FDA Should Regulate All E-Cigarettes, Electronic Nicotine Delivery Systems (ENDS), Zero Nicotine Electronic Devices (ZNEDS), and Associated Parts and Components as Covered 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In this public comment, we will provide preliminary findings from our recent unpublished pilot research focused on environmental scans at point of sales in Metropolitan Atlanta. We provide general information that describes the diversity of electronic cigarettes and the various components and parts of electronic nicotine delivery systems (ENDS). To inform our study, we used the Host, Agent, Vector, Environment (HAVE) Model, focusing on e-cigarettes as the Agent, to begin to understand exactly what is available to consumers. These data are meant to provide support for the regulation of e-cigarettes as a "covered tobacco product" by the Food and Drug Administration's Center for Tobacco Products. The findings we present are to support the inclusion of e-cigarettes as a "covered tobacco product" in the following FDA proposals:

"FDA ask for comments, including supporting facts, research, and other evidence, as to whether they should define components and parts of tobacco products and how those items might be distinguished from accessories of tobacco products. (page 4)"

"FDA also is proposing to prohibit the sale of covered tobacco products to individuals under the age of 18 and to require the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements."

Methods

We obtained these unpublished findings by analyzing preliminary data from the GSU TCORS pilot study entitled, "Understanding the E-Cigarette Landscape: An Environmental Scan of Point of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. Data collection period was June-August 2014. This pilot study was 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.

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 BM 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) and Georgia Tech University (Ga Tech). After mapping out all possible POS around GSU and Ga Tech, 2-4 POS were randomly selected within each of a 1-, 2-, and 3-mile radius of the campuses. 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 can serve as a targeted market segment.

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. We are in the process of compiling and completing the data entry, but have preliminary findings that are worthy to share at this time.

General Research Findings from the 2014 GSU Environmental Scan of Point of Sales and Website Forums

Categories of ENDS Products Identified

Through the data collected from the POS environmental scans, it was determined that among two urban campuses in Atlanta, there are currently 5 specific classifications of ENDS that are available. Listed below are the 1) specific classifications, 2) definitions and descriptions, and 3) locations where ENDS were identified.

1) **Manufactured products.** Defined as those devices that are pre-packaged with some types of branding. Brand names may be those such as Blu, NJoy, FIN, but may also be manufactured products with names that are less well known. Some specialty stores (tobacco, smoke shops, vape shops) manufacture their own devices as well. The manufactured products can either come as disposable or non-disposable, and some are marketed and sold as rechargeable. For those that are non-disposable, refillable cartridges can be purchased, and/or vials of e-liquid nicotine can be purchased to refill certain manufactured devices. Cartridge refills can be purchased at select BM POS. However, we have noted that for some specialty stores, the manufactured products are being phased out and being replaced by customizable ENDS products.

2) **Customizable ENDS products.** Defined as ENDS devices where the user has the ability to construct, create, and modify their own devices through readily available ENDs device parts. They are also referred to as "mods". Parts include selling the mouthpiece, chamber (tank), atomizers vaporize e-liquid and are reusable, battery packs, and e-liquid. Cartomizers are also available as separate parts, and are disposable. The apparent advantage is that end users can mix and match how the device looks and functions. Customizable style ENDS are currently sold at specialty stores; they are currently not available at gas stations or the other BM POS. However, gas stations do currently sell the e-liquid. Because of the rapidly changing environment for ENDS marketing and sales, it is not inconceivable that other POS such as gas stations/convenient stores may begin to sell ENDS as customizable devices.

3) **"Do It Yourself" (DIY).** Defined as ENDs that are completely constructed by purchasing various parts from local hardware stores and home-made e-liquids containing nicotine through online purchasing of nicotine. The internet has "tutorials" on how DIY e-liquid can be made and places to purchase nicotine. DIY were exclusively identified through the content analysis of the web forums. The pilot study will delve deeper into the web forums to conduct an environmental scan of the internet to better understand DIY. However, for the purposes of FDA proposed rules, it is important to be aware that DIY is one of the preferred ENDS.

4) **E-liquid vials.** Defined as products for use in ENDS that contain liquid either with or without nicotine that is vaporized and inhaled. Nicotine concentrations can vary from 0-24 mg/ml. Whether or not the e-liquid comes with nicotine, observations indicate that there are over 355 flavors. Our preliminary data also confirms that the flavors currently available are those that would be immediately identified by young people (e.g., Skittles, Cotton Candy, Gummi Bear, etc.). In fact, one specialty store sold over 200 flavors which were categorized into 4 distinct

categories, including “Desserts and Candy”. These 4 distinct flavor categories are being used and we added another category of “Other”, because many flavor names (e.g. Magnificent) did not fit into the other 4 categories.

5) **Zero Nicotine Electronic Devices (ZNEDS).** Defined as manufactured or customizable products that deliver zero nicotine. These include some e-hookahs, which deliver only flavored vapor. This also includes e-liquids. Using the Harm Reduction theory, the ZNEDS may be conceptualized as the “final step” for cigarette smokers as they are weaning themselves off nicotine. However, these products are sold in tobacco specialty stores as well as other BM POS.

Summary and Conclusions for Consideration by FDA

The preliminary findings from the pilot study indicate that products identified go well beyond nomenclature of “e-cigarettes”, but include a much broader nomenclature of electronic nicotine delivery systems (ENDS), under which e-cigarettes, e-hookah (nicotine containing), customizable, tanks, DIY fall under. In light of the fact that ENDs (Agent) have evolved and expanded beyond manufactured e-cigarette devices, but now include e-hookah, tanks, and separate parts that can be assembled, it will be especially critical for FDA to properly define nomenclature and define the various parts as constituents of ENDS devices that are currently marketed and sold for nicotine and non-nicotine vapor delivery. Most importantly, FDA should make it a priority to better understand the zero nicotine electronic devices (ZNEDS) in tandem with ENDS.

The DIY is another important classification to consider. While the parts are readily available from hardware stores, the nicotine can be purchased online and used for homemade e-liquids. Therefore, the FDA should be made aware of this and take immediate action to understand who are the liquid nicotine distributors and how DIY ENDS users are accessing and purchasing the nicotine liquid online. If there is continued nicotine sales online, then FDA should ensure that sales are prohibited to minors.

It is important to note that nicotine concentrations ranged from 0 to 24 mg/ml. Additional research is needed to test and assay the nicotine concentrations from the product to ensure that products are being sold with the marked amount. In addition, at this time, it will be important for FDA to make a decision on ZNEDS (e.g. e-hookah) and e-liquids with 0 mg/ml of nicotine. While the assumption is that these products may be benign and may be viewed as a way to wean tobacco users who are nicotine dependent, however they may actually be a gateway to using ENDS. Young persons may view ZNEDS as appealing and safer than ENDS. However, currently the ZNEDS are sold alongside with ENDS especially in tobacco specialty stores. In fact, it is difficult to assume that ZNEDS are completely benign especially since they are currently sold within tobacco specialty stores; are tobacco specialty stores really in the business to help tobacco users quit smoking? Therefore, serious consideration needs to be given to the regulation of ZNEDS that are currently being sold alongside ENDS products.

Finally, the number of e-liquid flavors identified in the environmental scan at POS is vast. Nicotine is a highly addictive substance; marketing e-liquids with an "assortment of flavors" may potentially lure youth to trying ENDS. In fact, a recent report published by CDC in September 2013 clearly indicated that e-cigarette use had significantly increased among U.S. middle and high school students between 2011 and 2012 (CDC, 2013).

Many of the flavor names include Skittles, Cotton Candy, Gummi Bear, which resemble the actual candy products. Also available are fruit flavors (watermelon, strawberry), and flavors that resemble soft drinks. The use of these flavors in marketing and sales of ENDS 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 2009, the Family Smoking Prevention and Tobacco Control Act prohibited flavors (except menthol) in cigarettes. While it is understood that additional empirical evidence is needed on the impact that ENDS flavors has on youth uptake, FDA should carefully consider that the mass number of flavors available and sold makes ENDS a "candy shop". If flavors are going to be continued to be allowed, it is particularly important to prohibit youth access to flavored ENDS products. This could include raising the minimum age of purchase, prohibiting access to POS for minors, and most importantly, restricting internet sales.

References

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