

Data to Support FDA Action to Regulate E-cigarettes and E-liquids and Ensure all Products have Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid (s), and Other Tobacco Products

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Background on the GSU TCORS: The GSU TCORS was funded to conduct research to increase the understanding of the **diversity of tobacco products, the communications and marketing of those products, particularly at the point of purchase, and how economics and public health policies affect tobacco use.** The current GSU TCORS research project is entitled: “The Science of Decision Making: Connecting People and Policy.” The research utilizes a multi-disciplinary approach that features collaboration among tobacco control experts, behavioral economists, epidemiologists, cognitive psychologists and communication researchers. The data and results from these studies will have direct implications for future FDA and NIH regulatory actions.

Objective/Purpose

In this public comment, we will provide preliminary findings from our pilot research conducted June to August 2014, which focused on point of sales audits across three separate college campuses in the state of Georgia. We specifically highlight the findings as it pertains to characterizing e-liquid products.

From the FDA website:

“The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) entitled “Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products” that appeared in the Federal Register of July 1, 2015. In the ANPRM, FDA requested comments, data, research results, or other information, that may inform regulatory actions that FDA might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.”

Methods

The unpublished findings were obtained by analyzing data from the GSU TCORS pilot study entitled, "Understanding the E-Cigarette Landscape: An Environmental Scan of Point of Sales and Website Forums" conducted as part of the Georgia State University (GSU) Tobacco Center of Regulatory Science. This study was a Pilot and Developmental Research project that was peer reviewed and approved by FDA and NIH and funded under GSU's RO1 research project "Conducting Consumer Behavior, Risk Perception and Media Research on Novel Tobacco Products" and was supported by Grant Number: 1P50DA036128-01. GSU IRB approval was obtained for the environmental scan pilot research study and determined to be exempt, non-human subjects. Data collection period was June-August 2014.

The "brick and mortar (BM)" point of sales (POS) identified for the environmental scan were based upon content analysis of web-based e-cigarette and vapor forums. E-cigarette forums are blogs where "community of e-cigarette users" can discuss and share the latest about e-cigarettes.

The POS were ranked based on a frequency count obtained from the content analysis of web blogging threads. Based on the content analysis of two web-based forums, the most commonly cited POS were:

- 1) Specialty Stores – vape, tobacco, smoke shops
- 2) Walmart
- 3) Gas Stations/convenience stores
- 4) Walgreens
- 5) Shopping mall
- 6) Grocery store
- 7) Rite aid

Using the above as the inclusion criteria for POS, a density map of all possible POS identified through the internet content analysis was created to identify the POS within a 1-, 2-, and 3-mile radius around Georgia State University (GSU), Georgia Tech University (Ga Tech), and University of Georgia (UGA). After mapping out all possible POS around GSU, Ga Tech, and UGA, 8 POS were randomly selected from each of the three campuses (total 24 POS). The final number of POS audited was 17 POS (6 POS did not have visible e-liquids and 1 POS was unsafe to enter). Environmental scan around college campuses are of interest because of the young adult and minority populations that tend to study, work, and/or reside around these locations and have traditionally served as a targeted market segment for the tobacco industry, and now the e-cigarette industry.

Two graduate research assistants collected data from POS at the same time to characterize specifically the ENDS products that are currently available. Pictures of ENDS products were taken within POS. Characteristics of the products were collected, coded and data were entered and recorded in Excel spreadsheets.

Research Findings on E-Liquids From the 2014 GSU Environmental Scan of Point of Sales and Website Forums

A total of 602 unique flavors were identified and were categorized as follows: 1) Tobacco and Menthol (16.6%); 2) Desserts and Candies (16.6%); 3) Fruits (20.6%); 4) Drinks (10.1%); 5) Other (36.0%). Tobacco and Menthol flavors identified in e-cigarette devices mimicked traditional tobacco cigarette flavors.

Examples of Desserts and Candies flavors include: “cotton candy”, “fruity pebbles”, and “gummi bear”. Examples of Fruit flavors included “georgia peach”, “green apple”, and “melon mania”. Drink flavors identified were “cola”, “rootbeer”, “orange crush”, and “cookie cream milkshake”. Other flavors included miscellaneous flavors that could not be categorized otherwise. Such as “red pirate”, “midnight express”, and “dragon’s breath”. All e-liquids were available with and without nicotine. Most flavored e-liquids were sold in stand-alone vials (91.0%). When sold with manufactured products, flavored e-liquids were mostly found in e-hookahs (10.6%). Nicotine concentrations ranged from 0 to 24 mg/ml.

Based on retail audit observations, none of the e-liquid vials had any child resistant packaging; while vials had warning labels, they were not consistently observed and for those with warning labels they were not readily visible. Below is an example of one vial identified.



Content analysis of web blogs revealed that making “Do It Yourself” (DIY) e-liquids was popular and common practice among e-cigarette users in which propylene glycol (PG), vegetable glycerin (VG), flavorings, and concentrations of nicotine ranging from 12mg to 99% pure are bought on the internet and mixed at home among persons without the experience and knowledge to handle nicotine, which is a toxic chemical.

Summary and Conclusions for Consideration by FDA

Currently, the e-cigarette and vaping industry is experiencing exponential economic growth with little regulatory authority over them. Over the past several years, there have been an increase in calls to poison centers due to children’s exposure to nicotine in e-liquids. Moreover, studies have found that concentration of nicotine on labels is not consistent with what is assayed in the vials.

The web blogs we analyzed revealed that the culture of DIY may be one of greatest risks because nicotine can be purchased online and used by amateurs to make homemade e-liquids. Our study also clearly documents that e-liquid vials observed at point of sales audits had no child resistant caps. Warning labels were hardly visible and there were a range of nicotine concentrations available. Most disturbing was the vast number of unique flavorings observed; over 600. These flavors have been known to lure children and youth. FDA must take measures to protect our children by ruling that all e-liquid products come with child resistant caps and bold face warning labels. More importantly, FDA should seriously consider regulating the sales and distributions of e-liquid vials.

Many of the flavor names found in our pilot study included “cotton candy”, “fruity pebbles”, and “gummi bear”. Examples of Fruit flavors included “georgia peach”, “green apple”, and “melon mania”. Drink flavors identified were “cola”, “rootbeer”, “orange crush”, and “cookie cream milkshake”. Other flavors included miscellaneous flavors that could not be categorized otherwise. Such as “red pirate”, “midnight express”, and “dragon’s breath”. The use of these flavors in marketing and sales of ENDS and e-liquids is akin to the flavors in traditional tobacco products, such as cigarettes, cigars, and smokeless tobacco. In the 2012 Surgeon General’s Report, Chapter 5 outlines in detail how the tobacco industry willfully conceptualized the use of flavors in cigarettes as a way to attract and interest young regular cigarette smokers (US DHHS, 2012). Some flavors that were conceptualized in the 1970s included cola and apple flavors (US DHHS, 2012). As discussed in tobacco industry documents, the industry has known and that “sweet” flavor additives can lure youth into using tobacco, thereby propagating nicotine dependence; in some cases with young children, this may lead to nicotine poisoning. In 2009, the Family Smoking Prevention and Tobacco Control Act prohibited flavors (except menthol) in cigarettes.

While these findings are from a very discrete geographical area with small sample sizes, a strength of the study is the photo documentation of products found at retail outlets. In particular, the stand alone e-liquid vials are of serious concern, given the variety of flavors and nicotine concentrations they come in, and without proper child-resistant caps. FDA needs to use the regulatory authority granted to them and require manufacturers to use child-resistant caps and proper warning labels. If changes to the vials are not made, children exposed to these products will continue to be at risk for nicotine poisoning.

References

- Centers for Disease Control and Prevention (CDC). Electronic Nicotine Device Use among Middle and High School Students, National Youth Tobacco Survey 2011-2012. Notes from the Field, September 6, 2013.
- U.S. Department of Health and Human Services (US DHHS). *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.