BLOWING ELECTRONIC SMOKE: ELECTRONIC CIGARETTES, REGULATION, AND PROTECTING THE PUBLIC HEALTH

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I. INTRODUCTION

A man walks into a bar, past a red and white "No Smoking" sign and sits down at a table. He pulls a small white cylinder from his pocket and puts it to his lips. The tip glows orange as he takes a deep drag, and after a long pause, he exhales a diffuse white plume from his mouth—all in full view of the bar staff and patrons. This man is not some scofflaw, defying a municipality's strict indoor smoking ban; in fact, he is completely in compliance with such a law.[1] He is a "vaper" and he is smoking an electronic cigarette, a device which delivers nicotine-laced water vapor to a user's lungs.[2] He is one of hundreds of thousands of Americans who now forego cigarettes and instead get their nicotine without any combustion or chewing of tobacco. By divorcing this addictive chemical from its natural medium of tobacco, and transmuting it into novel forms for human consumption, products like electronic cigarettes are challenging the tobacco industry's place as the dominant peddler of nicotine in the world.

For years, the traditional tobacco industry used the addictive powers of nicotine to create a massive, dedicated market of smokers, ensuring huge profits.[3] Tobacco use, and especially cigarette use, was ingrained in the social, political, and economic fabric of the United States; a federal statute even decreed that "[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States . . . ."[4] But in recent years, the prevalence and power of tobacco in the United States has waned. A litany of evidence has exposed the drastic health consequences of cigarette use,[5] and groundbreaking litigation has exposed the deceitful tactics that tobacco companies used to market their products while concealing the true effects of smoking.[6] During this time, smoking cessation aids, known as nicotine replacement therapy, became widely available to consumers. Along with aggressive anti-smoking campaigns, smoking bans, the social stigmatization of smoking, strong limits

1. *See infra* Part III.C.1 for a discussion of how electronic cigarettes are not prohibited by many state and local smoking bans.

2. Because they are inhaling aerosolized nicotine water vapor, the act of using an electronic cigarette has been dubbed "vaping," and the users dubbed "vapers," in order to dissociate them from traditional cigarettes. Dion Lefler, *Ban Doesn't Include Electronic Cigarettes*, WICHITA EAGLE, July 6, 2010, http://www.kansas.com/2010/07/06/1391740/ban-doesnt-include-electronic.html. *See infra* Part II.A for a description of the components and function of electronic cigarettes.

3. *See* Margaret Gilhooley, *Tobacco Unregulated: Why the FDA Failed, and What To Do Now*, 111 YALE L.J. 1179, 1186–87 (2002) (book review) (quoting an internal Addison tobacco company executive as saying "'[w]e are, then, in the business of selling nicotine, an addictive drug'"); Karen C. Sokol, *Smoking Abroad and Smokeless at Home: Holding the Tobacco Industry Accountable in a New Era*, 13 N.Y.U. J. LEGIS. & PUB. POL'Y 81 (2010) (discussing the tobacco industry and its regulation).

4. 7 U.S.C. § 1311(a) (2000), *repealed by* Fair and Equitable Tobacco Reform Act of 2004, Pub. L. No. 108-357, § 611, 118 Stat. 1418, 1521 (2004).

5. *See, e.g.*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: A REPORT OF THE SURGEON GENERAL 861 (2004), *available at* http://www.surgeongeneral.gov/library/smokingconsequences/index.html ("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, [and] 94,000 infant deaths.").

6. *See, e.g.*, United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 28 (D. D.C. 2006) (finding tobacco companies "marketed and sold their lethal product with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted"), *aff'd in part, vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009).

on tobacco advertising, and higher prices (due to local, state, and federal taxes), these factors resulted in a decline in the popularity of smoking: cigarette sales recently hit their lowest point since 1951.[7]

But the decline in cigarette sales does not mean that tobacco abstinence is on the rise, as many Americans have still not shaken free of nicotine's addictive grip.[8] Much of the decrease in cigarette use is being offset by increased sales of other tobacco products.[9] This suggests that many Americans are not interested in quitting smoking outright, but rather are seeking alternative ways to consume nicotine without the social stigma, financial costs, and notorious health risks of traditional cigarettes. For these Americans, electronic cigarettes could be an attractive option; indeed, the products are often marketed as "giv[ing] smokers all the pleasure and satisfaction of traditional smoking without all the health, social and economic problems."[10]

Electronic cigarettes have gained a small but dedicated following in the United States,[11] and although their sales are still minute compared to traditional tobacco products,[12] public interest and demand is growing.[13] As these products become more popular, they raise serious public health issues. Electronic cigarettes are marketed as a healthier alternative to traditional tobacco products, and some assert that these devices can be beneficial in terms of reducing overall tobacco use.[14] But little is known about the actual effects

7. *U.S. Cigarette Sales Hit 55-Year Low*, CBS & ASSOCIATED PRESS (Feb. 11, 2009, 6:43 PM), http://www.cbsnews.com/stories/2006/03/09/business/main1384910.shtml.

8. Indeed, 46.2 million Americans still smoke. THE HEALTH CONSEQUENCES OF SMOKING, *supra* note 5, at 9.

9. *See* Gregory N. Connolly & Hillel R. Alpert, *Trends in the Use of Cigarettes and Other Tobacco Products*, 299 JAMA 2629, 2629 (2008) (research letter) (reporting that an increase in sales of traditional tobacco products like snuff, snus, cigars and roll your own tobacco made up for 30% of the decline in cigarette sales in the same period).

10. *FAQ*, E CIGARETTE SOLUTION, http://www.ecigarettesolution.com/faq (last visited Sept. 27, 2011). *See also* 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 (stating that electronic cigarettes are viewed as having great appeal to US consumers because of the bans, regulations, and high taxes imposed on traditional cigarettes).

11. Ron Scheher, *Electronic Cigarettes: In Need of FDA Regulation?*, CHRISTIAN SCI. MONITOR, Oct. 17, 2009, http://www.csmonitor.com/USA/Society/2009/1017/p02s03-ussc.html (estimating 300,000 plus U.S. electronic cigarette users, according to the head of the Electronic Cigarette Association). It is difficult to get an exact idea for the size of the market for electronic cigarettes because the companies do not release sales figures. Katie Zezima, *Cigarettes Without Smoke, or Regulation*, N.Y. TIMES, Jun. 1, 2009, http://www.nytimes.com/2009/06/02/us/02cigarette.html. However, according to court documents, Smoking Everywhere, one of the largest electronic cigarette distributors, has sold over 600,000 units in the year since its founding, while NJOY, another distributor, sold 135,000 in the same period. Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 64 (D.D.C. 2010).

12. Like the number of electronic cigarette users, the gross sales figures for these devices are difficult to determine because so many distributors exist, but estimates place yearly sales of electronic cigarettes at $100 million dollars annually. David Wincher, *FDA Gets Tough on Claims by Makers of E-cigarettes*, ARIZONA DAILY STAR, Sept. 16, 2010, http://azstarnet.com/business/local/article_7148dc51-eca6-546e-ad27-2aee3bc1be23.html. This still vastly trails the $50 billion in annual sales of light cigarettes alone by the tobacco industry. Jonathan K. Noel et al., *Electronic Cigarettes: A New Tobacco Industry?* 20 TOBACCO CONTROL 81, 81 (2010).

13. *See* Cyrus K. Yamin et al., *E Cigarettes: A Rapidly Growing Internet Phenomenon*, ANNALS OF INTERNAL MED. 607, 607 (reporting that Google searches for "electronic cigarettes" have increased more than 5000% over the past two years).

14. *See generally* 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 (2011) ("Electronic cigarettes are designed to mitigate tobacco-related disease by reducing cigarette consumption and

of these products, and many are concerned about potential dangers to both users and the public at large.[15] These public health concerns have prompted regulation of electronic cigarettes at the federal, state, and local levels.

Many of these attempts at regulation have been frustrated, however, because while governments have designed regulatory schemes to address traditional tobacco products, electronic cigarettes do not fit neatly under their definitions. The application of tobacco-specific regulatory legislation to these nicotine-only products has created a great deal of uncertainty, and governments may need to amend these schemes to fill the regulatory gaps. This Note will explore these areas of uncertainty and argue that to protect the public health, government regulators and public health officials should take a cautious approach with electronic cigarettes, guarding against potential threats until conclusive evidence about the products can be gathered.

Part II of this Note will detail the background information on these new types of nicotine delivery products. It will then discuss the U.S. Food and Drug Administration's (FDA) separate regulatory schemes for drugs—the Food, Drug, and Cosmetic Act (FDCA)—and for tobacco products—the Family Smoking Prevention and Tobacco Control Act (TCA). It also discuss *Sottera, Inc. v. FDA*, which held that the FDA had no authority to regulate electronic cigarettes marketed for recreational purposes.[16]

Part III will first survey the public health issues posed by electronic cigarettes, examining the health dangers they pose as well as their potential to be used in a "harm reduction" role. Part III will then examine potential public health regulations of electronic cigarettes at the federal level. Finally, it will discuss state and local regulation of electronic cigarettes in the context of public smoking bans, and determine whether banning the public use of electronic cigarettes is justified, both legally and from a public health standpoint.

Finally, Part IV of this Note will suggest what kinds of regulatory actions are needed, at the federal, state, and local level, in order to protect the public health from the threats raised by electronic cigarettes.

II. BACKGROUND

A. New Technologies for Nicotine Delivery

The ability to separate nicotine from its traditional medium of tobacco prompted important changes for both the tobacco industry and public health; due to this ability, the past decade has seen enormous growth in the number of products that deliver nicotine to users without any burning, chewing, or ingestion of tobacco. Some of these products are the familiar, FDA-approved smoking cessation products like nicotine gum, patches, or nicotine inhalers. Others, however, are less familiar, such as electronic cigarettes, nicotine

smoking rates.").

15. Kristine A. Wollscheid & Mary E. Kremzner, *Electronic Cigarettes: Safety Concerns and Regulatory Issues*, 66 AM. J. HEALTH-SYS. PHARM. 1740, 1741 (2009).

16. Sottera, Inc. v. FDA, 627 F.3d 891, 898 (D.C. Cir. 2010).

water,[17] nicotine lollipops,[18] nicotine lip balm,[19] and nicotine hand gel.[20] These products, which are collectively known as "novel nicotine delivery systems," all entered the marketplace without any regulatory oversight or approval in the early 2000s. But these products were banned by the FDA as unapproved new drugs,[21] and only electronic cigarettes established any widespread popularity. First patented and introduced to the Chinese market in 2004, the devices began to reach American markets in 2006.[22]

Electronic cigarettes are designed to look and be used in the same manner as traditional cigarettes.[23] The devices deliver vaporized nicotine to the lungs without any combustion of tobacco.[24] Inside of a stainless steel tube or plastic tube, the devices consist of a smart chip with a rechargeable battery, a heating element—known as an atomizer—and a cartridge. [25] The cartridge consists of a liquid mixture of nicotine, water, and propylene glycol and glycerol, which facilitate the heating and vaporization process.[26] As the user inhales, electronics detect the airflow, activating the device's atomizer; the atomizer vaporizes the nicotine-water-propolyne glycol mixture, which is inhaled into the lungs in the same manner as a normal cigarette.[27] A LED light on the tip of the device even lights up when the user inhales, giving the appearance of burning tobacco.[28] While the devices are designed to look like cigarettes, there

17. Nicotine water was contained about four milligrams of nicotine in every 16.9 fluid ounce bottle, and was intended as a way for smokers to curb nicotine cravings when in situations where they were unable to smoke; it was marketed as a "refreshing break to the smoking habit." *See* Joel Arak, *FDA Shuts Off Nicotine Water Spigot*, CBS NEWS (Feb. 11, 2009), http://www.cbsnews.com/stories/2002/07/02/national/main514046.shtml.

18. Sold without prescriptions by pharmacists in Mississippi and Illinois, nicotine lollipops consisted of a sugar free candy base and flavoring infused with up to four milligrams of nicotine. The products were marketed as an easy way to quit smoking or as a way to avoid smoking when a smoker had a craving. *See* Warning Letter from David J. Horowitz, U.S. Dep't of Health and Human Servs., to Larry Melon, Ashland Drug (Apr. 9, 2002), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2002/ucm144842.htm

19. Nicotine lip balm, marketed by a pharmacy in Illinois, promised to help users "Lick the Habit"; by applying a balm containing nicotine salicylate to their lips, smokers could then lick their lips anytime they had a craving for a cigarette. *See* Warning Letter from David J. Horowitz, U.S. Dep't of Health and Human Servs., to Larry and Pat Frieders, The Compounding Pharmacy (Apr. 9, 2002), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2002/ucm144843.htm.

20. Once rubbed on the hands, the nicotine in the gel could quickly be absorbed through the skin to help curb cravings for cigarettes. Before being banned by the FDA, the gel was sold at Walgreens and other drug stores, and the manufacturer expected to bring in $200 million in annual sales. *See Gel Gives Nicotine Fix Through the Skin*, ABC NEWS (Jan. 21, 2007), http://abcnews.go.com/GMA/OnCall/story?id=2811066&page=1.

21. *See* Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 74 n.16 (D.D.C. 2010) (explaining that many novel nicotine delivery systems were banned under the FDCA because the manufacturers made express therapeutic claims), *aff'd, sub nom.* Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

22. Demick, *supra* note 10. Electronic cigarettes were created by Chinese pharmacist Hong Lik, who after seeing his father die from lung cancer, was inspired to find a safer way for users to obtain nicotine. *Id.* Prior to this, in the 1990s American tobacco companies developed reduced harm tobacco products which vaporized nicotine at low levels of combustion; however, these products never saw wide release. Yamin et al., *supra* note 13, at 607.

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

24. *Id.*

25. *Id. See also* Yamin et al., *supra* note 13, at 608 (giving a schematic of the typical design of an electronic cigarette).

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

27. *Id*.

28. Ware G. Kuschner et al., *Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging*

are also models that look like cigars or tobacco pipes, and even units resembling pens or USB ports for those who wish to "vape" discretely.[29] The cartridges are available in varying concentrations of nicotine and come in various flavors: while tobacco and menthol flavors are the most common, some cartridges contain fruit and candy flavors.[30] Consumers can buy replacement cartridges and bottles of "juice" (the nicotine-water-propolyne glycol mixture) to refill their electronic cigarettes.[31]

Electronic cigarettes are sold by a large number of small, usually foreign, companies; "[t]raditional cigarette makers have not been involved in the fledgling industry."[32] While they are sometimes sold at specialized mall kiosks, the main marketplace for electronic cigarettes resides on the internet.[33] Electronic cigarette companies often use affiliate marketing schemes, wherein product users become distributors and are paid for recruiting new customers online; thus, electronic cigarette users are very active in promoting the products.[34] Marketing for electronic cigarettes portrays the devices as a healthier alternative to traditional tobacco smoking: companies state that the products "will provide smokers the same delight, physical and emotional feelings they get in smoking traditional cigarettes," and is a way for "smokers [to] still get their nicotine," without getting "any harmful side effects of smoking traditional cigarettes."[35] Additionally, electronic cigarette companies often tout their products as "green," stating that the devices generally only contain a few components (compared to the thousands of chemicals present in tobacco smoke) and that they can be used around others without creating any environmental hazard.[36] Despite these claims of safety, electronic cigarettes have raised worries from a number of public health and regulatory officials.

Obviously, once nicotine has been separated from its natural medium of tobacco, manufacturers are able to transmit it through a number of different mediums; new forms, in addition to electronic cigarettes, are sure to be created in the future. Having surveyed how nicotine has been transformed into various new forms for human consumption, this Note will now turn and examine both the federal regulatory scheme for tobacco, and how the rise of electronic cigarettes challenged that scheme's existing definitions and structure.

B. The Federal Regulatory Framework For Traditional Tobacco

In order to determine how novel nicotine delivery products can be

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Health Care Challenges for the Primary Care Provider, 2011 INT'L J. GEN. MED. 115, 116 (2011).

29. *E-Cigarettes: Questions and Answers*, U.S. FOOD & DRUG ADMIN., Sep. 9, 2010, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm.

30. 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).

31. *Id*. at 2340.

32. Duff Wilson, *Judge Orders F.D.A. to Stop Blocking Imports of E-Cigarettes from China*, N.Y. TIMES, Jan. 16, 2010, http://www.nytimes.com/2010/01/15/business/15smoke.html.

33. *See* Yamin et al., *supra* note 13, at 607 (noting the growing marketplace for e-cigarettes on the internet).

34. *Id*.

35. Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 63–64 (D.D.C. 2010) (describing marketing materials of an electronic cigarette manufacturer).

36. Yamin et al., *supra* note 13, at 607.

regulated at the federal level, the current regulatory framework for drugs and tobacco must be examined. While the FDCA grants the FDA authority under drugs, it does not give it authority over tobacco; instead, the FDA has limited authority over tobacco under the TCA. As litigation about the regulatory status of electronic cigarettes has shown, this is a crucial distinction.

1. The FDCA and Brown & Williamson Tobacco*: The FDA's Failed Attempt to Regulate Traditional Tobacco*

The FDA has authority to regulate products as drugs, devices, or drug-device combination products under the FDCA.[37] The statute defines "drug" and "device" as a product intended to either treat or prevent disease, or intended to affect the structure or function of the human body.[38] The crucial determinant of whether the FDA can get jurisdiction over a product is the intent of the manufacturer: if a manufacturer intends for the product to be used to affect structure or function of the human body, it qualifies as a drug or device under the FDCA.[39] For instance, when a product is marketed making therapeutic claims, then the FDA has authority over it under the FDCA.[40] The FDA's mission, as defined by the FDCA, is to protect the public health by insuring that all drugs and devices are "safe and effective" for their intended use.[41] To do this, the agency must determine that a drug's benefits outweigh its risks.[42] The FDCA grants the FDA broad power to ensure devices are safe and effective: the agency may place restrictions on labeling and marketing, take measures to ensure that drugs are unadulterated, and require premarket approval for new drugs.[43]

Prior to 1996, the FDA had never attempted to assert jurisdiction over tobacco under the FDCA,[44] unless the tobacco manufacturer made express therapeutic claims.[45] Instead, the tobacco industry was regulated by a piecemeal series of federal statutes;[46] these statutes limited the labeling and

37. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000). *See generally*, Food Drug and Cosmetic Act, 21 U.S.C. §§ 301-399D (2006).

38. 21 U.S.C. § 321(g)(1) (2006) (defining drug); 21 U.S.C. § 321(h) (2006) (defining device). The FDA may regulate drug-device combinations as a drug, as a device, or as both. *Brown & Williamson Tobacco*, 529 U.S. at 126.

39. Action on Smoking and Health v. Harris, 655 F.2d 236, 238-39 (D.C. Cir. 1980).

40. *Id.*

41. 21 USC § 393(b)(2)(C) (2006). *See also Brown & Williamson Tobacco*, 529 U.S. at 126 ("This essential purpose pervades the FDCA.").

42. *Brown & Williamson Tobacco*, 529 U.S. at 140.

43. *Id.* at 140–41.

44. *See id.* at 143–60 (giving a detailed history of the FDA's disavowal of jurisdiction over tobacco and the passage of tobacco specific statutes by Congress).

45. *See Action on Smoking and Health*, 655 F.2d at 239 (stating that the FDA cannot assert jurisdiction over cigarettes under the FDCA absent health claims by the vendors or manufacturers). *See also* United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D. N.J. 1959) (holding that cigarettes advertised as a weight loss aid are a drug under the FDCA); United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336, 339 (D.N.J. 1953) (holding that labeling and advertising which created perception that cigarettes have the effect of preventing or mitigating common colds and viruses can be classified as drug under FDCA).

46. Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, § 202, 106 Stat. 323 (1992); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30; Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984);

advertising of tobacco products and focused on providing the public with information regarding the health consequences of smoking.[47] These statutes did not attempt to ban or regulate tobacco sales or manufacture.[48] But in 1996, the FDA asserted jurisdiction that tobacco as customarily marketed under the FDCA, based on its finding that nicotine qualified as a drug because the pharmacological effects of nicotine on the human body were so easily foreseeable that they could be deemed to be intended by the manufacturer.[49] The FDA concluded that cigarettes and smokeless tobacco products were a drug-device combination product because they deliver controlled amounts of nicotine to the human body.[50]

Tobacco companies challenged the FDA's jurisdiction, and in *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court held the FDA's regulations invalid because Congress had "precluded the FDA's jurisdiction to regulate tobacco products."[51] The Court never refuted the FDA's conclusion that the nicotine in tobacco was intended to affect the structure or function of the human body.[52] Instead, the Court cited the FDCA's purpose of ensuring the safety of drugs and devices intended for human consumption, and noted that the FDA is obligated to prevent the marketing of drugs or devices whose risks are not offset by the potential for therapeutic benefit.[53] The Court concluded that given the litany of evidence showing the dangers of tobacco use, if tobacco products were regulated under the FDCA the FDA would be required to ban them from the market; no measures the agency could take would make tobacco products safe for human use.[54]

But the Court, examining all of the tobacco related legislation passed since the 1960s,[55] reasoned that these statutes manifested Congress's intent that tobacco should remain on the market, despite all of the corresponding health consequences; regulation under the FDCA would violate that intent.[56] The Court reasoned Congress favored informing consumers about adverse health

Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175; Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87; Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965).

47. *See Brown & Williamson Tobacco*, 529 U.S. at 138–39 (stating that Congress favored informing consumers about adverse health risks of tobacco use over harming the nation's economy through an outright ban of tobacco).

48. *Id.*

49. *Id.* at 127.

50. *Id.*

51. *Id.* at 133.

52. *See id.* at 162 (Breyer, J. dissenting) ("[T]he majority nowhere denies . . . . [that] tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are 'intended to affect' the body's 'structure' and 'function,' in the literal sense of these words.").

53. *Id.* at 140 (majority opinion).

54. *Id.* at 135–36 (stating that cigarettes could never receive premarket approval under the FDCA). *See also* 21 U.S.C. § 360c(a)(1)(C) (2006) (defining Class III device); 21 U.S.C. § 360e(d)(2)(A) (2006) (defining premarket approval).

55. *See supra* note 43 (listing statutes).

56. *Brown & Williamson Tobacco*, 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.").

risks of tobacco use over harming the nation's economy through an outright ban of tobacco. Concluding that Congress's tobacco specific legislation had effectively foreclosed an interpretation of the FDCA that would cover tobacco products as customarily marketed, the Court struck down the FDA's assertion of authority, leaving tobacco unregulated once again.[57]

2. The Family Smoking Prevention and Tobacco Control Act

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act[58] (TCA) to "fill the regulatory gap" left by the Court's decision in *Brown & Williamson Tobacco*.[59] The TCA granted the FDA *sui generis* authority to regulate tobacco products. Congress, noting the agency's scientific expertise, found:

> It is essential that the [FDA] review products sold or distributed for use to reduce risks or exposures associated with tobacco products . . . . It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.[60]

The TCA gives the FDA authority to regulate tobacco products that are outside of normal provisions of the FDCA. The act defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption," and explicitly states that tobacco products shall not be considered a drug, device, or combination product under the FDCA,[61] and shall not be regulated under the provisions of the FDCA dealing with drugs and devices.[62]

The TCA's purpose is to give the FDA authority to regulate tobacco products to address public health concerns while still permitting the sale of tobacco to adults.[63] To achieve these ends, the TCA grants the FDA the general power to "require restrictions on the sale and distribution of a tobacco product, including restrictions on access to, and the advertising and promotion of the tobacco product if the Secretary determines that such regulation would be appropriate for the protection of the public health."[64] Specifically, the Act: (1) Requires tobacco companies to submit information regarding the ingredients, nicotine content, and harmful constituents of their products, as well as submit the results of any of the company's internal research;[65] (2) Creates an "adulterated" tobacco products category, imposing manufacturing

57. *Id.* at 155.
58. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).
59. Sottera, Inc. v. FDA, 627 F.3d 891, 894 (D.C. Cir. 2010).
60. Family Smoking Prevention and Tobacco Control Act, 123 Stat. at 1779.
61. *Id.* at 1783 (codified as 21 U.S.C. 321(rr)) (defining tobacco product).
62. *See id.* at 1786 (codified as 21 U.S.C. 387a(a)) (defining the FDA's authority over tobacco products).
63. *See id.* at 1781–82 (stating the TCA's purpose).
64. *Id.* at 1796 (codified as 21 U.S.C. § 387f).
65. *Id.* at 1790–91 § 904 (codified as 21 U.S.C. § 387d).

standards;[66] (3) Creates a "misbranded" tobacco products category, which subjects tobacco packaging to strict new labeling requirements;[67] (4) Allows the FDA to regulate tobacco advertising and marketing to the fullest extent possible under the First Amendment;[68] (5) Eliminates flavoring additives in cigarettes (except for menthol) designed to appeal to youths;[69] (6) Allows the FDA to establish standards for the content of tobacco products, including regulating nicotine yields and reducing harmful constituents;[70] (7) Establishes provisions for regulating "modified risk tobacco products;"[71] (8) Requires premarket approval for new tobacco products to determine their impact on the public health; [72] and (9) Establishes a Tobacco Products Scientific Advisory Committee to determine what regulations are necessary to protect the public health.[73] All of the FDA's new powers over tobacco under the TCA are subject to two large caveats: the agency cannot ban traditional tobacco products,[74] and cannot require that the nicotine yield of a tobacco product be reduced to zero.[75]

Many commentators have been highly critical of the TCA. A central concern is that the FDA, an agency charged with the protection of the public health, is now seen to be aligned with a harmful industry, and prevented from taking action that the agency's mission would demand: banning tobacco. The limited remedies and some of their procedural burdens to taking regulatory actions have also drawn the ire of commentators, especially what the FDA must show to perform a product recall.[76] They also criticize the fact that restrictions imposed on cigarettes are more onerous than those imposed on smokeless tobacco products, which are often marketed as less harmful by tobacco products, and, thus, accord legitimacy to the industry's push to make these products more mainstream.[77] And there is worry that by being regulated by the FDA, tobacco companies may seek to portray their products as safer.[78]

66. *Id.* at 1787–88 § 902 (codified as 21 U.S.C. § 387b).

67. *See id.* at 1788-89 § 903 (codified as 21 U.S.C. 387c). (defining misbranded tobacco product); *id.* § 201 (amending the Federal Cigarette Labeling and Advertising Act with new warning messages for cigarettes); § 204 (amending the Comprehensive Smokeless Tobacco Health Education Act of 1986 with new warning labels for smokeless tobacco products).

68. *Id.* at 1796 § 906 (codified as 21 U.S.C. § 387f(d)(1)) (2009).

69. *Id.* at 1799 § 907 (codified as 21 U.S.C. § 387g(a)(1)) (2009). The exception for menthol cigarettes is subject to a review by the Scientific Advisory Committee to determine whether the health impact of menthol cigarettes on racial and ethnic minorities. *Id.* at 387g(e)). The FDA does have the right to ban menthol if it determines it would further the public health.

70. *Id.* at 1800-01 § 907 (codified as 21 U.S.C. § 387g(a)(4)) (2009).

71. *Id.*

72. *Id.* at 1807 § 910 (codified as 21 U.S.C. § 387j). A new tobacco product can avoid the premarket 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.*

73. *Id.* § 917(a).

74. *See id*. § 907(d)(3)(A) (prohibiting the Secretary from banning all cigarettes, smokeless tobacco, cigars, pipe tobacco, and roll-your-own tobacco).

75. *Id.* § 907(d)(3)(B).

76. *See* James T. O'Reilly, *FDA Regulation of Tobacco: Blessing or Curse for FDA Professionals?*, 64 FOOD & DRUG L.J. 459, 468 (2009) (detailing the fourteen steps required for a recall of a tobacco product under the TCA and stating the TCA makes recall nearly impossible).

77. Sokol, *supra* note 3, at 128–32 (noting that the flavoring ban only applies to cigarettes, not smokeless tobacco products, that the labeling requirements for smokeless tobacco products are less stringent, and that there is no blanket prohibition against handing out free samples of smokeless tobacco but there is for cigarettes).

78. Robert J. Baehr, Note, *A New Wave of Paternalistic Tobacco Regulation*, 95 IOWA L. REV. 1663,

In spite of the concerns over the law, even critics concede that the TCA is the most effective tobacco control legislation to date.[79] It finally gives the FDA authority, albeit constrained authority, to help further its purpose of protecting the public health by regulating tobacco products. Thus, a two tiered system of federal regulations exists: the FDCA regulates drugs and devices, while the TCA regulates tobacco products. However, electronic cigarettes, which seem to fit under both definitions, have injected some ambiguity into this system, which will be explored in the next section.

C. Federal Regulation of Electronic Cigarettes

Like its regulations of other nontraditional nicotine products described in Part I.A. *supra*, the FDA first used the FDCA to assert its jurisdiction over electronic cigarettes; beginning in April 2009 (before the passage of the TCA), the FDA began detaining shipments of electronic cigarettes entering the country on the grounds that they were unapproved or adulterated drug-device combination products under the FDCA.[80] Electronic cigarette distributors challenged the FDA's actions, arguing that electronic cigarettes are tobacco products and according to *Brown & Williamson Tobacco*, cannot be regulated as a drug or device under the FDCA.[81] The District Court agreed and entered a preliminary injunction against application of the FDCA to detain electronic cigarettes.[82] The DC Circuit affirmed, holding that *Brown & Williamson Tobacco* and the TCA require that all tobacco products, including electronic cigarettes, be regulated under the TCA.[83]

First, the court rejected the FDA's argument that traditional tobacco products are exempt from the FDCA under *Brown & Williamson Tobacco*, but nontraditional tobacco products like electronic cigarettes could still be regulated under the FDCA.[84] The Supreme Court's holding applied to exempt *all* tobacco products as customarily marketed from the FDCA—there was no intent to restrict its holding to traditional cigarettes and smokeless tobacco.[85] Congress ratified the *Brown & Williamson* decision by granting the FDA authority to regulate tobacco products under the TCA only.[86] Electronic cigarettes meet the TCA's definition of tobacco products because the nicotine

1678 n. 92 (2010).

79. O'Reilly, *supra* note 76, at 460.

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

81. *Id*.

82. Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 78 (D.D.C. 2010), *aff'd sub nom*. *Sottera*, 627 F.3d at 899.

83. *Sottera*, 627 F.3d at 898.

84. *Id*. at 895.

85. *Id*. *See also Smoking Everywhere*, 680 F. Supp. 2d at 72. ("[T]he line drawn by the Supreme Court was not between traditional and non-traditional products, as FDA suggests, but between tobacco products as customarily marketed and those that claim therapeutic benefits.").

86. *Sottera*, 627 F.3d at 897. The mere fact that electronic cigarettes deliver nicotine does not mean they are intended to affect a structure or function of the human body (and thus a drug under the FDCA). This is because if mere nicotine delivery were sufficient to deem a product a drug or device under the FDCA it would "effectively dismantle the existing regulatory wall Congress erected between tobacco products and drug-device combinations" by including regular cigarettes in the definition as well. *Smoking Everywhere*, 680 F. Supp. 2d at 70.

in them is "derived from tobacco";[87] therefore, as customarily marketed, they could not be regulated under the FDCA.[88]

Second, while the DC Circuit noted that if electronic cigarettes were marketed for therapeutic purposes they could be regulated under the FDCA, it stated that the products did not make therapeutic claims.[89] It affirmed the District Court's holding that the FDA lacked evidence demonstrating that the intent of electronic cigarette manufacturers was for their products to be used for therapeutic purposes.[90] That court decided that the thrust of the electronic cigarette advertising was actually encouraging nicotine use by urging customers to use electronic cigarettes, and was not portraying electronic cigarettes as a way to treat nicotine addiction or withdrawal.[91] Therefore, electronic cigarettes were merely intended as recreational smoking devices.[92] The District Court distinguished electronic cigarettes from other nontraditional nicotine products regulated under the FDCA, such as Nicotine Water and Nicotine Lip Balm, because those products made express therapeutic claims.[93] Because electronic cigarette distributors made no express therapeutic claims, their products could not be regulated under the FDCA, but instead must be regulated under the TCA.[94]

The FDA declined to appeal the DC Circuit's ruling, stating that it would "comply with the jurisdictional lines established by *Sottera*."[95] This means that electronic cigarettes, as customarily marketed (i.e. marketed for recreational and not therapeutic purposes) will be regulated as a tobacco product under the TCA. However, the agency has not yet published any regulations pertaining to electronic cigarettes. This Note will examine potential regulations for electronic cigarettes under the TCA in Part III.B *infra*.

III. ANALYSIS

As noted above, existing regulatory systems that were designed to address conventional tobacco products have had a hard time classifying products like electronic cigarettes. Since arriving in the U.S. in 2007, electronic cigarettes have largely evaded the existing regulatory structures of the FDA and state agencies.[96] This Part will examine both how the FDA might regulate electronic

87. *Sottera*, 627 F.3d at 893, 897.

88. *Id.* at 898. *See* Family Smoking Prevention and Tobacco Control Act, Pub L. No. 111-31, § 901, 123 Stat. 1776, 1786 (2009) (codified as 21 U.S.C. § 387a(a)) (stating that tobacco products shall not be regulated under provisions pertaining to drugs or devices).

89. *Sottera*, 627 F.3d at 898.

90. *Id.* Evidently the FDA did not contest the issue of therapeutic intent on appeal. *Id. See also Smoking Everywhere*, 680 F. Supp. 2d at 74–75 (discussing whether electronic cigarettes are marketed with a therapeutic purpose).

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

92. *See id*. at 74 n.15 (noting that distributors had an express disclaimer that electronic cigarettes were not smoking cessation devices).

93. *Id*. at 74 n.16.

94. *Sotterra*, 627 F.3d at 898.

95. Letter to Stakeholders, Regulation of E-Cigarettes and Other Tobacco Products, from Lawrence R. Deyton, Director, Ctr. for Tobacco Prod., & Janet Woodcock, Director, Ctr. for Drug Evaluation and Research (Apr. 25, 2011), *available at* http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm.

96. Cobb et al., *supra* note 30, at 2340.

cigarettes under the TCA, and how state and local governments should deal with the products. But because the aim of regulation involving electronic cigarettes is to protect the public health, it is important to first examine the health effects of these devices; only then can it be determined what kind of regulation is most appropriate.

A. The Public Health and Electronic Cigarettes: A Path for Harm Reduction or an Unknown Hazard?

Whether electronic cigarettes pose a threat to public health is currently a subject of contentious debate. On the one hand, public health officials, regulatory agencies, and many anti-tobacco groups have argued that devices like electronic cigarettes are health risks: little is known about their effects on users or bystanders, but the products may contain hazardous materials, and nicotine use itself poses public health risks.[97] On the other hand, proponents of electronic cigarettes and other novel nicotine products have portrayed their products as a healthy alternative to traditional tobacco.[98] They insist that these products will actually be beneficial to the public health: they may provide an effective smoking cessation device, and can be utilized as part of an overall harm reduction strategy to wean nicotine addicts off of more-hazardous traditional tobacco products.[99] Which of these two paths is pursued will profoundly influence the regulatory strategy for electronic cigarettes, so it is important to gauge the public health impact of electronic cigarettes.

It must be noted, however, that there is a paucity of independent, reliable data on the product composition and health effects of electronic cigarettes,[100] although research in the field is increasing. Thus, it is likely that as knowledge about the devices grows, the public health debate might be conclusively resolved. But because the use of these products is becoming more prevalent, regulators and public health officials may have to make decisions based on the incomplete information presented below.

1. Health Hazards from Electronic Cigarettes

Electronic cigarette companies like to tout their products as a healthy alternative to traditional tobacco, and in truth they lack many of the harmful substances found in tobacco and tobacco smoke: there is no carbon monoxide in electronic cigarettes,[101] and they lack the vast number of chemical components found in traditional cigarettes.[102] However, that does not mean the devices are without danger.

There are three potential health risks that exist from the use of electronic

97. *See generally id*. at 2340–41.

98. *See generally* Cahn & Siegel, *supra* note 14, at 18.

99. *Id*.

100. Anna Trtchounian & Prue Talbot, *Electronic Nicotine Delivery Systems: Is There a Need for Regulation?*, 20 TOBACCO CONTROL 47, 47 (2011).

101. 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 OF1, OF8 (2010).

102. Cahn & Siegel, *supra* note 14, at 18.

cigarettes. First, there is a risk that the products will deliver carcinogenic materials to their users[103]: the FDA, in a preliminary study of the contents of electronic cigarettes, found that about half the samples contained tobacco-specific impurities and nitrosamines, both of which are carcinogens in humans.[104] Thus it appears that when the nicotine in these devices is synthesized from tobacco, some of the harmful constituents present in tobacco remain. Although it should be acknowledged that the concentration of these substances is far lower than in tobacco smoke,[105] long term use of the products could increase the risk of cancer for their users.

Second, nicotine use itself poses some health risks in addition to its highly addictive properties. Nicotine is capable of being converted into a carcinogen and can stimulate tumor growth.[106] Chronic exposure to nicotine is also associated with a variety of cardiovascular ailments, including heart disease.[107] And high doses of nicotine can cause potentially fatal nicotine poisoning, which poses a special risk to children.[108]

Third, electronic cigarettes are produced with very poor quality control.[109] The devices are often incorrectly labeled, contain the wrong dosages of nicotine, and have defective parts, including leaky nicotine cartridges.[110] The most concerning aspect of poor quality control is that the substances glycerin and diethylene glycol have been discovered in some electronic cigarette fluid; these substances are highly toxic and are associated with poisoning and death when ingested.[111] Although these substances were only found in a small sample of electronic cigarettes, the poor quality control utilized by manufacturers could lead to users giving themselves much higher dosages than expected, or being poisoned by toxic foreign substances.

It should be noted that the first two health dangers (the presence of low amounts of carcinogenic materials and health complications from nicotine) exist in FDA approved nicotine replacement therapy ("NRT") products as well.[112] In fact, the level of carcinogenic nitrosamines in electronic cigarettes is equivalent to the level found in the nicotine patch, which has been deemed "safe and effective" by the FDA.[113] However, the fact that the two products contain comparable carcinogen levels does not warrant a conclusion that electronic cigarettes are safe; NRT has been subject to extensive testing and

103. *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA*, U.S. FOOD AND DRUG ADMIN. (July 22, 2009), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm.

104. *Id.*

105. *See* Cahn & Siegel, *supra* note 14, at 18 (stating that the amount of tobacco specific nitrosamines is 500 to 1400 times greater in regular cigarettes than in electronic cigarettes).

106. Trtchounian & Talbot, *supra* note 100, at 47.

107. Wollscheid & Kremzner, *supra* note 15, at 1741 (listing possible harms from nicotine use including stroke, hypertension, and coronary artery disease).

108. Yamin et al., *supra* note 13, at 608.

109. *See generally* Trtchounian & Talbot, *supra* note 100, at 47–52 (noting a variety of design flaws, inconsistent labeling, and inconsistent components and nicotine levels in electronic cigarettes).

110. *Id.*

111. Cobb et al., *supra* note 30, at 2341; *Summary of Results: Laboratory Analysis of Electronic Cigarettes*, *supra* note 103.

112. Cahn & Siegel, *supra* note 14, at 18.

113. *Id.*

scrutiny to show that its dangers are outweighed by its potential benefits.[114] Electronic cigarettes have not been subject to the same oversight, and thus the carcinogens and toxins in them cannot be deemed to be at a level of acceptable risk. Just because electronic cigarettes are *safer* than traditional cigarettes does not mean they are *safe*.[115]

Thus the health risks raised by these products are substantial enough to warrant concern by regulatory agencies and public health officials. Moreover, these concerns, although uncertain, are important factors to consider when evaluating whether electronic cigarettes represent an avenue for harm reduction.

2. Use of Electronic Cigarettes as a Harm Reduction Strategy

Despite their potential health risks, electronic cigarette advocates see great potential in the use of these devices as a harm reduction strategy.[116] Harm reduction seeks to prevent the harmful health consequences of tobacco use without addressing the root problem of nicotine addiction.[117] The strategy has been summed up nicely:

> We can reduce tobacco related death and disease far more rapidly than we can reasonably expect to reduce nicotine use by focusing on the fact that people smoke for nicotine but die from the smoke. Applying harm reduction principles to public health policies on tobacco/nicotine is . . . simply a rational and humane policy . . . [and] a pragmatic response to [the] market . . . .[118]

While smokeless tobacco and NRT have been utilized in attempts to divert smokers away from cigarettes with very limited success,[119] electronic cigarette proponents see greater potential in electronic cigarettes. First, electronic cigarettes may be a more beneficial harm-reduction tool than smokeless tobacco because they pose fewer health risks than traditional smokeless tobacco.[120] Second, electronic cigarettes might be more effective at moving smokers away from traditional cigarettes than traditional NRT devices such as the nicotine patch or nicotine gum.[121] This is because electronic cigarettes not only provide nicotine, but also simulate the physical act of smoking, which might provide a psychological "placebo" effect which helps to increase the rate of cigarette abstinence.[122]

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114. *See supra* notes 41–43 and accompanying text (describing the FDA's drug approval standards).

115. Even those who advocate for the use of electronic cigarettes in a harm reduction context acknowledge that the presence of carcinogenic tobacco-specific nitrosamines in the products is troubling and means that "[the products] cannot be considered safe, as there is no threshold for carcinogenesis . . . ." Cahn & Siegel, *supra* note 14, at 26.

116. *See id.* at 27.

117. *Id.* at 16.

118. David Seanor et al., *Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic*, 18 INT'L J. DRUG POL'Y 70, 74 (2006).

119. *See, e.g.*, Micah L. Berman, *Tobacco Litigation Without the Smoke? Cigarette Companies in the Smokeless Tobacco Industry*, J. HEALTH CARE L. & POL'Y 7, 11–13 (2008) (explaining the negative effects of smokeless tobacco and the concerns that alternatives to cigarettes actually increase overall tobacco use).

120. *Id*.

121. Cahn & Siegel, *supra* note 14, at 22–23, 26.

122. *Id.* at 23, 26.

While the use of electronic cigarettes for harm reduction has great potential, there are some troubling issues with the strategy. First, it may be unwise to use a harm reduction strategy with a product for which little is known about its physiological effects or health consequences.[123] In essence, harm reduction should be based on demonstrable evidence that one product is actually safer than the other, not on unsubstantiated claims of safety,[124] and currently electronic cigarette manufacturers lack independent data demonstrating the safety of their products.

A second concern is the specter that electronic cigarettes might increase the overall prevalence of nicotine addiction in the population and provide a "gateway" path to traditional tobacco use; that is, that consumers will start using electronic cigarettes, become addicted to nicotine, and then migrate to traditional cigarettes.[125] This danger seems especially prominent with youths, who may be drawn to electronic cigarettes because of the availability of candy-like flavors and the marketing of electronic cigarettes as "green" and healthy.[126] Additionally, because electronic cigarettes are sold mainly over the internet, minors can easily acquire these products.[127] The dangers of electronic cigarettes serving as a gateway to traditional cigarettes are somewhat speculative, but are still concerning.[128] These concerns must be addressed by continuing to study the effects of the products and by regulatory control if harm reduction is to be a viable public health approach.

B. FDA Regulation of Electronic Cigarettes after Sottera

Two approaches for federal regulation of electronic cigarettes remain open in light of the ruling in *Sottera*. On the one hand, electronic cigarettes can be regulated under the FDCA if the manufacturer makes clear, express statements about therapeutic intent.[129] However, if marketed only for recreational use, electronic cigarettes must be regulated under the TCA.[130] While the FDA initially contested that the TCA did not give it adequate authority to regulate electronic cigarettes to protect the public health, the DC Circuit disagreed, stating that the TCA provided "broad regulatory authority" and was an "adequate remedy" for regulating tobacco products.[131] This section will examine how TCA might apply to electronic cigarettes, and whether it provides an adequate response to the health concerns discussed above.

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123. Cobb et al., *supra* note 30, at 2340.

124. *Id.* at 2342 ("[H]ealth and safety claims based on assumptions are unacceptable.")

125. *See* Yamin et al., *supra* note 13, at 608.

126. *Id.*

127. *See id.* ("[E]-cigarettes . . . can be purchased from Web sites that do not verify age."). Concerns about youths purchasing electronic cigarettes have caused many states to enact legislation prohibiting their sale to minors. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 119405 (West 2011); COLO. REV. STAT. ANN. § 18-13-121 (West 2011); N.H. REV. STAT. ANN. § 126-K:4 (2010); N.J. STAT. ANN. § 2A:170-51.4 (West 2011); UTAH CODE ANN. § 76-10-104 (LexisNexis 2011).

128. It is worth noting that, as of yet, there is no evidence of nonsmokers using electronic cigarettes. Cahn & Siegel, *supra* note 14, at 26.

129. *See* Sottera, Inc. v. FDA, 627 F.3d 891, 898 (D.C. Cir. 2010) (noting that the FDA is allowed to "regulate tobacco products marketed for therapeutic purposes" under the FDCA).

130. *Id*.

131. *Id*.

First, because the FDA has the ability to impose standards on the constituents of electronic cigarettes, it can make these products safer. The FDA may impose restrictions on the standards of tobacco products if "appropriate for the protection of the public health."[132] The FDA could proscribe nicotine yields, require the elimination of harmful constituents, and regulate the presence of additives and ingredients in electronic cigarettes.[133] Furthermore, the FDA could require testing of electronic cigarettes to make sure they conform to the product standards it sets.[134] These provisions will go a long way towards addressing the health risks posed by electronic cigarettes. The FDA could standardize the nicotine content of electronic cigarettes, which could curb the danger of nicotine poisoning to users. It could also seek to prevent dangerous substances like glycerine or diethylene glycol from contaminating electronic cigarettes. While the FDA could impose manufacturing standards,[135] because most electronic cigarette makers are not in the U.S., these standards would not have any direct effect. However, the FDA could brand any products containing poisonous substances as adulterated;[136] adulterated electronic cigarettes would be subject to seizure by the FDA.[137] These measures would help ensure the products are safer for their users.

Second, the FDA could stop electronic cigarette companies from targeting youths and non-smokers; this would prevent electronic cigarettes from creating new nicotine addicts, who might later start using traditional tobacco. The FDA can restrict the marketing of electronic cigarettes, and also subject them to labeling requirements.[138] Thus, under the TCA, the FDA could prohibit advertising that portray electronic cigarettes as safe or "green."[139] Labeling could inform consumers that electronic cigarettes have not been proven safe, and are not intended as a smoking-cessation device. Also, with its ability to eliminate "additives," the FDA could prohibit the candy-like flavorings which appeal to young people.[140] These measures would ensure that consumers are not misled into thinking that electronic cigarettes have been proven safe, and also ensure that minors are not targeted by advertising.

Finally, because so many of the public health concerns about electronic cigarettes stem from the uncertain and incomplete data around them, the FDA could address this by requiring manufacturers submit health information about their products. The FDA can require manufacturers to submit information about the product's constituent chemicals, as well as information about their

132. 21 U.S.C. § 387g(3)(A)(1) (2009).
133. *See id.* § 387g(4)(A)–(B).
134. *Id.* §§ 387g(4)(B)(ii), (iv).
135. *See id.* § 387f(e) (listing the FDA's authority to set manufacturing standards).
136. *See id.* § 387b (listing provisions for adulterated tobacco products).
137. *Id.* § 334(a)(2)(E).
138. *Id.* § 387f(d).
139. This kind of restriction might happen under the TCA's modified risk tobacco product provisions, which considers a product misbranded if it is marketed as being harmless or reducing the risk of disease unless the FDA approves such marketing by designating a product "modified risk." *See generally id.* § 387k (modified risk provisions). *See also* Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 75 (D.D.C. 2010) (stating that because electronic cigarettes are marketed as a healthier alternative to regular cigarettes, they fell within the TCA's definition of modified risk tobacco product).
140. *See* 21 U.S.C. § 387(1) (defining additives to include "substances intended for use as a flavoring . . .").

toxicological and physiological effects.[141] This will help public health officials to better evaluate the threat posed by electronic cigarettes, and thus craft a more appropriate regulatory response.

The methods detailed above are merely the ways for the FDA to address public health issues raised by electronic cigarettes; state and local governments have also addressed these concerns through their own regulations. This Note will now evaluate one way in which states seek to regulate electronic cigarettes: public smoking bans.

C. State and Local Regulation of Electronic Cigarettes

State and municipal governments will play an important role in the regulation of electronic cigarettes, just as they play an important role in regulating traditional tobacco products.[142] One prominent form of state and local regulation that will affect electronic cigarettes is the public smoking ban. Due to the serious dangers posed by environmental tobacco smoke (ETS), such as second hand[143] and third hand[144] smoke, many state and municipal governments restrict tobacco use in public places. These statutes seek to protect non-consenting individuals in the public domain from being exposed to harmful ETS.[145] These laws tend to prohibit smoking in the entire indoor public arena: public buildings, bars, restaurants, and enclosed workplaces.[146] Today, 39 states and 3,315 municipalities have laws restricting where smoking is allowed.[147] How these statutes apply to electronic cigarettes will play an important role in the public health response to the rise of electronic cigarettes.

This Part will first determine if state and local smoking bans, written with traditional tobacco use in mind, also ban the public use of electronic cigarettes. Second, it will examine the rationales used by governments which have explicitly banned the use of electronic cigarettes in public; these governments often apply the reasoning used to ban traditional tobacco products to also ban electronic cigarettes. However, those justifications have limited applicability to electronic cigarettes. Finally, using case law from challenges to public smoking bans as an analogy, this Part will analyze the legality of bans on the public use of electronic cigarettes.

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141. *Id.* § 387d(a).

142. *See* Demick, supra note 10 (discussing state bans, regulations, and high taxes imposed on traditional cigarettes).

143. *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF INVOLUNTARY EXPOSURE TO TOBACCO SMOKE: A REPORT OF THE SURGEON GENERAL 11–16 (2006), *available at* http://www.surgeongeneral.gov/library/secondhandsmoke/report/ (summarizing the adverse effects of secondhand smoke on reproduction, child development, respiratory disease, cancer, and cardiovascular disease).

144. See Roni Caryn Rabin, *A New Cigarette Hazard: 'Third Hand Smoke'*, N.Y. TIMES, Jan. 2, 2009, http://www.nytimes.com/2009/01/03/health/research/03smoke.html (discussing how even if not directly exposing others to second hand smoke, smokers still expose others to toxic chemicals because carcinogenic residue clings to hair, clothing, and furniture).

145. Patrick Kabat, Note, *"Till Naught but Ash Is Left to See": Statewide Smoking Bans, Ballot Initiatives, and the Public Sphere*, 9 YALE J. HEALTH POL'Y L. & ETHICS 128, 136 (2009).

146. *Id.* at 134.

147. *Overview List—How many Smokefree Laws?*, AM. NONSMOKERS' RIGHTS FOUND., (July 1, 2011), http://www.no-smoke.org/pdf/mediaordlist.pdf. *See also* Kabat, *supra* note 142, at 137–45 (classifying state smoking bans into five categories based on their restrictiveness, ranging from "Right to Smoke" states to "Draconian" states).

1. The Application of Existing Public Smoking Bans to Electronic Cigarettes

Much like the controversy over whether electronic cigarettes meet the FDCA definition of drug or device or whether they were merely tobacco products, electronic cigarettes also complicate the traditional definitions used by state and local laws which prohibit smoking in public places. The primary goal of a public smoking ban is to protect the public health by preventing non-consenting bystanders from being exposed to dangerous second-hand smoke. For this reason, many bans are limited to prohibiting the use of combustible tobacco: cigarettes, pipes, cigars, and the like.[148] Smokeless tobacco products like chewing tobacco or snus, which do not impose adverse health costs on non-users, are normally not constrained by the bans.[149]

This focus on banning combustible tobacco means that new forms of nicotine delivery, like electronic cigarettes, are outside the scope of such bans; the narrow definition given to the prohibited act precludes the bans from being extended to new products like electronic cigarettes. For instance, Kansas has a public smoking ban which is fairly typical, defining smoking as "possession of a lighted cigarette, cigar, pipe or burning tobacco in any other form or device designed for the use of tobacco."[150] The Kansas Attorney General concluded that this would not affect the use of electronic cigarettes because the devices lacked burning tobacco.[151] Thus, bans that focus on combustion of tobacco will not prevent vapers from using these devices in public places.

On the other hand, governments with vaguer definitions of "smoking" might be able to extend their bans to cover electronic cigarettes. Without the restrictive language requiring burning tobacco, a governmental body could conclude that electronic cigarette users are violating the ban because they are, in effect, "smoking." If the crux of the act of "smoking" is the inhalation in, and exhalation out, of smoke into the lungs, [152] then in this regard, electronic cigarettes are substantially similar to normal cigarettes. As the District Court in *Smoking Everywhere* stated, electronic cigarettes are "designed to look and to be used just like traditional cigarettes."[153] Functionally, users operate both in the same manner: with one product, nicotine carrying smoke is inhaled and exhaled, while with the other, nicotine laced water vapor is inhaled, but the physical actions of the user are no different.

However, a government using this kind of rationale to ban electronic cigarettes will be twisting the meaning of ordinary terms. A strong argument against this line of reasoning is that there can be no "smoking" without smoke, and because electronic cigarette users are not inhaling smoke (the byproduct of combustion), they are not "smoking."[154] Virginia's Attorney General issued an

148. *See, e.g.*, Smoke Free Illinois Act, 410 ILL. COMP. STAT. 82/10 (2010) (defining smoking).

149. *See* Kabat, *supra* note 145, at 137 (discussing the purpose of smoking bans is to protect non-users from ill effects of secondhand smoke).

150. Kansas Indoor Clean Air Act, KAN. STAT. ANN. § 21-4009(o) (West 2010).

151. Lefler, *supra* note 2.

152. *See Smoke*, DICTIONARY.COM, (last visited Sept. 27, 2011) (defining "smoking" as "to draw into the mouth and puff out the smoke of tobacco or the like").

153. Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 64 (D.D.C. 2010).

154. *See* Op. Va. Att'y Gen. (Apr. 27, 2010), *available at* http://www.oag.state.va.us/Opinions%20and%20Legal%20Resources/Opinions/2010opns/10-029-Peace.pdf.

advisory opinion refusing to interpret his state's public smoking ban in a manner that covered electronic cigarettes, stating that deeming the vapor created by electronic cigarettes to be smoke would not fit with the ordinary and plain meaning of the statutory terms.[155]

Therefore, unless existing public smoking bans are amended to specifically include electronic cigarettes, vapers will be free to use these devices in public places where traditional cigarettes would be banned.[156]

2. Keeping Vaping Out of the Public Domain: The Rationale for Extending Smoking Bans to Electronic Cigarettes

Some states and municipalities believe that the use of electronic cigarettes in places where ordinary tobacco use is banned constitutes a public health threat; noting that their current public smoking bans would not adequately prevent the use of electronic cigarettes, they have taken steps to amend their preexisting smoking bans. Currently, at least one state legislature—New Jersey—has extended its statewide indoor smoking ban to prohibit electronic cigarette use in this manner.[157] There is also new regulation at the local level: Somerset, Massachusetts;[158] Suffolk County, New York;[159] and King County, Washington;[160] among others, have all passed ordinances prohibiting electronic cigarette use in places where smoking is banned by specifically including electronic cigarette use as a banned activity. The justifications used by these governments in banning electronic cigarettes often echo the reasoning used to ban the public use of traditional cigarettes, even though these rationales do not perfectly translate to these novel nicotine delivery systems.

First, local governments have looked at potential health risks associated with electronic cigarettes and cited a policy of protecting "residents against untested nicotine products like e-cigarettes . . . ."[161] For example, New Jersey implied that electronic cigarettes could pose a secondhand risk to nonusers,

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155. *Id* at 2.

156. The Department of Transportation's (DOT) experience with its airline smoking ban reinforces the argument that bans which merely prohibit "smoking" must still be amended to cover electronic cigarettes. The DOT's current airline smoking ban merely states that "[a]ir carriers shall prohibit smoking on all scheduled passenger flights," with "smoking" being undefined. 14 C.F.R. § 252.3 (2009). The DOT initially stated that this language prohibiting "smoking" was sufficient for the ban to also cover electronic cigarettes. *See* Michael Felberbaum, *Use of E-Cigs Not Allowed on U.S. Flights*, ABC NEWS (Feb. 11, 2011), http://abcnews.go.com/Travel/wireStory?id=12893000. However, the DOT recently proposed to amend its ban to specifically cover the use of electronic cigarettes under the prohibited act of smoking. *See* Smoking of Electronic Cigarettes on Aircraft, 76 Fed. Reg. 57008, 57011–12 (proposed Sept. 15, 2011) (to be codified as 14 C.F.R. pt. 252). This suggests that the DOT reconsidered the issue and determined it needed specific language to cover the devices.

157. *See* N.J. STAT. ANN. § 26:3D–57 (West 2010) (defining the prohibition on indoor smoking ban to include "the inhaling or exhaling of smoke or vapor from an electronic smoking device").

158. Grant Welker, *Somerset Wants to Ban E-cigarettes*, WICKED LOCAL SWANSEA (Aug. 6, 2010), http://www.wickedlocal.com/swansea/news/x1869746351/Somerset-wants-to-ban-e-cigarettes.

159. Cnty, Legis., Suffolk Cnty., 2009, Res. No. 717, Adopting Local Law No. 29-2009 (N.Y. 2009) (amending Suffolk County Code ch. 437), *available at* http://legis.suffolkcountyny.gov/Resos2009/i1347-09.pdf [hereinafter Suffolk County Ban] (enacting legislation banning the use of electronic smoking devices in public places).

160. KING COUNTY, WASH., BOARD OF HEALTH CODE §§ 19.12.010–19.12.120 (2010), *available at* http://www.kingcounty.gov/healthservices/health/BOH/~/media/health/publichealth/documents/boh/code/BOHCodeTITLE19.ashx (restricting the sale, use and availability of electronic smoking devices).

161. Suffolk County Ban, *supra* note 159.

stating "risk to persons exposed to their smoke or vapor because of a known irritant contained therein and other substances that may . . . be identified as potentially toxic to those inhaling the smoke or vapor."[162] King County relied on the FDA's findings that the devices contained carcinogenic and mutanogenic materials when making its determination that electronic cigarettes represent a threat to public health.[163] Local governments clearly see the public electronic cigarettes as a public health threat.

A concern with protecting the health of its citizens is also the primary rationale of traditional public smoking bans; governments believe that citizens in the public domain should not have to be exposed to the harmful secondary effects of tobacco smoke.[164] Because smokers impose "negative externalities" on others by creating hazardous ETS,[165] governments believe it is fair to burden their freedom to smoke in public and favor the right of nonsmokers to have a healthier environment free of ETS.[166] But this rationale is primarily focused on preventing health risks to nonsmokers: "[S]tatewide ETS legislation does not seek to prevent smokers from harming themselves, but rather to prevent them from harming non-consenting bystanders by producing ambient tobacco smoke."[167] The protection of non-consenting bystanders has become the prevailing justification for public smoking bans.

The health risks local governments cite when banning electronic cigarettes do not seem to fit with this justification for traditional smoking bans. While there is a litany of evidence showing the health risks to nonsmokers from ETS, there is no evidence that electronic cigarettes could create health hazards to anyone not directly using the product. While the FDA's examination of electronic cigarettes did find hazardous constituents, the FDA never suggested that the vapor would be harmful when exposed to bystanders secondhand; instead, the FDA only mentioned the risks to actual users.[168] Direct inhalation of the electronic cigarette's water vapor is an obvious method for how users could be exposed to any hazardous chemicals, but no theory has been suggested as to how those same chemicals could be transmitted secondhand, once the user has exhaled the vapor from their lungs.[169] And

162. 2009 N.J. Sess. Law Serv. Ch. 182 (West).

163. King County, WA, Board of Health Code § 19.12.030.

164. Kabat, *supra* note 145, at 136.

165. Thomas A. Lambert, *The Case Against Smoking Bans*, 13 MO. ENVTL. L. & POL'Y REV. 94, 95–96 (2005).

166. *See* Kabat, *supra* note 145, at 137 (discussing the balancing of rights of smokers and nonsmokers).

167. *Id.* at 136. It is for this reason that only cigarettes and cigars are usually affected by smoking bans; other forms of tobacco use, like chewing tobacco or snus, are unaffected by these laws because although they can be harmful to the user, they do not create an environmental hazard that endangers the health of bystanders. *See supra* notes 145–146 and accompanying text.

168. *See FDA Warns of Health Risks Posed by E-Cigarettes*, FDA CONSUMER HEALTH INFO. (July 2009), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173430.pdf ("[L]aboratory analysis . . . indicates that electronic cigarettes expose *users* to harmful chemical ingredients" (emphasis added)).

169. During the author's research, he did not find any sources positing a theory for how secondhand exposure to electronic cigarette vapor could be hazardous. The few articles that did mention secondhand exposure merely noted the general lack of information about electronic cigarettes and suggested such a danger *could* possibility exist. *See, e.g.*, Wollscheid &. Kremzner, *supra* note 15, at 1740 ("The actual effects, including effects of secondary exposure, of the vapor are unknown."); Yamin et al., *supra* note 13, at 608 ("[E]-cigarettes may have other toxins, even in their exhaled secondhand vapor."). However, some statements suggest that the threat from secondhand exposure is minimal. *See* Press Release, Am. Ass'n Pub. Health

although electronic cigarettes could endanger their primary users, the public health justification for smoking bans does not seek to prevent a primary user from smoking because of the harm it does to his own body—paternalistic justifications in the smoking debate have not yet reached this far. Therefore, this first justification for banning the public use of electronic cigarettes does not closely follow the rationales of traditional smoking bans, because dangers to the primary user do not justify a ban, and the dangers to non-users are mere speculation.[170]

The second justification state and local governments cite when extending their smoking bans to electronic cigarettes is a "social norm" rationale, which theorizes that unrestricted electronic cigarette use in public will make traditional cigarette smoking seem acceptable.[171] The social norm rationale is often cited as a justification for traditional smoking bans; its advocates think bans decrease the prevalence of smoking by making the behavior socially costly.[172] This theory sees smoking bans as providing a normative community statement that smoking is unacceptable and emboldening criticism and isolation of smokers, which will motivate smokers to quit in order to regain social approval.[173] In this way, the net effect of the social norm rationale is to further the public health: if the social norming impact of smoking bans decreases the prevalence of smoking, then they will also decrease the prevalence of tobacco related death and disease. The social norm rationale was directly relied on by King County in banning electronic cigarette use: one county health official testified that "[b]y returning smoking to the public eye, public e-cigarette use threatens to undermine the social norming impact" of the public smoking ban.[174] Because electronic cigarettes are so similar in appearance to traditional cigarettes, a traditional smoker who sees a vaper using in public receives a "'powerful subliminal message'" that smoking in public is acceptable.[175] This would indirectly endanger public health by encouraging traditional cigarette use, potentially leading to more dangerous ETS.[176] Therefore, to preserve the appearance that smoking is unacceptable, governments may ban electronic cigarette use in public.

Physicians, AAPHP Statement re State Regulation of E-Cigarettes, at 2, *available at* http://www.aaphp.org/Resources/Documents/20100402AAPHPEcigLegisStatemnt.pdf [hereinafter AAPHP Statement] ("[W]e can confidently state that the risk to others sharing an indoor environment with one or more vapers . . . is almost sure to be much less than 1% the risk posed by environmental tobacco smoke.").

170. Whether a merely speculative threat to the health of nonusers is enough to justify a ban on electronic cigarettes on public health grounds is discussed in Part IV, *infra.*

171. Vanessa Ho, *King County bans public e-cigarette smoking*, SEATTLE P.I., Dec. 16, 2010, http://www.seattlepi.com/local/431933_e-cig-ban.html?source=mypi.

172. Lambert, *supra* note 165, at 103.

173. *See id.* at 102–104 (2005) (describing and criticizing the norm based theory of smoking bans). *See also* Dan M. Kahan, *Gentle Nudges v. Hard Shoves: Solving the Sticky Norms Problem*, U. CHI. L. REV. 607, 625–27 (2000) (stating that initial anti-smoking regulations resulted in a "gentle nudge" of the social norms towards disapproval of smoking, which in turn enabled stricter regulation of smoking in the public domain).

174. Vanessa Ho, supra note 171. *See also* KING COUNTY, WASH., BOARD OF HEALTH CODE § 19.12.030 (2010) (noting the Board of Health's fear that "the use of electronic smoking devices in public places and places of employment returns smoking to the public consciousness"); Welker, *supra* note 199 (quoting a Somerset official as saying "'[w]e don't want people to get the impression that you can sit in your local establishment and smoke'").

175. Ho, *supra* note 171.

176. *Id.* (describing the rationale used by King County in banning public use of electronic cigarettes).

The notion that electronic cigarette use will lead to the re-norming of actual cigarette use is a fairly weak justification for banning the public use of electronic smoking devices. Little to no empirical evidence exists supporting the notion that smoking bans actually make smoking less desirable, and they can even have the opposite effect; intrusive bans can make the products more appealing through a phenomenon called "norm backlash."[177] Likewise, there is no evidence to suggest that electronic cigarettes would encourage the use of traditional tobacco products and undermine smoking bans—like the potential for secondhand health effects, such a threat is speculative.[178] Furthermore, part of the social norm rationale is that smokers, by creating hazardous secondhand smoke, are participating in a socially unacceptable or blameworthy act, and this justifies curtailing their rights. However, if electronic cigarette use does not endanger bystanders, using the devices in public is not a blameworthy act, and the fact that it may be interpreted as condoning the blameworthy acts of others seems to be an unfair justification for limiting their freedoms.

A third, novel justification also exists for extending smoking bans to electronic cigarettes: the local government's interest in consistency and enforcement of its smoking ban. Local governments have reasoned that public electronic cigarette use would make enforcement of public smoking bans an "enforcement nightmare."[179] Because they appear similar physically and are used in the same manner, officials reason that they will have a hard time distinguishing vapers from actual cigarette smokers, which will enable actual violations of the smoking ban to escape detection or go unpunished.[180] Officials think that this uncertainty will undermine compliance with smoking regulations.[181] A fractured or unenforceable smoking ban could result in the re-emergence of secondhand smoke, to the detriment of the public health. Thus, in order to protect the cohesiveness and enforceability of their preexisting smoking bans, local governments prohibit use of electronic cigarettes where traditional smoking is also banned.

3. Potential Legal Challenges to Public Electronic Cigarette Bans

Bans on the use of electronic cigarettes in public places are sure to anger many users, who may resort to litigation.[182] But if vapers wish to challenge the legitimacy of these bans in court, they will face a difficult battle. Public smoking bans are consistently upheld "as valid exercises of state and local

177. *See* Lambert, *supra* note 165, at 11 (criticizing social norm justifications for smoking bans as lacking in empirical evidence showing they reduce the number of smokers).

178. *See* Ho, supra note 171 (quoting a dissenting member of the King County Board of Health as saying "'[w]e don't really know what the impact might be on social norms . . . [w]e're projecting.'").

179. Suffolk County Ban, *supra* note 159. *See also* KING COUNTY, WASH., BOARD OF HEALTH CODE § 19.12.030 (2010) (stating that public electronic cigarette use would "complicate[] enforcement of the state and county laws governing the smoking of tobacco products in public places").

180. Suffolk County Ban, *supra* note 159.

181. *Id.*

182. *See* David Williams, *Inclusion of E-Cigarettes in Smoking Ban has Some Users Feeling Burned*, WAVE 3 NEWS (Apr. 26, 2011), http://www.wave3.com/story/14406057/inclusion-of-e-cigarette-in-smoking-ban-has-some-users-feeling-burned (stating that vapers in Bullitt County, Kentucky, upset about a proposed ban on the public use of electronic cigarettes, filed a lawsuit against the Board of Health).

authority."[183] This is because as public health and safety regulations, smoking bans are reviewed under the deferential "rational basis" standard.[184] Courts have consistently rejected arguments that smoking bans should receive higher scrutiny because they impair smokers First Amendment rights[185] or their right to travel.[186] Courts also reject arguments that public smoking bans treat smokers as a "suspect class" under the Equal Protection Clause of the Fourteenth Amendment.[187] Likewise, bans on public use of electronic cigarettes will not merit heightened scrutiny, meaning that the rational basis test will apply and the ban will be presumed valid.[188] To defeat this presumption the challenging party must show it "has no foundation in reason and is a mere arbitrary or irrational exercise of power having no substantial relation to the public health . . . ."[189] It will be hard for vapers to meet this burden.

Vapers could argue that because there is little scientific evidence showing that electronic cigarettes are dangerous to users or nonusers, then public use bans are irrational. However, under rational basis review, a legislature is not required "to await concrete proof of reasonable but unproven assumptions before acting to safeguard that health of its citizens."[190] Instead, legislatures are given wide latitude to make choices "'based on rational speculation unsupported by evidence or empirical data,'" and courts do not second guess the wisdom of those choices.[191] Public use bans of electronic cigarettes have plausible public health rationales: as detailed above, initial tests found the devices contain toxic and carcinogenic materials.[192] And while there is no evidence that electronic cigarettes pose an environmental hazard, it is well within the legislature's right to speculate that such a threat could reasonably exist, given that exhaled vapor will come into contact with nonusers.[193] Outside of their potential health hazards, other government interests support banning public electronic cigarette use, such as preserving the ability to enforce existing smoking bans.[194] Thus, it is permissible to extend public smoking bans to electronic cigarettes.[195] Whether these bans are necessary to

183. *See generally* 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, 403–06 (2007) (discussing the case law on local smoking bans).

184. *Id.*

185. *See, e.g.*, NYC C.L.A.S.H., Inc. v. City of N.Y., 315 F. Supp. 2d 461, 472–80 (S.D.N.Y. 2004) (holding that public smoking bans do not impermissibly interfere with smokers' freedoms of association, assembly, or speech).

186. *Id.* at 480.

187. *Id.* at 481–83.

188. *Id.* at 486.

189. Nectow v. City of Cambridge, 227 U.S. 183, 187–88 (1928) (internal quotation marks omitted).

190. Beatie v. City of N.Y., 123 F.3d 707, 713 (2d Cir. 1997).

191. *NYC C.L.A.S.H.*, 315 F. Supp. 2d at 486 (quoting Heller v. Doe by Doe, 509 U.S. 312, 320 (1993)).

192. *See supra* Part III.A.1.

193. The prospect of second hand effects gives state and local governments a rational reason for distinguishing between electronic cigarettes and traditional NRT. While both types of products contain similar levels of carcinogens, electronic cigarettes create an environmental byproduct through their exhaled vapor, while NRT like nicotine patches or gum create no such byproduct; thus only electronic cigarettes could plausibly endanger nonusers.

194. *See supra* notes 179–81 and accompanying text.

195. *See* Kuhn v. Cnty. of Suffolk, No. 28869/2009, 2010 N.Y. Misc. LEXIS 5524 at *9–10 (N.Y. Sup. Oct. 15, 2010) (holding that Suffolk County's public use ban on electronic cigarettes was not arbitrary because

protect the public health is considered in the next section.

IV. RESOLUTION

Having surveyed how electronic cigarettes interact with or avoid current regulatory systems, we are left with the question of how these systems should adapt to the influx of these products. However, before deciding how to react, it is useful to consider the policy that will drive any changes and new approaches to regulation. This Note takes the position that, when engaging in regulation of electronic cigarettes (whether used recreationally or for therapeutic purposes), the overarching policy goal should be the protection of the public health. This goal may be balanced against other interests, such as the economic interests of electronic cigarette manufacturers, or the interest of vapers in having the unrestricted ability to use the devices in public. But when there is a conflict between these interests, protecting the public health should prevail. With this goal in mind, this Note advocates approaching electronic cigarettes in the following manner: First, given the current uncertainty about the health risks posed by electronic cigarettes, a harm reduction approach should not be adopted. Second, federal regulation under the TCA should be carefully crafted to address the public health risks posed by electronic cigarettes. Finally, to prevent bystanders from being harmed by unforeseen secondhand effects of electronic cigarettes, and to prevent an "enforcement nightmare, state and local governments should prohibit the use of electronic cigarettes in public spaces where traditional cigarettes are also banned.

A. Using Electronic Cigarettes for Harm Reduction is Improper

A harm reduction strategy, discussed in Part III.A.2, would seek to shift traditional tobacco users towards products like electronic cigarettes, which are touted as low risk. A harm reduction strategy would advocate for lax regulation of electronic cigarettes in order to make the products accessible to consumers and to ensure that the costs of complying with regulation would not drive companies out of business. However, because of the health risks from direct use and the potential for the devices to be used as a gateway to traditional tobacco, there are concerns about utilizing electronic cigarettes in this manner. Without conclusive data, the essence of the disagreement about the harm reduction utility of electronic cigarettes use comes down to presumptions: should regulatory bodies presume the devices are dangerous because preliminary analyses have shown there are potential risks?[196] Or, because logically the devices seem safer than traditional tobacco, should "[the] burden of proof [be] on the regulatory agency to demonstrate that the product is unreasonably dangerous for its intended use," as some proponents of electronic cigarettes have advocated?[197]

The interests of public health argue for the former approach; that is,

of the county's reliance on the health risks and enforcement issues created by electronic cigarettes).

196. *See, e.g.*, Cobb et al., *supra* note 30, at 2342 ("[H]ealth and safety claims based on assumptions are unacceptable.").

197. Cahn and Siegel, *supra* note 14, at 28.

putting the burden on electronic cigarette manufacturers to show that their products are safe. This is because there could be any number of unforeseen consequences stemming from the use of the devices. Without conclusive evidence about the health risks of electronic cigarette use, using them for harm reduction is premature, because "inherent in the concept of harm reduction is the process of premarket evaluation and demonstrable absence of unintended consequences . . . ."[198] Thus, in the interest of public health, it is not prudent to pursue a harm reduction strategy with electronic cigarettes until the products are shown not to be dangerous.

B. FDA Regulation should Address Quality Control and Marketing of Electronic Cigarettes

The public health requires active regulation of electronic cigarettes at the federal level, and from the standpoint of institutional competency, the FDA is well equipped to make an authoritative evaluation of the public health effects of electronic cigarettes and to regulate accordingly.[199] Failure to actively regulate would "vitiate whatever protection the Congress has created for the consumer."[200] But the FDA should take care that its regulations do not completely remove electronic cigarettes form the market, either directly or indirectly. Market removal could in fact cause more harm to the public health by taking away a product that many already rely upon to maintain their nicotine addiction; removal from the market might force electronic cigarette users to go back to using the assuredly more dangerous traditional cigarettes.[201] Furthermore, overly burdensome regulations could potentially drive electronic cigarette makers out of business, again forcing vapers to go back to traditional cigarettes.[202] Therefore, federal regulations should be crafted so that they address the most dangerous aspects of electronic cigarettes but are not so onerous that they take the products off the market.

The FDA can address many of the most glaring public health concerns raised by electronic cigarettes without resorting to an outright ban, whether it is regulating under the FDCA or the TCA. For instance, both acts give the agency the authority to impose labeling requirements: thus they could counteract the unsubstantiated health claims made by electronic cigarette

198. Cobb et al., *supra* note 28, at 2340.

199. Family Smoking Prevention and Tobacco Control Act, Pub L. No. 111-31, § 2(44), 123 Stat. 1776, 1780-81 (2009) (stating that the FDA possesses "the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of . . . labeling[] and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health").

200. Am. Pub. Health Ass'n v. Venemen, 349 F. Supp. 1311, 1317 (D.D.C. 1972).

201. Cahn and Siegel, *supra* note 14, at 28.

202. Regulation can favor large businesses by increasing the cost of overhead and production, and due to economies of scale, the larger companies can cope with this increase in cost while smaller companies cannot. Daniel Indiviglio, *Judge Overrules FDA On E-Cigarettes*, ATLANTIC, Jan. 15, 2010, http://www.theatlantic.com/business/archive/2010/01/judge-overrules-fda-on-e-cigarettes/33583. Some critics have argued that by attempting to regulate electronic cigarettes, the FDA is merely helping the tobacco industry by attempting to shackle newfound competitors in the electronic cigarette industry with burdensome regulation. *Id.* However, these critics often downplay the legitimate health concerns that would prompt the FDA to regulate electronic cigarettes.

manufacturers by requiring disclaimers that the devices have not been evaluated for safety or efficacy. The FDA could also impose regulations designed to prevent the devices from being marketed to children, by banning candy flavors and imposing age restrictions on the purchase of these devices. Finally, FDA regulation could address the poor quality control of electronic cigarettes by subjecting the devices to testing and recall, and imposing uniform manufacturing standards. This would help prevent hazardous substances from finding their way into the products which could poison the individual user. This should be the narrow scope of federal regulation of electronic cigarettes, at least until further studies produce more information.

Some may worry that a limited response by the FDA that leaves electronic cigarettes on the market is not sufficient to protect the public health. But state regulation might be able to fill the gaps left by the FDA. Given their traditional status as protectors of the public health, safety, and welfare, states may be able to adopt stronger regulations, depending on how they weigh the health threats and potential regulatory burdens.[203]

C. Public Smoking Bans should be Extended to Electronic Cigarettes

As for state and local smoking bans, public health interests support extending them to prohibit electronic cigarette use in public places. Because there is no evidence that electronic cigarette use poses any threat to non-consenting bystanders, many argue that such bans do nothing to protect public health. But again, this is a question of how much leniency the government should have to act when protecting the public health. Governments must have the flexibility to react to novel health threats as they arise. This is especially pertinent when dealing with novel nicotine delivery systems such as electronic cigarettes—a wide variety of nontraditional products now have the ability to transmit nicotine to users without combustion of tobacco,[204] and new methods are sure to be developed in the future. When such products enter the marketplace, there is rarely conclusive evidence about their health effects, because often they have not been studied. And when these products enter the marketplace, a lack of information showing they are unsafe should not lead to the presumption they are safe—absence of evidence is not evidence of absence. The burden should not be on the government to wait until all the empirical evidence is in before acting to regulate new nicotine delivery systems; it should be able to respond proactively to potential health threats.

Therefore, it would be prudent for state and local governments to adopt a cautious, better-safe-than-sorry approach, prohibiting electronic cigarette use in public places where traditional cigarettes are also banned until research indicates that they are not a hazard to non-users.[205] In the future, however,

203. As Justice Brandeis famously noted, a state can function as a laboratory, experimenting with different approaches to important public policy and safety issues. *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

204. *See supra* notes 17–20 (describing novel nicotine delivery systems other than electronic cigarettes).

205. Many public health researchers have adopted a better-safe-than-sorry approach to regulating electronic cigarettes in general, advocating regulation, or even removal from the market, until research shows the devices are safe. *See* Cobb et al., *supra* note 30, at 2341-42; Trtchounian & Talbot, *supra* note 100, at 52;

there is likely to be conclusive evidence on whether electronic cigarettes endanger non-consenting bystanders. If this evidence shows that electronic cigarettes are in fact not a danger to non-users,[206] should the devices be removed from the bans?

Such a step would not be required, although it might be a prudent policy for a government to adopt. But as noted above in Part III.C.2, *supra*, two other justifications support banning electronic cigarette use where traditional smoking is also banned: a social norm rationale, which bans electronic cigarettes to reinforce the appearance that society does not condone smoking, and a regulatory-efficiency rationale, which bans electronic cigarettes so that the ban on traditional cigarettes can be enforced effectively. These rationales are not concerned with the health effects of electronic cigarettes themselves. Instead, they protect the public health by preventing electronic cigarette use from increasing the prevalence of ETS from traditional tobacco products. Therefore, these rationales would still be relevant even if electronic cigarettes do not pose a danger to bystanders.

Given the deference with which local public health regulations are treated, these other rationales are most likely legally sufficient to support banning electronic cigarettes on public health grounds.[207] But from a policy perspective, other considerations come into play which may lead a government to avoid or rescind such bans if vaping does not pose a threat to non-consenting bystanders. For instance, equitable concerns may militate against banning electronic cigarettes in public spaces. Traditional smoking bans involve balancing the interests of smokers against the interests of non-smokers; given that there is such strong evidence showing the dangers of ETS to non-smokers, it is fair to burden the smokers. However, if electronic cigarettes are shown to pose no danger to others, and the only public health justification is that they may indirectly create ETS by encouraging traditional cigarette use, then that calculus changes. It seems unfair to burden vapers for such a tangential public health goal, and in effect, it punishes vapers for the health hazards created by a product which they do not use.

Furthermore, if electronic cigarettes are shown to present little danger, then it may be preferable to pursue a harm reduction strategy using electronic cigarettes.[208] If the public health would best be protected by a migration from traditional tobacco products to electronic cigarettes, one way to further such a

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Wollscheid & Kremzner, *supra* note 15, at 1741. Many public health organizations have also taken this position. *E.g*. World Health Org., Framework Convention on Tobacco Control, Control and Prevention of Smokeless Tobacco Products and Electronic Cigarettes, 6 (Sept. 15, 2010), *available at* http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_12-en.pdf. *But see* AAPHP Statement, supra note 169, at 2 (arguing that, given the relative risks of each product, traditional cigarette smokers should switch to electronic cigarettes, but taking no position on whether indoor smoking bans should cover electronic cigarettes).

206. There is a strong possibility that the evidence will indeed show that electronic cigarettes are not a hazard to non-users, because as of yet, no theory has identified a way in which the vapor from the devices could pose a danger through second-hand exposure. *See supra* note 169.

207. *See supra* Part III.C.3. Of course, such legislative deference would also protect a decision to exempt electronic cigarettes from public smoking bans. Just as courts have refused to recognize a "right" to smoke, they also have refused to recognize a "right" to be free from ETS. Raphael, *supra* note 183, at 405–06.

208. As this paper argues, a harm reduction strategy would only be prudent if it is shown that the dangers to both non-consenting bystanders *and* to users themselves are minimal or are deemed acceptable. The burden of presenting sufficient evidence should be put on the manufacturers, not the government.

strategy would be to exempt these products from public smoking bans, because a harm reduction strategy would seek to encourage traditional smokers to switch to electronic cigarettes. Allowing the products to be used where traditional cigarettes are banned would allow manufacturers to continue marketing an appealing feature of the products: the ability to use them "everywhere." It could also increase the appeal of the products by showing that while society does not approve of cigarette smoking, electronic cigarette use is socially acceptable.

Of course, the utility of encouraging electronic cigarette use in lieu of traditional cigarettes must be weighed against some competing factors. For instance, allowing electronic cigarette use in places where traditional cigarettes are banned would put additional burdens on regulators to enforce such a ban. Public health problems could result if electronic cigarette use actually increases the amount of ETS in public spaces. Also, the burdens resulting from different courses of actions should be considered; while exempting the products would marginally increase the freedom of vapers, if electronic cigarettes were still subject to smoking bans it would only be a minimal burden on their interests.[209] Weighing these kinds of competing concerns is the province of legislative policymaking. If electronic cigarettes are shown to pose little danger, then the rationales in favor of banning them to preserve the anti-smoking social norm and to ensure that tobacco smoking bans are enforceable may or may not be outweighed by the harm-reduction benefits of allowing their use. In this scenario, it would be up to lawmakers to evaluate the evidence and make the decision that best furthers the public health.

But for now, electronic cigarettes have not been shown to be safe for either users or nonusers, so the best course of action would be to impose a public use ban, pending further evidence.[210] This is in keeping with the overall public health response discussed in this Note: that a cautious approach at the federal, state, and local levels should seek to regulate electronic cigarettes at the level necessary to protect the public health, while taking care to ensure that regulation is not so burdensome that it prevents electronic cigarettes from being used in a harm-reduction capacity in the future, should the evidence warrant it.

V. CONCLUSION

The rise of electronic cigarettes has shown that when products are introduced into the market, they can often avoid regulatory authority because they do not fit neatly with existing regulatory classifications. Governments

209. A ban is not a complete prohibition on the use of electronic cigarettes, just on their use in public spaces where tobacco smoke is also banned. Thus the ban is only a minimal burden: to avoid its effects, vapers merely need to step outside.

210. As to the form of electronic cigarette bans, there are two options: updating the statutory language to include vaping in the definition of banned activities, or adopting a ban on all "smoking." While the latter standard might preserve the government's ability to apply the bans to new forms of novel nicotine delivery systems, it is also open to being challenged as vague and inapplicable to electronic cigarettes, which do not "smoke." *See supra* Part III.C.1. Therefore, the former, specific language approach is a better form of drafting; while it might necessitate revisiting and revising definitions, this does not impose a heavy burden on the government.

must be prepared to meet the regulatory challenges these new devices bring, with the goal of protecting the public health. Electronic cigarettes may eventually be proven to be safe, and thus could be an effective device for tobacco harm reduction. But for now, regulatory authorities should operate with the presumption that the devices pose dangers to public health. For this reason, regulation over their production, contents, marketing, and use in areas where traditional smoking is banned, is completely justified in order to protect the public health.