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Vape Away: Why a Minimalist Regulatory Structure is the Best Option for FDA E-Cigarette Regulation

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COMMENTS

VAPE AWAY: WHY A MINIMALIST REGULATORY STRUCTURE IS THE BEST OPTION FOR FDA E-CIGARETTE REGULATION

I. INTRODUCTION

People smoke to get a buzz.¹ Plain and simple. Every time a person decides to smoke a cigarette they make a personal cost-benefit decision. The benefits of smoking often include improved concentration and mood as well as providing sedative and euphoric effects.² On the other hand, the costs of smoking traditional, combustible cigarettes are quite high. The adverse effects of smoking combustible cigarettes have become common knowledge over the past fifty years, beginning with the required warnings on cigarette packs in the 1960s, as countless studies have affirmed the link between cigarette smoking and a seemingly endless list of negative health effects.³ By now, study results confirming the increased risk of several forms of cancer, birth defects, emphysema, and chronic bronchitis, just to name a few, have reached the

1. By “buzz,” I am referring to the physiological and psychological effects obtained when smoking a cigarette. Traditional, combustible cigarettes carry nicotine-laced smoke that enters the lungs, allowing the nicotine to flow to the brain through arterial circulation, which ultimately attaches to nicotinic receptors releasing various neurotransmitters. See Neal L. Benowitz, *Nicotine Addiction*, 362 *NEW ENG. J. MED.* 2295, 2295–96 (2010). Dopamine, one of the various neurotransmitters released, signals pleasure to the user while also reducing stress, anxiety, and other undesirable mental states. *Id.*

2. P. Caponnetto et al., *Electronic Cigarette: A Possible Substitute for Cigarette Dependence*, 79 *MONALDI ARCHIVES FOR CHEST DISEASE* 12, 15 (2013).

3. *Effects of Smoking on Your Health*, BE TOBACCO FREE, <http://www.betobaccofree.hhs.gov/health-effects/smoking-health/index.html> (last visited Apr. 14, 2014); *Tobacco Harm Reduction*, RJ REYNOLDS TOBACCO, <http://www.rjrt.com/pubhealth.aspx> (last visited Apr. 14, 2014) (“In 1969, the Public Health Smoking Act of 1969 required all cigarette packaging contain the statement: Warning: The Surgeon General has determined that cigarette smoking is dangerous to your health.”).

ears not only of “addicts” but the general public as well.⁴ Despite the numerous risks of cigarette smoking, many people decide that the benefits of smoking at least somewhat outweighs its health costs because one in every five adults in the United States smokes cigarettes.⁵

Many of those addicted to cigarettes or other tobacco products have attempted to quit or reduce their consumption through any means available, including nicotine gum, patches, lollipops, and, as of recently, electronic cigarettes. In fact, United States cigarette sales hit a low recently in 2005.⁶ A significant portion of this decline in combustible cigarette sales may be attributed to the increased sale of other tobacco products, such as nicotine gum.⁷ In 2004, electronic cigarettes, or e-cigarettes, entered the United States as a new alternative to combustible cigarettes and began to provide virtually all of the benefits of smoking while nearly eliminating all the costs.⁸ Nicotine-infused e-cigarettes provide the user with a familiar-looking, smokeless product without combustible tobacco and the endless list of health effects associated with it.⁹ E-cigarettes allow users to “vape” a nicotine fluid without

4. See U.S. DEPT OF HEALTH & HUMAN SERVS., SURGEON GENERAL’S REPORT: THE HEALTH CONSEQUENCES OF SMOKING 860–61 (2004) [hereinafter HEALTH CONSEQUENCES OF SMOKING], available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/pdfs/chapter7.pdf (“From 1965–1999, smoking has caused an estimated 4.1 million cancer deaths, 5.5 million CVD [cardiovascular disease] deaths, 2.1 million respiratory disease deaths, 94,000 infant deaths, and 11.9 million deaths total.”).

5. *Questions About Smoking, Tobacco, and Health*, AM. CANCER SOC’Y, <http://www.cancer.org/cancer/cancercauses/tobaccocancer/questionsaboutsmokingtobaccoandhealth/questions-about-smoking-tobacco-and-health-how-many-use> (last visited Apr. 14, 2014).

6. Melissa McNamara, *U.S. Cigarette Sales Hit 55-Year Low*, CBSNEWS (Mar. 9, 2006), <http://www.cbsnews.com/news/us-cigarette-sales-hit-55-year-low/> (highlighting the fact that cigarette sales, in 2005, hit their lowest point since 1951).

7. See The-wei Hu et al., *Cigarette Consumption and Sales of Nicotine Replacement Products*, 9 TOBACCO CONTROL, Supp. II, 2000, at ii62–63; Gregory N. Connolly & Hillel R. Alpert, *Trends in the Use of Cigarettes and Other Tobacco Products 2000-2007*, 299 J. AM. MED. ASS’N 2629, 2629 (2008), available at <http://www.jama.jamanetwork.com/article.aspx?articleid=182056&resultclick=3> (reporting that an increase in sales of traditional tobacco products made up for thirty percent of the decline in cigarette sales in the same period).

8. Kerry Cork, *To Vape or Not to Vape: Controversy Swirls Around E-Cigarettes*, 16 NALBOH NEWSBRIEF, no. 4, 2009, at 7, available at <http://www.publichealthlawcenter.org/sites/default/files/resources/article-cork-ecigarettes-12-09.pdf>. While e-cigarettes first entered the U.S. market in 2004, they did not become easily available in the U.S. until 2006. See Joan Lowy, *Ban Proposed on Electronic Cigarettes on Planes*, NBC NEWS, <http://www.nbcnews.com/id/44518729/ns/travel-news/t/ban-proposed-electronic-cigarettes-planes/#.U0FgZvldXi0> (last visited Apr. 14, 2014).

9. Compare Cork, *supra* note 8 (“Others view [e-cigarettes] as far less hazardous alternatives to combustible cigarettes, which include at least 60 known carcinogens . . .”),

inhaling the dozens of other chemical additives in combustible cigarettes that increase carcinogenicity.¹⁰ Instead of smoking, which requires burning tobacco, vaping allows e-cigarette users to inhale a vaporized nicotine mixture using a heated atomizer.¹¹ Vaping is *not* smoking. Hence, e-cigarette manufacturers often market their products as allowing smokers to have “all the pleasure and satisfaction of traditional smoking without all the health, social, and economic problems.”¹² However, despite the introduction of e-cigarettes and the significant decline in cigarette sales, an incredible number of Americans still remain hooked on tobacco and, specifically, the nicotine in it: 43.8 million Americans still smoke cigarettes.¹³

To say e-cigarettes have been controversial is certainly an understatement because health professionals and government regulators have vigorously contested the risks associated with e-cigarettes, as compared with combustible cigarettes. From a quantitative perspective, the simple ingredient list in e-cigarettes appears to be a less risky alternative to chemically-laden combustible cigarettes, but health professionals and the Food and Drug Administration (“FDA”) often take a different view.¹⁴ Pending federal regulations could have a stifling impact on the sale and distribution of this useful product.¹⁵

The jury is still out on whether nicotine itself poses serious health risks to consumers, but there is virtually no dispute, even

with Questions About Smoking, Tobacco, and Health, supra note 5 (“The smoke from [cigarettes and cigars] is made up of more than 7,000 chemicals, including over 60 known to cause cancer (carcinogens).”).

10. See HEALTH CONSEQUENCES OF SMOKING, *supra* note 4, at 860–61 tbl.7.3 (listing diseases and other adverse health effects caused by smoking).

11. For a more detailed explanation of an e-cigarette’s structure, see *infra* Part II.A.

12. E-CIGARETTE SOLUTION, <http://www.ecigarettesolution.com/faq> (last visited Apr. 14, 2014).

13. See *Questions About Smoking, Tobacco, and Health, supra* note 5.

14. See, e.g., Christie Aschwanden, *E-Cigarettes: A Step Forward for Smokers, or a Step into the Unknown?*, THE GUARDIAN (Sept. 24, 2013), <http://www.theguardian.com/society/2013/sep/24/ecigarettes-smoking-research-safety> (“There’s no question that e-cigarettes deliver fewer [toxic substances] than conventional cigarettes”); *E-Cigarettes: Known and Unknown Dangers*, SCI. DAILY, <http://www.sciencedaily.com/releases/2014/01/140129164653.htm> (last visited Apr. 14, 2014) (noting the strong hesitancy of Loyola University Health System physician and smoking cessation expert Phillip McAndrew in declaring e-cigarettes as a truly safe smoking alternative); *infra* note 19 and accompanying text.

15. Lawrence R. Deyton & Janet Woodcock, *Regulation of E-Cigarettes and Other Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Apr. 25, 2011), <http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm>.

from e-cigarette skeptics, that e-cigarettes generally provide a safer alternative to traditional cigarettes in terms of carcinogenic chemicals.¹⁶ The main e-cigarette ingredient causing concern is nicotine, but numerous studies have shown that nicotine, in small doses, is actually not that harmful.¹⁷ In fact, a highly regarded group of scientists have concluded that “nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.”¹⁸ Presently, strict FDA regulation of e-cigarettes is often proposed as a solution to stall e-cigarette sales until enough research has determined the degree of safety of the nicotine used in the vaping tool, but this may be the wrong direction considering the risk reduction e-cigarettes provide to combustible cigarette smokers.¹⁹

Strict regulation of e-cigarettes not only runs counter to the basic purposes of the FDA, it also implicates a previous United States Supreme Court decision, *FDA v. Brown & Williamson Tobacco Corp.*, which limited the FDA’s regulatory power over tobacco products.²⁰ Congress established the FDA to protect the public health “by assuring the safety, efficacy, and security” of drugs, devices, food, and cosmetics.²¹ However, drastically restricting e-cigarette availability would undermine this purpose by forcing traditional cigarette users to continue smoking their chemically-packed combustible cigarettes. Many current e-cigarette users previously smoked traditional, combustible cigarettes, which are significantly more detrimental to human health

16. See Phillip Gardiner, *E-Cigarettes: The Vapor This Time?*, TOBACCO-RELATED DISEASE RESEARCH PROGRAM 4 (Oct. 2, 2013), available at <http://www.trdrp.org/docs/E-Cigarettes%20The%20Vapor%20This%20Time.pdf> (“[M]any studies on e-cigarettes reveal a host of other chemicals, metals, VOCs, and carcinogens contained in e-cigarette vapor, most often at lower levels than in regular cigarette tobacco products.”).

17. See *infra* Part IV.A.

18. See John Britton, ROYAL COLL. OF PHYSICIANS, *Preface to HARM REDUCTION IN NICOTINE ADDICTION: HELPING PEOPLE WHO CAN’T QUIT* (2007).

19. See Linda Hurtado, *Some Say Vaping E-Cigarettes Is Worse than Smoking the Real Thing*, ABC ACTION NEWS (Aug. 16, 2011), <http://www.abcactionnews.com/news/health/some-say-vaping-e-cigarettes-is-worse-than-smoking-the-real-thing>.

20. 529 U.S. 120, 126 (2000) (holding that the FDA’s attempt to regulate tobacco products, at the time, was impermissible); see also *Sottera, Inc. v. FDA*, 627 F.3d 891, 895 (D.C. Cir. 2010) (striking down the FDA’s attempt to regulate e-cigarettes under the Food, Drug, and Cosmetic Act).

21. *About FDA: What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last updated Sept. 19, 2013).

than e-cigarettes.²² Therefore, to the extent strict regulations on e-cigarettes reduce the likelihood that smokers will replace their cigarette consumption with less dangerous e-cigarette consumption, those regulations would contradict the FDA's purposes. Further, the Supreme Court struck down a prior FDA attempt to regulate tobacco products in 2000 as over-reaching and going beyond the agency's delegated authority.²³ Even as recently as 2011, the FDA attempted to regulate e-cigarettes through an improper channel and a court criticized it for its constant power-grabbing attempts.²⁴ In regard to e-cigarettes, the FDA should not continue with its overreaching regulations that will inevitably waste time in the courtroom, but instead should focus its efforts on creating a minimalist regulatory structure that would inform the public of the limited e-cigarette health risks while keeping the reduced-risk vaporizers on the market.

In this comment, I will argue that the FDA should regulate e-cigarettes, but in doing so, it should take a minimalist approach to regulation. Instead of continuing its attempts to regulate tobacco products under the drug and device provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), an incredibly stringent statute, the FDA should focus its efforts under the Tobacco Control Act ("TCA"), which is tailored specifically to regulate tobacco products. While the FDA has extensive regulatory options under the TCA, much of this authority should not be applied to e-cigarettes. Part II will provide background information on e-cigarettes generally as well as steps the FDA has taken to regulate e-cigarettes and other tobacco products. E-cigarettes have been in the U.S. market for nearly eight years, but the FDA has yet to provide e-cigarette manufacturers with significant guidelines to facilitate compliance with its regulations. Instead, the FDA has only attempted to block e-cigarette imports using FDCA "authority" that the Supreme Court had to remind the FDA that it lacked in *Brown & Williamson*. Part III addresses the FDA's limited regulatory ability under the TCA and describes why it has

22. *Are E-Cigarettes Better for Your Health? The Doctors Weigh in . . .*, ADP HEALTH-INSIGHTS, <http://www.adphealthinsights.com/landing/ecigs.php> (last visited Apr. 14, 2014) ("In the United States alone, over 700,000 smokers have already switched to electronic cigarettes.").

23. *Brown & Williamson*, 529 U.S. at 126.

24. *Sottera*, 627 F.3d at 895; see also *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 78 (D.D.C. 2010) ("This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices under the FDCA.").

no regulatory authority over e-cigarettes under the FDCA. Unlike the TCA, if the courts interpret the FDCA to apply to e-cigarettes, the FDCA would become a convoluted statute that produces an absurd result: an inevitable ban on many tobacco products. On the other hand, Congress enacted the TCA precisely to give the FDA authority over tobacco products that it *did not* previously have under the FDCA. While the TCA does not confer as much power on the FDA, when compared to the FDCA, the TCA is specifically tailored to address health and safety issues directly related to tobacco products. Simply, the TCA is the *Tobacco Control Act* and the FDA should exercise its authority to regulate e-cigarettes under that statute rather than under the FDCA, a statute that grants it no such authority. Part IV presents alternatives to aggressive regulation of e-cigarettes as well as the benefits of a minimalist federal regulatory scheme that allows e-cigarette and other tobacco product users to fully benefit from the potentially reduced health risks of e-cigarettes. I will argue that the FDA should only set strict regulations for advertising, sale to minors, and product labeling/standards under the TCA while abstaining from requiring pre-market clinical tests that would take e-cigarettes out of consumers' hands. Using the federal regulations as a base, in accordance with the TCA, states would be able to strengthen regulation, but only in terms of e-cigarette conduct, such as amending public smoking bans to include e-cigarette vaping. Though it may seem like e-cigarettes are a regulatory "Wild West," limited FDA regulation of e-cigarettes under the TCA would actually improve public health by allowing the overwhelming number of combustible cigarette smokers a vaping alternative that is likely not as harmful as smoking traditional cigarettes.²⁵

II. E-CIGARETTES AND THE FEDERAL REGULATORY BACKGROUND

E-cigarettes are a novel product, introduced in the United States less than a decade ago,²⁶ but the tobacco industry has played an integral role throughout U.S. history. Tobacco has been used in the United States since 1612, but it was not until the 1960s that scientists realized the adverse health effects linked to

25. Melissa Block, *E-Cigarettes: A Nearly \$2bn Industry, A Regulatory Wild West*, NPR (Oct. 21, 2013, 4:37 PM), <http://www.npr.org/2013/10/21/239269426/e-cigarettes-a-nearly-2bn-industry-a-regulatory-wild-west>.

26. Cork, *supra* note 8, at 7; Lowy, *supra* note 8.

tobacco combustion.²⁷ As a result of the negative health implications associated with combustible cigarettes, numerous alternatives have been introduced in attempts to curb cigarette addiction. Some of these products have failed whereas others, such as nicotine gum, have endured for quite a while.²⁸ E-cigarettes, though, offer an advantage that past and present products do not: e-cigarettes give users the tactile feel and familiarity of a combustible cigarette while also delivering nicotine *not* laden with hundreds of chemicals. E-cigarettes have the potential to have an incredible, positive impact on the smoking community with the potential to reduce the tobacco-related death toll from 400,000 to 400 a year.²⁹

A. *What Is an E-Cigarette?*

Tobacco usage in the United States pre-dates the Revolutionary War and tobacco's rootedness in American culture has made it nearly impossible to eradicate despite the scientific studies linking tobacco usage to numerous forms of cancer and other diseases—making the introduction of the e-cigarette, a product with the potential to all but eliminate combustible cigarettes in the United States, all the more appealing. In the United States, Native Americans used tobacco products for medicinal and ceremonial purposes, but in 1612 the first commercial crop was cultivated in Virginia.³⁰ From 1612 forward, tobacco cigarettes grew in popularity, especially in the years following the Civil War.³¹ Not until 1964, though, were the adverse health effects associated with smoking combustible cigarettes widely known in the United States.³² That year, a 387-page report released by the newly formed Surgeon General's Advisory Committee on Smoking and

27. Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 HEALTH LAW., no. 1, at 13 (2010); *A Brief History of Tobacco*, CNN, <http://www.edition.cnn.com/US/9705/tobacco/history/> (last visited Apr. 14, 2014).

28. See Jake E. Henningfield & John Slade, *Tobacco Dependence Medications: Public Health and Regulatory Issues*, 53 FOOD & DRUG L.J. (SUPPLEMENT) 75, 86–87 (1998).

29. *E Cigarettes May Cover 2 of the Top 10 New Year's Resolution According to Some Experts and Reports*, BUS. JOURNALS (Jan. 4, 2010), http://www.bizjournals.com/prnews/wire/press_releases/2010/01/04/SF31533 [hereinafter *New Year's Resolution*] (statement of Joel Nitzkin, Chair of the Tobacco Control Task Force for the American Association of Public Health Physicians).

30. *A Brief History of Tobacco*, *supra* note 27.

31. *Id.*

32. *Id.*

Health highlighted startling facts associated with smoking, including “that the average smoker is nine to [ten] times more likely to get lung cancer than” a non-smoker, while also listing specific carcinogens in cigarette smoke.³³ Since then, the issues with combustible cigarettes have been documented time and time again as the small, paper wrapped nicotine delivery systems contain hundreds of toxic chemicals, of which sixty-nine have been found to cause cancer, not including the carcinogenic smoke released.³⁴ With the Surgeon General’s report raising awareness about the adverse health effects of cigarettes, researchers in the late 1960s began to study ways to get nicotine to cigarette users without the harmful effects associated with combustible cigarettes.³⁵ In short, they developed nicotine replacement therapies to deliver nicotine in a healthier way. As a result, nicotine replacement therapies taking the form of gum, inhalers, skin patches, and nasal sprays flooded the markets.³⁶ In 2004, a novel product marketed as a recreational alternative to combustible cigarettes was introduced to the United States: electronic cigarettes.

Electronic cigarettes, commonly referred to as e-cigarettes, are smokeless, flameless, battery-powered devices that vaporize liquid nicotine for the user to inhale.³⁷ The devices were first patented in China in 2003 and reached American markets the following year.³⁸ While the nicotine in e-cigarettes is derived from tobacco, the e-cigarette itself contains either very small amounts of tobacco or none at all.³⁹ E-cigarettes, therefore, allow the user to satisfy a nicotine craving, and get a “buzz,” without ingesting most of the

33. *Id.*; see *History of the Surgeon General’s Reports on Smoking and Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm (last updated July 6, 2009).

34. *Harms of Smoking and Health Benefits of Quitting*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cessation> (last visited Apr. 14, 2014).

35. *Nicotine Replacement Therapy*, NICORETTE, <http://www.nicorette.in/nicorette/nicotine-replacement> (last visited Apr. 14, 2014).

36. *Nicotine Replacement Therapy*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/007438.htm> (last visited Apr. 14, 2014).

37. Barbara Demick, *A High-Tech Approach to Getting a Nicotine Fix*, L.A. TIMES (Apr. 25, 2009), <http://articles.latimes.com/2009/apr/25/world/fg-china-cigarettes25>.

38. Cork, *supra* note 8, at 7. Once again, while introduced in 2004, they became widely available in the U.S. markets a few years later. See, e.g., Lowy, *supra* note 8.

39. Recent Case, *D.C. Circuit Rules FDA Cannot Block E-Cigarette Imports*—Sottera, Inc. v. FDA, 37 AM. J.L. & MED. 194, 194 (2011) (citing Sottera, Inc. v. FDA, 627 F.3d 891, 893 (D.C. Cir. 2010)) (“While the nicotine in e-cigarettes is derived from tobacco, the e-cigarette itself contains no tobacco.”).

harmful chemicals contained in traditional tobacco products such as cigarettes, cigars, and smokeless tobacco.⁴⁰ Although some organizations claim that the precise benefits and risks of e-cigarettes are still “uncertain,” other groups, such as the American Association of Public Health Physicians, actually recommend that those suffering from a nicotine addiction should consider using e-cigarettes as a long-term replacement for smoking combustible cigarettes.⁴¹ Organizations on both sides of the debate, though, agree that e-cigarettes should not be recommended for new users as a primarily recreational product.⁴²

Naturally, the perceived benefits of e-cigarette vaping, as opposed to smoking combustible cigarettes, have led to a surge in the e-cigarette industry, which now has about 3.5 million users in the United States.⁴³ From a market perspective, e-cigarette sales are predicted to exceed one billion dollars in U.S. sales by December 2014.⁴⁴ The vaporizers are sold both on the Internet and in stores and can cost anywhere from thirty to one hundred dollars for a starter kit and around ten dollars for a nicotine cartridge five-pack refill.⁴⁵ The estimated yearly cost of replacement car-

40. See Caponnetto et al., *supra* note 2, at 13–14.

41. *Principles to Guide AAPHP Tobacco Policy*, AM. ASS'N OF PUB. HEALTH PHYSICIANS, <http://www.aaphp.org/Tobacco> (last visited Apr. 14, 2014); *Questions and Answers on Electronic Cigarettes or Electronic Nicotine Delivery Systems (ENDS)*, WORLD HEALTH ORG. (July 9, 2013), http://www.who.int/tobacco/communications/statements/electronic_cigarettes/en/.

42. See RACHEL GRANA ET AL., BACKGROUND PAPER ON E-CIGARETTES (ELECTRONIC NICOTINE DELIVERY SYSTEMS), WHO COLLABORATING CTR. ON TOBACCO CONTROL 25 (2013); *Who Opposes E-Cigarettes, and Why?*, THE ECONOMIST (June 17, 2013, 11:50 PM), <http://www.economist.com/blogs/economist-explains/2013/06/economist-explains-11>.

43. Mary Diduch, *North Jersey Companies See Growth Along with E-Cigarette Industry*, NORTHJERSEY.COM (Jan 18, 2013), http://www.northjersey.com/news/187414911_North_Jersey_companies_see_growth_along_with_e-cigarette_industry.html. Just four years prior to Diduch's article, a study found only 300,000 e-cigarette users in the United States in 2009 as opposed to 3.5 million in 2013. See Ron Scherer, *Electronic Cigarettes: In Need of FDA Regulation?*, CHRISTIAN SCI. MONITOR (Oct. 17, 2009), <http://www.csmonitor.com/USA/Society/2009/1017/p02s03-ussc.html>.

44. See Diduch, *supra* note 43; see also Mariana Lopes, *E-Cigarettes: A Burning Question for U.S. Regulators*, REUTERS (Dec. 11, 2013), <http://www.reuters.com/article/2013/12/11/us-usa-ecigarettes-idUSBRE9BA0ZT2013211> (explaining that the market for e-cigarettes is expected to surge to up to \$10 billion by 2017); John Tierney, *A Tool to Quit Smoking Has Some Unlikely Critics*, N.Y. TIMES (Nov. 7, 2011), http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html?_r=0.

45. Ben McCampbell, *E-Cigarettes: Unanswered Questions*, AN APPLE A DAY (Feb. 28, 2014), <http://www.anapplemag.com/article/wellness/e-cigarettes-unanswered-questions>; Liz Neporent, *5 Things You Need to Know About E-Cigarettes*, ABC NEWS (Sept. 24, 2013), <http://abcnews.go.com/Health/facts-cigarettes/story?id=20345463#2>; see, e.g., MIG CIGS,

tridges is about six hundred dollars, which, when compared to the one thousand dollars plus a year that a “pack-a-day” combustible cigarette smoker pays, is fairly economical.⁴⁶

Structurally, e-cigarettes are made of three basic parts: (1) a nicotine cartridge, (2) an atomizer that vaporizes the nicotine through heat, and (3) a battery.⁴⁷ E-cigarettes come in a variety of designs in addition to the traditional cigarette shape, such as a pen or USB drive, and the nicotine mixtures, often referred to as “juice,” can be purchased in a variety of flavors.⁴⁸ Instead of using a match or lighter, the user simply inhales. The device then detects the airflow and activates the atomizer, and the nicotine-water-propylene glycol mixture is vaporized.⁴⁹ Physically, most e-cigarettes both look and feel similar to a traditional, combustible cigarette, but do not contain the array of chemical, carcinogenic ingredients found in combustible cigarettes.⁵⁰ As a result, e-cigarettes may be viewed as a safer alternative to combustible cigarettes.

While the debate regarding e-cigarette safety will inevitably linger, the vaporizers appear to be significantly safer than combustible cigarettes.⁵¹ Many view e-cigarettes as a lesser evil com-

<http://www.migcigs.com/com/5-pack-flavor-cartridges-p/crt5.htm> (last visited Apr. 14, 2014); VAPORZONE, <http://www.vaporzone.com/e-liquid-cartridges/vaporzone-express-vanilla-cartridges.html> (last visited Apr. 14, 2014); V2 CIGS, <http://www.v2cigs.com/products/v2-flavor-cartridges-5-pack#.Uz68RtyM5g0> (last visited Apr. 14, 2014).

46. Neporent, *supra* note 45.

47. See Nathan K. Cobb et al., *Novel Nicotine Delivery Systems and Public Health: The Rise of the “E-Cigarette,”* 100 AM. J. PUB. HEALTH 2340, 2341 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2978165/pdf/2340.pdf> (stating that the refill cartridges that contain the nicotine liquid used in e-cigarettes are sometimes referred to as “juice”); Wendy Koch, *E-Cigarettes: No Smoke, but Fiery Debate over Safety*, USA TODAY (Sept. 17, 2012), <http://usatoday30.usatoday.com/news/health/story/2012-08-18/electronic-cigarettes-smokeless-vaping-risks/57121894/1>.

48. Susan Cassidy, *How Electronics Cigarettes Work*, HOWSTUFFWORKS, <http://www.science.com/innovation/everyday-innovations/electronic-cigarette.htm/printable> (last visited Apr. 14, 2014); *Electronic Cigarettes (e-cigarettes)*, U.S. FOOD & DRUG ADMIN., <http://science.howstuffworks.com/innovation/everyday-innovations/electronic-cigarette.htm/printable> (last visited Apr. 14, 2014) [hereinafter *Electronic Cigarettes*].

49. *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

50. See Caponnetto et al., *supra* note 2, at 13, 16; cf. U.S. DEPT HEALTH & HUMAN SERVS., SURGEON GENERAL’S REPORT: HOW TOBACCO SMOKE CAUSES DISEASE—THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE, available at <http://www.ncbi.nlm.nih.gov/books/NBK53017/> (last visited Apr. 14, 2014) (discussing a number of non-cigarette products designed to mimic the appearance of traditional cigarettes).

51. See *infra* Part IV.A.

pared to tobacco cigarettes,⁵² while others are cautious about the safety of e-cigarettes in the absence of extensive FDA testing.⁵³ It is at precisely this point where the contentious debate over the marketing and use of e-cigarettes often occurs. While there are certainly some health and safety concerns regarding e-cigarettes, there is a strong possibility that e-cigarettes will improve public health: if effective at replacing traditional tobacco products, e-cigarettes could significantly decrease the number of tobacco users, and therefore the prevalence of tobacco-related health problems.⁵⁴ Despite the disagreements, e-cigarette supporters and critics would agree that there is not an abundance of independent, reliable data evaluating the benefits and risks of e-cigarettes both as a recreational product as well as a nicotine replacement option.⁵⁵ Although there is no substantial evidence that e-cigarettes are indeed dangerous to consumers, the FDA has attempted to impose strict regulations on e-cigarettes just as they attempted to do, albeit unsuccessfully, with combustible cigarettes. At this point, strict regulation would be both premature and detrimental to prior combustible cigarette smokers who have begun to use e-cigarettes as an alternative.

B. FDA's Recent Regulation Attempts

The federal government has long excluded cigarettes and other similar tobacco products from regulation. In 1914, the FDA's predecessor agency, the Bureau of Chemistry, claimed that it only had authority to regulate a tobacco product if the tobacco product's labeling indicated use for "the cure, mitigation, or prevention of diseases."⁵⁶ On the contrary, if the product's labeling indi-

52. See Danielle Dellorto, *FDA Hazy on E-Cigarettes' Safety*, CNN (Mar. 13, 2009), <http://www.cnn.com/2009/HEALTH/03/13/ecigarettes.smoking/>.

53. See Kian Ivey, *As E-cigarette Use Increases, Experts Investigate Health Risks*, BROWN DAILY HERALD (Dec. 6, 2013), <http://www.browndailyherald.com/2013/12/06/e-cigarette-use-increases-experts-investigate-health-risks/>; *Popularity Surges for E-Cigarettes, but Health Questions Unanswered*, ORAL CANCER NEWS (Feb. 22, 2011), <http://www.oralcancernews.org/wp/popularity-surges-for-e-cigarettes-but-health-questions-unanswered/>.

54. In the United States each year, smoking accounts for more 480,000 deaths. See CTRS. FOR DISEASE CONTROL & PREVENTION, *Adult Cigarette Smoking in the United States: Current Estimates*, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/ (last visited Apr. 14, 2014).

55. See Thomas J. Glynn, *Electronic Cigarettes-Boon, Bane, Blessing, or Boondoggle?*, AM. CANCER SOC'Y (May 3, 2011), <http://www.cancer.org/cancer/news/expertvoices/post/2011/05/03/electronic-cigarettes-e28093-boon-bane-blessing-or-boondoggle.aspx>.

56. USDA BUREAU OF CHEMISTRY, SERVICE AND REGULATORY ANNOUNCEMENTS 21,

cated use for “smoking or chewing or as snuff,” which were not considered medicinal uses, then the agency did not have regulatory authority.⁵⁷ Fast forward to 1964—when the FDA took a similar stance, the Surgeon General stated that the FDA did not have “authority in existing laws governing [the FDA]” to regulate combustible cigarettes.⁵⁸ Even in 1980, when public health groups pressured the FDA to regulate nicotine cigarettes as drugs under the FDCA, the FDA continued to claim that cigarettes marketed without health claims were not within the FDA’s regulatory purview.⁵⁹

In 1996, the FDA changed their usual practice of abstaining from tobacco product regulation. David Kessler, the FDA Commissioner at the time, issued a final rule asserting FDA regulatory authority over tobacco products under the FDCA.⁶⁰ The FDCA is a massive statute granting the FDA extensive jurisdiction over a wide swath of products, including food, drugs, cosmetics, and medical devices that, if applied to e-cigarettes, would expose them to “the more onerous regulatory burdens for drugs and devices merely because they claim to be healthier alternatives to traditional tobacco products.”⁶¹ Under Kessler’s final rule, the FDA concluded that the FDCA authorized the FDA to regulate nicotine as a drug and cigarettes as a combination drug and medical device product.⁶² Following this abruptly announced authority, the

24 (Apr. 2, 1914), available at <http://legacy.library.ucsf.edu/tid/qvx60C00/pdf>; see *Smoking & Tobacco Use: Legislation*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/by_topic/policy/legislation/ (last visited Apr. 14, 2014).

57. See SERVICE AND REGULATORY ANNOUNCEMENTS, *supra* note 56.

58. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 145 (2000).

59. See, e.g., Letter from the Food & Drug Admin. to John F. Banzhaf, III & Peter N. Georgiades, Action on Smoking and Health (Nov. 25, 1980), available at <http://www.tobaccodocuments.org/pm/2060433121-3132.html>.

60. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,396 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897); cf. Marian Burros, *F.D.A. Commissioner Is Resigning After 6 Stormy Years in Office*, N.Y. TIMES (Nov. 26, 1996), <http://www.nytimes.com/1996/11/26/us/fda-commissioner-is-resigning-after-6-stormy-years-in-office.html> (stating Kessler resigned in November 1996, following the release of the Federal Register).

61. *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 75 (D.C. Cir. 2010); see Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938).

62. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,397.

FDA promulgated a final rule to reduce tobacco consumption through labeling, promotion, and access restrictions.⁶³

Controversial does not begin to describe this rule, which generated over 700,000 comments during the regulation's required notice and comment period.⁶⁴ After the promulgation of the final rule, tobacco manufacturers, retailers, and advertisers quickly filed suit to challenge the rule, arguing that the FDA's regulation went far beyond its authority under the FDCA.⁶⁵ In 1998, the Fourth Circuit agreed with one of these challenges in *Brown & Williamson Tobacco Corp. v. FDA*: it held that the FDA did not have authority to regulate tobacco products under the FDCA.⁶⁶ The Supreme Court heard *Brown & Williamson* on appeal that same year and agreed with the Fourth Circuit, stating that Congress had "clearly precluded the FDA from asserting jurisdiction to regulate tobacco products."⁶⁷ Neither of the courts afforded *Chevron* deference to the FDA because the FDCA as a whole, and when read in light of subsequent tobacco-specific legislation, "gives the agency no authority to regulate tobacco products as customarily marketed."⁶⁸ *Chevron* deference, which generally means a court will defer to an agency's interpretation of a statute when that interpretation is reasonable, usually results in a high win rate for the respective agency.⁶⁹ Only when an agency is acting clearly beyond the scope of authority it was given by Congress to implement a statute will a court refuse to extend *Chevron* deference.⁷⁰ The Supreme Court did not refute that the nicotine in tobacco was intended to affect the structure or function of the

63. See *id.* at 44,397–98.

64. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126–27 (2000); see Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,418.

65. See Lars Noah & Barbara A. Noah, *Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products*, 48 ALA. L. REV. 1, 5–6 (1996); see also Barnaby J. Feder, *Tobacco Curbs Face Legal Fight*, N.Y. TIMES (Aug. 24, 1996), <http://www.nytimes.com/1996/08/24/us/tobacco-curbs-face-legal-fight.html>.

66. 153 F.3d 155, 176 (4th Cir. 1998); see *infra* Part III.B.2.

67. *Brown & Williamson*, 529 U.S. at 126.

68. *Id.* at 159. If tobacco products are not "customarily marketed" for ordinary recreational use and instead are marketed as therapeutic products, the FDA does have jurisdictional authority under the FDCA to regulate the product as a drug/device. See *infra* Part III.B.

69. See WILLIAM N. ESKRIDGE ET. AL., CASES AND MATERIALS ON STATUTORY INTERPRETATION 824 (2012) (noting that when the Court applies the *Chevron* framework, the agency wins 76.2% of time, representing a very high agreement rate).

70. See *id.* at 645.

human body, but instead reasoned that allowing the FDA to regulate tobacco products, namely cigarettes, under the FDCA would require the FDA to ban them altogether.⁷¹ A ban, the Court continued, would be contrary to Congress' intent, which favored informing consumers about adverse health risks of tobacco use instead of harming the nation's economy through an outright ban.⁷² In turn, *Brown & Williamson* makes clear that regulating tobacco products under the FDCA simply does not make sense.

After *Brown & Williamson*, and the FDA's subsequent removal of the regulations, Congress recognized the regulatory gap in the FDCA and enacted the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA") to provide the FDA with comprehensive regulatory authority over tobacco products.⁷³ Congress enacted the TCA in part "to provide *new* and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry efforts to develop, introduce, and promote less harmful tobacco products."⁷⁴ This created a two-tiered system where the FDA could regulate food, drugs, and cosmetics through the FDCA and tobacco products through the TCA. Despite the TCA's clear grant of authority to the FDA to regulate tobacco products, and the Court's earlier decision in *Brown & Williamson*, the FDA attempted to reassert its purported authority to regulate tobacco products under the FDCA in 2009.⁷⁵ This time the FDA targeted e-cigarettes by denying import shipments of e-cigarettes entry into the United States.⁷⁶

E-cigarettes fall within the TCA's broad definition of "tobacco product," and therefore cannot be considered a drug or device under the FDCA. Simply, e-cigarettes contain nicotine, which is de-

71. *Brown & Williamson*, 529 U.S. at 135; *see id.* at 162 (Breyer, J., dissenting) (confirming the majority did not deny that cigarettes are "intended to affect" the body's 'structure' and 'function'); *see also* 21 U.S.C. § 360c(a)(1)(C) (2012) (defining Class III device).

72. *Brown & Williamson*, 529 U.S. at 139 ("[T]he collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.").

73. 21 U.S.C. § 387 note (2012) (Findings subsec. 7) ("Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.").

74. *Id.* (Purpose subsec. 4) (emphasis added).

75. *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

76. *Id.*

rived from tobacco, and the TCA gives the FDA authority to regulate “any product made or derived from tobacco.”⁷⁷ Therefore, the FDA has claimed that they plan to focus their efforts on creating a comprehensive regulatory scheme to regulate e-cigarettes under the TCA.⁷⁸ That regulatory scheme has been in the making for over two years, but the FDA is expected to finally propose it in the near future and will most likely include stringent e-cigarette regulation with the potential to remove e-cigarettes from the market to undergo pre-market clinical tests.⁷⁹ Some e-cigarette manufacturers have also agreed that their product should be regulated, but, consistent with the FDA’s claim, under the TCA rather than the more stringent FDCA.⁸⁰ Despite the FDA’s letter of intent, there is certainly still the possibility that the FDA will attempt to regulate e-cigarettes under the FDCA because relevant case law is quite limited. Further, several critics and scholars believe the FDCA is still a viable option for e-cigarette regulation.⁸¹ Currently, though, e-cigarettes are distributed largely without government regulation and oversight for quality control, although other tobacco products, such as combustible cigarettes, are regulated.⁸² Accordingly, the FDA should regulate e-cigarettes under the TCA.

77. 21 U.S.C. § 321(rr)(1) (2012).

78. See Deyton & Woodcock, *supra* note 15.

79. See Megan McArdle, *E-Cigarettes: A \$1.5 Billion Industry Braces for FDA Regulation*, BLOOMBERG BUSINESSWEEK (Feb. 6, 2014), <http://www.businessweek.com/articles/2014-02-06/e-cigarettes-fda-regulation-looms-for-1-dot-billion-industry#pl>; Sara Zborovski, *The Regulation of E-Cigarettes: Trying to Fit a Square Peg into a Round Hole?*, HUFFINGTON POST BLOG (Dec. 19, 2013, 2:24 PM), http://www.huffingtonpost.com/sara-zborovski/e-cigarette-regulation_b_4468667.html; see also Deyton & Woodcock, *supra* note 15 (noting the FDA’s intent to propose a regulation that would extend the Agency’s “tobacco product” authorities in Chapter IX of the FDCA).

80. See Daniel Fisher, *Will Taxes and Regulation Rein in the Booming E-Cigarette Market?*, FORBES (Oct. 2, 2013), <http://www.forbes.com/sites/danielfisher/2013/10/02/will-taxes-and-regulation-rein-in-the-booming-e-cigarette-market>; see *infra* Part III.A.1.

81. See *The FDA & Deeming Regulations of E-Cigarettes*, CASAA, http://www.casaa.org/deeming_regulations.html (last visited Apr. 14, 2014).

82. Anna Edney, *FDA Scrutinizes E-Cigarette Marketing*, IDAHO STATESMAN (Oct. 21, 2013), <http://www.idahostatesman.com/2013/10/21/2826018/fda-scrutinizes-e-cigarette-marketing.html>. While combustible cigarettes are regulated under the TCA, nicotine gum is regulated under the FDCA because it claims a therapeutic benefit. See *Electronic Cigarettes*, *supra* note 48; Michael Siegel, *FDA Reply Brief in NJOY Electronic Cigarette Case Is Not Compelling Because It Ignores FDA Tobacco Law*, TOBACCO ANALYSIS (Aug. 3, 2010, 7:01 AM), <http://www.tobaccoanalysis.blogspot.com/2010/08/fda-reply-brief-in-njoy-electronic.html>.

III. LIMITED REGULATORY ABILITY OF THE FDA UNDER THE TCA

This Part argues that, despite the limited case law directing the FDA to regulate e-cigarettes under the TCA and critics that believe that FDCA regulation is more appropriate, the FDA must regulate e-cigarettes under the TCA. Given the FDA's prior attempts to reach beyond its historically recognized authority by promulgating regulations over tobacco products under the FDCA, the FDA might attempt to promulgate future e-cigarette regulations under the FDCA.⁸³ This Part will analyze both why the TCA is the appropriate regulatory avenue and why the FDCA is an inappropriate regulatory avenue.

A. *The FDA May Only Regulate E-Cigarettes Under the TCA*

1. Purpose of the TCA and the Potential Effect on E-Cigarettes

The argument that e-cigarettes, which are tobacco products, should be subject to FDCA regulation expressly contradicts provisions in the TCA. The TCA clarifies that tobacco products "shall not be subject to the provisions of subchapter V [Drugs and Devices]" of the FDCA.⁸⁴ Further discussion is hardly necessary as the TCA makes clear that if something falls under the TCA's definition of a tobacco product—a product made or derived from tobacco—then it shall not be regulated under the Drugs and Devices provisions of the FDCA.⁸⁵

The TCA gives the FDA authority, which *Brown & Williamson* suggests it previously lacked with regard to cigarettes, to regulate e-cigarettes as "tobacco products." In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act, informally referred to as the Tobacco Control Act, which amended the Food, Drug, and Cosmetic Act of 1938.⁸⁶ The TCA's purpose is to give the FDA authority to regulate tobacco products to address public health concerns while continuing to permit the sale of tobacco to

83. See Alicia Gallegos, *FDA Barred from Regulating E-Cigarettes as Medical Devices*, AM. MED. NEWS (Dec. 10, 2010), <http://www.amednews.com/article/20101229/profession/312299996/8/>.

84. 21 U.S.C. § 387a(a) (2012).

85. *Id.* § 321(rr) (2012).

86. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1781 (2009) (amending 21 U.S.C. § 301).

informed consumers.⁸⁷ The TCA specifically provides the FDA with authority to regulate, but not ban, recreational tobacco use—an authority Congress did not give to the FDA under the FDCA.⁸⁸ The TCA expressly states that “Federal and State governments have *lacked* the legal and regulatory authority and resources they need to comprehensively address the public health and societal problems caused by the use of tobacco products.”⁸⁹ In defining “tobacco product” broadly, so as to include “*any* product made or derived from tobacco” intended for human consumption, Congress intended to comprehensively regulate both traditional tobacco products, such as combustible cigarettes and smokeless tobacco, as well as more novel, unforeseen tobacco products derived from tobacco, such as e-cigarettes.⁹⁰

Necessarily, the definitions of “tobacco product” under the TCA and “drug” or “device” under the FDCA are irreconcilable.⁹¹ Congress has expressly stated: “The term ‘tobacco product’ does not mean an article that is a drug . . . a device . . . or a combination product . . . [in the FDCA].”⁹² Further, Congress granted additional regulatory powers to the FDA, including pre-market and post-market requirements, to specifically fulfill the Act’s larger purpose to “address issues of particular concern . . . especially the use of tobacco by young people and dependence on tobacco”—a purpose not expressly stated in the FDCA because the FDCA is not finely tailored, and therefore not well-suited, to address complex, tobacco-specific issues.⁹³ The purpose of the TCA, as the FDA has conceded, is not to “move the definitional line between tobacco products and drugs” as, again, Congress has determined that the terms are mutually exclusive.⁹⁴ E-cigarettes fall squarely in the more recent tobacco-tailored regulatory scheme of the TCA, not the FDCA.

87. 21 U.S.C. § 387a note (Purpose subsec. 1, 6).

88. *Id.* § 387g(d)(3) (2012).

89. *Id.* § 387 note (2012) (Findings subsec. 7) (emphasis added).

90. *Id.* § 321(rr)(1) (2012) (emphasis added).

91. *See* *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 66–67 n.4 (D.D.C. 2010).

92. 21 U.S.C. § 321(rr)(2).

93. *Id.* § 387 note (Purpose subsec. 2); *see also id.* (Findings subsec. 6–7, 14–15, 18); *id.* § 387j(a)(2) (2012).

94. *Smoking Everywhere*, 680 F. Supp. 2d at 66–67 n.4; *see* 21 U.S.C. § 387a(c)(1) (2012) (“Nothing in this subchapter . . . shall be construed to affect, expand, or limit the Secretary’s authority over . . . products under this chapter [Tobacco Products].”)

In light of the FDA consistently recognizing that it lacked FDCA regulatory authority over tobacco products until 1996, the TCA can be read to fill a regulatory gap in the FDCA: the FDCA does not apply to tobacco products that do not claim a therapeutic benefit, and, therefore, the FDA could not regulate those products prior to the TCA's enactment.⁹⁵ Only recently, starting with a 1996 federal regulation leading to the Supreme Court's landmark decision in *FDA v. Brown & Williamson Tobacco Corp.*, has the FDA attempted to regulate tobacco products under the FDCA.⁹⁶ Each time the FDA has attempted to regulate tobacco products under the FDCA, the courts have made clear such regulation does not fit within the FDCA's regulatory scheme.⁹⁷ Congress, through the TCA, made abundantly clear that the FDA's regulatory jurisdiction over tobacco products is entirely distinct from its preexisting jurisdiction over drugs, devices, and combination products.

The TCA provides the FDA all the authority Congress deemed appropriate to combat the public health and other issues presented by tobacco products—and ample authority to do so. The TCA is well-equipped to regulate the e-cigarette industry with a more lenient regulatory scheme, when compared to the stringent FDCA, which will ensure e-cigarettes remain available to users while ensuring a basic level of safety.⁹⁸ This balance is especially important to former heavy smokers seeking to avoid the harmful health effects of chronic tobacco use by replacing tobacco cigarettes with e-cigarettes.⁹⁹ While opponents of e-cigarettes claim

95. See 21 U.S.C. § 387a(a).

96. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000); Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,418 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

97. See, e.g., *Brown & Williamson*, 529 U.S. at 126; *Sottera, Inc. v. FDA*, 627 F.3d 891, 898–99 (D.C. Cir. 2010).

98. The TCA does not allow the FDA to outright ban cigarettes or to require cigarette manufacturers to reduce nicotine levels to zero. 21 U.S.C. § 387g(d)(3)(A) (2012) (prohibiting banning all cigarettes); *id.* § 387g(d)(3)(B) (prohibiting reducing the nicotine yield in tobacco products to zero); see *infra*, Part III.B.2.

99. *An Electronic Cigarette Ban: What Would Users Do?*, SMOKERS ANGEL, <http://www.ecigarettedirect.co.uk/research/ecig-user-survey/results.html> (last visited Apr. 14, 2014) (finding that 67.8% of e-cigarette users in the UK “completely replaced tobacco cigarettes with electronic cigarettes”); David Wenner, *Could E-Cigarettes Be the Solution You Need to Quit Smoking?*, PENN LIVE (Feb. 11, 2014, 11:45 AM), http://www.pennlive.com/midstate/index.ssf/2014/02/electronic_cigarettes_e-cigare_1.html (referencing the research of a Penn State scientist specializing in tobacco addiction and finding that e-cigarettes can provide a safer alternative for those smokers who have not succeeded with approved replacement devices).

that the nicotine in e-cigarettes has serious adverse health consequences, nicotine, often found in combustible cigarettes at much higher dosages than e-cigarettes, may not be that harmful.

2. Nicotine's Health Effects and Its Classification as a "Tobacco Product" Under the TCA

"Nicotine," to the general public, often carries a negative connotation, but this impression of the substance is usually unfounded. Nicotine is a colorless or pale yellow, oily liquid found in tobacco and related plants such as potatoes and tomatoes.¹⁰⁰ Although nicotine is an addictive substance, some scientists claim it is not especially hazardous in itself.¹⁰¹ Although the FDA is incredibly cautious when addressing nicotine, the UK Medicines and Healthcare Products Regulatory Agency has stated that "nicotine . . . is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease."¹⁰² The FDA's cautiousness seems to rest largely on skepticism and negative association: cigarettes are bad for your health and nicotine is in cigarettes. Ironically, it is difficult to find studies claiming nicotine is harmful to human health, in and of itself, whereas it is relatively easy to find many sources affirming that nicotine is actually not inherently harmful and instead is similar to other popular drugs such as caffeine.¹⁰³ Therefore, this FDA skepticism and over-cautiousness is misplaced.

The fact that e-cigarettes almost *solely* contain nicotine supports the argument that e-cigarettes are inherently less dangerous than combustible cigarettes, which are filled with various chemicals. Traditional, combustible cigarettes contain not only nicotine, but also numerous carcinogens and various other chemi-

100. Edward F. Domino et al., *The Nicotine Content of Common Vegetables*, 329 NEW ENG. J. MED. 437, 437 tbl.1 (1993), available at http://www.nejm.org/doi/full/10.1056/NEJM199308053290619?keytype=tf_ipsecsha&ijkey=09174147c440b96900667f3fef93fd3cd0100cee&&.

101. See Britton, *supra* note 18.

102. MEDS. & HEALTHCARE PRODS. REGULATORY AGENCY, MHRA PUBLIC ASSESSMENT REPORT: THE USE OF NICOTINE REPLACEMENT THERAPY TO REDUCE HARM IN SMOKERS 4 (2010), available at <http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con065622.pdf>.

103. See, e.g., Univ. of Alberta Med. School, Dep't of Pub. Health Sci., *All About Nicotine (And Addiction)*, TOBACCO HARM REDUCTION, <http://www.tobaccoharmreduction.org/faq/nicotine.htm> (last visited Apr. 14, 2014).

cals not found in e-cigarettes.¹⁰⁴ Over the past couple decades, the FDA has funded several committees and studies to address nicotine science and policy issues.¹⁰⁵ These committees include the Committee to Assess the Science Base for Tobacco Harm Reduction, which wrote the 2001 report *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, and the Committee on Scientific Standards for Studies on Modified Risk Tobacco Products, which wrote the 2012 report *Scientific Standards for Studies on Modified Risk Tobacco Products*.¹⁰⁶ Aside from general conclusions regarding combustible cigarettes' adverse health effects, both studies endorsed modified risk tobacco products, products marketed with a claim to reduce harm or the risk of tobacco-related disease,¹⁰⁷ and nicotine replacement products, such as the nicotine patch and gum.¹⁰⁸ Although *Clearing the Smoke* was published before e-cigarettes were marketed in the United States, the study still portrays products that have less combustion than combustible cigarettes, like e-cigarettes, as a less risky alternative.¹⁰⁹ The *Scientific Standards for Studies on Modified Risk Tobacco Products* report, released after e-cigarettes were marketed in the United States, acknowledged that scientists have found that e-cigarettes do, indeed, "hold promise for harm reduction."¹¹⁰ In

104. See Caponnetto et al., *supra* note 2, at 14.

105. See, e.g., Brady Dennis, *FDA Backs Low-Nicotine Cigarette Research as It Weighs New Regulatory Power*, WASH. POST (July 30, 2013), http://www.washingtonpost.com/national/health-science/fda-tests-low-nicotine-cigarettes-as-it-weighs-new-regulatory-power/2013/07/30/122c0954-efbd-11e2-9008-61e94a7ea20d_story.html; Elizabeth Fernandez, *UCSF Awarded \$20M Federal Grant on Tobacco Regulatory Sciences*, UCSF (Sept. 13, 2013), <http://www.ucsf.edu/news/2013/09/108946/ucsf-awarded-20m-federal-grant-tobacco-regulatory-sciences>; see also *Federal Overview: Poor Results in 2013*, AM. LUNG ASS'N, STATE OF TOBACCO CONTROL, <http://www.stateoftobaccocontrol.org/at-a-glance/federal-government/> (last visited Apr. 14, 2014) (referencing the FDA's 2013 report which found that menthol in cigarettes is more likely to lead to new users, primarily youth).

106. KATHLEEN STRATTON ET. AL., INST. OF MED., COMM. TO ASSESS THE SCI. BASE FOR TOBACCO HARM REDUCTION, *CLEARING THE SMOKE: ASSESSING THE SCIENCE BASE FOR TOBACCO HARM REDUCTION* (2001), available at http://books.nap.edu/openbook.php?record_id=10029; COMM. ON SCIENTIFIC STANDARDS FOR STUDIES ON MODIFIED RISK TOBACCO PRODS., *SCIENTIFIC STANDARDS FOR STUDIES ON MODIFIED RISK TOBACCO PRODUCTS*, (2012), available at http://books.nap.edu/openbook.php?record_id=13294.

107. *Tobacco Products: Modified Risk Tobacco Products*, FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297747> (last updated June 14, 2013). Congress made clear that these modified risk products "shall be regulated" under the TCA "and shall not be subject to the [drug/device provisions of the FDCA]." 21 U.S.C. §§ 387a(a), 387k (2012).

108. See STRATTON ET AL., *supra* note 106, at 4–5 & tbl.1.

109. See *id.* at 5.

110. See SCIENTIFIC STANDARDS FOR STUDIES ON MODIFIED RISK TOBACCO PRODUCTS,

sum, these two FDA-funded studies concluded, either directly or inferentially, that e-cigarettes can be a powerful tool in reducing tobacco-related disease and, therefore, should remain available to consumers absent compelling evidence that they are harmful.

Evidence that nicotine is not particularly harmful is fairly abundant even outside of U.S.-funded studies. The Royal College of Physicians (“RCP”) is a UK-based organization that produces reports similar to those published by the U.S. Surgeon General and has been at the forefront of tobacco policy since 1962.¹¹¹ In 2007, the RCP published *Harm Reduction in Nicotine Addiction: Helping People Who Can’t Quit* and made a case for “harm reduction strategies to protect smokers” which included using e-cigarettes to fulfill nicotine cravings rather than combustible cigarettes.¹¹² The preface of the report makes the bold claim that “smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.”¹¹³ In addition to its clear support of nicotine addicts getting their nicotine from sources aside from combustible cigarettes, the RCP report study also critiques nicotine regulatory structures in general: “[T]he regulatory systems that currently govern nicotine products in most countries, including the UK, actively discourage the development, marketing and promotion of significantly safer nicotine products to smokers.”¹¹⁴ The two American groups and the RCP make clear that because nicotine addiction is not going away anytime soon, it seems counter-intuitive to have drawn-out regulatory procedures and limiting schemes that restrict access to e-cigarettes and other sources of nicotine, while combustible cigarettes, which are regarded as more dangerous, remain widely accessible throughout the United States. Because of their reduced harm, when compared to com-

supra note 106, at 50.

111. See Jim Solyst, *Toward a Comprehensive Policy on Nicotine Delivery Products and Harm Reduction*, 67 FOOD & DRUG L.J. 393, 395 (2012). See generally *Smoking and Health (1962)*, ROYAL COLL. OF PHYSICIANS, <http://www.rcplondon.ac.uk/resources/smoking-and-health-1962> (last visited Apr. 14, 2014) (chronicling the significance of a landmark 1962 report to “the RCP’s enduring role in public health . . . [and] five decades of action on tobacco control”).

112. See Britton, *supra* note 18, at *Preface*, 183, 225–27 (arguing that harm reduction strategies, such as vaping e-cigarettes instead of smoking combustible cigarettes, require more supportive regulatory structures).

113. See *id.* at *Preface*.

114. See *id.*

bustible cigarettes, the FDA should loosely regulate e-cigarettes, as they have the potential to positively impact current combustible cigarette smokers.

Although e-cigarettes do not contain any tobacco and do not burn like “real cigarettes,” they fall within the TCA’s definition of “tobacco products” because they contain nicotine derived from tobacco.¹¹⁵ Simply put, e-cigarettes deliver nicotine that is derived from tobacco to humans in vapor form.¹¹⁶ Therefore, e-cigarettes clearly meet the definition of a “tobacco product.”¹¹⁷ Congress omitted any reference to specific tobacco products in its broadly worded definition of “tobacco product,” which demonstrates that by its definition of tobacco products, Congress likely intended to include within that definition a broader range of products than just traditional combustible cigarettes and anticipated that newly developed products like e-cigarettes would also fall under TCA regulation.¹¹⁸ A “tobacco product,” under the TCA, certainly encompasses e-cigarettes.

3. The FDA’s Specific Authority Under the TCA

Although there are nicotine products on the market, such as Nicoderm CQ gum, which are regulated by the FDA under the FDCA, each of these FDCA-regulated products have an important commonality: they make therapeutic claims.¹¹⁹ Conversely, e-cigarettes do not predominantly make such claims, and in turn should be classified by the FDA as a tobacco product that cannot be regulated under the FDCA.¹²⁰ Following the same logic in *Brown & Williamson*: because e-cigarettes do not make therapeutic claims, the FDA lacks jurisdiction to regulate e-cigarettes as a drug/device combination.¹²¹ Hence, this regulatory gap for non-therapeutic-claiming tobacco products, such as combustible cigarettes, smokeless tobacco, and e-cigarettes, acted as a catalyst for

115. See 21 U.S.C. § 321(rr)(1) (2012).

116. See Demick, *supra* note 37.

117. See 21 U.S.C. § 321(rr)(1).

118. *Id.*

119. See, e.g., NICODERM CQ, <http://www.nicodermcq.com> (last visited Apr. 14, 2014) (containing slogans such as “NOW, Quit on your own terms”).

120. See, e.g., BLU CIGS, <http://www.blucigs.com> (last visited Apr. 14, 2014) (containing slogans such as “freedom to have a cigarette without the guilt”).

121. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000).

the enactment of the TCA.¹²² To be clear, while many of e-cigarettes' benefits lie in the fact that they are a form of harm reduction, these claims are predominantly *not* manifested by the manufacturers.¹²³ Whereas products such as Nicoderm CQ are expressly advertised to stop smoking, e-cigarette manufacturers do *not* make these claims. E-cigarette manufacturers' objective intent when advertising is important, as at least one court has looked at how manufacturers market their products—"the objective intent of the persons legally responsible' for labeling the product"—and determined that e-cigarettes are marketed not as therapeutic devices, but as recreational alternatives to combustible cigarettes.¹²⁴ Because the FDCA is largely irrelevant to e-cigarette regulation, the FDA's specific regulatory authority under the TCA becomes quite relevant.

Under the TCA, and outside of the normal provisions of the FDCA, the FDA has the authority to regulate tobacco products, which are "any product[s] made or derived from tobacco . . . intended for human consumption."¹²⁵ The TCA (1) requires tobacco companies to submit to the FDA information regarding their products' ingredients and related research;¹²⁶ (2) creates an "adulterated tobacco products" category, which allows the FDA to impose manufacturing standards,¹²⁷ and creates a "misbranded tobacco products" category, which subjects tobacco packaging to strict labeling requirements;¹²⁸ (3) allows the FDA to regulate tobacco advertising and marketing, while also eliminating most flavoring additives in cigarettes that are designed to appeal to youths;¹²⁹ (4) allows the FDA to regulate nicotine yields;¹³⁰ (5) establishes provisions for regulating "modified risk tobacco products;"¹³¹ (6) requires pre-market approval for new tobacco products

122. See 21 U.S.C. § 387 note (2012) (Findings subsec. 7).

123. See *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 73 (D.D.C. 2010).

124. *Id.* (citing 21 C.F.R. § 201.128 (2013)).

125. 21 U.S.C. § 321(rr)(1) (2012). The TCA explicitly states that tobacco products shall not be considered a drug, device, or combination product under the FDCA. *Id.* § 321(rr)(2). Technically, the Center for Tobacco Products ("CTP") is responsible for enforcing the TCA, but because the CTP is within the FDA I will continue to refer to the FDA as the enforcement agency for the TCA. See *id.* § 387a(e) (2012).

126. *Id.* § 387d(a)(1), (4) (2012).

127. *Id.* § 387b (2012).

128. *Id.* § 387c (2012)

129. *Id.* § 387f(d)(1) (2012); *id.* § 387g(a)(1)(A) (2012).

130. *Id.* § 387g(a)(4)(A)(i).

131. *Id.* § 387k (2012).

to determine their impact on the public health;¹³² and (7) establishes a Tobacco Products Scientific Advisory Committee to propose regulations necessary to protect the public health.¹³³ Despite these powerful regulatory tools, the FDA can neither ban traditional tobacco products nor can they require nicotine yields of tobacco products to be reduced to zero.¹³⁴

More concisely, the TCA grants the FDA the authority to regulate ingredients, testing, development, manufacture, packaging, labeling, advertising, distribution, sale, and health and safety disclosures of tobacco products. While this list of authorities is quite broad and powerful, it is especially necessary to provide basic protection to the general public regarding combustible cigarettes.¹³⁵ If the FDA were to fully utilize all of its regulatory authority on e-cigarettes, it would be a grave mistake impeding the development and distribution of a product that is immensely beneficial to the smoking population, and the secondhand smoke-breathing population, of the United States.¹³⁶ A looser regulatory structure would ensure that e-cigarette manufacturers provide accurate information regarding their nicotine cartridges and do not target youth populations, while keeping the vaporizers available for those, mainly combustible cigarette smokers, who benefit from and have come to rely on them.

B. *The FDA Has No Ability to Regulate E-Cigarettes Under the FDCA*

The FDA first attempted to regulate e-cigarettes in 2010 under its FDCA “authority” and was quickly corrected by the United States Court of Appeals for the D.C. Circuit. Applying the reasoning from the Supreme Court’s landmark decision in *Brown & Williamson*, the court reminded the FDA that it cannot regulate to-

132. *Id.* § 387j (2012). A new tobacco product can avoid the pre-market review process if the manufacturer can show it is “substantially equivalent” to another commercially marketed product on the market as of February 15, 2007. *Id.* § 387e(j) (2012).

133. *Id.* § 387q (2012).

134. *Id.* § 387g(d)(3)(A) (prohibiting banning); *id.* § 387g(d)(3)(B) (prohibiting reducing nicotine yields to zero).

135. See HEALTH CONSEQUENCES OF SMOKING, *supra* note 4, at 861.

136. See *id.*; *Health Effects of Secondhand Smoke*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/ (last visited Apr. 14, 2014) (citing secondhand smoke as causing health problems such as severe asthma attacks, respiratory infections, and sudden infant death syndrome).

bacco products, which claim no therapeutic benefits for their users, under the FDCA.¹³⁷ In fact, if the FDA had the authority to regulate cigarettes and related products under the FDCA, the statute would require the products to be banned.¹³⁸ Congress did not intend for these products to be banned, which Congress made clear in the TCA, while also expressly stating that the FDA cannot require manufacturers to reduce nicotine yields to zero.¹³⁹ The FDCA is not tailored to the specific issues that tobacco products raise, such as their effect on younger populations. The TCA is tailored to these specific issues. The FDA should focus its time and efforts on implementing an effective, albeit minimalist, regulatory structure under the TCA rather than waste more time aggressively trying to force a square peg into a round hole by attempting to use the FDCA to regulate e-cigarettes.

1. *Sottera, Smoking Everywhere*, and Therapeutic Products

In *Sottera, Inc. v. FDA*, the D.C. Circuit properly prevented the FDA's attempt to block e-cigarette imports under the FDCA, and other courts likely will block future, similar attempts as well if e-cigarette manufacturers continue to market their products as a recreational alternative to combustible cigarettes. Although Congress passed the TCA in 2009, after e-cigarettes were prominently marketed in the United States, the FDA continued its attempts to regulate tobacco products, including e-cigarettes, under the FDCA. In *Sottera*, the FDA denied the entry of certain e-cigarettes—imported and distributed by NJOY—into the United States under a drug/device provision of the FDCA.¹⁴⁰ Co-party Smoking Everywhere, another importer and distributor of e-cigarettes, moved for a preliminary injunction, arguing that the FDA can regulate e-cigarettes under the TCA, but not the FDCA.¹⁴¹ More specifically, Smoking Everywhere argued that the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.* gave the FDA authority under the FDCA only if e-cigarettes claimed a therapeutic effect, which they do not.¹⁴² The court made short work of the case, holding that the FDA cannot

137. *Sottera, Inc. v. FDA*, 627 F.3d 891, 893, 899 (D.C. Cir. 2010).

138. *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 70 (D.D.C. 2010).

139. 21 U.S.C. § 387g(d)(3)(B).

140. *Sottera*, 627 F.3d at 893.

141. *Id.*

142. *Id.*

regulate “customarily marketed” tobacco products under the FDCA drug/devices provisions.¹⁴³

While the FDA asserted that “nicotine is a drug” under the FDCA, and therefore subject to regulation under the FDCA regardless of whether the manufacturer made therapeutic claims, the court clarified that Congress enacted the TCA to fill the regulatory gap regarding tobacco products in the FDCA.¹⁴⁴ Specifically, the TCA broadly defines a tobacco product as “any product made or derived from tobacco” and “does not mean an article that is a drug under [the FDCA’s drug provision].”¹⁴⁵ Further, the court reasoned, the TCA does not “affect, expand, or limit” the FDA’s drug/device authority under the FDCA.¹⁴⁶ Any product subject to TCA regulation cannot simultaneously be subject to drug or device classification under the FDCA.¹⁴⁷ It would be difficult for a statute to be clearer: the FDCA cannot be used to regulate tobacco products not claiming a therapeutic benefit.¹⁴⁸

In *Smoking Everywhere, Inc. v. FDA* the U.S. District Court for the District of Columbia emphasized that e-cigarettes, as ordinarily marketed, do not claim therapeutic benefits for their users, and, therefore, the FDA cannot regulate e-cigarettes under the FDCA.¹⁴⁹ The petitioners in *Sottera* argued that their e-cigarettes were “marketed and labeled for ‘smoking pleasure,’” not as a therapeutic product.¹⁵⁰ While the FDA in *Sottera* ultimately did

143. *Id.* at 898.

144. *Id.* at 894; see 21 U.S.C. § 321(g)(1)(C) (2012) (defining drug as an article that affects the structure or function of the body); Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,400 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897) (claiming cigarettes and smokeless tobacco fall under FDA regulatory authority without mention of therapeutic claims).

145. 21 U.S.C. § 321(rr)(1)–(2). A better reading of this section may be “that products made or derived from tobacco that *are* marketed for therapeutic purposes are not ‘tobacco products’ within the meaning of the Tobacco Control Act, and are therefore subject to regulation under the . . . FDCA.” *Sottera*, 627 F.3d at 903 (Garland, J. concurring) (emphasis added).

146. 21 U.S.C. § 387a(c)(1) (2012).

147. *Id.* § 321(rr)(2).

148. Rather than exercise its undisputed jurisdiction to regulate e-cigarettes under the TCA, the FDA has spent more than a year litigating its right to regulate e-cigarettes under a statute not intended to authorize the regulation of customarily marketed tobacco products.

149. See *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 75, 78 (D.D.C. 2010).

150. *Sottera*, 627 F.3d at 893. In fact, Congress seemed to believe that tobacco products in general do not make therapeutic claims (as defined by the FDCA) because the TCA provides the FDA authority over tobacco products *without requiring* therapeutic claims. See §

not contest the e-cigarette manufacturer's claim that its products are not marketed for therapeutic use, the trial court discussed the issue in more detail in a prior action that was later consolidated.¹⁵¹ In *Smoking Everywhere*, the court held that the FDA had no authority to treat e-cigarettes as drug-device combination under the FDCA when they only purport to offer consumers the same recreational effect as a combustible cigarette.¹⁵² According to the court, the fact that e-cigarettes *may* be used by consumers as a way to treat nicotine addiction without turning to combustible cigarettes did not require e-cigarettes to be classified as a therapeutic product.¹⁵³ The court made clear that "the 'intended use' of a product is determined by 'the objective intent of the persons legally responsible' for labeling the product."¹⁵⁴ Here, the court found that the FDA's claim was unsupported by the required "substantial evidence" that *Smoking Everywhere* objectively intended to market its products as therapeutic.¹⁵⁵

In fact, e-cigarette manufacturers likely want the exact opposite of smoking cessation. The FDA's claim that e-cigarettes, like those in *Smoking Everywhere*, are objectively intended to "prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction" runs counter to the foundational business model of e-cigarettes: *keep* people addicted to nicotine while eliminating the other harmful additives found in combustible cigarettes.¹⁵⁶ An obvious, likely valid, assumption is that e-cigarette companies want to *encourage* rather than "prevent, mitigate, or treat" nicotine use.¹⁵⁷ If e-cigarettes are marketed as simply an alternative to combustible cigarettes, it is difficult, if not impossible, for the FDA to meet its burden to show that e-cigarettes are objectively intended to treat nicotine addiction and withdrawal.¹⁵⁸ Per the

321(rr)(1) (making no reference to therapeutic-claiming tobacco products).

151. *Sottera*, 627 F.3d at 898–99; see *Smoking Everywhere*, 680 F. Supp. 2d at 73–75.

152. *Smoking Everywhere*, 680 F. Supp. 2d at 73–74.

153. *Id.* at 73–75.

154. *Id.* at 73; see 21 C.F.R. § 201.128 (2013) (defining intended use of a product by looking at "the objective intent of the persons legally responsible for" labeling the product). It should be noted that the regulation cited refers to products that are drugs, which e-cigarettes are not, but a similar labeling standard under the TCA may be applied to require e-cigarette manufacturers to make clear on their packaging that their product is not intended for a therapeutic use, but instead for recreational use. *Id.*

155. *Smoking Everywhere*, 680 F. Supp. 2d at 73.

156. *Id.* (internal quotation marks omitted). The company name itself, "Smoking Everywhere," likely illustrates the company's intent as well.

157. *Id.* at 74.

158. *Id.* at 73. If e-cigarette manufacturers *did* change their current marketing strate-

court's decision, e-cigarettes are marketed and intended as recreational smoking devices and, thus, cannot be regulated under the FDCA.¹⁵⁹

Although tobacco products making express therapeutic claims properly fall within the FDA's jurisdictional authority under the drug/devices provisions of the FDCA, e-cigarette manufacturers do not make these therapeutic claims. As of now, e-cigarettes manufacturers not making therapeutic claims remain outside the scope of the FDCA. A look at the University Medical and Dental School of New Jersey's webpage, which organizes a large collection of cigarette and tobacco advertising, reveals that several e-cigarette advertisements feature the product's ability to be smoked anywhere, leave no adverse smell, allow a user to inhale no tar or smoke, and mitigate social stigma.¹⁶⁰ These types of advertisements hardly portray e-cigarettes as "therapeutic" in a broad sense of the word, let alone within the narrowed meaning of "therapeutic" defined by the FDCA.¹⁶¹ To avoid confusion about what constitutes an "objective intent" to market e-cigarettes as therapeutic, and therefore triggers regulation under the stricter FDCA, the FDA should issue a guidance document directed at the e-cigarette industry clarifying or giving examples of what is and is not a therapeutic claim.

2. *Brown & Williamson* and the Absurd Result of Regulating E-Cigarettes Under the FDCA

Finally, the FDA's contention in *Sottera* and *Smoking Everywhere* that nicotine is a drug, is excluded from the definition of "tobacco product," and therefore can be regulated under the FDCA produces an absurd result Congress most likely did not intend.¹⁶² As discussed in the Supreme Court's decision in *Brown &*

gies and began advertising their products as therapeutic, then FDCA regulation is more viable.

159. *Id.* at 74 n.15 (noting an express disclaimer on the packaging that the product is not a smoking cessation device).

160. *Trinkets & Trash: Artifacts of the Tobacco Epidemic*, RUTGERS SCH. OF PUB. HEALTH, <http://trinketsandtrash.org> (last visited Apr. 14, 2014) (using the "Category" box, search for "E-cigarettes").

161. See 21 C.F.R. § 3.2 (2013) (defining, within another definition, "'therapeutic' action or effect [to] include[] any effect or action . . . intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body").

162. *Smoking Everywhere*, 680 F. Supp. 2d at 70, 75.

Williamson, if the FDA had authority to regulate cigarettes and smokeless tobacco under the FDCA, then the FDA would effectively be required to ban them.¹⁶³ Because the FDA has repeatedly found that “tobacco products” are “unsafe,” “dangerous,” and that “[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined,” tobacco products would necessarily be immediately removed from the market.¹⁶⁴ Importantly, the FDCA allows the FDA to forbid the introduction of “any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded,” and defines a misbranded drug or device as one “dangerous to health when used in the dosage or manner . . . suggested in the labeling.”¹⁶⁵ Therefore, given the FDA’s conclusion that tobacco is dangerous and unsafe, the FDCA likely would require the FDA to ban tobacco products as “misbranded” drugs. Further, there is no viable option available after tobacco products are labeled misbranded as there are no labeling options that provide “adequate directions for use . . . necessary for the protection of users” because use, in and of itself, endangers and harms users.¹⁶⁶ These labeling problems are somewhat expected given that e-cigarettes are not intended to treat nicotine addiction; instead they simply provide a less risky, recreational alternative to combustible cigarettes that already “endanger” their users.

Additionally, section 360c(a) of the FDCA requires the FDA to place regulated devices into one of three classifications based on a “reasonable assurance of safety and effectiveness.”¹⁶⁷ While the FDA has not classified tobacco products under the FDCA (because they do not have the authority to regulate them under the FDCA), it is safe to assume that they would be placed in Class III because they “present[] a potential unreasonable risk of illness or injury” based on the FDA’s prior findings regarding tobacco.¹⁶⁸ As a Class III device, tobacco products would be subject to pre-

163. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137 (2000).

164. *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996).

165. 21 U.S.C. § 331(a) (2012); *id.* § 352(j) (2012).

166. *Id.* § 352(f).

167. *Id.* § 360c(a)(1)(A)–(C) (2012).

168. *Id.* § 360c(a)(1)(C)(ii); *see Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. at 44,398.

market approval, which requires a “showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.”¹⁶⁹ The language “safe under the conditions of use prescribed” is directed at drugs and devices intended to treat various health conditions or products making therapeutic claims, hence, when applied to e-cigarettes the result is nonsensical because e-cigarettes do not *treat* a health condition nor do they make therapeutic claims.¹⁷⁰ Further, viewing these provisions in parallel with the TCA leads to a direct conflict. Section 387g of the TCA expressly prohibits the FDA from “requiring the reduction of nicotine yields of a tobacco product to zero” which, if e-cigarettes were regulated under the FDCA, would be the result.¹⁷¹ Again, there does not seem to be a feasible way for the FDA to make a finding of “reasonable safety” in regard to tobacco products based on their past findings of dangerousness.¹⁷²

The convoluted, cumbersome nature of regulating tobacco products under the FDCA may be one of the reasons Congress enacted an entire tobacco-specific statute, the TCA, to begin with. Reviewing the relevant substantive provisions of the FDCA demonstrates that the FDCA’s drug/device regulation focuses on items intended to benefit public health—the focus is not on products like e-cigarettes that *lack* a therapeutic purpose. The FDCA is not a regulatory option for the FDA, and instead of making additional repackaged arguments under the statute that courts like the *Smoking Everywhere* court will inevitably reject, the FDA should focus its regulatory efforts where they are properly received: under the TCA, using a minimalist scheme to regulate basic product safety while keeping e-cigarettes available to those who use, and often rely, on them.¹⁷³

169. 21 U.S.C. § 360e(d)(2)(A) (2012).

170. *Id.* § 360e(a)(1)(C)(ii); see *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010); *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 73 (D.D.C. 2010).

171. 21 U.S.C. § 387g(d)(3) (2012).

172. See *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. at 44,412 (specifically using the phrase “reasonable assurance that the device is safe”).

173. Jordan Paradise, *No Sisyphian Task: How the FDA Can Regulate Electronic Cigarettes*, 13 YALE J. HEALTH POL’Y L. & ETHICS 326, 362, 369, 371, 374 (2013). The FDA has already been chastised for “ironically, notwithstanding that Congress has now taken the unprecedented step of granting FDA jurisdiction over [tobacco] products, . . . remain[ing] undeterred.” *Smoking Everywhere*, 680 F. Supp. 2d at 78.

IV. A MINIMALIST FEDERAL REGULATORY SCHEME IS MOST BENEFICIAL TO THE PUBLIC

E-cigarettes need to be available to the public, where they can be incredibly effective at reducing the enormous, adverse impact that smoking combustible cigarettes has on human health, instead of caught up in a regulatory web that likely will take years to be formally approved.¹⁷⁴ The Center for Disease Control has made clear that “[i]n both 2010 and 2011, e-cigarette use was significantly higher among *current* smokers compared to both former and never smokers.”¹⁷⁵ This supports the idea that e-cigarettes are not primarily attracting non-smokers, but instead are providing an alternative to those who smoke combustible cigarettes. This Part argues that the FDA should utilize its TCA authority to regulate e-cigarettes in the most efficient manner to ensure that they remain available to consumers that want to use them while providing a basic threshold of safety. A British study of smoking reductions over the past fifty years attributes a large amount of the success in cutting back to political leadership with “a pragmatic willingness to apply measures that are likely to work in the public interest.”¹⁷⁶ A minimalist regulatory scheme would illustrate the FDA’s pragmatic willingness to work in favor of the public interest, not against it.

The minimalist regulatory regime proposed in this Part is centered on the fact that “if we get all tobacco smokers to switch from regular cigarettes (to electronic cigarettes), we would eventually reduce the US death toll from more than 400,000 a year to less than 4,000, maybe as low as 400.”¹⁷⁷ In a recent study, the RCP predicts that the “[m]arket could be opened to a new generation of innovative nicotine products that will provide smokers with an opportunity to choose an effective low-hazard alternative that is

174. Even the Center for Disease Control concedes that e-cigarettes “appear to have far fewer of the toxins found in smoke compared to traditional cigarettes.” *About One in Five U.S. Adult Cigarette Smokers Have Tried an Electronic Cigarette*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/media/releases/2013/p0228_electronic_cigarettes.html (last visited Apr. 14, 2014).

175. *Id.* (emphasis added).

176. ROYAL COLL. OF PHYSICIANS, FIFTY YEARS SINCE SMOKING AND HEALTH: PROGRESS, LESSONS AND PRIORITIES FOR A SMOKE-FREE UK 54 (2012) [hereinafter FIFTY YEARS], available at <http://www.rcplondon.ac.uk/sites/default/files/fifty-years-smoking-health.pdf>.

177. *New Year’s Resolution*, *supra* note 29.

attractive and competitive with cigarettes at the point of sale.”¹⁷⁸ However, overregulation of a product that does not need it would make these options virtually non-existent for smokers today. E-cigarettes have many advantages over combustible cigarettes and by creating a minimalist regulatory scheme under the TCA that regulates advertising, labeling requirements, and general product standards involving safety and proper function, these advantageous products can remain available on the market to help potentially reduce the U.S. tobacco-related death toll.

A. *The Advantages of E-Cigarettes over Combustible Cigarettes and Other Tobacco Products*

While e-cigarette manufacturers have received substantial criticism for touting their product as a healthy alternative to traditional, combustible cigarettes, there is no dispute that e-cigarettes simply do not contain many unhealthy components that combustible cigarettes do contain. There is no real scientific dispute over the fact that switching to vaping e-cigarettes instead of smoking combustible cigarettes means users can avoid the myriad of toxins and other carcinogens created by tobacco combustion.¹⁷⁹ For example, e-cigarettes do not contain any carbon monoxide.¹⁸⁰ Carbon monoxide, at low levels of exposure, such as those present when a user smokes a combustible cigarette, causes “headaches, dizziness, disorientation, nausea and fatigue.”¹⁸¹ Likewise, e-cigarettes lack the vast number of chemical components found in combustible cigarettes such as arsenic, formaldehyde, and vinyl chloride.¹⁸² These chemicals, along with the other

178. See FIFTY YEARS, *supra* note 176, at 53–54.

179. Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH. POL’Y 16, 27–28 (2011) (“[E]lectronic cigarettes are a much safer alternative to tobacco cigarettes.”).

180. Andrea R. Vansickel et al., *A Clinical Laboratory Model for Evaluating the Acute Effects of Electronic “Cigarettes”: Nicotine Delivery Profile and Cardiovascular and Subjective Effects*, 19 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1945, 1945, 1952 (2010), available at <http://cebp.aacrjournals.org/content/19/8/1945.full.pdf+html?sid=709e3fee-2ccc-41e4-bb63-d9f303ae08f4>.

181. *An Introduction to Indoor Air Quality (IAQ): Carbon Monoxide (CO)*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/iaq/co.html> (last visited Apr. 14, 2014).

182. See Cahn & Siegel, *supra* note 179, at 18 (noting that the primary components of e-cigarettes are propylene glycol, nicotine, and glycerin); *Harms of Smoking and Health Benefits of Quitting*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cessation> (last visited Apr. 14, 2014).

250 harmful chemicals in tobacco smoke can cause health risks such as cancer, heart disease, stroke, and asthma.¹⁸³ The dangerous chemicals listed above simply are not found in e-cigarettes and therefore pose no risk to e-cigarette users.

Further, e-cigarettes can serve as a valuable harm reduction device—one that can reduce tobacco-related death and disease much more rapidly than a reduction of nicotine use.¹⁸⁴ E-cigarettes have the potential to be more effective at moving smokers away from traditional cigarettes than traditional nicotine reduction devices, such as the nicotine patch or nicotine gum, because e-cigarettes provide the nicotine as well as simulate the physical act of smoking, creating a psychological placebo effect increasing the rate of cigarette abstinence.¹⁸⁵ The tactile feel of an e-cigarette, and the hand-to-mouth action of vaping one, has a physiological and psychological impact on users, albeit to a lesser degree than combustible cigarettes, that mimics the effects of ingesting nicotine.¹⁸⁶ Studies have also shown that nearly half of vapers using e-cigarettes as a smoking cessation tool stopped smoking combustible cigarettes as a result of using an e-cigarette.¹⁸⁷

Seeing that e-cigarettes expose users to less of the harmful chemicals in cigarettes and carcinogens in cigarette smoke, the FDA's concerns about greater potential public harm resulting from e-cigarettes are entirely speculative. The FDA has acknowledged that there is little scientific data addressing the health risks of e-cigarettes because they have been subject to little testing and analysis, making the long-term health consequences unknown.¹⁸⁸ While there are scattered scientific opinions asserting that nicotine and potential contaminants in e-cigarettes pose risks to smokers because nicotine itself is addictive and potentially harmful in high doses, the FDA's own analysis of e-cigarettes

183. *Harms of Smoking and Health Benefits of Quitting*, *supra* note 182.

184. David Sweanor et al., *Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic*, 18 INT'L J. DRUG POL'Y 70, 74 (2006), available at <http://www.sciencedirect.com/science/article/pii/S0955395906002416>.

185. See Cahn & Siegel, *supra* note 179, at 22–23, 26; Caponnetto et al., *supra* note 2, at 16.

186. See Caponnetto et al., *supra* note 2, at 16.

187. Michael B. Siegel et al., *Electronic Cigarettes as a Smoking-Cessation Tool: Results from an Online Survey*, 40 AM. J. PREVENTIVE MED. 472, 472 (2011).

188. See *Electronic Cigarettes*, *supra* note 48.

undermines these opinions.¹⁸⁹ The amount of nicotine in e-cigarettes is often¹⁹⁰ comparable to the amount of nicotine in combustible cigarettes, but, as previously discussed, nicotine itself is not harmful.¹⁹¹

The amount of nicotine in e-cigarettes found in the FDA study was considerably lower than the amount of nicotine in combustible cigarettes.¹⁹² The study detected “[t]obacco specific nitrosamines and tobacco specific impurities [“TSI”],” but at “very low levels.”¹⁹³ If the FDA removed e-cigarettes from the market due to their TSI levels, their reasoning would be circular and they would waste time approving a constituent—TSI—that has *already* been approved at *equal* levels as those found in e-cigarettes.¹⁹⁴ That said, the levels of nicotine and TSIs found in e-cigarettes, by the FDA itself, can hardly amount to a significant public danger that the FDA needs to address by unleashing its full regulatory powers under the TCA. Writer Jacob Sullum aptly summarizes the argument for limited federal government regulation of e-cigarettes: “[R]egulations will restrict information about and access to a potentially lifesaving product, thereby increasing smoking-related illness and death in the name of public health and consumer protection.”¹⁹⁵ This potential result is clearly contrary to the FDA’s primary purpose to protect public health and can easily

189. Memorandum from B.J. Westenberger, Deputy Dir., CDER/OPS/OTR, Div. of Pharmaceutical Analysis, to Michael Levy, Supervisor Regulatory Counsel, CDER, Office of Compliance, Div. of New Drugs & Labeling Compliance (May 4, 2009) [hereinafter Westenberger Study] (emphasis added), available at <http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf> (“Tobacco specific nitrosamines and tobacco specific impurities were detected in both products at *very low levels*”); see also Cahn & Siegel, *supra* note 179, at 18 (stating that the amount of tobacco-specific nitrosamines, a tobacco contaminant “is orders of magnitude lower than TSNA levels in regular cigarettes”).

190. “Often” is used because some e-cigarettes that have been tested provided more nicotine than what the product was labeled to deliver; this can be solved using the later described minimalist regulatory scheme’s focus on product standards. See *infra* Part IV.B.2.

191. See Cahn & Siegel, *supra* note 179, at 22; see also *infra* Part II.A.2.

192. See Cahn & Siegel, *supra* note 179, at 22; Westenberger Study, *supra* note 189, at 2–3.

193. Westenberger Study, *supra* note 189, at 1.

194. Riccardo Polosa et al., *A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette*, HARM REDUCTION J., Oct. 2013, at 1, 4, available at <http://www.harmreductionjournal.com/content/pdf/1477-7517-10-19.pdf> (“[T]his amount [of TSI] is equal to the quantity reported to be present in a nicotine medicinal patch.”); see also Cahn & Siegel, *supra* note 179, at 18 (“[W]e already have more comprehensive knowledge of the chemical constituents of electronic cigarettes than tobacco ones.”).

195. Jacob Sullum, *No Smoke, Yet Ire*, REASON.COM (Oct. 23, 2013, 7:00 AM), <http://reason.com/archives/2013/10/23/no-smoke-yet-ire>.

be avoided through a loose regulatory scheme promulgated under the TCA.

B. Where the FDA Should Focus Its TCA Regulatory Authority over E-Cigarettes

Pursuant to its TCA authority, the federal government should issue guidelines for the categories listed in this section that e-cigarette manufacturers would be required to abide by when promoting and developing their products. These guidelines, as detailed in each respective section, should aim to maintain a balance between keeping the majority of e-cigarettes on the market and preventing advertising and sale to minors. By leaving most e-cigarettes on the market while only removing those that clearly have adverse health risks, e-cigarette users will be able to continue reaping the benefits of vaping an e-cigarette over smoking a combustible cigarette or using any other tobacco product.

1. Advertising and Sale to Minors

If the FDA is concerned that e-cigarettes are being marketed to minors, the TCA ensures that the FDA “has the authority to address . . . the use of tobacco by young people.”¹⁹⁶ Though the FDA has not explicitly regulated e-cigarette advertising through the TCA, it would be wise to include e-cigarette advertising with combustible cigarettes under the statute because the advertising and promotion concerns with both products are identical: warning the public about the hazards of smoking and “protect[ing] the public . . . from being inundated with images of cigarette smoking in advertising.”¹⁹⁷ By regulating e-cigarettes in the same manner as combustible cigarettes, the FDA should prevent television, internet, radio, and billboard advertisements for e-cigarettes, all of which are “advertising and promotion of the tobacco product.”¹⁹⁸ However, e-cigarette advertisements should be available at the point of sale wherever combustible cigarettes can be purchased in order to present a potentially lower-risk alternative.

196. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, § 3(2), 123 Stat. 1776, 1781 (2009).

197. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 547–48 (2001).

198. 21 U.S.C. § 387f(d)(1) (2012).

The effect of tobacco marketing and promotion on America's youth is probably the largest concern encompassed in the TCA, and therefore, e-cigarette regulations should protect minors.¹⁹⁹ Nearly half of the congressional findings in the TCA that address the impact and effects of smoking and tobacco marketing on younger populations evidence clear congressional concern.²⁰⁰ One of the findings, in particular, summarizes this idea: "The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults."²⁰¹ To serve this primary purpose of the TCA, the FDA should devise a regulatory scheme that balances limiting minors' exposure to e-cigarettes with allowing e-cigarettes to remain available to informed adults. By requiring identification at purchase and restricting online e-cigarette sales to websites that are able to accurately check a purchaser's age, the FDA could drastically curb e-cigarette sales to minors, because currently, e-cigarettes are mainly sold over the Internet on sites where minors are often not being screened for their age when purchasing products.²⁰² Though many states have enacted legislation to prohibit sale of e-cigarettes to minors, this simply illustrates the need for the FDA to move quickly in proposing regulations that would fill the regulatory gaps the states have begun to fill.²⁰³ After promulgation of a federal rule on e-cigarette advertising and sales to minors, an expansive preemption clause to the TCA should preempt state laws to avoid differing piecemeal legislation enacted by various states.

The FDA should also prohibit advertising and other marketing techniques that are clearly intended to target minors.²⁰⁴ The use of candy-like flavorings such as grape, vanilla, and chocolate tends to only appeal to young people and likely would not help adults smoking combustible cigarettes switch to a potentially

199. *See id.* § 387 note (2012) (Findings).

200. *See id.*

201. *Id.* (Findings subsec. 1).

202. Customers can purchase e-cigarettes and any other necessary supplies from mall kiosks and other specialty locations, but a large marketplace for e-cigarettes is the Internet. *See Fisher, supra* note 80; Ilya Pozin, *Electronic Cigarettes: Booming Industry or Health Fiasco?*, FORBES (Apr. 4, 2013), <http://www.forbes.com/sites/ilyapozin/2013/04/11/electronic-cigarettes-booming-industry-or-health-fiasco/>.

203. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 119405(a) (West 2012) (making it unlawful to sell an e-cigarette "to a person under 18 years of age").

204. E-cigarettes have received significant criticism for allegedly targeting youth, especially because of their flavored nicotine cartridges. *See, e.g.*, Bridget M. Kuehn, *FDA: Electronic Cigarettes May Be Risky*, 302 J. AM. MED. ASS'N 937, 937 (2009).

less-harmful e-cigarette instead.²⁰⁵ Despite this implicit attempt to market e-cigarettes to minors, evidence suggests that e-cigarette manufacturers have not been too successful in attracting minors that are new to tobacco products. Nine out of ten teenagers who tried e-cigarettes were already smokers, meaning that e-cigarettes may actually serve as a successful harm reduction technique keeping teens from using combustible cigarettes laced with many more toxic and carcinogenic chemicals.²⁰⁶ Further, less than ten percent of students surveyed from the sixth to twelfth grades who have used e-cigarettes had never smoked a combustible cigarette, and it very well could be that those students would have used combustible cigarettes instead of starting with e-cigarettes.²⁰⁷ Based on these survey results, e-cigarettes are largely *not* attracting minors who have never smoked before, but the government's interest in protecting minors from nicotine addiction still justifies regulating e-cigarette advertisements.

Although evidence suggests that e-cigarettes may actually help minors and adults who smoke find a potentially less-hazardous alternative to cigarettes, regulating advertising and sales to minors similarly to combustible cigarettes upholds the overriding purpose of the TCA. If an adult or a minor is *not* addicted to nicotine or smoking cigarettes, it cannot be in the best interest of public health to attract new users to what could be a dangerous hobby-come-addiction.²⁰⁸ Removing flavoring additives and tempting advertisements from the airwaves would help prevent attracting new tobacco product users, but allowing some e-cigarette advertisements where combustible cigarettes are traditionally sold, such as convenience stores, would best serve the public interest by having the option of a potentially less harmful nicotine delivery system available.

205. 21 U.S.C. § 387g(a)(7)(A) (2012) (noting that flavoring or coloring additives have been banned from cigarettes in light of the fact that they might potentially be attractive to minors); *id.* § 387(1) (defining additives to include “any substances intended for use as a flavoring or coloring”); see Kuehn, *supra* note 204, at 937.

206. See Jacob Sullum, *CDC Belatedly Reveals That Smoking By Teenagers Dropped While Vaping Rose*, FORBES (Nov. 20, 2013), <http://www.forbes.com/sites/jacobsullum/2013/11/20/cdc-belatedly-reveals-that-smoking-by-teenagers-dropped-while-vaping-rose/>.

207. *Notes From the Field: Electronic Cigarette Use Among Middle and High School Students—United States, 2011–2012*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 6, 2013), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>.

208. Congress found that “[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products.” 21 U.S.C. § 387 note (Findings subsec. 4).

2. Labeling and Product Standards

The TCA grants the FDA authority to establish labeling and product standards for tobacco products, and the FDA should utilize this authority to ensure e-cigarette users are accurately informed about the product they are using.²⁰⁹ The FDA should promulgate a simple label requirement that e-cigarette packaging contain some form of a nicotine comparison chart and a statement that the product is not FDA approved. The “not FDA approved” label, which would include a short list of the potentially harmful chemicals in e-cigarettes, would serve as a sufficient warning to consumers that the product is not, in a sense, backed by the FDA. Moreover, a short list of only the potentially harmful chemicals in e-cigarettes would be sufficient to communicate any necessary information to consumers curious about the safety of the product. Combustible cigarette labels are only required to report amounts of twenty different harmful chemicals on their packaging, making it illogical to require e-cigarette manufacturers to disclose more.²¹⁰ This requirement may actually work in favor of e-cigarettes, though, as instead of smokers being inundated with the long list of harmful chemicals on the side of a cigarette pack, e-cigarette users would probably only be confronted with a short list of essentially all the ingredients: propylene glycol, water, nicotine, and glycerin.²¹¹

In addition to labeling requirements, the FDA should regulate e-cigarettes to ensure product standards are met and that the labeling on e-cigarette products contains accurate information. Despite the fact that e-cigarette devices themselves rarely malfunction, consistency in product standards should be universal because e-cigarettes have been shown, though very infrequently, to contain the wrong dosages of nicotine when compared with the amount advertised.²¹² This could lead to consumer misinformation

209. *Id.* § 387g(a)(4)(C).

210. See Anna Yukhananov, *FDA: Big Tobacco Must Tell You What You're Smoking*, REUTERS (Mar. 30, 2012), <http://www.reuters.com/article/2012/03/30/fda-tobacco-idUSL2E8EU7DV20120330>.

211. See Caponnetto et al., *supra* note 2, at 13.

212. See, e.g., *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/newsevents/publichealthfocus/ucm173146.htm> (last updated July 22, 2009) [hereinafter *Summary of Results*] (“Three different electronic cigarette cartridges with the same label were tested and each cartridge emitted a markedly different amount of nicotine with each puff. The nicotine levels per puff ranged from 26.8 to 43.2 mcg nicotine/100 mL puff.”).

as well as consumers ingesting higher levels of nicotine than they intended.²¹³ If e-cigarettes are being used to control nicotine intake without the additional chemicals that combustible cigarettes contain, then it is critical that this information is clearly and accurately communicated to consumers.

A simple regulation that would allow a universal product standard that could be easily and efficiently checked by the FDA is a simple light system on the e-cigarette itself.²¹⁴ If all e-cigarette manufacturers attached a sensor system on their e-cigarettes that measured the amount of nicotine passing through the atomizer and logged these amounts on a light scale, they could quickly and accurately convey the necessary information to the consumer.²¹⁵ While this would likely increase the cost of e-cigarettes, it is less costly than having the product taken off the market and unavailable for sale. A light system, with each increment notating a fixed amount of nicotine inhaled, could also be easily checked by the FDA for accuracy: simply check if the amount of nicotine released and the light reading match. If a device is not working properly or transmitting the wrong information, the FDA could label the product as “misbranded” until the specific manufacturer fixed the issue.²¹⁶ Regulation of the devices themselves does not appear to be necessary as incident reports are incredibly rare and can be properly handled through another legal avenue such as products liability.²¹⁷

While e-cigarette labeling has, at times, been inconsistent in properly communicating to users the amount of nicotine consumed in using an e-cigarette, studies have shown that e-cigarettes still generally appear to deliver less nicotine than combustible tobacco cigarettes.²¹⁸ Despite delivering fewer carcino-

213. *See id.*

214. *See Paradise, supra* note 173, at 371.

215. The apparent assumption is that the sensors would work and be accurate.

216. 21 U.S.C. § 387c (2012) (articulating criteria for being labeled as “misbranded”).

217. There have been relatively few reported injuries in the United States from e-cigarette use. For a product that has been on the market for several years, having relatively few reported accidents is incredibly impressive. *See* Mikaela Conley, *Man Suffers Severe Injuries After E-Cigarette Explodes in His Mouth*, ABC NEWS (Feb. 15, 2012), <http://abcnews.go.com/Health/electric-cigarette-explodes-fla-mans-face/story?id=15645605>; *Electronic Cigarette Explodes in Muskogee Woman's Hand*, FOX23.COM (Apr. 18, 2012), <http://www.fox23.com/mostpopular/story/Electronic-cigarette-explodes-in-Muskogee-womans/ek2x6P6rvkyLu5cMrvGwVQ.csp>.

218. Richard J. O'Connor, *Non-cigarette Tobacco Products: What Have We Learnt and Where Are We Headed?*, 21 TOBACCO CONTROL 181, 183–84 (2012). Further, although the

gens and less nicotine than combustible cigarettes, e-cigarettes should still be regulated to assure that the products are clearly and accurately conveying information to their user. A simple note (“not FDA approved”), short ingredient list, and nicotine light system could be utilized to convey adequate, accurate information to consumers using e-cigarettes while also keeping the products available to the public.

B. *Additional TCA Provisions the FDA Should Focus on Less*

Aside from advertising, sale to minors, product labeling, and product standards, the FDA should abstain from asserting any other regulatory authority under the TCA. Instead, basic guidelines for e-cigarette manufacturers to reference when developing their products would be enormously helpful in developing a safe and effective product for those looking for an alternative to combustible cigarettes while keeping e-cigarettes on the market and available to those who could benefit from them.

1. Disclosure of Ingredients and Pre-Market Approval

The TCA gives the FDA sweeping regulatory power when it comes to ingredient disclosure and reporting, but because of the scrutiny e-cigarettes have already received prior to any successful FDA regulatory attempts, the FDA already has most of this data. Specifically, though, the TCA authorizes the FDA to require testing and reporting of ingredients by each e-cigarette manufacturer.²¹⁹ While all ingredients must be disclosed, it appears most important that the “harmful and potentially harmful constituents” (“HPHC”) be reported in accordance with the FDA’s updated HPHC list.²²⁰ This will make a required disclosure quite simple. While this list appears daunting and akin to a regulatory inferno, the benefit with e-cigarettes is that “we actually have a much bet-

FDA can regulate nicotine yield standards under the TCA as well, because e-cigarettes generally deliver less nicotine than combustible cigarettes, setting a requirement consistent with that for tobacco cigarettes would likely not have an effect on the e-cigarette industry. See 21 U.S.C. § 387g(a)(4)(A)(i) (2012).

219. 21 U.S.C. § 387d (2012).

220. *Id.* § 387d(e); *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm> (last visited Apr. 14, 2014).

ter idea what is in electronic cigarette vapor than what is in tobacco smoke.”²²¹ E-cigarettes have fewer toxic effects than traditional cigarettes and evidence also suggests that they are safer than traditional cigarettes—arguments that e-cigarettes are not safe nearly all stem from the argument that there is *not enough* information to declare them safe rather than definitive evidence to say that e-cigarettes are actually not safe.²²² Granted, e-cigarettes surely bring a general uncertainty due to their novelty, but all of the actual ingredients found in e-cigarettes have been studied, and approved, in one form or another by the FDA. In fact, the ingredients that predominantly compose e-cigarettes are water, nicotine, propylene glycol, and glycerin: all of which are safe or have been formerly approved by the FDA.²²³ Consequently, because the FDA has already approved all the e-cigarette ingredients, requiring further testing is simply inefficient.

The FDA keeps a running list of potential e-cigarette risks on its website to keep consumers informed about the products.²²⁴ As a result of several scientific studies, the agency found carcinogenic materials in e-cigarettes that may be transmitted to users.²²⁵ However, the chemical contaminants found by the FDA, particularly nitrosamines, exist in e-cigarettes at an immensely lower rate than in approved combustible cigarettes.²²⁶ Even within the same nicotine alternatives industry, nicotine patches that often contain the same amount of nitrosamines have been approved by

221. Jacob Sullum, *The Lunatic War on E-Cigarettes*, N.Y. POST (Oct. 23, 2013), <http://www.nypost.com/2013/10/23/the-lunatic-war-on-e-cigarettes/> (internal quotation marks omitted) (statement of public-health professor Michael Siegel).

222. See O'Connor, *supra* note 218, at 184.

223. See Caponnetto et al., *supra* note 2, at 13. Water is obviously not harmful and for a more detailed analysis of nicotine, see *supra* Part III.A. Propylene glycol is approved by the FDA for many different pharmaceuticals, has undergone extensive testing, and is used in many different food and other consumer products. See *id.*

224. *Electronic Cigarettes*, *supra* note 48. According to the FDA's website, there may be risks in the normal operations of e-cigarettes given that there have been reports of various e-cigarette related illnesses and hospitalizations. *Id.*; see also *FDA Warns of Health Risks Posed by E-Cigarettes*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/consumerupdates/ucm173401.htm> (last visited Apr. 14, 2014) (reiterating the FDA's concern about e-cigarettes' risks including increased addiction among young people, potential for youth to experiment with other tobacco products, and the uncertainty of potentially toxic ingredients).

225. See *Electronic Cigarettes*, *supra* note 48; see also *Summary of Results*, *supra* note 212.

226. See Cahn & Siegel, *supra* note 179, at 18 (finding that combustible cigarettes contain 500 to 1400 times the amount of nitrosamines than what the FDA found in e-cigarettes).

the FDA as safe and effective.²²⁷ Only trace amounts of nitrosamines in the “high nicotine” cartridge of one brand of e-cigarettes was found at a similar amount already present in a nicotine patch.²²⁸ E-cigarettes, based on their ingredients, must be considered safe, or at least much safer than their combustible cigarette counterparts. Therefore, the isolated incidence of nitrosamines in e-cigarettes should not require the FDA to further regulate e-cigarettes beyond the extent suggested above because conventional cigarettes and other nicotine delivery devices have similar, or greater, nitrosamine levels.

The FDA has also discovered other harmful chemicals, glycerin and diethylene glycol (“DEG”), in some e-cigarette fluid, but yet again the substances were only found in a small sample of e-cigarettes at a very low rate.²²⁹ In fact, after finding DEG in one cartridge tested in 2009, at least fifteen studies were conducted by different researchers and all failed to find any evidence of this chemical in any other e-cigarettes.²³⁰ When the FDA actually found DEG in *one* of the eighteen e-cigarettes samples, the substance only composed one percent of the nicotine fluid, which is not a toxic quantity for humans.²³¹ While seeing DEG on an ingredient list may be troubling for some, recognizing its very minimal, non-toxic presence in e-cigarettes should calm concern.

E-cigarette manufacturers should submit their full ingredient listings to the FDA, but due to the testing that has already been done on the products, the lack of significant findings, and the potential that e-cigarettes have to counteract the harmful effects of smoking combustible cigarettes, the FDA should not require any form of pre-market approval for e-cigarettes already being sold. Pre-market approval of new e-cigarettes entering the market should simply entail demonstrating that the product is nearly identical to those already on the market. The logic behind allowing e-cigarettes to stay on the market is simple: e-cigarettes “de-

227. Daniel F. Hardin, *Blowing Electronic Smoke: Electronic Cigarettes, Regulation, and Protecting the Public Health*, 2011 U. ILL. J.L. TECH. & POL'Y 433, 446 (2011); see Caponnetto et al., *supra* note 2, at 14 tbl.1.

228. See Caponnetto et al., *supra* note 2, at 13, 14 tbl.1.

229. See *Summary of Results*, *supra* note 212.

230. Cahn & Siegel, *supra* note 179, at 18; Roxanne Palmer, *E-Cigarettes as Effective as Nicotine Patches in Helping Smokers Quit: Study*, INT'L BUS. TIMES (Sept. 8, 2013), <http://www.ibtimes.com/e-cigarettes-effective-nicotine-patches-helping-smokers-quit-study-1403523>.

231. See Caponnetto et al., *supra* note 2, at 13–14.

liver a nicotine vapor *without* the combustion products . . . responsible for nearly all of [combustible cigarette] smoking's harmful effects."²³² When given only the options of smoking cigarettes or completely giving up nicotine, many smokers will refuse to give up cigarettes and, instead, will continue their addiction; this is the scenario the FDA could force e-cigarette users into.²³³ The FDA should not be forcing the people it is responsible for protecting into a harmful scenario. The ingredients in e-cigarettes may certainly contribute to nicotine dependence, "but the desire of a cigarette-free world is just that—a dream. . . . [especially because of] nicotine's beneficial effects such as the improved ability to pay attention, concentrate and remember, as well as the capacity of relieving symptoms of mood impairments."²³⁴ A pragmatic response by the FDA, in the best interest of the public health, is to not require onerous regulatory procedures restricting and potentially eliminating access to these lower-risk products.

2. Products with Therapeutic Claims

As discussed, the FDA has jurisdictional authority to regulate e-cigarettes claiming therapeutic effects that are different than customarily marketed cigarettes, and at this point, courts have held that e-cigarettes do not make therapeutic claims.²³⁵ Congress was clear that the FDA should have authority over products expressly claiming a therapeutic benefit, but the FDA has not been clear about its interpretation of what constitutes a therapeutic product. The FDA should focus on making their interpretation of the FDCA more clear. Two and one-half years ago, the FDA considered issuing a guidance document regarding therapeutic claims and triggers for regulation as a drug or medical device, but it has failed to follow through.²³⁶ E-cigarette manufacturers only have prior case law to attempt to adhere to, but because of the novelty of the e-cigarette industry and the incessant attempts of the FDA to regulate e-cigarettes improperly under the FDCA, it is anything but clear what the FDA may consider a therapeutic claiming product.

232. *Id.* at 14.

233. *See id.* at 16.

234. *Id.*

235. *See supra* Part III.B.

236. *See* Deyton & Woodcock, *supra* note 15.

A large amount of e-cigarette advertising appears just like a recent FIN, an e-cigarette manufacturer, promotional: a bar scene where a few e-cigarette users are able to vape their e-cigarettes in public having vapor trailing behind them while doing it.²³⁷ While this type of commercial does not appear to advertise e-cigarettes as “therapeutic,” more guidance is necessary from the FDA to prevent e-cigarette manufacturers from unanticipated FDCA regulation should their promotion of the product make “therapeutic” claims.

C. State and Local Options and Smoking Bans

If e-cigarettes are eventually regulated under the TCA, the statute explicitly preserves the right of the state and local governments to restrict the sale, distribution, and possession of tobacco products as they see necessary.²³⁸ This can be done by tobacco tax laws, which arguably have the strongest effect on the price of tobacco products, but another option is through amending smoke-free laws that ban smoking to include a vaping ban.²³⁹ Smoke-free laws often define “smoking” as “the burning of . . . [any] matter or substance which contains tobacco or any other matter that can be smoked.”²⁴⁰ But e-cigarettes are not burned—instead they are vaped. Unless amended, these smoke-free laws likely will not cover e-cigarettes, but because these laws are primarily designed to protect non-consenting individuals in public from being exposed to dangerous secondhand smoke, e-cigarettes do not pose as large of a problem.²⁴¹ Regardless, states and locali-

237. *FIN Electronic Cigarettes: Rewrite the Rules*, YOUTUBE (May 25, 2013), http://www.youtube.com/watch?v=zvUFgVxs_7k.

238. 21 U.S.C. § 387p(a)(1) (2012). See generally Michael Freiberg, *Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products*, 21 ANNALS HEALTH L. 407 (2012) (discussing state and local regulatory options after enactment of the TCA).

239. Freiberg, *supra* note 238, at 416.

240. See, e.g., N.J. STAT. ANN. § 26:3D-57 (West 2006) (emphasis added).

241. See Letter from Kenneth T. Cuccinelli, II, Att’y Gen., Commonwealth of Va., to Christopher K. Peace, Member, House of Delegates, Commonwealth of Va. (Apr. 27, 2010), available at <http://www.oag.state.va.us/opinions%20and%20legal%20resources/opinions/2010opns/10-029-peace.pdf> (stating that traditional cigarettes burn “carbonaceous materials” with small particle byproducts, whereas vapor is similar to water evaporating from a tea kettle); see also Patrick Kabat, Note, “*Till Naught but Ash Is Left to See*”: *Statewide Smoking Bans, Ballot Initiative, and the Public Sphere*, 9 YALE J. HEALTH POL’Y L. & ETHICS 128, 136 (2009) (identifying secondhand smoke as a “serious public health hazard” per several Surgeons General). As recently as December 30, 2013, some localities have adopted legislation to regulate e-cigarette usage in the same way combustible cigarettes are regulated. See, e.g., Morgan Winsor, *Bloomberg Signs His Last 22 Bills; One Regulates*

ties believing their constituents would benefit from smoking bans amended to include e-cigarettes would likely be permitted to pass such laws by referring to the potential health risks associated with e-cigarettes and a locality's "current public health laws governing indoor smoking bans" because the federal government has "been slow to respond meaningfully" to e-cigarette regulation."²⁴² Notwithstanding, amending public smoking bans is an option available to states and localities that do not feel that a minimalist approach to e-cigarette regulation is sufficient.

States and localities are often uniquely situated to enforce a more personalized, effective regulatory regime simply based on their more localized concerns and deeper understanding of their respective constituents. Regarding e-cigarettes specifically, there is virtually no current federal regulation, and therefore, states and localities have been left with the opportunity to take regulatory initiative; they have done just that.²⁴³ The FDA need not remain absent from e-cigarette regulation, as discussed already, but an observation of the past few years suggests that states and localities are well-equipped to address regulatory gaps and increase protection where necessary. For example, in *Kuhn v. County of Suffolk* the Suffolk County, New York legislature found e-cigarettes to be harmful, issued a local law "banning the sale of e-cigarettes to individuals under nineteen," and banning the use of e-cigarettes in all public forums.²⁴⁴ Despite the petitioners contention that the law, Resolution No. 717-2009, was arbitrary and capricious, a court determined that the resolution was a valid exercise of governmental power because it had a rational basis, supported by facts and information, to anticipate a potential danger and "provide against it before it materializes."²⁴⁵ Presently, thirty-nine states, the District of Columbia, and 3964 municipalities have laws in place restricting smoking in public, similar to

E-Cigarette Use, CNN (Dec. 30, 2013), <http://www.cnn.com/2013/12/30/politics/mayor-bloomberg-last-bills/>.

242. Suffolk Cnty., N.Y., Res. No. 717, § 1 (Apr. 28, 2009). Again, this rationale is not necessarily consistent with the primary rationale behind most state-wide/local public smoking bans—to prevent smokers from imposing negative externalities on others by creating hazardous tobacco smoke—because there is no evidence that electronic cigarettes could create health hazards to anyone not directly using the product. See Thomas A. Lambert, *The Case Against Smoking Bans*, 13 MO. ENVTL. L. & POL'Y REV. 94, 95–96 (2005).

243. See, e.g., *Kuhn v. Cnty. of Suffolk*, No. 48869/2009, 2010 N.Y. Misc. LEXIS 5224 *2–3 (N.Y. Sup. Ct. Oct. 15, 2010).

244. *Id.* at *2–3.

245. *Id.* at *8–9.

the restriction in *Kuhn*, supporting the idea that states and municipalities certainly have the ability to react to their respective local conditions in a manner that is best for their constituents.²⁴⁶

There are several examples similar to Suffolk County, but, even where absent, a lack of local or state regulation does not mean that state or local government is unable to pass similar legislation. Instead, it may actually suggest that the respective locale does not believe a regulation is needed or that the state may believe e-cigarettes are a safer alternative to combustible cigarettes. Whereas areas like Suffolk County, a population-dense county making up over half of Long Island, may experience issues with e-cigarettes causing “fear, stress and confusion” in public places where combustible cigarettes are banned, other areas may not have the same issue.²⁴⁷ Less populous states like Nevada and Kentucky, for example, may actually want to encourage their combustible cigarette-saturated counties to make the switch to e-cigarettes for a variety of reasons; one may be that the state may believe e-cigarettes *are* a safer alternative to combustible cigarettes.²⁴⁸

States and localities may also simply follow a “social norm” rationale, theorizing that permitting e-cigarette use in the public domain makes traditional cigarette smoking seem acceptable.²⁴⁹ While this rationale seems to underestimate human intelligence and situational awareness, it is nevertheless still an option for greater regulation if particular states and localities feel that it is necessary.²⁵⁰ Arguments may also be made for consistency and enforcement of a smoking ban, because otherwise regulating smoking in the public domain could quickly become an “enforcement

246. *Overview List—How Many Smokefree Laws?*, AM. NONSMOKERS RIGHTS FOUND. <http://www.no-smoke.org/pdf/mediaordlist.pdf> (last updated Jan. 2, 2014).

247. Suffolk Cnty., N.Y., Res. No. 717, § 1 (Apr. 28, 2009); *Kuhn*, 2010 N.Y. Misc. LEXIS 5524, at *3.

248. See *Demographics of Tobacco Use*, ORAL CANCER FOUND., <http://www.oralcancerfoundation.org/tobacco/demographics.php> (last visited Apr. 14, 2014) (finding that smoking prevalence among adults in Nevada is 31.5% and in Kentucky is 29.7%).

249. Vanessa Ho, *King County Bans Public E-Cigarette Smoking*, SEATTLE POST-INTELLIGENCER (Dec. 15, 2010), <http://www.seattlepi.com/local/article/King-County-bans-public-e-cigarette-smoking-904130.php>.

250. See *id.* (claiming traditional smokers who see a vaper using in public receives a “powerful subliminal message” that smoking in public is acceptable).

nightmare.”²⁵¹ Of course, these bans may be challenged, but the chances of success for petitioners are quite low.²⁵²

States may also have the ability to act more quickly than the federal government and can deal directly with the e-cigarette manufacturers. For example, in October of 2010, California brought a suit against Smoking Everywhere to stop the company from targeting sales and advertising to minors and claiming that its products are safe alternatives to tobacco.²⁵³ Smoking Everywhere settled the case and agreed to California’s demands.²⁵⁴ Although this approach is typically not favored by the e-cigarette industry, it is nonetheless another regulatory option.²⁵⁵ E-cigarette manufacturers have a strong interest in *less* regulation, and if meeting the demands of particular states means keeping their product on the market and avoiding a stricter regulatory option, e-cigarette manufacturers will respect the particular state’s bargaining power. That is exactly what happened in the case of Smoking Everywhere in California.

A distinct feature of the TCA is the ample authority expressly preserved to state and local governments to regulate tobacco products.²⁵⁶ Congress was careful to not limit the authority of states to “enact . . . any law, rule, [or] regulation . . . with respect to tobacco products” that strengthens requirements already set forth in the TCA.²⁵⁷ With a minimalist federal structure balancing basic protection from the potential risks e-cigarettes present while keeping the vaporizers available for consumers and past smokers, states would be well situated to identify potential issues

251. Suffolk Cnty., N.Y., Res. No. 717, § 1 (Apr. 28, 2009).

252. See Jordan Raphael, Note, *The Calabasas Smoking Ban: A Local Ordinance Points the Way for the Future of Environmental Tobacco Smoke Regulation*, 80 S. CAL. L. REV. 393, 401, 403–06 (2007) (discussing the case law on local smoking bans); *Inclusion of E-Cigarette in Smoking Ban Has Some Users Feeling Burned*, WAVE 3 NEWS (Apr. 7, 2011), <http://www.wave3.com/story/14406057/inclusion-of-e-cigarette-in-smoking-ban-has-some-users-feeling-burned>.

253. Maggie Fox, *FDA Cannot Block E-Cigarette Imports: U.S. Court*, REUTERS (Dec. 8, 2010), <http://www.reuters.com/article/2010/12/08/us-fda-cigarettes-idUSTRE6B70D020101208>.

254. *Id.*

255. Eliza Gray, *Regulating E-Cigarettes Could Have Unintended Consequences*, TIME (Dec. 16, 2013), <http://www.nation.time.com/2013/12/16/regulating-e-cigarettes-could-have-unintended-consequences/>. Miguel Martin, the president of an electronic cigarette manufacturer in New Jersey says he is “looking forward to federal regulation. But each state doing its own thing in absence of a federal framework . . . is a mistake.” *Id.*

256. See 21 U.S.C. § 387p(a)(1) (2012).

257. *Id.*

for their particular constituencies and address them through amending or enacting legislation.

V. CONCLUSION

The FDA surely has an interest to ensure the safety of e-cigarettes, but to the extent e-cigarettes pose any specific and imminent risk of harm, the TCA authorizes the FDA to comprehensively regulate e-cigarette's manufacture, sale, advertising, and labeling. E-cigarette manufacturers have acknowledged the FDA's ability to do just that. The FDA, on the other hand has stubbornly continued attempting to regulate e-cigarettes under the FDCA, which is simply not structured to regulate non-cigarette tobacco products without producing the absurd result of banning tobacco products all together. The FDA has recently announced its intention to regulate e-cigarettes under the TCA, as it should have from the beginning, but no regulation has been proposed yet.²⁵⁸ Assuming that the FDA will carry through with its promise, it should take a minimalist approach to e-cigarette regulation under the TCA.

People are going to remain addicted to nicotine, and e-cigarettes appear to provide nicotine in a much safer way than traditional, combustible cigarettes. Left with a choice between the two, e-cigarettes are the better choice; however, the FDA's prior attempts to regulate the vaporizers under the stringent provisions of the FDCA imply that proposed regulations under the TCA, the proper regulatory avenue, will be stringent as well. Adopting a strict regulatory scheme that will require pre-market approval for a product that is already being used effectively could waste time. More importantly, it could force e-cigarette users to focus their nicotine addiction back on traditional, combustible cigarettes, the same combustible cigarettes laced with over sixty carcinogenic chemicals not found in e-cigarettes. By regulating advertising, labeling, and general product standards, the FDA can reasonably ensure the safety of e-cigarettes, which in turn will reduce the number of combustible cigarette smokers. A minimalist regulatory structure is a win-win scenario for the FDA: requiring a baseline level of safety and consistency while fulfilling

258. See *Electronic Cigarettes*, *supra* note 48; Alec Torres, *Government War on E-Cigarettes Leaves Smokers Gagging*, NATIONAL REVIEW ONLINE (Feb. 20, 2014), <http://www.nationalreview.com/article/371487/government-war-e-cigarettes-leaves-smokers-gagging-alec-torres>.

the agency's primary purpose to promote public health, which, in this case, is achieved through a reduced-risk product. E-cigarettes should be seen as a *solution* to endemic issues yet to be solved: cigarette smoking and tobacco-related death. Instead of taking a stringent, overly cautious regulatory approach, the FDA should ensure a minimum safety threshold while keeping e-cigarettes available to those that need them.

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