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December 28, 2015

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue Suite CC-5610 (Annex J)
Washington, DC 205580

Re: Proposed Information Requests to Marketers of Electronic Cigarettes
Docket Number: FTC File No. P144504

The Tobacco Center of Regulatory Science at Georgia State University (TCORS) is pleased to submit this comment to assist the U.S. Federal Trade Commission (FTC) in their consideration of proposed information requests to marketers of electronic cigarettes.

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.

This notice was published pursuant to the Paperwork Reduction Act of 1995, enacted to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government."¹

The GSU TCORS finds the proposed information collection necessary and believes it will prove useful to the scientific community and public at large. We make several recommendations on the following pages including:

- Provide further clarification of how manufacturers will be selected
- FTC must collect more detailed information on product characteristics
- FTC must collect more detailed information on product marketing

¹ 44 U.S.C. Chapter 35, Section 3501 (1995)

We believe our recommendations, if adopted, could "ensure the greatest possible public benefit" from the resources expended in this data collection.

This Proposed Study is Necessary and Will Prove Invaluable

Accurate data on electronic cigarette sales and marketing would promote the development of regulatory science. Currently, electronic cigarettes remain largely unregulated at the Federal level with the U.S. Food and Drug Administration in the process of finalizing regulations that would deem electronic cigarettes under their tobacco products authority.² Under the Family Smoking Prevention and Tobacco Control Act (TCA), tobacco products are regulated on the public health standard, this unique standard considers the risks and benefits of the tobacco product on the population as a whole, not just current users.³ This standard is grounded in a firm commitment to regulatory science, using scientific knowledge gained through carefully executed research to craft effective regulations and to identify emerging issues where future regulatory action may be appropriate. Detailed data on how electronic cigarettes are sold and marketed will be invaluable in helping identify the population health impact of electronic cigarettes and informing future FDA action and developing evidence based regulations.

Currently, obtaining data regarding electronic cigarettes sales or marketing is difficult. Available estimates are largely the result of retail scanner data conducted by private firms.⁴ Although useful, these reports fail to accurately capture the entire electronic cigarette market. This is in part due to the nature of the electronic cigarette market as internet sales and those occurring outside of traditional retail channels such as in specialty vape shops are not tracked.⁵ This gap in data is significant. Certain segments of the market, such as pen-style or tank-size e-cigarettes, are sold almost exclusively through these untracked channels.⁶ Furthermore, this segment of the market has experienced the greatest growth in recent years, while traditional electronic cigarette sales have plateaued.⁷ In the absence of accurate data surrounding market share, evaluating how the changes in product variety and marketing translates to differences in perception of risk, social norms, and patterns of use remains difficult, further hindering efforts to develop evidenced based regulation for these products.

² 21 CFR Parts 1100, 1140, and 1143 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

³ 21 USC 387f

⁴ See Nielsen service descriptions located at http://www.nielsen.com/us/en/links/service_descriptions.html See also Kantar Media MARS Consumer Health Study; IRI Infoscan; Euromonitor

⁵ Nielsen Convenience Track and All Outlets Combined channels, which include convenience stores (independent and chain), drug stores, food/grocery stores, and mass merchandisers but exclude Walmart, club stores like Sam's Club and BJ's, and dollar stores.

⁶ Huang et al. The impact of price and tobacco control policies on the demand for electronic nicotine delivery systems *Tob Control* 2014;0:1–7. doi:10.1136/tobaccocontrol-2013-051515 See also: Seidenberg et al. Differences in the design and sale of e-cigarettes by cigarette manufacturers and non-cigarette manufacturers in the USA *Tob Control*. 2015 Nov 6. pii: tobaccocontrol-2015-052375. doi: 10.1136/tobaccocontrol-2015-052375. [Epub ahead of print]

⁷ Wells Fargo Report 11/18/15. Summary available at <http://www.wsj.com/articles/e-cig-sales-rapidly-lose-steam-1447798921>

FTC Should Clarify How They Will Select Manufacturers

As the agency is well aware, one of the FTC's main responsibilities is to investigate partnerships and corporations.⁸ Since 1967, the FTC has published reports on sales and marketing expenditures by the major cigarette and smokeless tobacco manufacturers. These reports provide detailed sales and market data from the five largest cigarette manufacturers. For cigarettes, this provides a useful and accurate market representation as these five firms represent virtually the entire cigarette market. The current proposal for electronic cigarettes seeks to collect data from fifteen firms, five large and ten smaller manufacturers. As sales data for electronic cigarettes sold through non-tracked channels is difficult to monitor, GSU TCORS is concerned as to how the FTC will ensure these fifteen manufacturers represent a comprehensive overview of the market. In the proposed rule, the the FTC has not elaborated on how these fifteen manufacturers will be selected or whether these will include manufacturers who specialize in either device or e-liquid products. In the past several years, the number of electronic cigarette brands has grown exponentially and we recognize collecting information from all electronic cigarette manufacturers may be unfeasible.⁹ Given the great diversity in the market, we recommend the agency expand the number of firms required to report in order to provide the most accurate representation of the electronic cigarette market.

FTC Must Collect More Detailed Data on Electronic Cigarettes

All electronic cigarettes operate using the same basic principle, a battery is used to power an atomizer, heating the liquid solution to produce a vapor which is inhaled by the user. However, no standard definition or formulation of an electronic cigarette exists. Rather, product design and ingredients vary by manufacturer.¹⁰

Traditionally, FTC reports on cigarette and smokeless tobacco have provided detailed market share data on the basis of a variety of product characteristics including tar rating, presence of a filter, cigarette length, and characterizing flavors. We strongly support the FTC's proposal to collect similarly detailed data on electronic cigarette product characteristics including characterizing flavors, nicotine content, liquid capacity for devices, and channel of sale. Collection of such detailed data will provide key insight into the relationship between product attributes of electronic cigarettes and patterns of electronic cigarette use as well as how risky these products are perceived to be by current and potential users.

Under the current proposal, the FTC specifically invites comment on whether the agency should collect data that are differentiated according to flavors. The GSU TCORS strongly recommends the agency collect flavor information. Under the Tobacco Control Act, tobacco companies are prohibited from producing cigarettes containing any characterizing flavor other than tobacco or

⁸ 15 U.S.C. § 46(b), (c) (2010)

⁹ Zhu S-H, Sun JY, Bonnevie E, et al. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control*. 2014;23(Suppl 3):iii3-iii9. doi:10.1136/tobaccocontrol-2014-051670.

¹⁰ World Med. Ass'n, Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems (Oct. 2012), available at <http://www.wma.net/en/30publications/10policies/e19/>.

menthol.¹¹ However, this prohibition is limited to flavored cigarettes and electronic cigarette manufacturers continue to market e-cigarette cartridges in a variety of candy-like flavors that appeal to youth.¹² Collecting detailed flavor data would help public health community and regulators determine the role electronic cigarette flavors play in determining patterns or reasons of use, harm perceptions, and social norms. Similarly, the FTC has specifically invited comment on whether the agency should collect data that are differentiated according to nicotine content. We recommend the FTC collect on nicotine content, as research suggests the level nicotine content is related to reasons for and patterns of device use.

In addition to the product characteristics already proposed by the FTC, we recommend the agency collect data on electronic cigarette device specifications and capabilities. As mentioned above, although all electronic cigarettes operate using the same basic principle, there exists substantial product differences between individual devices. As the market matures, the variety of products that provide nicotine and/or other additives to the user has grown. Recently, there appears to be a trend away from devices resembling combustible cigarettes in favor of more powerful refillable devices. These newer and more advanced devices have significant differences in device specifications and capability with products differing in areas such as device power, coil material, temperature regulation, battery power, and even air intake.¹³ Accurate sales data regarding these device differences is critical as early research suggests such product variety may result in substantial differences for nicotine delivery, patterns or reasons of use, and puff topography.¹⁴ In the past, the FTC has treated various models of cigarette differently, collected data differentiating between “light” and “full-bodied” cigarettes and flavored versus non-flavored cigarettes. Such differences were shown to have significant effect on puff topography,

¹¹ 21 U.S.C. § 387g(a)(1)(A)

¹² Corey CG, Ambrose BK, Apelberg BJ, King BA. [Flavored Tobacco Product Use Among Middle and High School Students--United States, 2014](#). *MMWR Morb Mortal Wkly Rep*. 2015 Oct 2;64(38):1066-70. doi: 10.15585/mmwr.mm6438a2. PubMed PMID: 26421418.

¹³ Brown CJ, Cheng JM. Electronic cigarettes: product characterization and design considerations. *Tobacco Control*. 2014;23(Suppl 2):ii4-ii10. doi:10.1136/tobaccocontrol-2013-051476.

¹⁴ Ramôa CP et al. Electronic cigarette nicotine delivery can exceed that of combustible cigarettes: a preliminary report. *Tob Control*. 2015 Aug 31. pii: tobaccocontrol-2015-052447. doi: 10.1136/tobaccocontrol-2015-052447. [Epub ahead of print] See also: Farsalinos KE, Spyrou A, Stefopoulos C, et al. Nicotine absorption from electronic cigarette use: comparison between experienced consumers (vapers) and naïve users (smokers). *Scientific Reports*. 2015;5:11269. doi:10.1038/srep11269. See also: Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Voudris V. Evaluation of Electronic Cigarette Use (Vaping) Topography and Estimation of Liquid Consumption: Implications for Research Protocol Standards Definition and for Public Health Authorities' Regulation. *International Journal of Environmental Research and Public Health*. 2013;10(6):2500-2514. doi:10.3390/ijerph10062500. See also: Talih S, Balhas Z, Eissenberg T, Salman R, Karaoghlanian N, El Hellani A, Baalbaki R, Saliba N, Shihadeh A. [Effects of user puff topography, device voltage, and liquid nicotine concentration on electronic cigarette nicotine yield: measurements and model predictions](#). *Nicotine Tob Res*. 2015 Feb;17(2):150-7. doi: 10.1093/ntr/ntu174. Epub 2014 Sep 3. PubMed PMID: 25187061.; Farsalinos KE, Spyrou A, Tsimopoulou K, Stefopoulos C, Romagna G, Voudris V. Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices. *Scientific Reports*. 2014;4:4133. doi:10.1038/srep04133.

use patterns, and perceptions of risk.¹⁵ Collecting similarly detailed data on electronic cigarette device types would allow researchers to further examine the role of product characteristics.

Furthermore, we recommend the FTC require detailed information that distinguishes product sales by retail channel and is product and brand specific. Current FTC reports on cigarette and smokeless tobacco have been limited to aggregated data that is not brand or product specific.

Another issue the FTC has invited comment is whether the FTC should seek state by state data. We believe the collection of state by state data will prove invaluable. In the absence of federal regulation, many states have moved to regulate the electronic cigarette market. As of this writing, 48 states and 2 territories prohibit the sales of e-cigarettes to minors.¹⁶ Twenty-three states and more than 600 local laws restrict the use of electronic cigarettes in specified venues.¹⁷ Several states require child resistant packaging. Data differentiated by state will be useful to evaluate the impact of state and local electronic cigarette regulations.

Need for Marketing Data

One of the primary public health concerns surrounding electronic cigarettes is the potential harms posed by the expansion of nicotine use among youth and young adults. In the past several years, use of electronic cigarettes by these groups has grown rapidly, with electronic cigarettes replacing cigarettes as the most popular tobacco product used by high school aged youth.¹⁸ Electronic cigarettes are not subject to many of the advertising prohibitions associated with traditional tobacco products and minimal quantitative data exists on how electronic cigarettes are being marketed and what efforts, if any, are being used to prevent youth exposure to advertising. Electronic cigarette advertising is difficult to track as it is largely conducted via websites and social media, partly due to the relatively low cost of such advertising.¹⁹ We have little data on what electronic cigarettes companies are doing to prevent online purchase of their products by

¹⁵ Kozlowski, L.T., Frecker, R.C., Khouw, V., Pope, M. The misuse of “less-hazardous” cigarettes and its detection: Hole-blocking of ventilated filters. *American Journal of Public Health* 70: 1202-1203, 1980.; Lombardo, T., Davis, C.J., Prue, D.M. When low tar cigarettes yield high tar: Cigarette filter ventilation hole blocking and its detection. *Addictive Behaviors* 8: 67-69, 1983.; Zacny, J.P., Stitzer, M.L. Cigarette brand-switching: Effects on smoke exposure and smoking behavior. *Journal of Pharmacology and Experimental Therapeutics* 246(2): 619-627, 1988.

¹⁶ National Conference of State Legislators available at <http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx>

¹⁷ American Nonsmokers’ Rights Foundation (as of Oct. 2 2015) available at <http://www.no-smoke.org/pdf/ecigslaws.pdf>

¹⁸ Centers for Disease Control and Prevention. [Tobacco Use Among Middle and High School Students—United States, 2011–2014](#). *Morbidity and Mortality Weekly Report*, 2015;64(14):381–5

¹⁹ Emery SL, Vera L, Huang J, Szczypka G. Wanna Know about Vaping? Patterns of Message Exposure, Seeking and Sharing Information about E-Cigarettes across Media Platforms. *Tobacco control*. 2014;23(0 3):iii17-iii25. doi:10.1136/tobaccocontrol-2014-051648.; Pepper JK, Emery SL, Ribisl KM, Brewer NT. How U.S. Adults Find Out About Electronic Cigarettes: Implications for Public Health Messages. *Nicotine & Tobacco Research*. 2014;16(8):1140-1144. doi:10.1093/ntr/ntu060. Kornfield R, Huang J, Vera L, Emery SL. Industry Watch: Rapidly Increasing Promotional Expenditures for E-cigarettes. *Tobacco control*. 2015;24(2):110-111. doi:10.1136/tobaccocontrol-2014-051580.

minors although current safeguards do not appear effective.²⁰ Requiring companies to report how they verify customer age for internet sales would be useful to see if more stringent regulatory action is required in the future.

Another issue on which the FTC has invited comment involves the collection of data on electronic cigarette giveaways separately from sales. We believe the FTC should collect this information separately in order to accurately reflect market transactions. Once the FDA deeming regulation is finalized, free samples of e-cigarettes will be prohibited under the Food Drug and Cosmetic Act.²¹ However, consumer coupons and price discounts paid to retailers or wholesalers to reduce the price of tobacco products are still permitted under the TCA.²² For combustible cigarettes and smokeless tobacco products, such discounts have been substantial, accounting for the majority of industry marketing expenditures and serving as a significant counter to the use of excise taxes to increase tobacco prices.²³ Therefore, we recommend the FTC collect data on all forms of price-related marketing, rather than limit collection to product giveaways.

Conclusion

In closing, we appreciate opportunity to comment on this proposed information collection program. We urge the FTC to consider our recommendations in order to create a comprehensive report of electronic cigarette sales and marketing expenditures. Attention to these matters would provide the best possible information to policy makers at both the FTC and FDA and would truly satisfy the purposes of the Paperwork Reduction Act of 1995: to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government" and further the goal of the agency to keep the public informed regarding the manufacture and advertisement of tobacco products.²⁴

Sincerely,

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²⁰ Williams RS, Derrick J, Ribisl KM. Electronic Cigarette Sales to Minors via the Internet. *JAMA pediatrics*. 2015;169(3):e1563-e1563.

²¹ 21 C.F.R. § 1140.16(d)(1) prohibits the provision of "free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act)."

²² 21 § U.S.C. 387(a)1

²³ Marlo Miura, Tobacco Control Legal Consortium, Regulating Tobacco Product Pricing: Guidelines for State and Local Governments (2010), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-pricing-2010.pdf>; Tobacco Control Legal Consortium, Price-Related Promotions for Tobacco Products: An Introduction to Key Terms and Concepts (2011), available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-fspricerelatedpromotions-2011_0.pdf.

²⁴ 15 U.S.C. §§ 1331(1), 1335a