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

Re: Clarifying when products made or derived from tobacco are regulated as drugs, devices, or combination products.

Docket Number: FDA-2015-N-2002

The Tobacco Center of Regulatory Science at Georgia State University (TCORS) is pleased to submit this comment to assist the U.S. Food and Drug Administration (FDA) in their proposed rule to clarify when products made or derived from tobacco are regulated as drugs, devices, or combination products.

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.

The FDA draft rule provides two circumstances where a product made or derived from tobacco would be excluded from the definition of tobacco product and instead be subject to regulation under the FDA drug, device or combination authority. If the FDA determines the product is intended for use in either (i) diagnosis, cure, mitigation, treatment, or prevention of a disease (referred to as the “disease prong”); or (ii) affecting the structure or function of the body in any way that is different from effects of nicotine that were “customarily” claimed in marketing prior to the *Brown & Williamson* decision.

Currently there exists a great deal of consumer confusion regarding when products made or derived from tobacco should be regulated as drugs, tobacco products, or modified risk tobacco products. GSU TCORS strongly supports agency efforts to clarify and articulate these distinctions as one of the primary purposes of the Food Drug and Cosmetic Act is the protection of the public against false or otherwise misleading representations regarding products entering

the market. In response to the agency invitations for comment, we recommend the FDA take several actions to help further clarify the distinctions between these products including:

- Enforcement must be taken against tobacco products making explicit or implicit drug claims related to smoking cessation.
- Claims explicitly referring to the delivery of a pharmacologically active dose of nicotine should be treated as drug claims under the structure/function provision as they were not “customarily marketed” prior to *Brown & Williamson*

### **The FDA Regulatory Framework for Nicotine is Confusing to Consumers**

As illustrated in the FDA draft rule, the determination of whether a product is defined as a drug or medical device is based on the intended use of the product. Conversely, whether an article is defined as a tobacco product is based on composition. Unlike other areas of FDA product regulation, a product cannot be regulated under the tobacco products authority and the drug or device authority simultaneously. Thus intended use remains essential in determining how products made with or derived from tobacco are regulated when various claims suggest an intention to market an article as a drug.

Intended use is determined by the objective, rather than subjective intent of the persons legally responsible for labeling the article.<sup>1</sup> To determine intended use, the FDA may look to “any . . . relevant source,” including, but not limited to, the product's labeling, promotional claims, general marketing plan, and advertising.<sup>2</sup> Moreover, the FDA may consider direct and circumstantial evidence, taking into account any circumstances surrounding the distribution of the product or the context in which it is sold.<sup>3</sup> In an attempt to ensure firms do not escape regulation by avoiding expressed claims about their product, intended use may be determined if the the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.<sup>4</sup> However, courts have noted that sufficient evidence of consumer use requires a “substantial showing” and that courts have “accorded limited discretion to the Administration in its attempt to establish the requisite intent based primarily upon consumer use”.<sup>5</sup>

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<sup>1</sup> 21 C.F.R. § 201.128

<sup>2</sup> *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980); *United States v. Storage Spaces Designated Nos. “8” and “49,”* 777 F.2d 1363, 1366 (9th Cir. 1985); *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976)).

<sup>3</sup> *U.S. v. Travia*, 180 F.Supp.2d 115, 119 (D.D.C. 2001)).

<sup>4</sup> 21 C.F.R. § 201.128

<sup>5</sup> *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980)

Although not specifically directed towards the regulation of electronic cigarettes, the FDA draft rule highlights the difficulty faced by consumers in evaluating various statements from electronic cigarette manufacturers and the widespread confusion about what claims are appropriate. In the aftermath of *Sottera*, the FDA has proposed to regulate electronic cigarettes generally under their tobacco product authority.<sup>6</sup> Since *Sottera*, a growing body of research has developed suggesting the intended use claimed by many electronic cigarette manufacturers differs significantly from the actual use reported by current and former users of these products.<sup>7</sup> Rather, the actual use reported by current and former users of these products and even the expressed statements made by many manufacturers suggest a significant number of electronic cigarette claims meet the definition of drugs intended for either: the treatment of a disease or to effect the structure function of the body.

### **There Exists Widespread Misconception Regarding the Use of ENDS as Cessation Aids**

Following *Brown & Williamson* and *Sottera*, if a manufacturer of a tobacco product makes any claims or statements about the intended use of the product that falls within the drug or medical device definition, those statutory and regulatory provisions will apply. Claims related to smoking cessation have historically been considered drug claims under the disease prong in the context of curing or treating nicotine addiction and its symptoms, treatment of tobacco dependence, or relapse prevention. Such products require premarket approval from the FDA or risk being prosecuted as misbranded.<sup>8</sup> Despite this restriction, there exists widespread belief that electronic cigarettes provide an effective method of smoking cessation.<sup>9</sup> In recent years many consumers seeking to quit tobacco products have turned to electronic cigarettes over FDA proven aids.<sup>10</sup>

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<sup>6</sup> RIN 0910–AG38: 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

<sup>7</sup> Rutten LJ, Blake KD, Agunwamba AA, Grana RA, Wilson PM, Ebbert JO, Okamoto J, Leischow SJ. [Use of E-Cigarettes Among Current Smokers: Associations Among Reasons for Use, Quit Intentions, and Current Tobacco Use](#). *Nicotine Tob Res.* 2015 Oct;17(10):1228-34. doi: 10.1093/ntr/ntv003. Epub 2015 Jan 14. PubMed PMID: 25589678; PubMed Central PMCID: PMC4592339.

<sup>8</sup> 21 U.S.C. § 352

<sup>9</sup> Berg CJ, Barr DB, Stratton E, Escoffery C, Kegler M. [Attitudes toward E-Cigarettes, Reasons for Initiating E-Cigarette Use, and Changes in Smoking Behavior after Initiation: A Pilot Longitudinal Study of Regular Cigarette Smokers](#). *Open J Prev Med.* 2014 Oct;4(10):789-800. PubMed PMID: 25621193; PubMed Central PMCID: PMC4304080; Berg CJ, Haardoerfer R, Escoffery C, Zheng P, Kegler M. [Cigarette users' interest in using or switching to electronic nicotine delivery systems for smokeless tobacco for harm reduction, cessation, or novelty: a cross-sectional survey of US adults](#). *Nicotine Tob Res.* 2015 Feb;17(2):245-55. doi: 10.1093/ntr/ntu103. Epub 2014 Jun 20. PubMed PMID: 24951496; PubMed Central PMCID: PMC4311172.; Nonnemaker J, Kim AE, Lee YO, MacMonegle A. [Quantifying how smokers value attributes of electronic cigarettes](#). *Tob Control.* 2015 Nov 6. pii: tobaccocontrol-2015-052511. doi: 10.1136/tobaccocontrol-2015-052511. [Epub ahead of print] PubMed PMID: 26546152.

<sup>10</sup> Cataldo, J.K. Sheon, N., Hunter, M., Petersen, M.A. (2014) Risk and Benefit Perceptions in the Use of Conventional and Emerging Tobacco Products Among Older Smokers, NIH/FDA Tobacco Regulatory Science Conference, Bethesda, MD, April 28,2014; Harrell PT, Marquez NS, Correa JB, Meltzer LR, Unrod M, Sutton SK, Simmons VN, Brandon TH. [Expectancies for cigarettes, e-cigarettes, and nicotine replacement therapies among](#)

This confusion is unsurprising as many electronic cigarette manufacturers continue to make explicit and implicit claims that these products are smoking cessation aids.<sup>11</sup> A recent study of over one hundred fifty electronic cigarettes websites, thirty one percent were found to have made explicit smoking cessation claims.<sup>12</sup> Aside from explicit claims on their websites, many manufacturers use their websites, social media, and blogs to promote studies, testimonials, and media reports related to the use of electronic cigarettes as cessation aids.<sup>13</sup> Despite the considerable number of explicit cessation related claims, FDA enforcement actions have been extremely limited thus far.<sup>14</sup> Enforcement actions by the FDA and the FTC for other regulated products have made clear that company and manufacturer websites, social media content, are considered sources of promotional claims for purposes of enforcement.<sup>15</sup> Increased monitoring and surveillance of manufacturer and distributor claims on labels and in advertising and promotion by the CDER and the CTP would assist in identifying problematic claims.

**Claims explicitly referring to the delivery of a pharmacologically active dose of nicotine were not made for “tobacco products as customarily marketed” and should be treated as drug or device claims under the structure/function prong.**

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[e-cigarette users \(aka vapers\)](#). Nicotine Tob Res. 2015 Feb;17(2):193-200. doi: 10.1093/ntr/ntu149. Epub 2014 Aug 28. PubMed PMID: 25168035; PubMed Central PMCID: PMC4438353.

<sup>11</sup> Grana R, Ling P. Smoking Revolution? A content analysis of electronic cigarette retail websites. American Journal of Preventive Medicine. 2014;46(4):395-403; Yamin CK, Bitton A, Bates DW. [E-cigarettes: a rapidly growing Internet phenomenon](#). Ann Intern Med. 2010 Nov 2;153(9):607-9. doi: 10.7326/0003-4819-153-9-201011020-00011. PubMed PMID: 21041581.; Paek HJ, Kim S, Hove T, Huh JY. [Reduced harm or another gateway to smoking? source, message, and information characteristics of E-cigarette videos on YouTube](#). J Health Commun. 2014;19(5):545-60. doi: 10.1080/10810730.2013.821560. Epub 2013 Oct 11. PubMed PMID: 24117370. Truth Initiative (formerly American Legacy Foundation). Vaporized: E-Cigarettes, Advertising, and Youth, available at [http://truthinitiative.org/sites/default/files/LEG-Vaporized-E-cig\\_Report-May2014.pdf](http://truthinitiative.org/sites/default/files/LEG-Vaporized-E-cig_Report-May2014.pdf) (accessed November 17, 2015)

<sup>12</sup> Truth in advertising study (September 2015) available at <https://www.truthinadvertising.org/smoking-out-e-cigarette-adclaims/>

<sup>13</sup> Paek HJ, Kim S, Hove T, Huh JY. [Reduced harm or another gateway to smoking? source, message, and information characteristics of E-cigarette videos on YouTube](#). J Health Commun. 2014;19(5):545-60. doi: 10.1080/10810730.2013.821560. Epub 2013 Oct 11. PubMed PMID: 24117370.

<sup>14</sup> To date, the agency has taken action against only eight electronic cigarette companies, sending warning letters for a range of issues. Since *Sottera*, none have been related to drug claims. Available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/>

<sup>15</sup> U.S. Food & Drug Admin. Warning Letter to Quincy Bioscience Manufacturing Inc. (Oct. 12, 2012), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm324557.htm>; U.S. Food & Drug Admin. Warning Letter to Oasis Consumer Healthcare, LLC (Feb. 11, 2013), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm339773.htm>; U.S. Food & Drug Admin. Warning Letter to Big Mountain Drugs (Feb 4, 2013), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm340264.htm>; FTC Guidance Document: Advertising and Marketing on the Internet (2000) available at <https://www.ftc.gov/tips-advice/business-center/guidance/advertising-marketing-internet-rules-road>

Absent a disease related claim, the FDA draft states a product made or derived from tobacco may be regulated under the FDA drug or device authority is if the product is intended to effect the structure or function of the body in any way that is different from effects of nicotine that were “customarily” claimed in marketing prior to the *Brown & Williamson* decision. The GSU TCORS agrees with the inquiry proposed by the FDA on how to interpret whether a particular product made or derived from tobacco is “customarily marketed”. However, we disagree with the agency decision to consider all claims related to nicotine delivery as customarily marketed and thus excluded from its drug and device authority to be a mistake. In the FDA draft, the agency provides several examples of claims it does not believe to fall within its drug and device authority including “satisfying smoking alternative,” “provides all the pleasure of smoking,” “get your nicotine fix,” or “provides smokers the same delight, physical and emotional feelings”. Although euphemisms for nicotine delivery were common prior to *Brown & Williamson*, the role of nicotine was not “customarily marketed” at that time. In permitting explicit claims related to the delivery of a pharmacologically active dose of nicotine, the proposed rule will only further consumer confusion, frustrating the stated purpose of the rule. As a result of this decision, claims such as “satisfying alternative to smoking”, “alternative source of nicotine”, “the nicotine hit that smokers crave”, or “get your nicotine fix” are considered tobacco product claims but claims such as “reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking” presents evidence of an article’s intended use as a drug.

FDA is correct in recognizing that claims related to satisfaction, pleasure, enjoyment, and refreshment frequently serve as euphemisms for nicotine delivery.<sup>16</sup> Such claims were commonplace prior to *Brown & Williamson*, particularly in advertising for “light or low-tar” cigarettes.<sup>17</sup> However, explicit claims related to the effects of nicotine were not commonly and legally claimed prior to *Brown & Williamson*. A major argument put forward by the tobacco industry in *Brown & Williamson* was that the FDA was limited to relying on advertising claims and other representations to the public to determine intended use.<sup>18</sup> Not only was the role of nicotine not “customarily marketed”, tobacco companies continually made public statements dismissing the addictive nature of nicotine.<sup>19</sup> Furthermore, these companies actively concealed the role nicotine played in cigarettes through the suppression and concealment of scientific research and the use of document destruction policies. The extent of these practices were only revealed through the 2006 racketeering case against the tobacco companies, *United States v.*

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<sup>16</sup> Hearing before the House Subcommittee on Health and the Environment, 103d Cong., 2d Sess., 628 (1994); Stanford research into the impact of tobacco advertising available at [http://tobacco.stanford.edu/tobacco\\_main/subtheme.php?token=fm\\_mt007.php](http://tobacco.stanford.edu/tobacco_main/subtheme.php?token=fm_mt007.php); See also [http://tobacco.stanford.edu/tobacco\\_main/subtheme.php?token=fm\\_mt011.php](http://tobacco.stanford.edu/tobacco_main/subtheme.php?token=fm_mt011.php); [http://tobacco.stanford.edu/tobacco\\_main/subtheme.php?token=fm\\_mt003.php](http://tobacco.stanford.edu/tobacco_main/subtheme.php?token=fm_mt003.php)

<sup>17</sup> Rutgers School of Public Health Online Surveillance System & Archive of Tobacco Products & Marketing Materials available at <https://trinketsandtrash.org/index.php>; Stanford research into the impact of tobacco advertising available at [http://tobacco.stanford.edu/tobacco\\_main/subtheme.php?token=fm\\_mt007.php](http://tobacco.stanford.edu/tobacco_main/subtheme.php?token=fm_mt007.php)

<sup>18</sup> Hearings before the House Subcommittee on Health and the Environment, 103d Cong., 2d Sess., 628 (1994); Susan H. Carchman, Should the FDA Regulate Nicotine-Containing Cigarettes? Has the Agency Established a Legal Basis and, If Not, Should Congress Grant It?, 51 Food & Drug L.J. 85, 114-32 (1996)

<sup>19</sup> *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006)

*Philip Morris*, decided six years after *Brown & Williamson*. Even today, tobacco companies, aside from those selling electronic cigarettes, do not mention nicotine their marketing.

As noted in the FDA draft rule, no court has addressed whether certain structure/function claims for products made or derived from tobacco that generally were not made for “tobacco products as customarily marketed” should be treated as drug or device claims. Given that explicit claims related to the effects of nicotine were not commonly and legally claimed prior to *Brown & Williamson*, claims explicitly stating that a tobacco product provides an alternate source of nicotine such as “get your nicotine fix,” or “the nicotine hit that smokers crave” should be viewed as drug claims under the structure/function prong.

Section 321(g) (1) (C), known as the structure/function prong, was added to the Food Drug & Cosmetic Act in order to expand the reach of the drug definition to cover products marketed for their physiological effects, which at the time escaped regulation. Although the statutory definition of drug is determined by intended use rather than on the mere pharmacological activity, unlike the disease provision, a substance may be considered a drug under the structure/function provision even when the intended effect is solely physiologic.<sup>20</sup> In *Sottera*, NJOY repeatedly emphasized the fact that statements promoting users to switch from traditional cigarettes to electronic cigarettes attempt to perpetuate rather than treat nicotine addiction and its symptoms thus making the regulation such products under the disease prong inappropriate.<sup>21</sup> However, these claims do demonstrate an intent to effect the structure and function of the body and as shown above, were not commonly and legally marketed prior to *Brown & Williamson* leaving the FDA free to regulate under their existing medical product authority.

GSU TCORS recognizes that the decision to exempt all structure function claims related to nicotine delivery, is one of enforcement discretion and may lowers the agency’s potential enforcement burden arising from the review of nicotine structure function claims on a case by case basis. However, drawing the line at this exemption will likely serve to blur the line between claims of alternative delivery of nicotine and cessation claims, an already challenging problem outlined in detail above.

## **Conclusion**

In closing, we appreciate opportunity to comment on the FDA’s proposed rule. We urge the FDA to consider our recommendations to ensure the final rule is helpful in rectifying consumer and manufacturing confusion and clarifying classification of claims for products made or derived

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<sup>20</sup> *United States v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001); *E.R. Squibb & Sons, Inc. v. Bowen*, 870 F.2d 678 (D.C. Cir. 1989); *United States v. 23, More or Less, Articles*, 192 F.2d 308 (2d Cir. 1951); *United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change*, 409 F.2d 734 (2d Cir. 1969); *United States v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away Temp. Wrinkle Smoother, Coty"*, 415 F.2d 369 (3d Cir. 1969); *United States v. Storage Spaces Designated Nos. 8 & 49 Located at 277 E. Douglas, Visalia, Cal.*, 777 F.2d 1363 (9th Cir. 1985)

<sup>21</sup> *Smoking Everywhere, Inc. v. U.S. Food & Drug Admin.*, 680 F. Supp. 2d 62 (D.D.C.)

from tobacco. We believe that our recommendations, coupled with more rigorous agency surveillance of inappropriate claims will greatly aid the agency in achieving its goal of protecting public health.

Sincerely,

Kyle R. Gregory, JD, MSHA  
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Tobacco Center of Regulatory Science  
Georgia State University