



Kathryn A. Forbes, CPA
Chair
National Board of Directors

Ross P. Lanza fame, Esq.
Past Chair

John F. Emanuel, Esq.
Vice Chair

Penny J. Siewert
Secretary/Treasurer

Harold P. Wimmer
National President and CEO

CORPORATE OFFICE

55 West Wacker Drive
Suite 1150
Chicago, IL 60601
Phone: (312) 801-7630

ADVOCACY OFFICE

1301 Pennsylvania Avenue NW
Suite 800
Washington, DC 20004
Phone: (202) 785-3355
Fax: (202) 452-1805

www.lung.org

August 8, 2014

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

Re:Docket Number FDA-2014-N-0189

Dear Commissioner Hamburg:

The American Lung Association has submitted comprehensive comments with our partner organizations about the Food and Drug Administration's (FDA) Deeming Tobacco Products proposed rule (proposed deeming regulation). These comments are submitted as a supplement to those comments and will highlight key policy points. These comments represent the views of the American Lung Association.

The American Lung Association is the nation's oldest voluntary health organization and is the leading organization working to save lives by improving lung health and preventing lung disease. Tobacco use is the leading cause of preventable death in the United States and a primary cause of lung disease. Tobacco kills 480,000 Americans each year and another 16 million Americans suffer from a tobacco-caused disease.¹ Tobacco use and exposure to secondhand smoke are the overwhelming causes of lung cancer and chronic obstructive pulmonary disease (COPD).

I. FDA Must Follow the Mandate of the Tobacco Control Act and Its Public Health Standard

The Family Smoking Prevention and Tobacco Control Act (TCA), which was passed by Congress with overwhelming bipartisan support in 2009, is very clear about the public health mandate of the FDA's Center for Tobacco Products (CTP). The TCA establishes the public health standard, which it states "...shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account –

- a. the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- b. the increased or decreased likelihood that those who do not use tobacco products will start using such products."²

II. Basic Authority over All Tobacco Products

The FDA must have basic oversight authority over all tobacco products. No tobacco product is safe and all are addictive. Indeed, the TCA which gives FDA authority over all tobacco products states:

A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.³

The American Lung Association fervently opposes the exemption of any tobacco product, including cigars, from basic FDA oversight and urges that the final regulation give FDA basic oversight over all tobacco products. The Lung Association was deeply troubled to see that while FDA proposed to assert basic authority over all tobacco products in the version of the proposed deeming regulation it sent to the White House Office of Management and Budget, the White House added an “option” for exempting certain cigars, according to the redlined version of the proposed deeming regulation.⁴ The American Lung Association finds this proposed weakening of FDA’s basic oversight wholly unacceptable and strongly urges the FDA to reject any exemptions for any tobacco products in the final rule.

There is real concern that if the deeming regulation does not include all tobacco products that the public may wrongly assume that some products are less harmful than others. This is especially the case for cigars, as the significant and serious health effects caused by cigar use are clearly and plainly stated in the National Cancer Institute’s Monograph 9, which in 1998, made clear that cigar use is not safe. “There is sufficient evidence to conclude that a causal relationship exists between regular cigar use and cancers of the lung, larynx, oral cavity, and esophagus. Heavy cigar smoking, particularly for those who inhale, causes an increased risk of coronary heart disease and chronic obstructive pulmonary disease.”⁵ The 2014 Surgeon General’s report further underscores the need for FDA to have basic oversight over all tobacco products, including all cigars, as it cites the increase in use of cigars by youth.⁶ Finally, it is contrary to the plain reading of the statute to exempt any tobacco product from FDA oversight.

One of the major conclusions of the 2014 Surgeon General’s report states, “The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.”⁷ Exempting any tobacco product from basic FDA oversight – especially those with such well-established public health consequences – would set a troubling precedent and may lead to further exemptions for other tobacco products. That would inherently contradict the intent of Congress when it passed the TCA.

Furthermore, the TCA does not require FDA to regulate all tobacco products in the exact same manner. It requires FDA to determine what is “appropriate for the protection of public health” (Sec. 906(d)) based on the science. That means that FDA may or may not determine that different provisions apply to cigars, or other tobacco products based on the public health standard. However, it must have basic oversight authority over all cigars in order to protect the public health.

“Basic authority” includes, but is not limited to, the provisions outlined in the 2011 letter to stakeholders from FDA:

Moreover, Chapter IX of the Food, Drug, and Cosmetic Act (FD&C Act) subjects “tobacco products” to general controls, such as registration, product listing, ingredient listing, good manufacturing practice requirements, user fees for certain products, and adulteration and misbranding provisions. Chapter IX also subjects “new tobacco products” (i.e., products that

are first marketed or modified after February 15, 2007) and “modified risk tobacco products” (i.e., products that are “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products”) to premarket review. Although the statute places certain “tobacco products” immediately under the general controls and premarket review requirements in Chapter IX (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco), it also permits FDA, by regulation, to extend those controls to other categories of “tobacco products.”

FDA plans to take the following steps to ensure that appropriate regulatory mechanisms govern all “tobacco products” and all other products made or derived from tobacco after the Sottera decision:

- The Agency intends to propose a regulation that would extend the Agency’s “tobacco product” authorities in Chapter IX of the FD&C Act, which currently only apply to certain specifically enumerated “tobacco products,” to other categories of tobacco products that meet the statutory definition of “tobacco product” in Section 201(rr) of the Act. The additional tobacco product categories would be subject to general controls, such as registration, product listing, ingredient listing, good manufacturing practice requirements, user fees for certain products, and the adulteration and misbranding provisions, as well as to the premarket review requirements for “new tobacco products” and “modified risk tobacco products.”⁸

A “*tobacco product*” as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act is “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product...” Since cigars are “made or derived from tobacco” and “intended for human consumption,” cigars fall squarely under the definition of “tobacco products,” and no exception should be made for any cigar.

The statutory definition of “tobacco product” and the provisions outlined in this stakeholder letter must apply to all tobacco products. In addition, the Lung Association urges FDA to include in the final rule the following provisions as outlined in the proposed deeming regulation:

1. Requirement for minimum age of purchase of 18 years old
2. Prohibition of vending machine sales in facilities that allow individuals under the age of 18 to enter
3. Health warnings for product packages and advertisements

The Lung Association also urges that the final rule include a prohibition on free samples of all tobacco products.

III. Effective Dates & Compliance Timeframe

The American Lung Association strongly opposes the 24 month compliance policy for manufacturers of newly deemed products to submit marketing applications. This time frame is excessive and will further jeopardize public health. The tobacco industry has had sufficient time to prepare for the pending regulatory efforts – indeed it has been 3 years since FDA first issued its letter to stakeholders, announcing its intent to assert jurisdiction over all unregulated tobacco products.⁹

As highlighted in the redlined version of the proposed deeming regulation sent to the White House by FDA, FDA’s original proposal was to allow a 12 month compliance timeframe.¹⁰ The American Lung Association finds the two year time period proposed by the White House for basic compliance entirely unacceptable. Continued lack of basic oversight and the existing “wild, wild west” status quo will only result in more children becoming addicted to tobacco products and fewer existing users quitting. *The*

American Lung Association strongly supports FDA's original 12 month proposal and urges it be the standard in the final regulation. This 12-month time period is particularly necessary for cigars, which have been on the market for decades and are well-established.

Additional Public Health Safeguards Needed for Newly Deemed Products

The plain language of the Tobacco Control Act clearly states that FDA should order any product not on the market before February 15, 2007 – including e-cigarettes – be removed from the marketplace until a new product application is submitted per the requirements in Section 910 of the TCA. The American Lung Association considers compliance with the statutory language appropriate for the protection of public health.

However, if FDA does not require these products to be removed from the marketplace, recognizing the established and troubling public health consequences of e-cigarette use (during what should only be a 12 month waiting period from the date of the final rule), FDA should make clear what standards apply for pre-market review of e-cigarettes. These standards should include, but not be limited to:

1. Childproof containers for e-cigarettes, including disposables, e-liquids, and other refillable devices
2. No toxins in e-liquids other than nicotine
3. No carcinogens or harmful or potentially harmful constituents
4. No flavors

FDA should provide further guidance to manufacturers that outlines these and any other requirements that are appropriate for the protection of public health *prior* to a manufacturer receiving a marketing authorization. *No* product should be permitted a marketing authorization unless these standards are met. The American Lung Association also urges FDA to use its enforcement discretion to protect the public health and youth initiation specifically (See Section XI).

IV. Prioritization of Substantial Equivalence Orders

The American Lung Association is deeply troubled by FDA's current practice regarding prioritization of substantial equivalence (SE) applications. At present, FDA is reviewing SE applications of currently-deemed products not currently on the market *before* it reviews applications of products presently for sale. The American Lung Association strongly asserts this is in violation of FDA's statutory responsibilities of protecting public health.

It is quite apparent that the cigarette industry intentionally flooded FDA with SE applications. Indeed a total of 4,490 SE applications for cigarettes were submitted to FDA as of December 31, 2013. In order to protect the public health, FDA must re-focus its SE review process by prioritizing applications of tobacco products presently on the market and then reviewing applications of products not presently in the marketplace.

It is the position of the American Lung Association that no additional flexibility for tobacco product manufacturers of any kind would be appropriate for the protection of public health.

V. Components, Parts and Accessories

In its proposal, FDA suggests including tobacco product components and parts in its oversight authority but not accessories. The American Lung Association agrees that components and parts must be included within its authority but also urges FDA to include accessories as well in the final rule. The Lung Association asserts exempting accessories is *not* appropriate for the protection of public health.

It is imperative that FDA be very clear in its oversight of any tobacco product, component, part and accessory. Any item involved with the inhalation, ingestion or use of a tobacco product *must* be included in FDA's authority. For example, while FDA may need not have authority over an ashtray or humidor, as neither are used with the inhalation or ingestion of tobacco products, it must be able to regulate pipes, hookahs, vaporizers, and other items that are used in conjunction with tobacco products.

There are numerous examples as to why exempting accessories is not appropriate for the protection of public health, and why FDA must include accessories in the final regulation:

- The Lung Association is concerned that e-cigarette vaporizers that are sold separately and not with liquids may claim they are accessories – despite the fact that they are necessary for the inhalation and use with e-cigarettes. Indeed, vaporizers are able to be modified or “hacked” which an initial study from Roswell Park Cancer Institute found could increase toxins and other dangerous components, including formaldehyde.¹¹ There are countless online videos showing how to “hack” an e-cigarette. [This video](#) talks about how to change the device to increase the temperature of the vapor.¹²
- There are numerous products for sale, including the “[Tar Stopper](#)” a product that claims to “effectively reduce tar, nicotine and other hazards from your cigarette smoke without altering the flavor or taste of your cigarette.”¹³ The Tar Stopper (Appendix J) is used with the inhalation of cigarettes, but would likely otherwise be considered an accessory by its manufacturer. Given the stated health claims and the unknown consequence of its use, it must be regulated by FDA in order to protect public health.

The tobacco industry has a long track record of manipulating legal loopholes to maximize addiction and its profits. Any exemption of a component, part or accessory is subject to similar manipulation. FDA must have authority over all components, parts and accessories involved with the use of any tobacco product.

VI. Flavored Tobacco Products

The American Lung Association was deeply disappointed to see that FDA stated it did not have sufficient evidence to include the elimination of candy, fruit and other non-nicotine flavored products in its proposed deeming regulation. The evidentiary record on why the industry manufacturers and markets flavored tobacco products is well-established, which is one of the reasons Congress required the elimination of almost all cigarettes with characterizing flavors within three months of the passage of the Tobacco Control Act in 2009.^{14,15}

The American Lung Association calls on FDA to move forward with product standards to remove from the marketplace any product currently regulated by FDA with a characterizing flavor other than tobacco. The Lung Association urges FDA to use its enforcement discretion to ensure the removal of flavors from newly deemed products, including e-cigarettes (see Section XI – Enforcement Discretion) which studies estimate have 7,700 flavors,¹⁶ as well as hookah. Please refer to Appendix N for examples of blatant marketing to children using candy – and fruit – flavored products.

VII. Additional Comments Regarding Cigars

As stated above, the American Lung Association strongly opposes any exemption to basic oversight of any tobacco product, including any cigar. A spokesperson for one “premium” cigar company that has

advocated for both a legislative and regulatory exemption from FDA oversight has publically stated that it considers its \$1.00 and \$2.00 machine-made cigars to be “premium” cigars.¹⁷

Health Effects of Cigars

While the health risks of cigar smoking are not the same as cigarette smoking, cigar smoke is composed of the same toxic and carcinogenic constituents found in cigarette smoke. According to the National Cancer Institute, cigar smoking causes cancer of the oral cavity, larynx, esophagus and lung, and cigar smokers are at increased risk for an aortic aneurysm.¹⁸ Daily cigar smokers, particularly those who inhale, have an increased risk of heart disease and chronic obstructive pulmonary disease (COPD).

The 2012-2013 National Adult Tobacco Survey found that 17.4 million American adults smoke cigars, and among adult cigar smokers who provided information about the type of cigar usually smoked, 62 percent primarily smoked “cigarillos & other mass market cigars,” 18 percent smoked little filtered cigars and 20 percent smoked “premium” cigars. Almost 60 percent of current cigar smokers either smoke or have smoked cigarettes. Cigarette users who also smoke cigars are at higher risk for developing tobacco-related diseases because they tend to inhale cigar smoke more deeply.¹⁹

Cigar smoking is not limited to adults; it is the second most common form of tobacco use among youth. According to national surveys, 16.5 percent of high school boys currently smoke cigars (i.e., large cigars, cigarillos, and small cigars),²⁰ and each day close to 3,000 kids under 18 years old try cigar smoking for the first time.²¹ Young adults (e.g., 15.9 percent of 18 to 24 year olds) are also much more likely to be cigar smokers than older adults (e.g., 4.9 percent of 45 to 64 year olds).²²

FDA Not Required to Regulate All Tobacco Products Identically

The Tobacco Control Act does not require FDA to regulate all tobacco products in the same way or manner. Instead, FDA is required to determine what is appropriate for the protection of public health. That can only occur if FDA has basic authority – which can only occur with registration, ingredient disclosure and research disclosure – over cigars. FDA can then use that information as well as existing data and regulatory science to determine the appropriate public health protections. Regardless, FDA must be able to halt sales to kids of any tobacco products, require warning labels and have other basic authority over all products, including all cigars, in order to protect public health.

VIII. Additional Comments Regarding E-Cigarettes

As a result of the *Sottera* lawsuit, on April 25, 2011, the FDA announced it would regulate almost all e-cigarettes as tobacco products.²³ At present, there is no federal oversight of e-cigarettes.

E-Cigarette Use Among Youth Exploding

Data released in September 2013 by the Centers for Disease Control and Prevention (CDC) show an alarming increase in e-cigarette use among middle school and high school students in the U.S. From 2011-2012, the number of students in grades 6-12 reporting having ever used an e-cigarette doubled from 3.3 percent to 6.8 percent. Recent use of e-cigarettes among 6-12 year olds increased from 1.1 percent to 2.1 percent.²⁴

FDA Must Have Authority to Stop Reduced Risk and Marketing to Kids Within One Year

The original deeming proposal submitted by FDA to the White House proposed a one year period for e-cigarette and other newly deemed products to register and submit substantial equivalence proposals to FDA.²⁵ The American Lung Association strongly urges that the original time period – not the two year

period proposed in the proposed deeming regulation released on April 24 – be included as the standard and time period in the final rule.

It is imperative that FDA begin its efforts to protect public health by requiring registration, ingredient disclosure and product consistency within and across e-cigarette brands. FDA must also be able to begin enforcing youth access age restrictions for e-cigarettes, ensuring that retailers sell to only those 18 and older.

FDA's own testing of e-cigarette products in 2009 highlight the urgent need for product consistency and basic oversight. In a summary of results released by FDA, the agency found "quality control processes used to manufacture these products are inconsistent or non-existent." FDA's analysis also showed that products claiming to have no nicotine had nicotine in virtually all of the cartridges FDA tested.²⁶

The Public Health Standard Applies

As discussed earlier in the American Lung Association's comments, the Tobacco Control Act's public health standard must apply to the regulation and oversight of all tobacco products, including e-cigarettes. FDA must faithfully enforce the law, and use all of its enforcement tools to halt the sale of any product that makes health claims or implied or direct reduced harm and modified risk claims unless the FDA has issued an order under Section 911 (g).

The American Lung Association is deeply disturbed by years of egregious claims and marketing made by the e-cigarette industry. In January 2010, one e-cigarette company stated that its product was physician-recommended for pregnant women (see Appendix G). The e-cigarette industry has known that basic oversight would potentially be coming over three years ago – an additional 2 year delay after the final rule is published is unacceptable and not in keeping with the Center for Tobacco Products' mission to protect the public health.

Misbranded & Adulterated Standards Must Also Apply to "Low" Nicotine Claims

Just as cigarettes made implied health claims by claiming to have "low tar," similar claims are now being made by e-cigarette manufacturers. According to one study, "the most popular claims were that the products are healthier (95%), cheaper (93%), and cleaner (95%) than cigarettes; can be smoked anywhere (88%); can be used to circumvent smoke-free policies (71%); do not produce secondhand smoke (76%); and are modern (73%)." ²⁷

The American Lung Association asserts that FDA must use its authority to prevent or halt any e-cigarette manufacturer's claim that e-cigarettes contain "low nicotine," as these claims clearly fall under its Section 911 authority. Lower nicotine claims are likely to result in users believing the product is less addictive or less harmful – neither of which have been proven to be true.

E-Liquid Standards Must Be Released Immediately

In April 2014, the CDC released data that found calls to the nation's poison centers for e-cigarette exposure poisonings are rapidly increasing. The study found that while most calls involving e-cigarette liquid poisoning came from accidental ingestion of the e-cigarette or its liquid, about one-sixth of the calls related to someone inhaling these items. Exposure through the eye and the skin were also reported. Poison centers reported approximately half of all calls regarding e-cigarette exposures were about a child under the age of 6 but over 40 percent of calls involved someone over the age of 20.²⁸

FDA must act to prevent accidental ingestions, poisonings and other exposures by requiring manufacturers to immediately require childproof containers and devices.

CDER Must Use Its Existing Authority to Crack Down on Therapeutic Claims

The American Lung Association also calls on FDA's Center for Drug Evaluation and Research (CDER) to faithfully enforce the law and halt the sale of any product that makes therapeutic claims absent any prior approval from CDER that the product is safe and effective for users. (See Appendix N for examples)

IX. Additional Comments Regarding Hookah

FDA must have authority over hookah and other water pipe tobacco products and begin its oversight immediately upon finalizing the deeming regulation. Data on the use of hookah by young adults show that between 22 percent and 40 percent of all college students have used hookah in the last year.²⁹ The 2013 Monitoring the Future survey found that 21 percent of high school seniors had used hookah in the past year.³⁰

The American Lung Association also submits for FDA review its [hookah policy brief](#)³¹ and its [2007 hookah report](#)³² which supports FDA oversight over hookah and its products, components and accessories, as well as the immediate need for FDA to prohibit characterizing flavors other than tobacco.

X. Warning Labels

It is the position of the American Lung Association that all tobacco products and their advertising must be required to include warning labels. No tobacco product, including cigars sold individually, should be exempt from warning label requirements.

FDA should require that warning labels make clear that all products under FDA authority – including e-cigarettes – are tobacco products. This is especially important for e-cigarettes and other new or novel products that may presently be sold in candy – or fruit – flavors or look different from traditional tobacco products, such as dissolvables.

Warning Labels on Cigars

Cigars sold in multi-packs must include a warning label on the exterior packaging. Recognizing the proven harms of all cigar use per the National Cancer Institute³³ and the U.S. Surgeon General,³⁴ even those sold individually should include a warning label. The warning label could be included on the tube (if applicable), or FDA could require a paper warning be handed to the purchaser or require retailers to put cigars in bags that are pre-printed with the warning labels.

In addition, recognizing that many manufacturers already are required through an agreement with FTC to include warning labels, FDA should require its five warning labels on cigars within 12 months of the date of the final regulation.

Size of Warning Labels

FDA asked for comment on the size of warning labels. The American Lung Association does not believe that 30 percent is a sufficient size for warning labels, and instead urges FDA to move forward with the statutory requirement for cigarette warnings of 50 percent.

FDA Must Include Reproductive Health Warnings for Cigars

The evidence is clear that tobacco smoke – including cigar smoke – causes reproductive and developmental effects.³⁵ FDA itself includes in the proposed deeming rule that cigarette and cigar smoke are quite similar – and the associated health consequences on reproductive health must be included in a warning label on all cigars. FDA must require cigars to include the reproductive health warning label on all cigars.

XI. Enforcement Discretion

Recognizing the significant and severe public health threat caused by unregulated tobacco products, including little cigars and e-cigarettes, the American Lung Association urges FDA to use its enforcement discretion immediately upon finalization of the deeming regulation. Such enforcement action can be done without additional rulemaking, can use the existing scientific evidence that is well-established regarding the use of flavors in marketing to youth, and would allow FDA to respond appropriately to protect public health. Historically, the courts have given great deference to agencies when they have exercised such enforcement or prosecutorial discretion, and only set aside agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

The proposed deeming regulation acknowledges FDA's broad discretion in determining how and if e-cigarettes and other tobacco products can remain on the market after they are deemed tobacco products under the agency's authority. Using its enforcement discretion, FDA can permit e-cigarettes to remain in the marketplace if their marketing is only targeted at adults. That would allow FDA to require the withdrawal of all e-cigarettes with characterizing flavors other than tobacco. FDA can also make the same requirement of little cigars.

XII. Regulatory Impact Analysis

The regulatory impact analysis (RIA) included in the proposed deeming regulation is fundamentally flawed and should be rejected and redone in keeping with the requirements. The American Lung Association finds it wholly unacceptable that there is any economic consideration for the so-called "lost" smoking pleasure as a result of the proposed deeming regulation. Tobacco use is the leading cause of preventable death in the United States and 16 million Americans live with a tobacco-related disease.³⁶ The 2014 U.S. Surgeon General's report found that nicotine is highly addictive.³⁷ The idea that smokers – 69 percent of whom want to quit³⁸ -- lose pleasure as a result of better oversight over all tobacco products is preposterous and unacceptable.

The RIA does not include sufficient evidence to be re-created, nor does it sufficiently consider the reduction in healthcare costs, home health services, medications and nursing home care that often come with tobacco-caused chronic diseases.

Finally, any costs that incur to the manufacturers as the result of compliance with the deeming regulation are likely to benefit public health in two ways. In addition to the overall provisions in the deeming rule that are necessary and appropriate for the protection of public health, the cost of manufacturers complying with the new regulations will be passed along to consumers, thereby increasing the price of tobacco products – and reducing use. This is a win-win for our nation's health.

XIII. Additional Recommendations and Comments

Minimum Age and Vending Machines

The logical outgrowth of the proposed regulation would result in FDA interpreting the minimum age provisions included in the proposed deeming regulation (face-to-face sales, the prohibition of vending machine sales in locations that permit youth under the age of 18 to enter) to also include Internet sales of tobacco products. The Lung Association urges FDA to issue further clarification in the form of guidance or other appropriate methods to ensure compliance with this important provision, or in the final rule.

The Lung Association strongly agrees with FDA's proposal to extend current vending machine restrictions to newly deemed product sales.

FDA Must Determine Whether Products Contain Nicotine – Not Rely on Company Assertions

Recognizing the tobacco industry has a proven track record of manipulating its products and deceiving the public, it is imperative FDA first determine and verify that there is no nicotine or tobacco in products that would otherwise be considered to be tobacco products before such claims are permitted to be made. This should apply to e-cigarettes, as well as hookah and other products. FDA's initial 2009 laboratory test of e-cigarettes determined that all but one of the products tested that claimed to contain no nicotine tested positive for low-levels of nicotine.³⁹ Look alike products that are advertised as "nicotine-free" or "no addiction" are making a therapeutic claim and therefore should be subject to enforcement by FDA's Center for Drug Evaluation and Research (CDER). Absent any prior approval from CDER that the product is safe and effective for users such products cannot be sold. No tobacco companies should be given the benefit of the doubt on any therapeutic claims nor about the contents of any tobacco or look-a-like product.

It was clearly the intent of Congress to cover all tobacco products and not create gaps where products fall into a regulatory void. Finding 12 in the Tobacco Control Act finds:

It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.⁴⁰

Clearly the exemption of any tobacco product from basic oversight provisions is not keeping with the intent of Congress and its determination that such regulation is in the significant to the U.S.

No Additional Flexibility for Manufacturers is Appropriate for the Protection of Public Health

No Proven Established "Continuum" of Tobacco Products

The American Lung Association was deeply troubled to see that the proposed deeming regulation was altered after it was received by White House and a section called the "Continuum of Tobacco Products" was inserted. The Lung Association is particularly alarmed by the following:

...there are distinctions in the hazards presented by various nicotine-delivering products. Some have advanced views that certain new non-combustible tobacco products (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products given the carcinogens in smoke and the dangers of secondhand smoke. To the extent that certain products are shown to be less harmful, they could help reduce the overall death and disease toll from tobacco product use at a population level in the United States. This is a function of the

existence of a continuum of nicotine-delivering products that pose differing levels of risk to the individual.

The American Lung Association objects to the pre-determined conclusion included in this preamble. It does not reference or allude to the public health standard FDA's Center for Tobacco Products is obligated to follow which must determine the impact on public health – not an individual's health. This is an erroneous reading of the TCA and would put it at odds with the clear standard Congress established that the overall public health must be protected.

No Substantial Equivalence Exemptions

Among the proposed products that would be brought under FDA's authority, the American Lung Association urges FDA not to grant any exemptions to SE requirements that would allow for manufacturers to add or delete additives or increase or decrease the use of an additive. There should be no SE exemptions and SE should only be granted once FDA has a full understanding of the impact on the product and if any changes would be appropriate for the protection of public health.

Small Manufacturers

The American Lung Association urges no further delays or exemptions be granted for small manufacturers as part of the proposed deeming regulation. The Tobacco Control Act contains numerous provisions for smaller manufacturers and those should be applicable in the instance of newly deemed products as well. However, FDA should not give *any* manufacturer – regardless of its size – any additional time to comply with provisions that prohibit manufacturers from making claims that would come under Section 911, or with regard to selling products to youth.

The toll of tobacco is well documented. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, 2014* shows that more than 480,000 people die each year by tobacco-caused disease and nearly 20 million have died since the first Surgeon General's report in 1964. More than five years have passed since President Obama signed the landmark Family Smoking Prevention and Tobacco Control Act into law. This deeming proposal sat for more than six months at the White House Office Management and Budget, far exceeding the 90 day review envisioned by Executive Order 12866. The American Lung Association requests that this deeming rule be finalized as quickly as possible. We call for the rule to be final by December 31, 2014 but certainly no later than April 25, 2015.

The American Lung Association appreciates the opportunity to submit these comments on behalf of the 33 million Americans living with lung disease. We urge FDA to finalize these comments by December 31, 2014.

Sincerely,



Harold P. Wimmer
National President and CEO

Appendices

The American Lung Association is pleased to include the following appendices in support of our comments:

- Appendix A: [Big Tobacco's Guinea Pigs: How an Unregulated Industry Experiments on America's Kids and Consumers](#)
- Appendix B: [Big Tobacco's Next Frontier: Sustaining Addiction & Hooking Kids with Other Tobacco Products](#)
- Appendix C: [Cutting Tobacco's Rural Roots: Tobacco Use in Rural Communities](#)
- Appendix D: [Deadly in Pink: Big Tobacco Steps Up Its Targeting of Women and Girls](#)
- Appendix E: [The Emergence of New Smokeless Tobacco Products](#)
- Appendix F: [The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General, 2014](#)
- Appendix G: "Is Electronic Cigarette Meant for Women Too? Find out if E-cig does not affect women in any way" Press Release (*Please see attached*)
- Appendix H: [Smoking and Tobacco Control Monographs, Monograph 9: Cigars: Health Effects and Trends](#)
- Appendix I: [Smoking Out a Deadly Threat: Tobacco Use in the LGBT Community](#)
- Appendix J: Tar Stopper Image (*Please see attached*)
- Appendix K: [Too Many Cases, Too Many Deaths: Lung Cancer in African Americans](#)
- Appendix L: [The United States of America v. Phillip Morris US, INC, et al Final Opinion](#)
- Appendix M: [Vaporized: E-Cigarettes, Advertising, and Youth](#)⁴¹
- Appendix N: Compilation of E-Cigarette Flavors and Marketing Images (*Please see attached*)
- Appendix O: Compilation of Photos and Advertising from around the United States (*Please see attached*)

¹ U.S. Department of Health and Human Services, ["The Health Consequences of Smoking-50 Years of Progress," A Report of the Surgeon General](#) (January, 2014).

² The Family Smoking Prevention and Tobacco Control Act, H. 1256, 111th Cong., 1st sess. (June 22, 2009).

³ The Family Smoking Prevention and Tobacco Control Act, H. 1256, 111th Cong., 1st sess. (June 22, 2009).

⁴ Food and Drug Administration, ["TAB B Deeming NPRM Redline Changes Re Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations On the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products,"](#) Regulations.gov, 2014, accessed 2014.

⁵ National Cancer Institute, "Monograph 9 Health Effects and Trends: Cigars," *Smoking and Tobacco Control Monographs* (May 21, 2012): i.

⁶ U.S. Department of Health and Human Services, ["The Health Consequences of Smoking-50 Years of Progress," A Report of the Surgeon General](#) 31 (January, 2014): 734-35.

⁷ U.S. Department of Health and Human Services, ["The Health Consequences of Smoking-50 Years of Progress," A Report of the Surgeon General](#) 31 (January, 2014): 7.

⁸ Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products, April 25, 2011, <http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm>

⁹ Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products, April 25, 2011, <http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm>

Center for Tobacco Products and Center for Drug Evaluation and Research, ["Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products,"](#) U.S. Department of Health and Human Services, April 25, 2011, accessed 2014.

-
- ¹⁰ Food and Drug Administration, [“TAB B Deeming NPRM Redline Changes Re Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations On the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.”](#) Regulations.gov, 2014, accessed 2014.
- ¹¹ Maciej Fik et al., [“Carbonyl Compounds in Electronic Cigarette Vapors--Effects of Nicotine Solvent and Battery Output Voltage,”](#) *Oxford Journals Nicotine and Tobacco Research* (May 15, 2014).
- ¹² Mashable, [“How to Hack Your Own E-Cigarettes”](#) (video), January 24, 2014, accessed July 17, 2014.
- ¹³ [“Tar Stopper Disposable Cigarette Filters,”](#) The Smoking Store, 2014, accessed 2014.
- ¹⁴ The Family Smoking Prevention and Tobacco Control Act, Public Law 111–31, 111th Congress, 1st Session (June 22, 2009) <http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>. Accessed August 5, 2014.
- ¹⁵ The one notable exception is menthol. The [American Lung Association has urged FDA](#) to remove menthol cigarettes from the marketplace.
- ¹⁶ Shu-Hong Zhu et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation,” *Tobacco Control* (July 2014, Suppl 3).
- ¹⁷ Greg Allen, [“Fate of Decades-Old Cigar Factory Dangles By a Phrase.”](#) *National Public Radio*, July 15, 2014, accessed August 1, 2014.
- ¹⁸ National Cancer Institute, “Monograph 9 Health Effects and Trends: Cigars,” *Smoking and Tobacco Control Monographs* (May 21, 2012).
- ¹⁹ Catherine G. Corey et al., “Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults – United States, 2012–2013,” *Morbidity and Mortality Weekly Report*, August 1, 2014 / 63(30); 650–654.
- ²⁰ Centers for Disease Control and Prevention, [“Youth Risk Behavior Surveillance—United States, 2013,”](#) *Morbidity and Mortality Weekly Report* (June 13, 2014).
- ²¹ Substance Abuse and Mental Health Services Administration, “Results from the [2012 National Survey on Drug Use and Health](#),” (2013).
- ²² Brian King, Shanta Dube, Michael Tynan, “Current Tobacco Use Among Adults in the United States: Findings From the National Adult Tobacco Survey,” *American Journal of Public Health* (November 2012).
- ²³ Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products, April 25, 2011, <http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm>
- ²⁴ Centers for Disease Control and Prevention, [“Electronic Cigarette Use Among Middle and High School Students – United States, 2011–2012,”](#) *Morbidity and Mortality Weekly Report* (September 6, 2013):729–30.
- ²⁵ Food and Drug Administration, [“TAB B Deeming NPRM Redline Changes Re Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations On the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.”](#) Regulations.gov, 2014, accessed 2014.
- ²⁶ Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted By FDA. <http://www.fda.gov/newsevents/publichealthfocus/ucm173146.htm>. Accessed August 4, 2014.
- ²⁷ Rachel Grana, Pamela Ling, “Smoking Revolution? A Content Analysis of Electronic Cigarette Retail Websites,” *American Journal of Preventive Medicine*, (April 2014):395–403.
- ²⁸ Centers for Disease Control and Prevention, [“Calls to Poison Centers for Exposures to Electronic Cigarettes – United States, September 2010–February 2014,”](#) *Morbidity and Mortality Weekly Report* (April 4, 2014):292–3.
- ²⁹ U.S. Department of Health and Human Services, [“Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General,”](#) Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, (2012).
- ³⁰ Lloyd Johnston, Patrick O’Malley, Jerald Bachman, John Schulenberg, Richard Miech, “Monitoring the Future National Survey Results on Drug Use, 1975–2013. [2013 Volume 1: Secondary School Students](#),” (June 2014).
- ³¹ American Lung Association, [“Hookah Smoking-a Growing Threat to Public Health,”](#) *Smokefree Communities Project* (2013): 1, accessed 2014.
- ³² American Lung Association, [“An Emerging Deadly Trend: Waterpipe Tobacco Use,”](#) *American Lung Association Tobacco Policy Trend Alert* (February, 2007), accessed 2014.
- ³³ National Cancer Institute, “Monograph 9 Health Effects and Trends: Cigars,” *Smoking and Tobacco Control Monographs* (May 21, 2012).
- ³⁴ U.S. Department of Health and Human Services, [“The Health Consequences of Smoking-50 Years of Progress,”](#) *A Report of the Surgeon General* (January, 2014).

-
- ³⁵ U.S. Department of Health and Human Services, ["How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis of Smoking-Attributable Disease,"](#) *A Report of the Surgeon General* (December, 2010).
- ³⁶ U.S. Department of Health and Human Services, ["The Health Consequences of Smoking-50 Years of Progress,"](#) *A Report of the Surgeon General* (January, 2014).
- ³⁷ U.S. Department of Health and Human Services, ["The Health Consequences of Smoking-50 Years of Progress,"](#) *A Report of the Surgeon General* (January, 2014).
- ³⁸ U.S. Department of Health and Human Services, ["The Health Consequences of Smoking-50 Years of Progress,"](#) *A Report of the Surgeon General* (January, 2014).
- ³⁹ U.S. Food and Drug Administration, ["Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA,"](#) U.S. Department of Health and Human Services, April 22, 2014, accessed 2014.
- ⁴⁰ The Family Smoking Prevention and Tobacco Control Act, Public Law 111–31, 111th Congress, 1st Session (June 22, 2009) <http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>. Accessed August 5, 2014.
- ⁴¹ Legacy Foundation, ["Vaporized: E-Cigarettes, Advertising, and Youth,"](#) *Legacy for Health* (May, 2014).

Appendix G

http://www.officialwire.com/main.php?action=posted_news&rid=54235&catid=1076

Is Electronic Cigarette Meant For Women Too? Find out if E-cig does not affect women in any way

Published on January 12, 2010

by *Harry Heiti*

(OfficialWire)

LOS ANGELES, CA



www.electroniccigarette123.com

Cigarette smoking kills an estimated 178,000 women in the United States annually. The three directing smoking-related causes of death in women are lung cancer (45,000), heart disease (40,000), and chronic lung disease (42,000). Women who smoke have an increased risk for other cancers, including cancers of the oral cavity, pharynx, larynx (voice box), esophagus, pancreas, kidney, bladder, and uterine cervix.² Women who smoke double their risk for developing coronary heart disease and increase by more than tenfold their likelihood of dying from chronic obstructive pulmonary disease.

The doctors recommend for traditional cigarette smokers the [electronic cigarette](#) or the e-cig product. Most especially for pregnant smokers the doctor recommended it for them. Our electronic cigarettes have the same look and feel as traditional cigarettes, but are completely free of tar, carcinogens and other toxins. Since the cigarettes are non-flammable and do not contain

tobacco, you have the freedom of smoking virtually everywhere!

The cigarettes are rechargeable and use advanced micro-electronic technology to deliver nicotine to the user. The nicotine cartridges come in a variety of concentrations making it easy for you to slowly breakdown your intake. The draw from a cigarette is almost identical to traditional smoking. The 'smoke' which is produced is actually vapor and therefore a friendlier alternative to your environment.

"Traditional" smoking has proven to be a hazard to the health, often leading to lung- and cardiovascular diseases amongst heavy smokers. A single tobacco cigarette contains over 4000 chemical substances which are inhaled by the smoker.

New Smoke [e cigarettes](#) give smokers their nicotine dose, but don't pass on other harmful substances to you or your environment. Our products are your ideal alternative to traditional cigarettes!

Guaranteed 30-day program on how to quit smoking. Order now to have a chance to get **BONUS ITEMS!**

Visit www.electroniccigarette123.com or call 1-888-288-4847.

Contact

Media Report

Harry Heiti

gstatsinfo@gmail.com

Tel: 8882884847

Appendix J: Tar Stopper Image



Appendix N: Compilation of E-Cigarette Flavors and Marketing Images

1. <http://www.v2cigs.com/pages/electronic-cigarette-flavors>



GRAPE



BUBBLEGUM



e-Liquid CottonCandy
10ml eLiquid



ECIGARETTE ^{USA}
another way to smoke



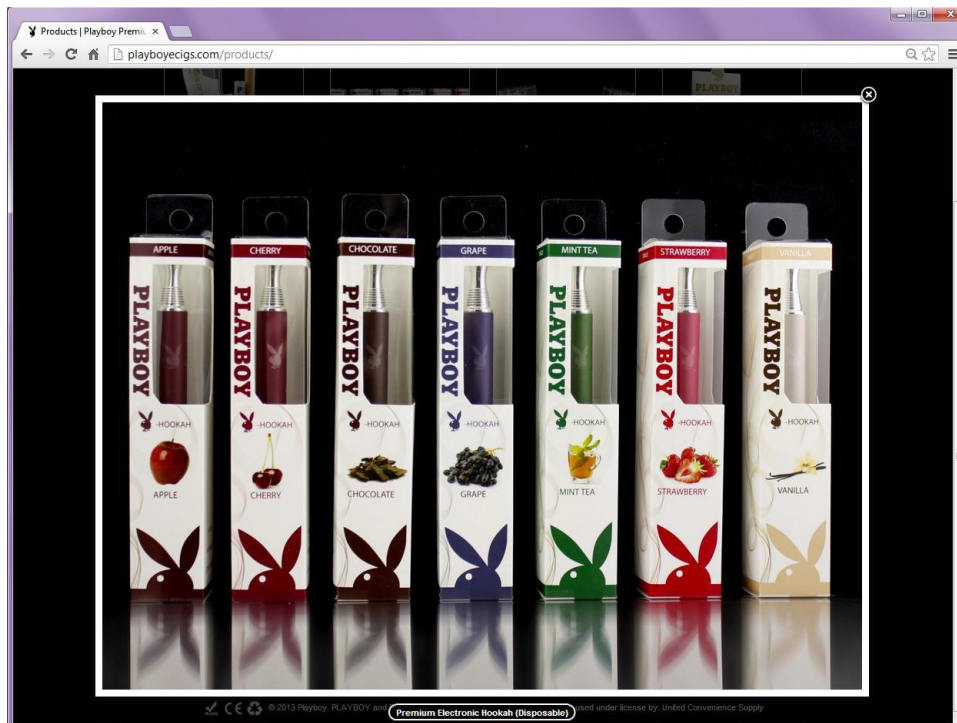
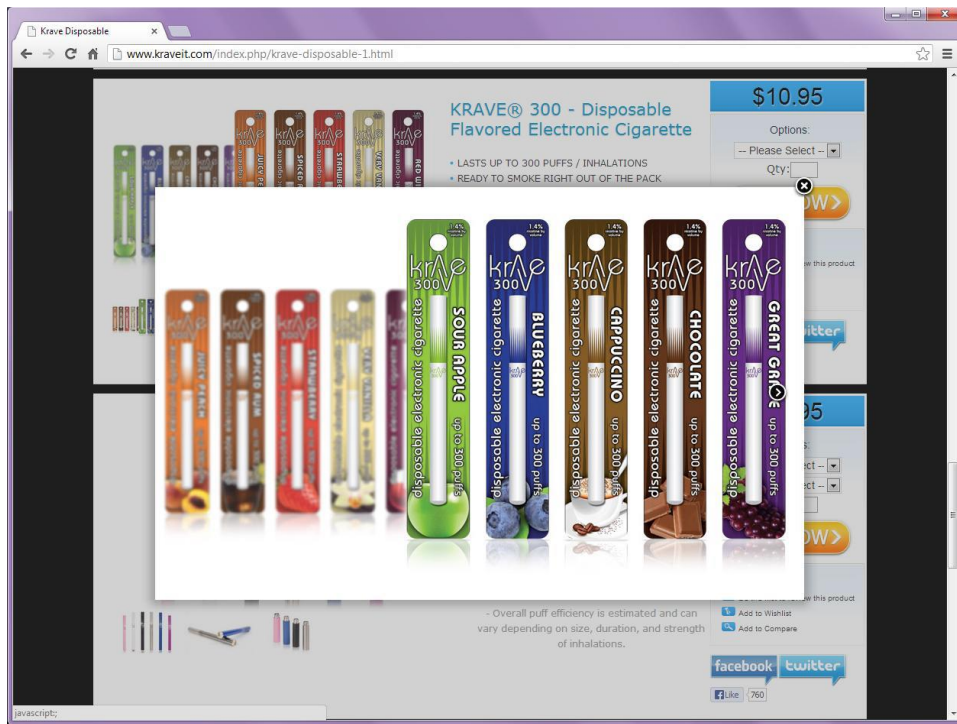
Logic Smoke
e-cigarette Liquid
10ml eLiquid
The Pleasures of Vaping

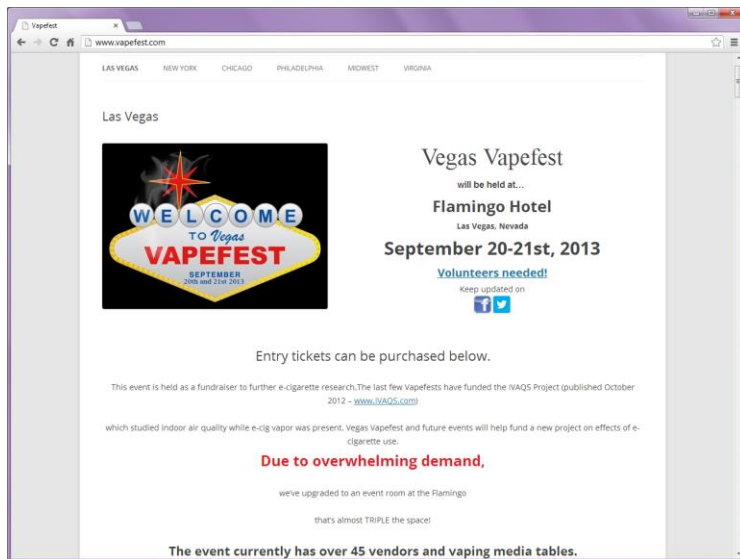
Logic Smoke
e-cigarette Liquid
10ml

x high (24mg)
high (16mg)
med (11mg)
low (6mg)
non (0mg)

CottonCandy Flavor









Cotton Candy E-Liquid



Availability: Usually Ships in 24 Hours

Choose your options...

Nicotine level

First, Select Nicotine level

Qty: 1

[add to cart](#)

★ Add to Wish List

Customers also bought...



Watermelon E-Liquid

Pina Colada E-Liquid

Strawberry E-Liquid

Blueberry E-Liquid

Our Price: \$8.99

Our Price: \$8.99

Our Price: \$8.99

Our Price: \$8.99

[add to cart](#)[add to cart](#)[add to cart](#)[add to cart](#)[add to cart](#)[add to cart](#)[add to cart](#)[add to cart](#)





Website <http://www.vapor4life.com/e-cig-cartomizers?limit=all>

Description (e.g. health claim, candy-flavor)

Vapor4Life E-Cigarette

Flavors include: cola, waffle, pancake, cinnamon roll, vanilla milkshake, peanut butter cup





Chocolate Thunder

Loose yourself in the smooth, creamy
flavors of milk chocolate and almonds.



Gummy bear Candy



COTTON CANDY



Dragon Cigarette.com

KOOKIE KRISP





CHERRY



What's Your Taste?

Choose E-cigarette Cartridge From 7
Delicious Flavors by XEO E-cigarettes !!

World's Most Powerful E-cigarette
Available in 7 Flavors!!

Tastes your Mouth Crave For,
Which Flavor you Smoke?









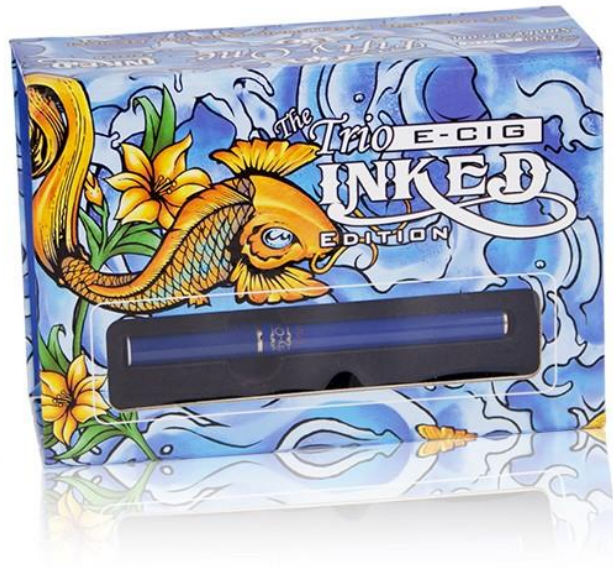
DESSERT FLAVORS



Biscotti

NicQuid
Flavoring with Nicotine





Date 10/30/13

Website http://www.trinketsandtrash.org/viewImage.php?file_name=213855.jpg

Description

Njoy e-cigarettes as an alternative to quitting tobacco as a New Year's resolution.



RESOLUTION SOLUTION.

**INTRODUCING THE NJOY KING ELECTRONIC CIGARETTE.
IN 2013, SMOKERS FINALLY HAVE A REAL ALTERNATIVE.**

It's the first electronic cigarette with the look and feel of the real thing, and authentic flavor developed in the USA by our Master Flavorist. So this New Year, you can get rid of the smoke and keep the flavor. You've got NJOY on your side.



**CIGARETTES, YOU'VE
MET YOUR MATCH.**

AVAILABLE AT CONVENIENCE STORES NATIONWIDE.

njoy.com

©2013 NJOY, Inc. All rights reserved. NJOY is a registered trademark of NJOY, Inc. All other trademarks are the property of their respective owners. NJOY is not a tobacco product. For more information, visit www.njoy.com.

Date 10/30/13

Website http://www.trinketsandtrash.org/viewImage.php?file_name=213543.jpg

Description

Blu e-cigarettes as a better alternative to quitting.



Date 9/19/13

Website <http://www.v2cigs.com/pages/electronic-cigarette-flavors>

Description (e.g. health claim, candy-flavor)

V2 Cigs

Flavors: Red (Marlboro), Sahara (Camel), Congress (Parliament), Menthol, Peppermint, Mint Tea, Cherry, Chocolate, Coffee, Vanilla, Cola

Don't Quit, Switch!
See Why Millions
Have Switched To V2 Cigs.



America's #1 Electronic Cigarette Brand



No Smoke
No Odor
No Guilt
No Kidding!

See Why >

Date: 10/30/2013

NE Where Electronic Cigarettes <http://www.newhere.com/index.php>

QUIT SMOKING with
ELECTRONIC CIGARETTES



NE
WHERE™
ELECTRONIC CIGARETTES

Bruno Mars:

PRNewswire
A UBM plc company

Send a release

Become a member For journalists
Member sign in For bloggers
Global sites

Search

Advanced Search

Products & Services News Releases

Products & Services

Knowledge Center

Browse News Releases

Contact PR Newswire

See more news releases in [Entertainment](#) | [Music](#) | [Health Care & Hospitals](#) | [Tobacco](#)

Bruno Mars Signs On As Investor With NJOY, America's Top Selling Electronic Cigarette Brand

Like 0

Twitter LinkedIn +1 More

Pop star Bruno Mars is giving up tobacco in favor of NJOY e-cigs, investing in the brand. (PRNewswire/JOY)

SCOTTSDALE, Ariz., May 30, 2013 (PRNewswire) – NJOY, America's number one electronic cigarette company, has announced that global music superstar and 13-time Grammy Award nominee Bruno Mars has joined the company as an investor. While the terms of the investment were not disclosed, Mars stated that he often uses NJOY's King product in place of traditional cigarettes and is convinced that it is a revolutionary alternative to cigarettes.

(Photo: <http://photos.njoykings.com/prnh20130530/NY23178>)

"I've been using NJOY Kings instead of cigarettes these days and I'm sticking to it," said Mars. "I believe in the product and the company's mission."

"Bruno Mars is an exciting addition to NJOY and we are pleased to have him join as an investor," said Craig Weiss, Chief Executive Officer of NJOY. "Adding Bruno to our team expands our reach, raising further awareness of the NJOY brand and our company mission to obsolete cigarettes." Weiss added, "Many of our investors use our product and recognize the potential NJOY has to challenge the status quo and change people's lives for the better."

Featured Video

Canyon Creek Ranch® Launches National "Better Way Project" To Help make A Difference In The Lives Of Pets And The People Who Love Them

Journalists and Bloggers

Visit PR Newswire for Journalists for releases, photos, ProNet experts, and customized feeds just for Media.

View and download archived video content distributed by MultiVu on



Bruno Mars @BrunoMars

Day 1 E-Cig. Gotta do it!!! This is for you mom
pic.twitter.com/QFg80wBIJa

 Hide photo
  Reply
  Retweeted
  Favorite
  More



8,680
 RETWEETS

9,137
 FAVORITES



Katy Perry:



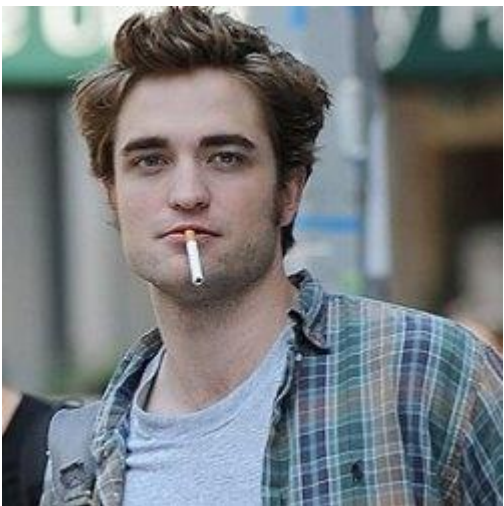
Leonardo DiCaprio:



Katherine Heigl:



Robert Pattinson:



Britney Spears:



Cigar Advertising:













Kanye West



Jay Z

Appendix O: Compilation of Photos and Advertising from around the United States

Picture of e-Cigarette Store and advertising for store, Washington



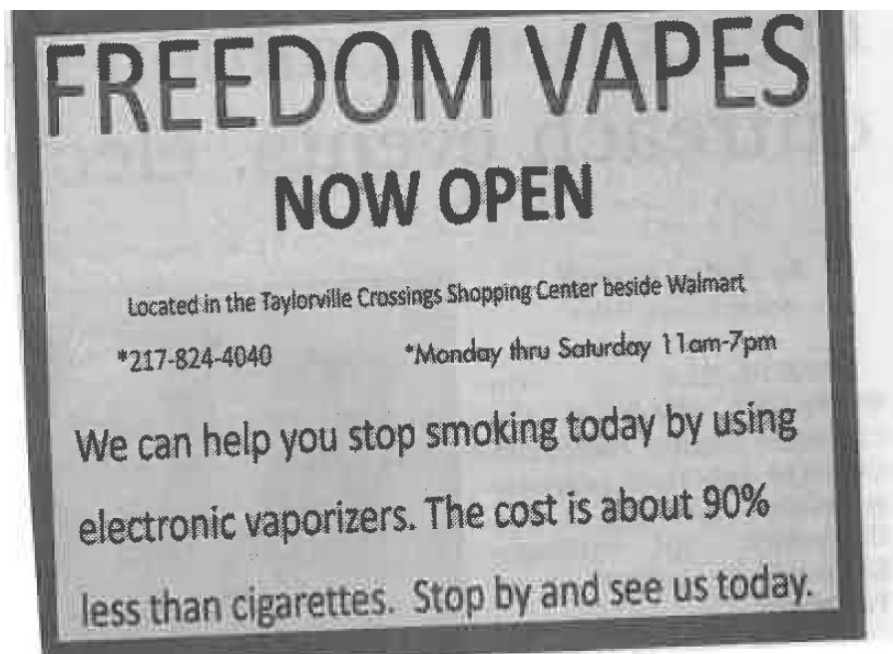


E-Cigarettes sold next to candy, Orange Service Area, Wilbur Cross Parkway, CT





Advertisement and story in the *Breeze Courier* for store located in Taylorville Crossings Shopping Center, Taylorville, IL



FREEDOM VAPES OPENS AT TAYLORVILLE CROSSING



TAYLORVILLE — Pictured are Freedom Vapes owners Thomas and Lena Ray and Amy and Mike James.

Andy Lasswell/Breeze-Courier

Vaping 90 percent cheaper than smoking, owners say

TAYLORVILLE - Four ingredients or four-thousand ingredients.

That's what Amy James, co-owner of Freedom Vapes in Taylorville, has to say about the choice between smoking cigarettes and using a vaporizer device.

Amy and her husband Mike James, along with Thomas and Lena Ray, recently opened Freedom Vapes at the Taylorville Crossing shopping center. The two couples are

trying to help area smokers quit by offering a similar experience, just without all the chemicals and carcinogens.

Vaporization works by using a battery powered device to turn liquid into vapor.

Vaping has become an increasingly popular alternative to smoking cigarettes. While Lena says there are a good number of vaping enthusiasts out there, the primary customer is an individual who is attempting to quit

smoking. Freedom Vapes offers a full-line of starter kits, tanks, mods and e-juices. According to Lena, most people who start vaping start with a very small amount of nicotine and gradually wean themselves off until they are vaping nicotine-free.

Vaping, according to Freedom Vapes, is also about 90 percent cheaper than smoking cigarettes.

There are also the hobby-

ists who enjoy vaping, and that's where the quality of Freedom Vapes' e-juice comes into play.

Amy and Lena say they have had a good reception from the community since their recent opening and invite anyone to come visit them who is thinking about quitting smoking.

Freedom Vapes is located in the Taylorville Crossing shopping center and can be reached at (217) 824-4040.

Floor Mat at Circle K Convenience Store, Louisville, KY



Young Girls Advertising E-Cigarettes, Appleton, WI



Story from Amber, WI

Her issue:

He father went to the E-Cigarette Café at 3812 Roosevelt Rd. Kenosha, Wi 53142 to purchase a refill on his e-cig. He noticed that the guy took it to the back room where it appeared that he had large plastic containers filled with fluid. Shortly after the man smoked his new refilled e-cigarette he broke out in a bad rash. He went to his physician who felt that the rash probably was caused by the e-cigarette. The man returned to E-Cigarette Café and asked them if others had also reported a rash after smoking this product. The person at the counter said that they actually had a number of people who developed rashes. The complainant was very concerned about:

1. *Was this manufacturing?*
2. *Who was regulating just what was in the liquid?*
3. *Where did the liquid come from?*
4. *Why is there no protection for folks who buy this product?*
5. *Shouldn't the health dept. be monitoring this like they would do food preparation/cleanliness?*
6. *Why did the city allow them a license with no restrictions?*

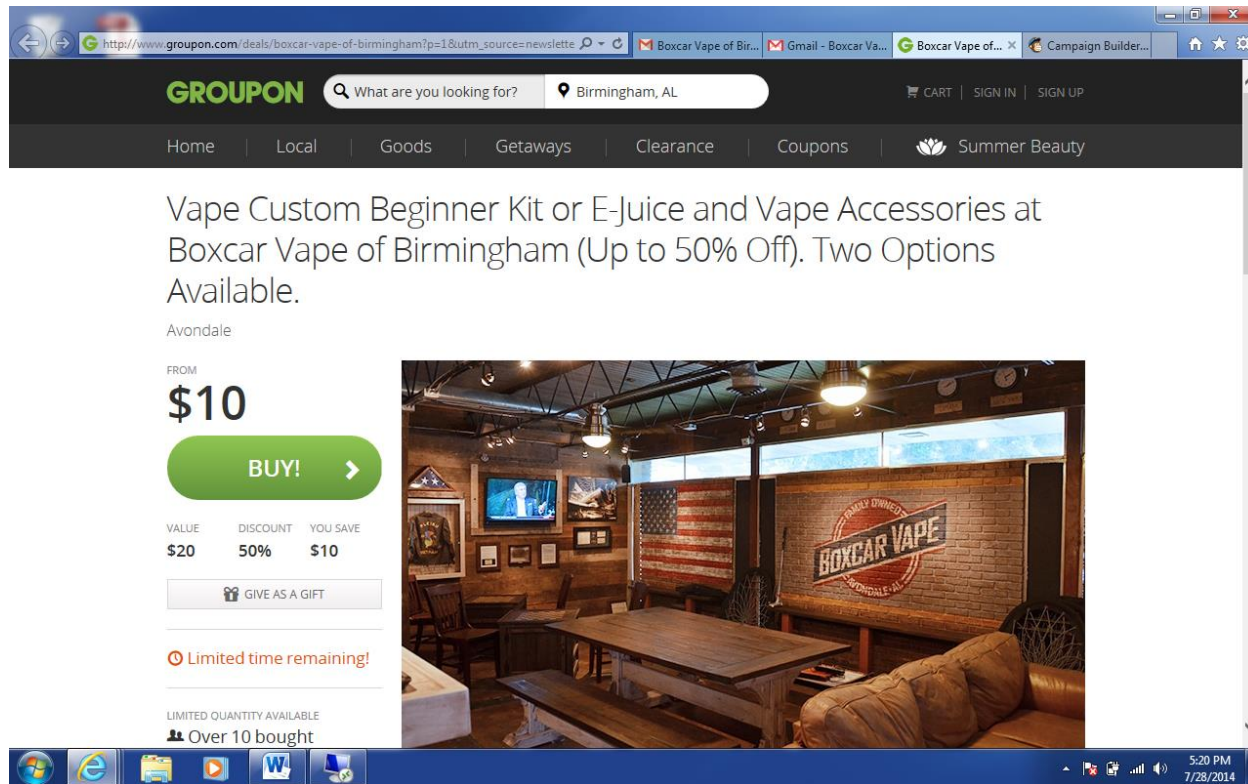
Billboard, Janesville, WI



Examples of E-Cigarette Advertising, AL

Groupon Deal for E-Cigarette(s)

Link: http://www.groupon.com/deals/boxcar-vape-of-birmingham?p=1&utm_source=newsletter&utm_medium=email&sid=a53a8542-f935-4212-ad16-ba218ca02100&division=birmingham&user=2bd4c1f418b5c392917e6213fa46dc87bc140a909dbfa3bed3cfb933d0c8264b&date=20140722&s=body&c=button&d=deal-page&utm_campaign=a53a8542-f935-4212-ad16-ba218ca02100



groupon What are you looking for? Birmingham, AL

Home Local Goods Getaways Clearance Coupons Summer Beauty

Vape Custom Beginner Kit or E-Juice and Vape Accessories at Boxcar Vape of Birmingham (Up to 50% Off). Two Options Available.

Avondale

FROM

\$10

BUY!

VALUE	DISCOUNT	YOU SAVE
\$20	50%	\$10

 GIVE AS A GIFT

 Limited time remaining!

LIMITED QUANTITY AVAILABLE

 Over 10 bought

5:20 PM 7/28/2014

http://www.groupon.com/deals/boxcar-vape-of-birmingham?ps1&utm_source=newsletter

Boxcar Vape of Bir... Gmail - Boxcar Va... Boxcar Vape of... Campaign Builder...

LIMITED QUANTITY AVAILABLE
Over 10 bought

Choose between Two Options

- \$10 for \$20 worth of e-juice and vape accessories
- \$35 for a Vape Custom Beginner Kit (\$58.75 value), which includes:
 - 1 EGO battery
 - 2 Aspire BDC tanks
 - 1 Aspire coil pack
 - 1 Bottle of standard juice (includes seven popular brands and various flavors)
 - 1 Ego zippered case
 - 1 USB charger

Boxcar Vape of Birmingham

Patrons can't just leave after entering Boxcar Vape of Birmingham. Ok, technically they can, but there's really no reason why they would. Boxcar looks more like a cafe or lounge than a Birmingham vape shop—that is, until you notice the men and women puffing on more than 100 flavors from black-cherry tobacco to watermelon bubblegum, with nicotine levels ranging from 0 to 24mg. On special nights, the space might even host casino games or competitions to see who can blow the largest vape cloud known to man or man's best friend, Gary.

Dark wood defines Boxcar Vape's vibe, from the paneled walls to tables, many of which double as chess boards. It's here that in addition to vape products, the staff serves up coffee and baked goods, including cookies and cupcakes from Birmingham-based Dreamcakes. As one would expect from their location on the Avondale Brewing Campus, the team also serves up bottles of Avondale beer.

The retail side of Boxcar Vape helps patrons recreate the lounge experience at home. The inventory includes all the necessary gear: batteries, tanks, mods, and e-liquids.

[ASK A QUESTION](#)

Reviews

- Birmingham Business Journal feature

In a Nutshell

Pick up a vape bundle package or stock up on vape accessories inside a cafe/lounge space serving coffee, baked goods, and beer

The Fine Print

Expires 90 days after purchase. Valid only at listed locations. Limit 1 per person, may buy 1 additional as a gift. Limit 1 per visit. Must use promotion value in 1 visit. Not valid with any other sales, discounts, or promotions. Must be 19 or older. Valid in-store only. Valid only for the purchase of E-Juice and Vape Accessories. Merchant is solely responsible to purchasers for the care and quality of the advertised goods and services.

[Company Website](#)



Avondale
4120 3rd Ave S
Birmingham, Alabama 35222
205-868-3601
[Get Directions](#)

Link: <http://www.groupon.com/deals/the-vape-loft-1>

http://www.groupon.com/deals/the-vape-loft-1

Campaign Builder - Pre-deliver... The Vape Loft Birmingham ...

GROUPON Birmingham, AL

Home | Local | Goods | Getaways | Clearance | Coupons | Summer Beauty

\$15 for \$30 worth of E-Cigarettes and Supplies at The Vape Loft

Birmingham

\$15

[BUY!](#)

VALUE	DISCOUNT	YOU SAVE
\$30	50%	\$15

[GIVE AS A GIFT](#)

Limited time remaining!

LIMITED QUANTITY AVAILABLE
Over 20 bought



http://www.groupon.com/

Over 20 bought

The Deal

• \$15 for \$30 worth of e-cigarettes and supplies

Electronic Cigarettes: No Smoke, No Fire

Nearly five million electronic cigarettes were sold in the United States in 2012—a sign of their ever-increasing popularity. Read on to learn more about this smoke-less phenomenon.

E-cigarette: A device that uses battery power to heat a liquid mixture for users to inhale as a vaporized aerosol. Also known as an e-cig, electronic vaping device, personal vaporizer, or electronic nicotine delivery system (ENDS), an e-cigarette may resemble a real cigarette or look much different, depending on the model and added attachments ("mods").

Vaping: The act of inhaling vaporized liquid from an e-cigarette. Users often call themselves "vapers"—not to be confused with the all-ghost barbershop quartet known as The Vapors.

E-liquid: The stuff, also known as "juice," that gets vaporized inside the e-cig. The solution usually consists of water and either vegetable glycerin or propylene glycol—the same substance (recognized by the FDA as safe for use as a food additive) that smoke machines use to create fake smoke. Juices come in a variety of flavors, including fruit, coffee, and tobacco.

Milligrams: The unit by which e-liquids typically measure the amount of nicotine in the formula. Concentrations can be as high as 16 milligrams to as low as none at all—an ideal option for users who simply want the sensation of vaping without the addictive element.

Atomizer: The heating element that vaporizes the e-liquid. When the atomizer is permanently attached to the e-liquid cartridge, it's called a cartomizer. Atomizers are durable and meant to be paired with refillable juice cartridges, while cartomizers are generally found on models designed for short-term use.

[ASK A QUESTION](#)

In a Nutshell

Enjoy tobacco without smoke or tar through high-tech atomizers, vaporizers, and flavored liquids

The Fine Print

Expires 90 days after purchase. Limit 1 per person, may buy 1 additional as gift. Limit 1 per visit. Must use promotion value in 1 visit. Must be 19 years of age. Not valid for sale items. Merchant is solely responsible to purchasers for the care and quality of the advertised goods and services.

[Company Website](#)



Birmingham
720 29th Street South
Birmingham, Alabama 35233
912-713-5830
[Get Directions](#)

E-Cigarette Industry Event Sponsorship

Link: <http://www.secretstages.net/> ; <http://www.secretstages.net/2014-sponsors/>

SECRET STAGES

ABOUT LINEUP TICKETS CONTACT

VULCANVAPE THE ORIGINAL VAPORIZERS

SECRET STAGES

BIRMINGHAM, ALABAMA'S MUSIC DISCOVERY FESTIVAL

AUGUST 1+2, 2014



THE GREEN SEED (BIRMINGHAM, AL)

00 weeks 04 days 00 hours 28 minutes 27 seconds

Put email here for awesome.

GET OUR EZINE!

© 2014 Secret Stages. Site designed by Sam George

http://www.secretstages.net/2014-sponsors/

SECRET STAGES

ABOUT LINEUP TICKETS CONTACT

2014 Sponsors

Secret Stages is presented by



VULCANVAPE
THE LOGICAL ALTERNATIVE

A HUGE THANKS TO ALL OF THIS YEARS SPONSORS! WE COULDN'T DO IT WITH OUT YOU.

2014 Lineup (More to come!)

- Adia Victoria (Nashville, TN)
- All Them Witches (Nashville, TN)
- Armand Margjeka (Birmingham, AL)
- Baghouse (Athens, GA)
- Bent Denim (New Orleans, LA)
- Body of Light (Nashville, TN)
- Boog Brown (Atlanta, GA)
- Brian Olive (Cincinnati, OH)
- Brothers (Athens, GA)
- Captain Green (Baton Rouge, LA)
- CYNE (Gainesville, FL)
- D1n.Only (Orlando, FL)
- Disfigurement (Atlanta, GA)
- Doc Aquatic (Asheville, NC)
- Doc Dailey Music (Muscle Shoals, AL)
- Ex-Cult (Memphis, TN)
- Faun and a Pan Flute (Atlanta, GA)
- Feral Child (Birmingham, AL)

00 04 00 26 25
weeks days hours minutes seconds

Put email here for awesome.

GET OUR EZINE!

f t i

http://www.secretstages.net/2014-lineup/doc-aquatic-asheville-nc/

© 2014 Secret Stages. Site designed by Sam George

5:33 PM 7/28/2014

Product Placement of E-Cigarettes in Costco





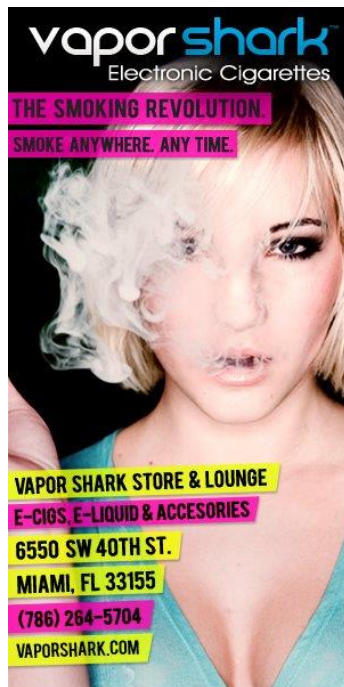
Advertisement Following Smokefree Law Passage



Delivery Truck at a Vermont Hospital



Advertisement



Advertisements on cars in the Parking Lot of a High School in Saco, Maine





E-Cigarette Vending Machine



E- Juice in Virginia

