signature is written in a cursive, flowing style.

Matthew L. Myers
President
Campaign for Tobacco-Free Kids

APPENDIX

Marketing Examples of Electronic Cigarettes



**ARIEL
MEREDITH**

Stylized by
OPHIL
★ ★ ★
Hair by
ANITA L. JEWELL and
DIRTHEASHEN

assists

FOR BENT: 2 bedrooms, 1 bathroom, 1000 sq. ft. of living space, stainless steel appliances, granite countertops, hardwood floors, central air conditioning, \$150,000. Call 562-447-1111 for more information.

FOR BENT: 2 bedrooms, 1 bathroom, 1000 sq. ft. of living space, stainless steel appliances, granite countertops, hardwood floors, central air conditioning, \$150,000. Call 562-447-1111 for more information.

MISSED CONNECTION

READY TO SATISFY

Hey Smoker -

We've crossed paths before, and it's time we meet again.

I'm all about satisfying like a cigarette without the better.

FIND ME AT: www.blucigs.com/PLUS

NEW & IMPROVED

Get MORE with PLUS⁺

- + Bigger Battery, Lasts 2x Longer
- + Pre-filled blu Tanks™
- + Rapid Battery Charging
- + Enhanced Flavor and Draw

blu PLUS⁺

RECHARGEABLE

blu PLUS⁺

HIGH CLASSIC TOBACCO

blu

NOT FOR SALE TO MINORS. ©2015 LOEC, Inc. WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical. "blu", "blu e-cigs", "blu logo", "blu Plus⁺" and the Plus+ logo are trademarks of Lorillard Technologies, Inc.

blu e-cigarettes advertisement (on right) placed opposite magazine content, *Sports Illustrated* Swimsuit Edition, February 20, 2015



MARKTEN[®]
e-vapor

Play whatever you feel.

TM

Available in *Classic* and *Menthol*.

-25% nicotine by weight at time of manufacture.
MARKTEN, FourDraw and related design marks are trademarks of Nu Mark LLC. © 2014 Nu. Mark LLC. F426

WARNING: This product is not intended for use by women who are pregnant or breast feeding, or persons with or at risk of heart disease, high blood pressure, diabetes, or taking medicine for depression or asthma. Nicotine is addictive and habit forming, and it is very toxic by inhalation. Nicotine can increase your heart rate and blood pressure and cause dizziness, nausea, and stomach pain. Inhalation of this product may aggravate existing respiratory conditions.

MARKTEN[®] 25%
CLASSIC
EVAPOR

The only e-vapor with **FourDraw[®]** technology for a full draw.

For ALL of US
SMOKERS WANTING
SATISFACTION...
THIS IS WHAT IT
LOOKS LIKE.

Learn
more at:
www.blucigs.com/plus

Get MORE with
PLUS+[™]

- + Bigger Battery, Lasts **2x** Longer
- + **FEATURING** Pre-filled blu Tanks[™]
- + Rapid Battery Charging
- + Enhanced Flavor and Draw

NOT FOR SALE TO MINORS. ©2015 LOEC, Inc. WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical. blu, blu Cigs, the blu logo, the blu Plus+ logo, the Plus+ logo and blu Tanks are trademarks of Lorillard Technologies, Inc. (Photography by Francesco Carrazzini)

blu e-cigarettes, *Car and Driver* (April 2015), *Men's Journal* (April & May 2015, *Playboy* (April & June 2015), Maxim (June/July 2015), <http://trinketsandtrash.org/detail.php?artifactid=9859&page=1>; <http://trinketsandtrash.org/detail.php?artifactid=9882&page=1>

For ALL of US
SMOKERS WANTING
SATISFACTION...
THIS IS WHAT IT
LOOKS LIKE.

Learn
more at:
www.blucigs.com/plus

Get MORE with
PLUS+[™]

- + Bigger Battery, Lasts **2x** Longer
- + **FEATURING** Pre-filled blu Tanks[™]
- + Rapid Battery Charging
- + Enhanced Flavor and Draw

NOT FOR SALE TO MINORS. ©2015 LOEC, Inc. WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical. blu, blu Cigs, the blu logo, the blu Plus+ logo, the Plus+ logo and blu Tanks are trademarks of Lorillard Technologies, Inc. (Photography by Francesco Carrazzini)

blu e-cigarettes, *Car and Driver*, *Playboy* (May 2015); *Men's Journal* and *Popular Mechanics* (June 2015), <http://trinketsandtrash.org/detail.php?artifactid=9993&page=1>; Also appeared in *Cosmopolitan* (April 2015)



MARKTEN
E-CIG

So you can ease into your space.

The only e-vapor with FourDraw® technology.
Full draw. Fully rechargeable.

MARKTEN, FOURDRAW and related design marks and trademarks of Nu, Mark LLC

WARNING: This product is not intended for use by women who are pregnant or breast feeding, or persons with or at risk of heart disease, high blood pressure, diabetes, or taking medicine for depression or asthma. Nicotine is addictive and habit forming, and it is very toxic by inhalation. Nicotine can increase your heart rate and blood pressure and cause dizziness, nausea, and stomach pain. Inhalation of this product may aggravate existing respiratory conditions.

© 2014 Nu, Mark LLC 10308

To do list

1. Study
2. Groceries
3. Band practice
4. Vape time

LIFETIME WARRANTY

KANDYPENS™

K-VAPE
TRUE CONVECTION
TECHNOLOGY™

WWW.VAPORATION.COM
YOUR ONLINE VAPORIZER SUPERSTORE

K

WORLDWIDE

Kandy Pens e-cigarette, Rolling Stone, June 4, 2015

JUUL @JUULvapor · Jun 2

JUUL
Enjoy Smoking Evolved 25% off by signing up. Spread the love: juulvapor.com #JUUL #JUULvapor #VAPORIZED



RETWEET


1



12:36 PM - 2 Jun 2015 · Details






Hide photo






Introducing JUUL - Smoking Evolved

JUULvapor

JUUL  25

+ Add to  Share  More

Share  Embed  Email




<https://youtu.be/0Ej3tkca5HQ>

Start at:


Published on May 31, 2015



PAX Labs' Juul e-cigarette, May 31, 2015,
<https://www.youtube.com/watch?v=0Ej3tkca5HQ>






Introducing JUUL - Smoking Evolved

JUULvapor

JUUL  25

+ Add to  Share  More



Share  Embed  Email

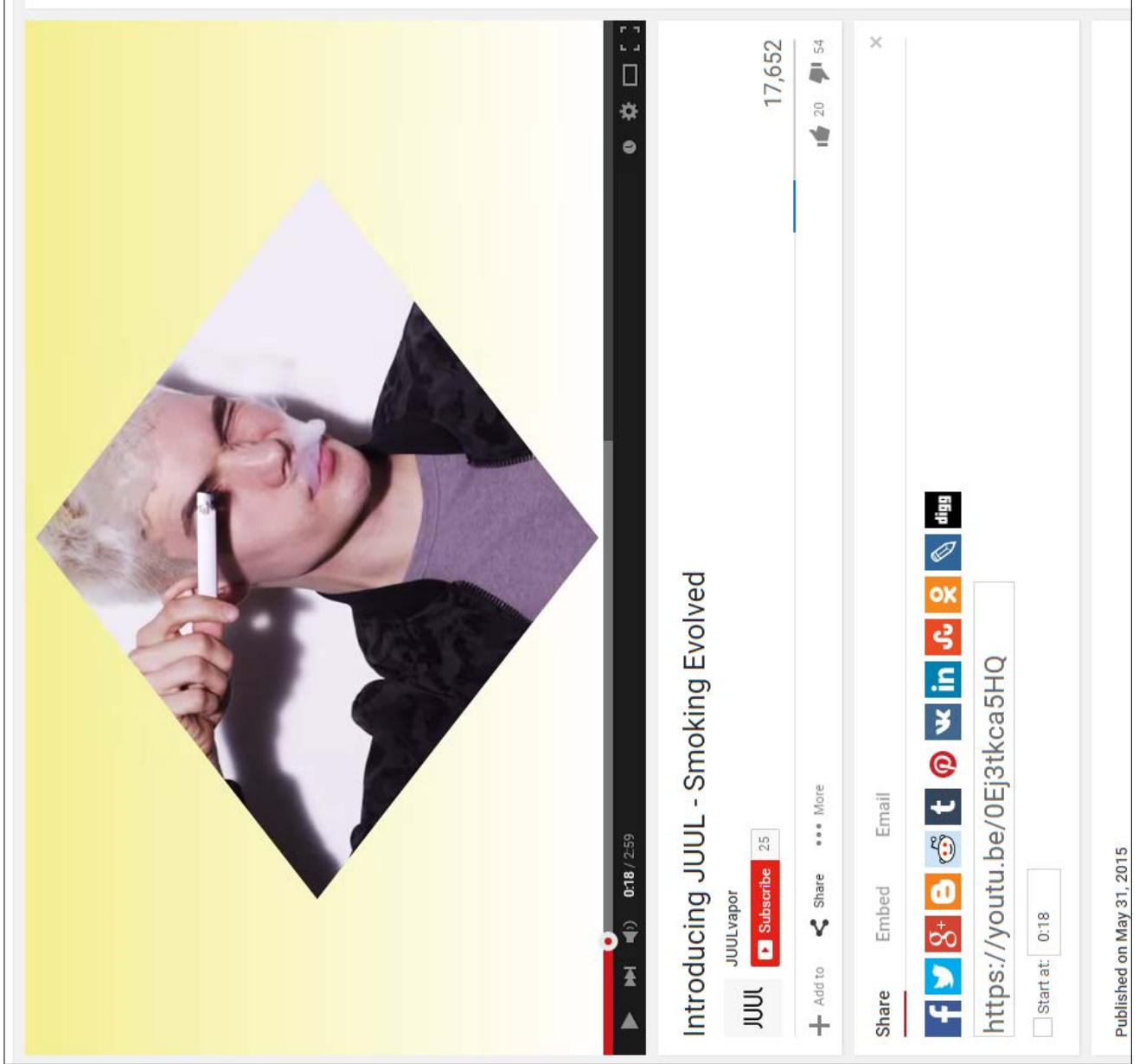


<https://youtu.be/0Ej3tkca5HQ>

Start at:

Published on May 31, 2015

17,652  20  54



0:18 / 2:59

17,652

Introducing JUUL - Smoking Evolved

JUULvapor

[Subscribe](#) 25

[Add to](#) [Share](#) [More](#)

17 20 54

Share Embed Email


[f](#) [g+](#) [e](#) [t](#) [vk](#) [in](#) [su](#) [x](#) [digg](#)

<https://youtu.be/0Ej3tkca5HQ>

Start at: 0:18

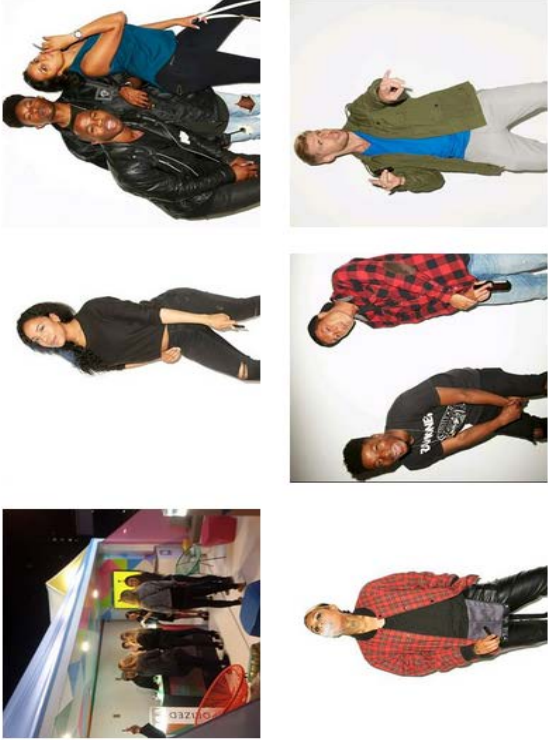
Published on May 31, 2015

PAX Labs' Juul e-cigarette, May 31, 2015, <https://www.youtube.com/watch?v=0Ej3tkca5HQ>

JUUL SHOP- AUTO-SHIP STORE LOCATOR SUPPORT- MY ACCOUNT- 

BUY NOW





#JUULVAPOR
Join the conversation




Sign up to get 25% off first purchase.
Discount code will be e-mailed to you.

Email ZIP

SUBSCRIBE



0:07 / 2:38

"Cowboy Smoke Joke"

Mistic Ecigs

9,648

31 36

Published on Jan 14, 2015
HAUS™ by Mistic® presents "Cowboy Smoke Joke," an online parody directed by Hayden 5, which features a day in the life of an outdated "urban cowboy," well, sort of, that visits The Big Apple and receives quite the reception from unsuspecting New Yorkers.

Mistic Ecigs, January 14, 2015, <https://www.youtube.com/watch?v=8yv-3vgmcq4>

ENTER THE FREEDOM PHOTO CONTEST!
WIN THE ULTIMATE VIP EXPERIENCE
 THE PHOTO WITH THE MOST VOTES WINS!

SPONSORED BY **blu** ELECTRONIC CIGARETTES

HOW DO YOU EXPRESS YOUR FREEDOM?

THE WINNER OF THE **ULTIMATE VIP EXPERIENCE** FROM BLU WILL RECEIVE:

2 VIP PASSES TO BUKU
 BACKSTAGE TOUR DURING FESTIVAL +
 ON-STAGE VIEWING (SELECT ARTISTS)

- VIP ONLY PREMIUM VIEWING AREAS OF THE THREE MAIN STAGES
- ACCESS TO THE VIP ONLY S.S. BLU-KU, A NEW ORLEANS-STYLE RIVER BOAT DOCKED ON THE MISSISSIPPI RIVER ALONG THE FESTIVAL GROUNDS, FEATURING:
 - OPEN BAR
 - VIEWS OF THE MAIN STAGE AND FESTIVAL GROUNDS FROM THE BOAT'S TOP DECK
 - EXCLUSIVE VIP-ONLY ARTIST PERFORMANCES
 - BUKU 2015 POSTER

NOT FOR SALE TO MINORS. ©2015 LOEC, Inc. WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical. blu™, blu eCigs® and the blu logo are trademarks of Lorillard Technologies, Inc.

BUKU Music & Art Project
 February 28 - ✨



Show us how you express your freedom and you could WIN THE **ULTIMATE VIP EXPERIENCE** from blu eCigs!

BUKU and blu eCigs® are giving away the Ultimate Experience passes to #BUKU2015. All you have to do is take a picture showing blu and BUKU how you express your freedom. Do you show off your freedom by what you wear? Maybe it's the car you drive? Take a picture and upload it through BUKU's Facebook page. The photo with the most votes wins!

Enter Here → <http://on.fb.me/17DODWc>

Adult smokers, check out blucigs.com to take your freedom back today.

blu e-cigarettes sponsorship of BUKU Music & Art Project, February 28, 2015, <https://www.facebook.com/BUKUproject>



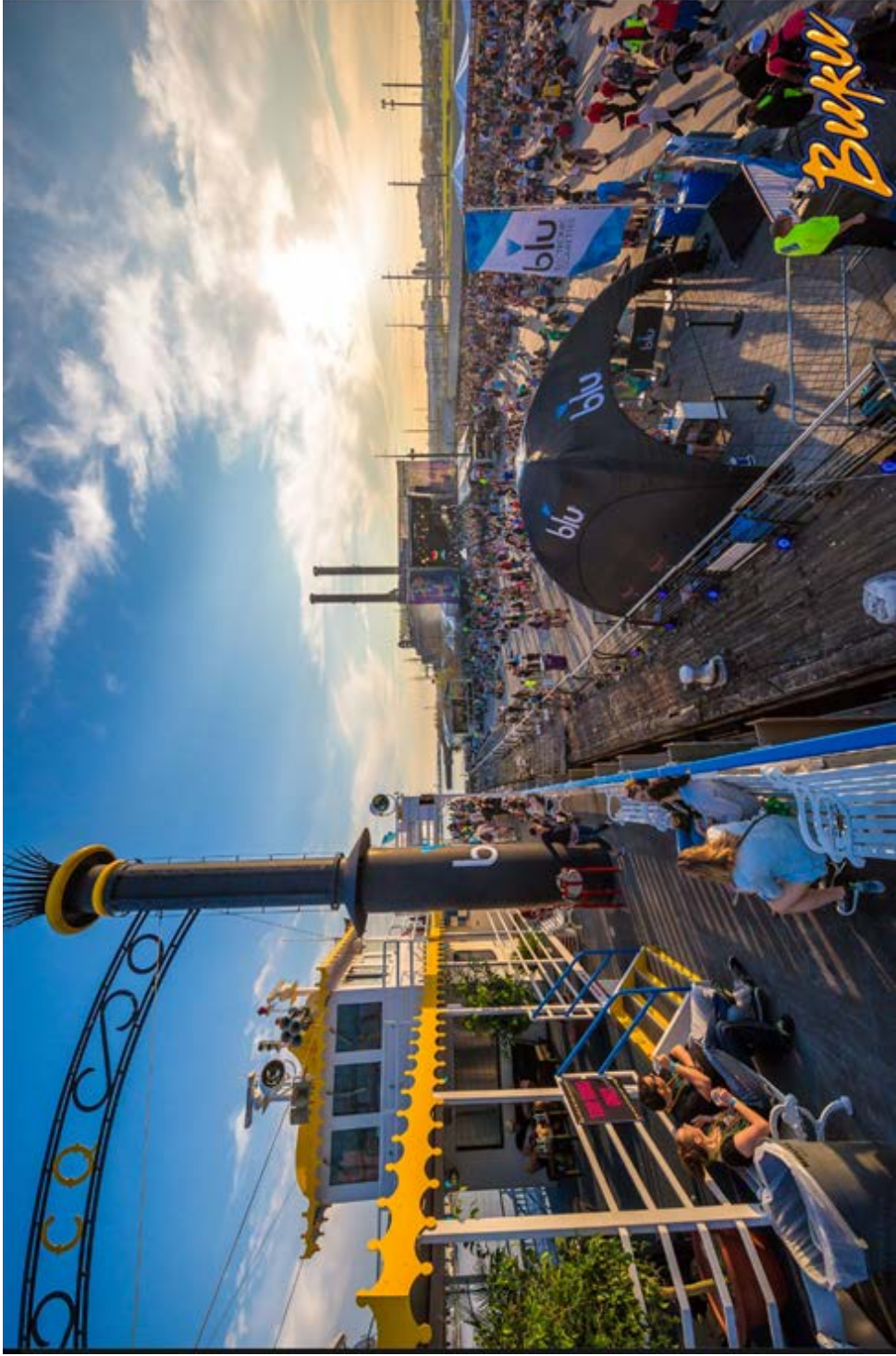
BUKU Music & Art Project

February 6 · #

blu cigs is back with the S.S. BLU-KU! Complete with three levels, open bars for 21+, private pop-up performances and views of both the Big 'Sip and the Power Plant Stage.

You can't beat the experience on the VIP-only S.S. BLU-KU!

blu e-cigarettes sponsorship of BUKU Music & Art Project, February 6, 2015, <https://www.facebook.com/BUKUproject>



BUKU Music & Art Project
April 7 - 8
Views from the B.S. BLU@BU - at BUKU Music & Art Project

blu e-cigarettes sponsorship of BUKU Music & Art Project, April 7, 2015, <https://www.facebook.com/BUKUproject>



blu e-cigarettes sponsorship of BUKU Music & Art Project, April 7, 2015, <https://www.facebook.com/BUKUproject>



SMOKIN' PHILADELPHIA Summer

CONCERT CALENDAR



blu
ELECTRONIC CIGARETTES
NOT FOR SALE TO MINORS
© 2015 blu eCigs

MAY
WED, MAY 27
THE SCRIPT
ELECTRIC FACTORY
215.627.1332
electrifyfactory.info

SAT, MAY 30
PURITY RING
UNION TRANSFER
215.232.2100
uphill.com

SAT, MAY 30
ROOTS PICNIC
FESTIVAL PIER AT PENN'S LANDING
215.629.3200
festivalperphilly.com

CONTINUED INSIDE

WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

SMOKIN' PHILADELPHIA Summer

CONCERT CALENDAR

blu
ELECTRONIC CIGARETTES
NOT FOR SALE TO MINORS
© 2015 blu eCigs

JUNE

WED, JUNE 3
NOEL GHER
MAM THEATER
215.993.1999
kimmelcenter.org

THURS, JUNE 4
THE EARLY NOBBER
UNION TRANSFER
215.232.2100
uphill.com

FRI, JUNE 5
MASON PORTER
WORLD CAFE LIVE
215.222.1400
philly.worldcafe.com

FRI, JUNE 5
THE IDEA MEN
MILKBOYPHILLY.COM

SAT, JUNE 6
BEANIE SIGEL
LIVING ARTS
215.922.1011
venue.tophilly.com

SAT, JUNE 6
LANA DEL REY
BORGATA, A.C.
609.317.1000
theborgate.com

THURS, JUNE 11
HOLLY MIRANDA
BOOT & SADDLE
267.639.4528
bootandsaddlephilly.com

FRI, JUNE 12
MELISSA ETHERIDGE
CROSSAN.COM/CROSSAN-AC
609.348.4411
cossan.com/crossan-ac

JUNE 12-13
TAYLOR SWIFT
WELLS FARGO CENTER
215.336.3600
wellsfargocenterphilly.com

SAT, JUNE 13
STATES STREET
MEDIA, PA
215.232.2100
uphill.com

SUN, JUNE 14
MARC COHN & SHAWN COLVIN
KESWICK THEATRE
215.572.7650
keswicktheatre.com

WED, JUNE 17
THE DILLINGER ESCAPE PLAN
MILKBOYPHILLY.COM

JUNE 18-21
FIREFLY FESTIVAL
WELLS FARGO CENTER
312.253.6545
fireflyfestival.com

FRI, JUNE 19
NEW KIDS ON THE BLOCK
WELLS FARGO CENTER
215.336.3600
wellsfargocenterphilly.com

SAT, JUNE 20
MORRISSEY
ACADEMY OF MUSIC
215.893.1999
kimmelcenter.org

SAT, JUNE 20
PATTERN IS MOVEMENT
JOHNNY BRENDA'S
215.739.9684
johnnybrendas.com

SAT, JUNE 20
FAREWELL TOUR
JOHNNY BRENDA'S
215.739.9684
johnnybrendas.com

SAT, JUNE 20
THIRD COAST KINGS
THE FIRE
267.671.9298
thefirephilly.com

TUES, JUNE 23
D'ANGELO AND THE YANQUARD
KESWICK THEATRE
215.572.7650
keswicktheatre.com

THURS, JUNE 25
MURRAY CLOSE
KESWICK THEATRE
215.572.7650
keswicktheatre.com

THURS, JUNE 25
MISSION OF BURMA
KESWICK THEATRE
215.572.7650
keswicktheatre.com

THURS, JUNE 25
THE DILLINGER ESCAPE PLAN
MILKBOYPHILLY.COM

FRI, JUNE 26
DAR WILLIAMS & JILL SOBBLE
LIVE
215.222.1400
philly.worldcafe.com

FRI, JUNE 26
JOHNNY BRENDA'S RECORD RELEASE
JOHNNY BRENDA'S
215.739.9684
johnnybrendas.com

SAT, JUNE 27
HALL & OATES
BORGATA, A.C.
609.317.1000
theborgate.com

SAT, JUNE 27
IMAGINE DRAGONS
WELLS FARGO CENTER
215.336.3600
wellsfargocenterphilly.com

SAT, JUNE 27
KELLIE PICKLER
MAM THEATRE
215.993.1999
kimmelcenter.org

SAT, JUNE 27
PHILLY BLOCO
WELLS FARGO CENTER
215.336.3600
wellsfargocenterphilly.com

JUNE 27-JULY 4
WAWA WELCOME AMERICA
WELLS FARGO CENTER
215.336.3600
wellsfargocenterphilly.com

SUN, JUNE 28
SHOW OF THE SUMMER
HERSHEY PARK STADIUM
717.538.1111
hersheyparkstadium.com

TASTE OF COUNTRY MUSIC FESTIVAL

JUNE 12-14, 2015

AT HUNTER MOUNTAIN, NY

Contact Us

[HOME](#)
[TICKETS](#)
[LINEUP](#)
[THE EXPERIENCE](#)
[CAMPING & LODGING](#)
[FESTIVAL INFO](#)
[CONTACT](#)
[APP](#)

2015 PERFORMERS: [TIM MCGRAW](#) | [TOBY KEITH](#) | [KEITH URBAN](#) | [BILLY CURRINGTON](#) | [ELI YOUNG BAND](#) | [JERROD NIEMANN](#) | [SARA EVANS](#) | [+ MORE!](#)

Our Proud Sponsors

HUDSON VALLEY'S OFFICIAL RAM DEALER

NEWS

5 Things You Need to Know for Taste of Country Music Festival
June 2, 2015 11:09 AM

Thursday Night Campground Party
May 19, 2015 8:19 AM

Wristband Shipping Dates
May 4, 2015 5:49 PM

Taste of Country Music Festival Daily Lineup and Single Day Tickets
April 16, 2015 6:57 AM

Keith Urban Added to 2015 Taste of Country Festival Lineup
October 1, 2014 6:15 AM

Hank Williams, Jr. Thompson Square + More Close 2014 Taste of Country Music Festival [Pictures]
June 15, 2014 11:20 PM

How old do you have to be to attend the festival without a chaperone?

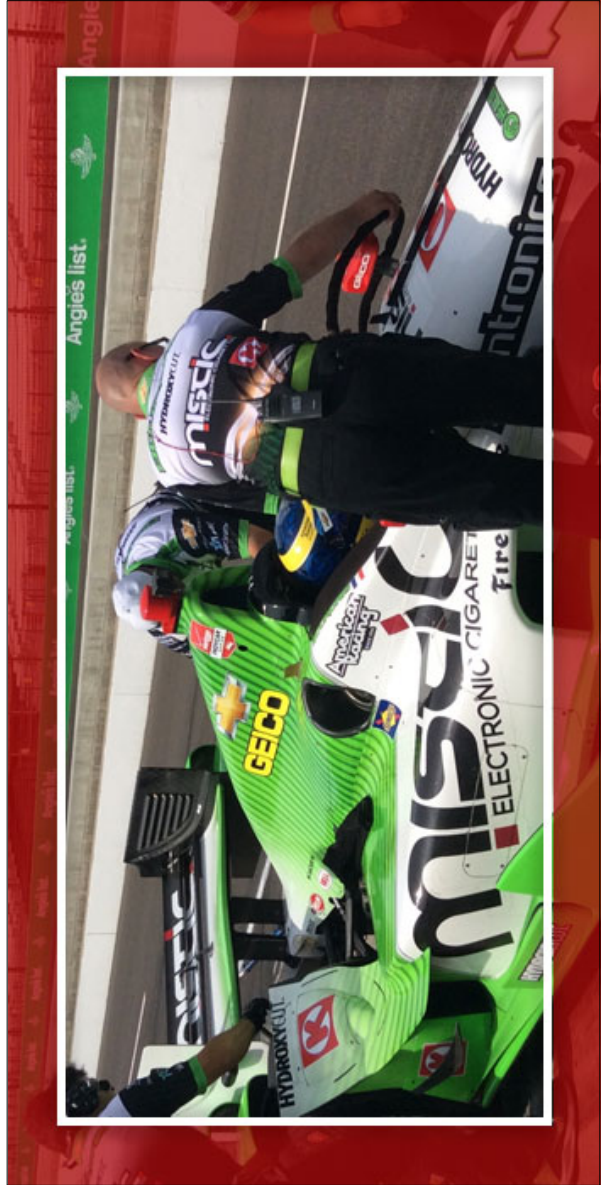
You need to be 16 or older to attend without a chaperone. A chaperone must be over 18 years old.

blu e-cigarettes sponsorship of Taste of Country Music Festival, June 2015, <http://tasteofcountryfestival.com/>

Mistic ECigs blog, June 3, 2015,
<http://blog.misticcigs.com/piquet-jr.-takes-podium-in-2015-red-bull-grc-race-series-opener>



Mistic ECigs blog, May 11, 2015,
<http://blog.misticcigs.com/mistic-racing-teams-bourdais-secures-best-finish-of-season-at-indy>



Pin it Like Image Share

VAPELIFE: NJOY ST...
NJOY

FREE VAPE TASTING!
FRIDAY 9.12.14

NEW YORK
HICKSVILLE 413 JERUSALEM AVE, 2-6PM.


FLORIDA
FORT LAUDERDALE 1040 BAYVIEW DR, SUITE 140, 2-6PM.
FORT LAUDERDALE 1529 E. LAS OLAS BLVD, 2-6PM.

ILLINOIS
HOMWOOD 18747 DIXIE HWY, 2-6PM.

TEXAS
IRVING 5003 N. O'CONNOR RD, 2-6PM.
DALLAS 6833 W NORTHWEST HWY, 2-6PM.

ARIZONA
GILBERT 785 W ELLIOT RD, 2-6PM.

Uploaded by user



Also on these boards

See more boards

Follow Board



NJJOY

September 11, 2014 · 🌟

Taste NJJOY's 10 e-liquids at 7-11 today through Saturday! TASTE UNTIL 6pm tonight! For participating 7-11 locations, click here --> <https://www.njjoy.com/blogs/njjoy-vape-samples-at-7-11>

NJOY Facebook post, September 11, 2014,

<https://www.facebook.com/NJOYecigs/photos/a.279512282061314.76917.201825096496700/846361412043062/?type=1&permPage=1>





vapestreet_lv

FOLLOW

99 likes

2h

vapestreet_lv Love candy flavors? If you haven't yet, come in and try Trolli! A sour gummy worms mix that'll leave you wanting more!

Available in store and online

4850 W. Flamingo Rd. Suite 28
Las Vegas, NV 89103
702-724-8244

Online orders 
www.vape-street.com

#Trolli #Liqfix #Fruity #vaper #vapor
#vaping #vapestagram #vapelife
#vapelyfe #calivapors #westcoastvapers
#vapeshop #vapeon #vapecommunity
#vapehard #vapeporn #vapenation
#vapefriends #ecig #ecigs
#iminlovewithadripper
#dontdripanddrive #nosmoking
#vegsvapers #vapestreet
#vapestreet_lv



Add a comment...

000

Vape Street, Instagram, June 16, 2015, https://instagram.com/p/4AF3BxIwKA/?taken-by=vapestreet_lv

BEST PRACTICES FOR MIXING



HOW TO FILL YOUR TANK
 NJOY tanks are top filled to help prevent spills. To fill, unscrew the mouthpiece and tilt to a 45° angle. Make sure to avoid the center hole! For best results, use a new tank for each recipe, and replace after 2 weeks of use.

COUNT DROPS FOR MORE PRECISION
 Each .10 mL of e-liquid is roughly equivalent to 5 drops.

MIX IT UP
 For best mixing, layer the flavors (add half of each and repeat), roll the tank a few times and let it sit for a few minutes.

SOME FLAVORS MAKE A BIG IMPACT
 Use care when adding Double Espresso, Vanilla Bean, Butter Crunch, and Single Malt Scotch—a little goes a long way.

EXPERIMENT WITH SWAPPING SIMILAR INGREDIENTS
 If you have a favorite fruit flavor (Peach Tea, Blood Orange, Black & Blue Berry, or Pomegranate) feel free to substitute it in any recipe you like.

GO DIY
 Don't feel discouraged if your first experiment isn't a keeper. Most of the flavor in an e-liquid is experienced as aroma, and aromas don't always combine in the same ways as food. Sometimes they sing like you might expect, and sometimes they fall flat.

VAPING E-LIQUIDS



AVAILABLE IN 10 FLAVORS AND 2 NICOTINE STRENGTHS

- BLACK & BLUE BERRY
- BUTTER CRUNCH
- VANILLA BEAN
- BLOOD ORANGE
- SINGLE MALT SCOTCH
- DOUBLE ESPRESSO
- POMEGRANATE
- MENTHOL
- PEACH TEA
- CLASSIC TOBACCO

HowToNJOYvaping.com

A COMPLETE GUIDE

TO EVERYTHING YOU NEED TO KNOW ABOUT VAPING

NJOY
 VAPING

CAUTION: All e-liquids contain nicotine, a highly addictive substance. Nicotine is known to be addictive. All e-liquids contain propylene glycol, vegetable glycerin, and flavorings. Some e-liquids may contain other ingredients. Nicotine is addictive and can be harmful. All e-liquids are for use only with devices that are designed to be used with e-liquids. ©2015 NJOY Inc. All rights reserved.

VAPE MIXOLOGY Recipe Book



VAPE YOUR TREAT BY MIXING FLAVORS!

NJOY
 VAPING

Intended for adult consumers of legal smoking age. Recipes are for vaping e-liquids only. Never eat or drink!

BLUEBERRY PIE W/ WHIPPED CREAM



20 DROPS OF BLACK & BLUE BERRY



2 DROPS OF BUTTER CRUNCH

REPEAT & LAYER



3 DROPS OF VANILLA BEAN



NJOY
September 26, 2014 · #

Want to vape the taste of blueberry pie with whipped cream? You can mix NJOY e-liquids to do it! Read how, click here -> <http://bit.ly/1xpCvml>

Like · Comment · Share

4 people like this.

1 share



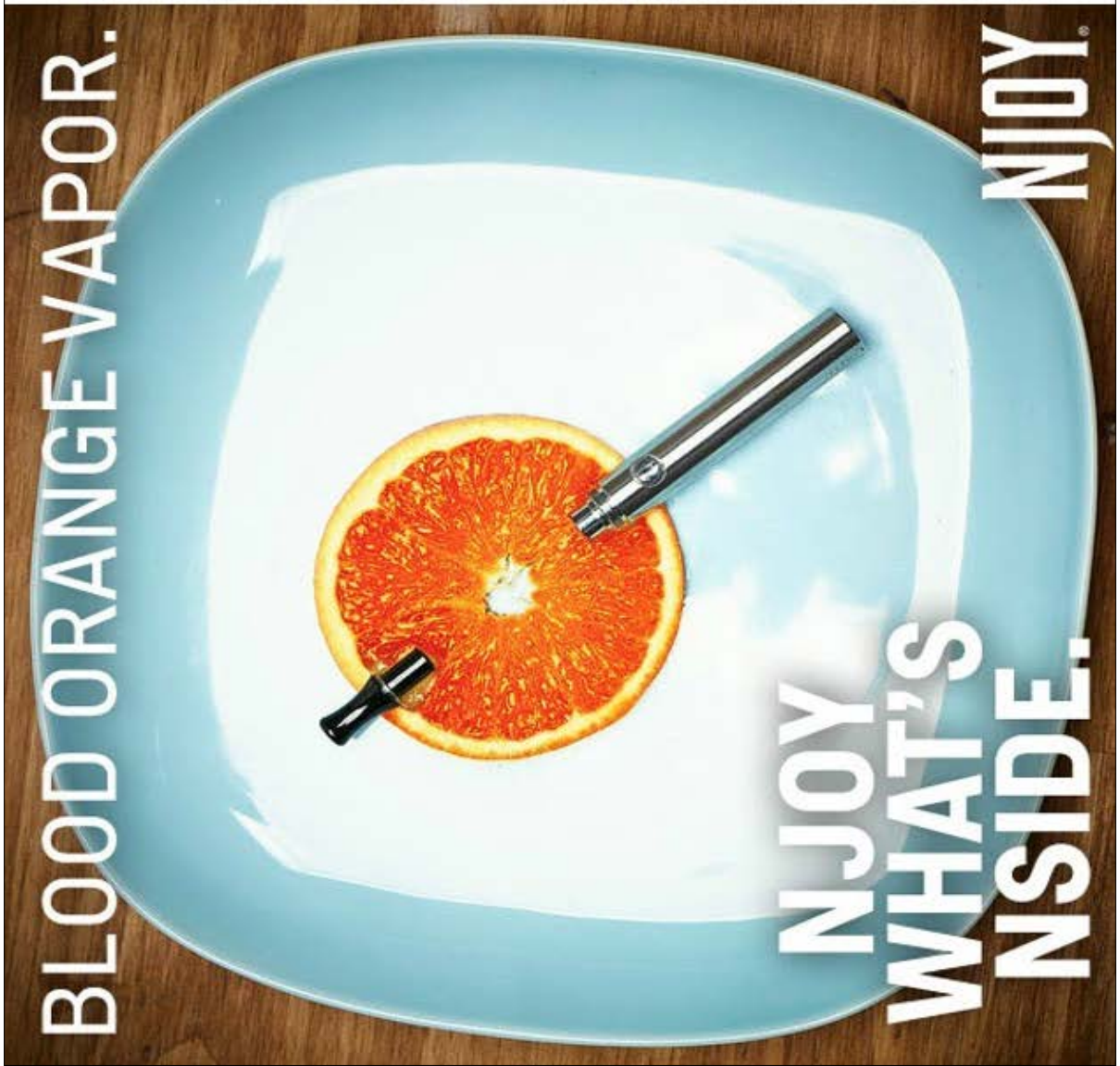
Jess Gamble I was not impressed with the black and blueberry liquid. 😞

Like · Reply · September 27, 2014 at 11:14pm



Jon Davenport Even experiment with a couple of drops of Single-Malt Scotch for some bourbon/rum cake undertones

Like · Reply · September 27, 2014 at 1:56am



njoyvape

FOLLOW

13 likes

42w

njoyvape Blood Orange e-liquid from NJOY. Get yours on NJOY.com

njoyvape #vapelite

njoyvape #vape



Add a comment...

000

NJOY e-cigarettes, posted on Instagram June 16, 2015, <https://instagram.com/p/sQhKujH13k/>



NJOY @NJOYVape · Feb 19

The Artist Collection goes international!

Order yours now at: vaperama.com

[#njoyac](https://twitter.com/njoyac) [#vapelife](https://twitter.com/vapelife)



[View photo](#)



blu 18 hrs · 🌐
Cherry Crush is definitely the cherry on top that we all want.
#MybluFlavor



175 Views
Like · Comment · Share

27 people like this.

 Kristen Halley Cherry crush is my absolute favorite
Like · Reply · 🔄 3 · 17 hrs

 Jim Devoy Once again blu proves how great their customer service is.
Thanks for the help today.
Like · Reply · 🔄 1 · 17 hrs

 View 3 more comments

Most Relevant*

blu e-cigarettes, Facebook post, June 9, 2015,
<https://www.facebook.com/blucigs/videos/vb.235706558591/10153303050493592/?type=2&theater>



blucigs

FOLLOWING

64 likes

5w

blucigs blu Disposables just got better! More vapor, longer lasting, and an optimized flavor to match the tanks, make these disposables the best yet! #blucigs #blunation #vaping

debsamliz Love my cherry disposables! A little expensive though 😊

kathycarr63 #blunation #blucigs #ThatsaPlus

karen_ducharme @blucigs will the price increase? 😊😊😊 please say NO

youngog50 #blunation#blucigs#blutast ic

youngog50 when will we see cherry for blu plus?#go #blunation

bolts363 #blunation

kathycarr63 #blunation

youngog50 #blunation

youngog50 luv my #blu eCigs#1

youngog50 #blusCigs!!!



Add a comment...

000

blu e-cigarettes, posted on Instagram May 11, 2015, <https://instagram.com/p/2j17YDza9-/>



blucigs

FOLLOWING

56 likes

23w

blucigs #TriviaTuesday #Vaping #VapeLife #bluNation

view all 99 comments

waynejones1947 #ThatsAPlus

waynejones1947 #blunation

waynejones1947 #bluplusreview

draculadoug my Girfriend Beth loves Cherry Crush

leeavancebrooks #blunation

badboy_7_3 #bluplusreview

badboy_7_3 #blunation

awesome_unclegrandpa Hoo Yah Vivid Vanilla

mikestory65 #mybluisbetter

apexwolverine86 Cherry Crush

emilymedina313 #mybluisbetter

emilymedina313 #blunation

emilymedina313 #ThatsAPlus



Add a comment...

000

blu e-cigarettes, posted on Instagram January 6, 2015, <https://instagram.com/p/xho8Jxza5B/?taken-by=blucigs>

blu blu ecigs® @blucigs · May 30

If you like Pina Coladas...you NEED these blu PLUS+ tanks - then your #weekend will be complete! #bluGoesWherever



RETWEETS 44 FAVORITES 8

1:47 PM · 30 May 2015 · Details

Hide photo