No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes

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ABSTRACT:

The adverse effects of smoking have fostered a natural market for smoking cessation and smoking reduction products. Smokers attempting to quit or reduce consumption have tried everything: "low" or "light" cigarettes; nicotine-infused chewing gum, lozenges, and lollipops; dermal patches; and even hypnosis. The latest craze in the quest to find a safer source of nicotine is the electronic cigarette. Electronic cigarettes (e-cigarettes) have swept the market, reaching a rapidly expanding international consumer base. Boasting nicotine delivery and the tactile feel of a traditional cigarette without the dozens of other chemical constituents that contribute to carcinogenicity, e-cigarettes are often portrayed as less risky, as a smoking reduction or even a complete smoking cessation product, and perhaps most troubling for its appeal to youth, as a flavorful, trendy, and convenient accessory.

The sensationalism associated with e-cigarettes has spurred outcry from health and medical professional groups, as well as the Food and Drug Administration (FDA), because of the unknown effects on public health. Inhabiting a realm of products deemed "tobacco products" under recent 2009 legislation, e-cigarettes pose new challenges to FDA regulation because of their novel method of nicotine delivery, various mechanical and electrical parts, and nearly nonexistent safety data. Consumer use, marketing and promotional claims, and technological characteristics of e-cigarettes have also raised decades old questions of when the FDA can assert authority over products as drugs or medical devices. Recent case law restricting FDA enforcement efforts against e-cigarettes further confounds the distinction among drugs and medical devices, emerging e-cigarette products, and

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traditional tobacco products such as cigarettes, cigars, and smokeless tobacco.

This Article investigates the e-cigarette phenomenon in the wake of the recently enacted Family Smoking Prevention and Tobacco Control Act of 2009 (TCA). It examines the tumultuous history of attempts at tobacco regulation by reflecting on the history of Congressional activity to regulate tobacco sales and promotion. Furthermore, this Article suggests a feasible approach to strengthening regulation of e-cigarettes under the existing statutory framework. This approach includes increased scrutiny of manufacturer and distributor claims that trigger drug and medical device provisions, utilization of new tobacco product and modified risk tobacco product provisions, and promulgation of new FDA regulations and guidance specifically directed at e-cigarettes.

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INTRODUCTION

The American public conscience has wrestled with knowledge of the adverse effects of smoking for decades, perpetuating an embattled division in the United States between smokers (and those who believe smoking is a personal freedom) and non-smokers (and those who believe that the public health risks and resulting health care costs outweigh personal freedom arguments). In response to the negative health effects of tobacco products and cigarettes in particular, a natural market for smoking cessation and smoking reduction products has emerged over the last 30 years. Those attempting to quit or reduce consumption have tried everything: "low" or "light" cigarettes; nicotine-infused chewing gum, lozenges, and lollipops; dermal patches; and even hypnosis. Regardless of one's position on the personal freedom argument, smoking is not only dangerous to health, it is an addiction—the human body becomes dependent on nicotine through a variety of mechanisms.

The latest craze in the quest to find a "safer" source of nicotine is the electronic cigarette. Electronic cigarettes (e-cigarettes) have swept the market, reaching a rapidly expanding international consumer base. They are composed of three basic standardized parts: the nicotine cartridge; the atomizer, which vaporizes the nicotine; and the battery that powers it.[1] Boasting the tactile feel of a traditional cigarette and rapid nicotine delivery without the dozens of other chemical constituents that contribute to the carcinogenicity of traditional cigarettes and cigarette smoke,[2] e-cigarettes are often portrayed as "safer" than traditional cigarettes, as a smoking reduction or even a complete smoking cessation product, and perhaps most troubling for its appeal to youth, as a flavorful, trendy, and convenient accessory.

The broad appeal of e-cigarettes is skyrocketing given the now incontrovertible scientific evidence of the destructive impacts of smoking on public health, including a consistent statistic that smoking accounts for

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1 Tobacco Fact Sheet: Electronic Cigarettes (E-Cigarettes), Legacy for Longer Healthier Lives, http://www.legacyforhealth.org/content/download/582/6926/version/4/file/Fact_Sheet-eCigarettes.pdf (last updated Dec. 2012).

2 U.S. Surgeon Gen., A Report of the Surgeon General: How Tobacco Smoke Causes Disease—The Biology and Behavioral Basis for Smoking-Attributable Disease Fact Sheet, U.S. Dep't Health & Human Servs., http://www.surgeongeneral.gov/library/reports/tobaccosmoke/ factsheet.html (last visited Apr. 5, 2013).

nearly 5.4 million cancer-related deaths worldwide each year,[3] including approximately 443,000 in the United States.[4] The attraction to e-cigarettes crosses many segments of the population: the heavy smoker wanting to quit or significantly cut back on cigarettes or nicotine use, the occasional smoker seeking a healthier alternative, the smoker seeking a legal way to get a nicotine fix in public places with smoking bans, the non-smoker who wants to try e-cigarettes for the nicotine without the harmful additives, and even the young hipster who wants to complete her technological portfolio with a sleek and popular device that looks and feels like a real cigarette, but brings with it an "atomizer" and celebrity endorsements. The use of e-cigarettes is on the rise—with group identity to "vaping"[5]—and is becoming a strong presence in various social media outlets and easy product purchasing online through distributors and affiliates or at convenience stores and retail establishments.

However, the sensationalism associated with e-cigarettes has spurred outcry from health and medical professional groups, as well as the Food and Drug Administration (FDA), because of the unknown effects on public health and an absent safety profile. Inhabiting a realm of products deemed "tobacco products" under recent 2009 legislation and subsequent case law,[6] e-cigarettes pose new challenges to FDA regulation because of their novel method of nicotine delivery, various mechanical and electrical parts, and nearly nonexistent safety data. Consumer use, marketing and promotional claims, and technological characteristics of e-cigarettes have also raised decades-old questions of when the FDA can assert authority over products as drugs or medical devices.

In the wake of the recently enacted Family Smoking Prevention and Tobacco Control Act (TCA), it is urgent to examine the scope and limitations of the legislative provisions as applied to the recent phenomenon of e-cigarettes. This Article will argue that the recent 2010 D.C. Circuit case *Sottera, Inc. v. FDA*[7] has hindered FDA attempts to regulate products that

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3 Tobacco Free Initiative: Tobacco Facts, WHO, http://www.who.int/tobacco/mpower/tobacco_facts/en/index.html (last visited Apr. 5, 2013).

4 CDC, Current Cigarette Smoking Among Adults—United States, 2011, 309 JAMA 539, 539-40 (2013).

5 Users refer to the process of vaporizing the nicotine within the electronic cigarette as "vaping." *See, e.g.*, Linda Hurtado, Some Say "Vaping" E-Cigarettes is Worse Than Smoking the Real Thing, ABC News (Aug. 16, 2011), http://www.abcactionnews.com/dpp/news/health/some-say-vaping-e-cigarettes-is-worse-than-smoking-the-real-thing.

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

7 *Id.*

fall outside the traditional realm of cigarettes and smokeless tobacco, thwarting Congressional purpose and introducing the potential for significant future public harm. However, despite the *Sottera* decision, the FDA retains powers to proceed against e-cigarettes, including drug and medical device provisions within the Food, Drug, and Cosmetic Act (FDCA), tobacco product provisions of the TCA (integrated into the FDCA) regarding new tobacco products and modified-risk tobacco products, and authority to promulgate product-specific regulations.

This Article does not condemn e-cigarettes, but propels the regulatory discussion forward. The Article proceeds in six parts, providing both a descriptive and prescriptive analysis of the FDA authority to regulate e-cigarettes after *Sottera*. Part I briefly examines fundamental issues of smoking, nicotine addiction, and the public health. Part II examines the tumultuous history of attempts at tobacco regulation by reflecting on the history of Congressional activity to regulate tobacco advertising and promotion, and particularly the monumental 2000 Supreme Court decision *FDA v. Brown & Williamson Tobacco Co.*,[8] which struck down the FDA's assertion of jurisdiction over cigarettes using drug and medical device frameworks. Part III analyzes the legislative provisions and overarching authority imparted to the FDA over tobacco products contained in the TCA. Part IV examines e-cigarettes and industry characteristics, various marketing and promotional tactics, public perceptions about the products, and public health perspectives and scientific studies. Part V examines the culmination of the FDA's attempts to regulate e-cigarettes in *Sottera* and highlights its present position on jurisdiction over these products. Part VI suggests a feasible approach for strengthening FDA regulation of e-cigarettes. The Part also discusses the importance of the scope of intent and intended use in marketing and advertising of the FDCA, the application of the drug and device provisions of the FDCA and the new product and modified-risk product provisions of the TCA, and the opportunity for the development of product-specific requirements through FDA regulations and guidance.

I. ADDICTION, NICOTINE, AND THE PUBLIC HEALTH

Scientists, health and medical professionals, regulators, policymakers, health advocates, and various other stakeholders have devoted tomes to the health effects of smoking and use of tobacco products. The Centers for Disease Control and Prevention (CDC) report that smoking costs the United

[8] 529 U.S. 120 (2000).

States an estimated $96 billion annually in direct medical expenses and an additional $97 billion in lost productivity.[9] This Article does not endeavor to reprise that literature, but only to touch on foundational theories of nicotine addiction and public health. The arguments contained in the Article stem from the position that nicotine itself is a dangerous substance because of its addictive qualities. Efforts to temper current cigarette and tobacco use should be encouraged; therefore, e-cigarettes may be less harmful for heavy or moderate smokers because they may reduce exposure to carcinogens and other toxic chemicals that cause serious disease and death. However, any use of products that contain pure nicotine[10] is potentially harmful based on theories of addiction and dependence. There are a multitude of risks that deserve consideration when contemplating appropriate regulation including the need for premarket assessment for product safety, restrictions on access, appropriate scope of advertising and promotion, and assurance of truthful and non-misleading labeling of such products.

Among other reasons, smokers smoke for the nicotine. Nicotine addiction is characterized as a form of drug dependence recognized in the current edition of the American Psychological Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-IV).[11] The most common form of nicotine delivery is the cigarette, which contains hundreds of toxic chemicals—69 of which have been found to cause cancer.[12] Tobacco smoke itself is a human carcinogen.[13] The cigarette (or cigar, cigarillo, or smokeless tobacco) is merely a conduit, a delivery vehicle for the nicotine contained within the tobacco. Aside from the carcinogenic and toxic effects of tobacco, smokers become addicted to the nicotine.[14]

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[9] CDC, Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004, 57 MORBITY & MORTALITY WKLY. REP., 1226, 1226-28 (2008).

[10] The products contain other ingredients as well, including propylene glycol, ethanol, glycerol (glycerin), acetylpyrazine, guaiacol, myosmine, and cotinine. *See, e.g.*, *FAQs*, NJOY, http://www.njoy.com/pages/FAQs.html (last visited Apr. 5, 2013).

[11] AM. PSYCHOLOGICAL ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS: DSM-IV-TR (4th ed. text rev. 2000); *see, e.g.*, Neal L. Benowitz, *Neurobiology of Nicotine Treatment Addiction: Implications for Smoking Cessation Treatment*, 121 AM. J. MED., at S3, S4 (Supp. 2008); Caroline Cohen et al., *CB1 Receptor Antagonists for the Treatment of Nicotine Addiction*, 81 PHARMACOLOGY BIOCHEMISTRY & BEHAV. 387, 388 (2005).

[12] U.S. Surgeon Gen., *supra* note 2.

[13] *Id.*

[14] *See generally*, Neal L. Benowitz, *Nicotine Addiction*, 362 NEW ENG. J. MED. 2295 (2010); John A. Dani & Steve Heinemann, *Molecular and Cellular Aspects of Nicotine*

Decades of research identify the neural and pharmacologic basis of nicotine addiction induced by smoking. Inhaled smoke carries nicotine into the lungs where it is absorbed and enters arterial circulation.[15] It then flows into the brain, where it binds to nicotinic cholinergic receptors and releases various neurotransmitters.[16] Dopamine, a monoamine neurotransmitter, signals pleasure to the user, while also simultaneously reducing stress and anxiety.[17] "[N]icotine addiction is a combination of positive reinforcements, including enhancement of mood and avoidance of withdrawal symptoms."[18] Conditioning has a secondary role in nicotine addiction: smokers associate particular cues (e.g., social situations, environmental factors, moods) with the high of smoking, often causing relapse when those seeking to quit smoking are confronted with those cues.[19]

Society generally imparts an assumption of risk and right of personal choice on the person using potentially harmful products such as illicit drugs, alcohol, and other common vices.[20] However, smoking introduces measurable harmful effects on third parties exposed to secondhand smoke.[21] Smoking bans and restrictions on use are directed at curbing this secondhand exposure to tobacco smoke in public places and workplaces. Recent studies have also begun to highlight lingering "thirdhand" smoke that remains as residue in carpeting, walls, and other structures for up to 30 years and is potentially toxic, particularly to children climbing, crawling, or playing in or on the contaminated areas.[22]

While nicotine use and addiction have long been linked to tobacco use and smoking of traditional tobacco products such as cigarettes, cigars, and

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Abuse, 16 NEURON 905 (1996); Dorothy K. Hatsukami et al., *Tobacco Addiction*, 371 LANCET 2027 (2008); Steven R. Laviolette & Derek van der Kooy, *The Neurobiology of Nicotine Addiction: Bridging the Gap from Molecules to Behaviour*, 5 NATURE REV. NEUROSCIENCE 55 (2004).

[15] Benowitz, *supra* note 14, at 2295.

[16] *Id.* at 2295-96.

[17] *Id.* at 2298.

[18] *Id.*

[19] *Id.*

[20] *See, e.g.*, Jim Leitzel, Regulating Vice: Misguided Prohibitions and Realistic Controls 3-10 (2008); Smoking: Risk, Perception & Policy (Paul Slovic ed., 2001).

[21] Unfiltered: Conflicts over Tobacco Policy and Public Health 21-27 (Eric A. Feldman & Ronald Bayer eds., 2004).

[22] Ware G. Kuschner et al., Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging Health Care Challenges for the Primary Care Provider, 4 INT'L J. GEN. MED. 115, 118-19 (2011).

smokeless tobacco, e-cigarettes are raising similar health and safety considerations. One attraction to e-cigarettes is that they do not burn tobacco and other harmful chemicals, but instead vaporize nicotine into a fine mist that is inhaled by the user. As discussed in Part IV, however, these products may directly pose a health threat to users given the available levels of nicotine, the lack of cues that serve to signal the end of a typical cigarette, and the potential for electrical components in the products to malfunction. E-cigarette cartridges contain up to twenty times the nicotine of a single cigarette, and the process of vaping lacks the normal cues associated with cigarette completion, such as the butt of the cigarette ending a dose.[23] Furthermore, e-cigarettes are manufactured from metal and ion components that introduce concerns about faulty products and malfunctions. The research on whether vaping e-cigarettes has a detrimental secondhand effect is currently inconclusive; state and local restrictions on e-cigarette use are driven largely by the concern that they have similar damaging effects on bystanders as traditional cigarettes.

Together with general safety concerns, e-cigarettes also have a different risk profile than traditional cigarettes. Although the risks of e-cigarette use are likely less than traditional cigarettes for heavy or moderate smokers, e-cigarettes may also attract regular users who otherwise were social smokers or non-smokers. Measures of a product's overall safety are driven by a risk-benefit analysis: heavy or moderate smokers (and those exposed to their secondhand smoke) would benefit from reducing or eliminating the risks of cigarette use (including lung cancer, heart attack, stroke, adverse pregnancy, and sudden death).[24] Yet those who would not smoke a cigarette, and vulnerable populations such as youth and adolescents, carry a different risk profile. Non-smokers or social smokers who begin using e-cigarettes are exposed to the addictive qualities of nicotine and possible other harmful chemicals present in trace amounts. In addition to the compelling likelihood of e-cigarettes supporting or inducing nicotine addiction in users, and possibly serving as a gateway product for subsequent cigarette use, these products raise a host of potential health and safety problems that have yet to be fully explored.

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[23] *See infra* Part IV.C.

[24] U.S. Surgeon Gen., *supra* note 2.

II. THE HISTORY OF TOBACCO REGULATION AND THE LEGACY OF FDA V. BROWN & WILLIAMSON TOBACCO CO.

A. The Awakening

The tobacco industry has enjoyed a spectacular run. As a longstanding cash crop in the United States and abroad, tobacco leaves and their products have long thrived in the marketplace. Historical research reveals that tobacco has been cultivated since 5000 BC and was widely used in the Americas by the time Columbus reached their shores in 1492.[25] Prior to scientific advancements in toxicology and carcinogen research, little was known about the constituents comprising tobacco products sold primarily in the form of rolled cigars and cigarettes, chewing snuff, and pipe tobacco. It was not until the U.S. Surgeon General's declaration in 1957 that a causal connection had been discovered between smoking and lung cancer that the adverse health effects of smoking began to confront the American public.[26] In 1964, the Surgeon General's subsequent *Smoking and Health* report presented striking statistics supporting the position that smoking was a leading cause of preventable death.[27] Data indicated that by 1964 there had already been 12 million premature deaths attributable to smoking in the United States alone.[28] Subsequent data released in federal government reports revealed a definitive link between nicotine dependence and neurological chemistry of the brain, with addictive effects similar to those of heroin and cocaine.[29]

Shortly after the 1964 report, Congress began enacting legislation restricting various aspects of tobacco industry labeling and advertising practices. Six core statutes were enacted by Congress between 1965 and 2000: the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965;[30] the Public Health Cigarette Smoking Act of 1969;[31] the Alcohol and

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[25] Arthur W. Musk & Nicholas H. De Klerk, *History of Tobacco and Health*, 8 RESPIROLOGY 286, 286 (2003).

[26] The Reports of the Surgeon General: Brief History, NAT'L LIBRARY MED., http://profiles. nlm.nih.gov/ps/retrieve/Narrative/NN/p-nid/58 (last visited Apr. 5, 2013).

[27] Advisory Comm., U.S. Dep't of Health, Educ. & Welfare, Smoking and Health (1964).

[28] *Cancer Facts and Figures 2010*, AM. CANCER SOC'Y 42 (2010), http://www.cancer.org/ acs/groups/content/@nho/documents/document/acspc-024113.pdf.

[29] Office of the Surgeon Gen., U.S. Dep't of Health & Human Servs., The Health Consequences of Smoking: Nicotine Addiction 6-9, 145-239 (1988).

[30] Federal Cigarette Labeling and Advertising Act, Pub. L. 89-92, 79 Stat. 282 (1965).

Drug Abuse Amendments of 1983;[32] the Comprehensive Smoking Education Act of 1984;[33] the Comprehensive Smokeless Tobacco Health Education Act of 1986;[34] and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992.[35] These statutes did not ban or limit cigarettes and smokeless tobacco products, but only restricted particular aspects of industry representations in order to ensure that consumers were aware and informed of the adverse health effects.[36]

Faced with increasing evidence of smoking's ill effects, health care professionals and consumer safety groups submitted various citizens' petitions to the FDA urging the agency to regulate cigarettes and tobacco products based on its overriding public health mission to protect consumers from unsafe products.[37] As data accumulated over the next several decades, so did demands (and petitions) for FDA action.[38] Despite the mounting evidence of the dangers of smoking, FDA Commissioners throughout the end of the 20th century continued to deny these petitions and to toe the line that they lacked the authority to regulate.[39]

B. Commissioner Kessler's 1996 Regulations

Former FDA Commissioner David Kessler announced a new position in August 1996[40] in an effort to remedy FDA inaction in the face of a public health epidemic brought about by smoking and secondhand smoke. Through the process of notice and comment rulemaking, the FDA issued two final rules asserting jurisdictional authority over tobacco products on the basis

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[31] Public Health Cigarette Smoking Act, Pub. L. No. 91-222, 84 Stat. 87 (1969).

[32] Alcohol and Drug Abuse Amendments, Pub. L. No. 98-24, 97 Stat. 175 (1983).

[33] Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984).

[34] Comprehensive Smokeless Tobacco Health Education, Pub. L. No. 99-252, 100 Stat. 30 (1986).

[35] Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, 106 Stat. 394 (1992).

[36] For a detailed description of the scope and chronology of these statutes, see FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 148-56 (2000).

[37] *Id.* at 152-56.

[38] *Id.*

[39] *Id.* at 156.

[40] Supreme Court precedent confirms the ability of an agency to change a position relating to statutory interpretation, no matter how long-standing, as long as it supplies a reasoned analysis and the new position conforms to the statute. *See* Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29 (1983).

that nicotine is a drug[41] and classifying cigarettes and smokeless tobacco as combination drug and medical device products,[42] triggering premarket safety and efficacy requirements provided in the FDCA. This was a controversial move, to say the least.

The FDCA is the voluminous statute granting the FDA jurisdictional authority over various products, including food, cosmetics, animal and human drugs, medical devices, and radiological products.[43] Drugs are defined in the FDCA as (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article.[44]

A device is similarly defined by its intended use, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[45]

Kessler reasoned that because nicotine was an addictive substance affecting the "structure or function of the body" and had significant

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[41] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,419 (Aug. 28, 1996) (to be codified in scattered sections of 21 C.F.R.).

[42] *Id.* at 44,396-44,618. The proposed rule was published in August 1995. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (Aug. 11, 1995).

[43] Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified with some differences in language at 21 U.S.C. §§ 301-399f (2006)).

[44] 21 U.S.C. § 321(g) (2006).

[45] *Id.* § 321(h).

pharmacological effects, it fell under the FDA's statutory authority[46] as a drug[47] and, furthermore, cigarettes and smokeless tobacco were delivery devices.[48] The FDA deemed the "psychoactive, or mood-altering, effects on the brain"[49] "intended"[50] for purposes of the FDCA because they "are so widely known and foreseeable"[51] that manufacturers have deliberately designed cigarettes to provide these effects to consumers.[52]

Based on its newly announced jurisdictional authority, the FDA promulgated a 223-page final rule targeted toward reducing tobacco consumption among children and adolescents.[53] The regulations focused on labeling, promotion, and access to cigarettes and smokeless tobacco by children and adolescents. Provisions included age and photo identification requirements for purchase, prohibitions on free samples, prohibitions on promotional items bearing a brand name, prohibitions on purchases by means of self-service displays or vending machines (except in adult establishments), restrictions on print advertisements to black and white text only, limitations on outdoor advertising near public schools or playgrounds, and prohibitions on brand name sponsorship.[54] The rulemaking has been described as the longest in FDA history with 700,000 comment submissions received during the course of agency considerations.[55]

The final rule further required cigarette and smokeless tobacco

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[46] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,631. This position utilizes the definition of drug as a product "intended to affect the structure or function of the body." 21 U.S.C. §321(g) (Supp. 2011).

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

[48] *Id.* at 44,402.

[49] *Id.* at 44,631-32.

[50] Intent and intended use is the underlying trigger for drug regulation under the FDCA. *See infra* Part III.B.

[51] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,687.

[52] *Id.*

[53] *Id.* at 44,418.

[54] *Id.* at 44,396.

[55] CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., COMPLIANCE WITH REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS [REVISION TO DRAFT GUIDANCE] 2 (2011) (citing 155 Cong. Rec. S6407 (June 10, 2009) (statement of Sen. Kennedy)).

manufacturers to submit reports of adverse events to the FDA.[56] The FDA indicated that this regulatory scheme would "achieve[] the best public health result for these products."[57]

While many health professionals lauded the regulations, the FDA was simultaneously rebuked for not going far enough to remove the products from the market.[58] Citing the touchstone risk-benefit assessment underpinning its decisions regarding safety[59] in the drug and medical device realm,[60] the FDA emphasized that due to the potential for consumer withdrawal and large-scale addiction treatment needs, as well as the likely emergence of a black market for banned products, it would closely assess, though not entirely ban, tobacco.[61]

The change in agency position provoked extensive criticism from the tobacco industry. A consortium of tobacco manufacturers, retailers, and advertisers swiftly filed suit alleging that the FDA lacked the jurisdiction to regulate tobacco products, that the FDA did not have authority to promulgate the regulations under the FDCA,[62] and that the restrictions on

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[56] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,615.

[57] *Id.* at 44,413.

[58] *See, e.g.*, Shankar Vedantam, *Clinton Clamps Down on Tobacco*, FRESNO BEE, August 24, 1996, at A1.

[59] While the term "safety" is never defined within the FDCA, the FDA has interpreted it to be based on a risk-benefit assessment, where a product's benefits must outweigh its risks in order for it to be approved to enter the market. The FDA evaluates new drugs based on information provided in the New Drug Application, including the clinical trial data, intended use, patient population, dosage and administration, adverse effects, contraindications, etc. An FDA Commissioner has described the inquiry into risk as depending on a variety of factors, including "[t]he interaction of the drug with body processes," "[t]he manner in which the drug is absorbed, distributed in body tissues, and excreted," "[w]hether active compounds arise from the metabolism of the drug by the body," [t]he influence of other chemicals, such as other drugs or even articles of food or drink upon the activity of the drug in question," and "how the activity of the drug in animals compares with its activity in man." *Drug Safety: Hearings Before a Subcomm. of the H. Comm. on Gov't Operations*, 88th Cong. 566 (1964) (testimony of George Larrick, Comm'r, FDA).

[60] Requirements for drugs and medical devices and the combination product paradigm are detailed elsewhere. *See, e.g.*, Jordan Paradise, *Reassessing Safety for Nanotechnology Combination Products: What Do Biosimilars Add to Regulatory Challenges for FDA?*, 56 ST. LOUIS L. J. 465, 478-90, 494-96 (2012).

[61] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,398.

[62] The FDA had asserted authority to promulgate regulations under 21 U.S.C. §360j, which deals with restricted medical devices. Regulations Restricting the Sale and Distribution

advertising violated the First Amendment.[63] The Fourth Circuit held that Congress had not granted jurisdiction to the FDA to regulate tobacco products, thereby bringing an abrupt end to the FDA's short-lived victory over the tobacco industry.[64]

C. Cigarettes and the Supreme Court

The Supreme Court affirmed the Fourth Circuit in a 5-4 decision in *FDA v. Brown & Williamson Tobacco Co.*[65] holding that Congress had clearly "intended to exclude tobacco products from the FDA's jurisdiction."[66] Invoking *Chevron U.S.A. v. Natural Resources Defense Council*,[67] the Court gave no deference to the FDA's 1996 final rules and instead divined a congressional intent to exclude tobacco products from FDA jurisdiction: "reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain the Congress has not given the FDA the authority to regulate tobacco products as customarily marketed."[68]

Crucial to Justice O'Connor's majority opinion was the fact that the FDCA was enacted on the premise that all drugs and devices overseen by the FDA must satisfy hurdles of both safety and efficacy requirements before entering the market. O'Connor reasoned that, given the scientific evidence linking smoking to cancer and other health risks, the danger inherent in cigarettes would necessitate that the FDA remove them completely from the market, a result that Congress surely did not intend.[69]

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of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,399.

[63] Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374 (M.D.N.C. 1997), *rev'd sub nom.* Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000). The district court held that the FDA had authority to regulate tobacco products and to promulgate regulations regarding labeling and access, but that the promotion and advertising restrictions contained within the regulations exceeded statutory authority. *Id.* at 1380-1400.

[64] *Brown & Williamson*, 153 F.3d 155. The court did not reach First Amendment questions.

[65] 529 U.S. 120.

[66] *Id.* at 121.

[67] 467 U.S. 837 (1984). This case sets forth an analytical framework for courts regarding deference to federal administrative agencies in the interpretation of statutes that they administer.

[68] Brown & Williamson, 529 U.S. at 161.

[69] *Id.* at 121-22.

The decision states,

[i]n its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market under the FDCA's misbranding . . . and . . . device classification . . . provisions.[70]

A powerful dissent trails the majority opinion, highlighting both the basic purpose and the literal language of the FDCA together with the compelling evidence linking cigarettes to pharmacological addiction. In his dissent, Justice Breyer (joined by Justices Stevens, Souter, and Ginsburg) argues:

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.[71]

After the decision, the FDA withdrew the regulations.

Brown & Williamson is infamous not only for its outcome, but also for the strained and tortuous application of the legendary two-step test first espoused in *Chevron*[72] to determine whether a court should afford deference to an administrative agency decision interpreting a statute that it administers.[73] The *Brown & Williamson* decision examined the unique history of tobacco including the multitude of statutory schemes and federal agencies charged with particular aspects of tobacco regulation, the FDA's

[70] *Id.* at 121.

[71] *Id.* at 162 (Breyer, J., dissenting).

[72] 467 U.S. 837. *Chevron* involved regulations promulgated by the Environmental Protection Agency (EPA) under the authority of the Clean Air Act of 1977. By regulation, the EPA set forth a definition of a "source" of air pollution, which was upheld by the Court as a permissible reading of the statute. *Id.* at 840, 866.

[73] These two steps are: (1) whether Congress has directly spoken on the precise question at issue in front of the court (i.e., is the statute unambiguous?); and (2) if the statute is silent or ambiguous, the court will defer to the agency's reasonable or permissible interpretation of the statute. If the statute is determined unambiguous at step 1, the court will apply plain language statutory interpretation rather than proceed to step 2. *Id.* at 842-43.

past stance that it did not have authority to regulate tobacco products, and the broad framework of the FDCA, to conclude that the FDA lacked jurisdiction. The Court provided "[t]his is hardly an ordinary case" and that tobacco has "a unique place in American history and society" and "its own unique political history."[74] In essence, the Court utilized the "extraordinary"[75] history of tobacco rather than consulting the language of the FDCA to conclude that Congress had unambiguously spoken on the issue of whether the FDA had authority over tobacco products, and had resoundingly rejected jurisdiction through other means outside the FDCA itself.[76]

III. CONGRESSIONAL RESPONSE: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009

Congress eventually provided the FDA with the requisite jurisdiction and authority to regulate tobacco products. Nine years after Brown & Williamson, Congress amended the FDCA and the FCLAA by enacting the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA).[77] Signed into law by President Obama in July 2009, the TCA inserts a substantial new chapter codified within the FDCA, which grants the FDA sweeping oversight and enforcement authority over tobacco products, including cigarettes and smokeless tobacco.[78] Thus, the TCA supplements the FDCA statutory scheme rather than supplanting it.

The wide-ranging legislation creates a new Center for Tobacco Products (CTP) within the FDA,[79] requires manufacturers to register their

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[74] *Brown & Williamson*, 529 U.S at 159-60.

[75] Jack M. Beermann, End the Failed Chevron Experiment Now: How Chevron Has Failed and Why It Can and Should Be Overruled, 42 CONN. L. REV. 779, 821 (2010).

[76] For further analysis and discussion of the case, see Elizabeth Brown Alphin, Federal Tobacco Regulation: The Failure of FDA Jurisdiction Over Tobacco and the Possibility of Compromise Through a Congressional Scheme, 40 BRANDEIS L. J. 121 (2001); Joseph A. Fazioli, Chevron Up in Smoke?: Tobacco At the Crossroads of Administrative Law, 22 HARV. J.L. & PUB. POL'Y 1057 (1999); Marguerite M. Sullivan, Brown & Williamson v. FDA: Finding Congressional Intent Through Creative Statutory Interpretation—A Departure From Chevron, 94 NW. U. L. REV. 273 (1999); and Roseann B. Termini, The Legal Authority of the United States Food and Drug Administration To Regulate Tobacco: Calling on Congress, 74 ST. JOHN'S L. REV. 63 (2000).

[77] Pub. L. No. 111-31, 123 Stat. 1776 (codified in scattered sections of 5 U.S.C., 15 U.S.C. and 21 U.S.C. (2006)).

[78] *See infra* Part III.A & B.

[79] 21 U.S.C. § 387a(e) (2006).

products,[80] mandates adherence to manufacturing practice requirements,[81] requires disclosure to FDA of ingredients for all tobacco products,[82] grants the FDA authority to establish product standards,[83] permits the FDA to reduce nicotine (though not eliminate it) and other harmful ingredients,[84] bans misleading descriptors without substantiation,[85] enlarges tobacco product warning labels and requires graphic images on packaging,[86] and bans fruit and candy flavorings in cigarettes (although menthol is subject to further scientific study rather than an outright ban).[87] The FDA has since taken steps to implement the TCA, including issuing multiple guidance documents for industry.[88]

Several aspects of the TCA are particularly relevant to a discussion of e-cigarettes: the evident foundational concern from Congress regarding youth and adolescent tobacco use that emerges from the legislative history preamble; the scope of requirements for both new tobacco products and modified-risk tobacco products; and the statutory implications of the therapeutic claims made by manufacturers or distributors.

A. Congressional Goals and Legislative History

Congress was undeniably focused on protecting youth and adolescents from the powerful advertising and marketing force of the tobacco industry. The TCA enumerates 49 findings of Congress—21 of which specifically address the impact and effects of smoking and tobacco marketing on youth

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[80] *Id.* § 387e.

[81] *Id.* § 387e(e).

[82] *Id.* § 387d.

[83] *Id.* § 387g.

[84] *Id.* § 387g(d)(3).

[85] *Id.* § 387k.

[86] *Id.* § 1333.

[87] *Id.* § 387g.

[88] *See, e.g.*, CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORTING HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS AND TOBACCO SMOKE UNDER SECTION 904(A)(3) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2012) [hereinafter REPORTING HARMFUL CONSTITUENTS]; CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., REGISTRATION AND PRODUCT LISTING FOR OWNERS AND OPERATORS OF DOMESTIC TOBACCO PRODUCT ESTABLISHMENTS (2009) [hereinafter REGISTRATION AND PRODUCT LISTING].

and adolescents.[89] In fact, the second identified purpose of the TCA is "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco."[90] The legislation expressly calls for the reintroduction of the 1996 FDA regulations struck down in *Brown & Williamson*,[91] which have since been codified in 21 CFR §1140. The FDA has also issued draft guidance to industry detailing the scope of the provisions contained within those regulations.[92]

B. Statutory Structure and FDA Implementation

Historically, the FDA has struggled with the definitional frameworks drafted by Congress; scientific and technological advancements and novel products present particular challenges to the jurisdictional boundaries created by the legislative definitions. This is an acute problem for FDA regulation of e-cigarettes, as detailed below.

1. Tobacco Products

A tobacco product is defined by the TCA as

> any product made or derived from tobacco that is intended for human consumption, including any component, part, accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).[93]

The statute further provides that the definition does not include an article that is a drug, a device, or a combination product, which are subject to the drug and medical device provisions.[94] Therefore, any product subject to drug or device classification cannot simultaneously be a tobacco

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[89] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, § 2, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C. (2006)).

[90] *Id.* § 3(2).

[91] 21 U.S.C. § 387a-1 (2006).

[92] CTR. FOR TOBACCO PRODS., *supra* note 55.

[93] 21 U.S.C. § 201(rr)(1) (2006).

[94] *Id.* § 201(rr)(2). The statute also states "A tobacco product shall not be marketed in combination with any other article or product under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement)." *Id.* §201(rr)(4).

product.[95] The threshold question is whether a given e-cigarette product should be classified as a tobacco product or a drug, medical device, or drug-device combination product.[96]

The definitions and requirements for drugs and medical devices hinge specifically on the intended use of the product: is the product "intended to affect the structure or any function of the body of man or other animals" or "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"? If so, it is categorized as a drug and subject to the relevant statutory and regulatory provisions. Is the product an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent" that is "intended to affect the structure or any function of the body of man or other animals" or "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals"? If so, it is categorized as a medical device and subject to the relevant statutory and regulatory provisions. If a product shares features of both, it is regulated as a drug-device combination by the FDA.

A key feature of the definition of tobacco product is the phrase "or derived from tobacco."[97] Clearly, cigarettes and cigars are made from tobacco because the products themselves contain tobacco in some form along with other ingredients. Smokeless tobacco, sold in the form of either snuff or chewing tobacco, likewise contains tobacco as the core ingredient.[98] Unlike traditional cigarettes and smokeless tobacco, e-cigarettes have become popular precisely because they are promoted as having a single key ingredient: nicotine. And nicotine is derived from tobacco. Based on a literal reading of the statute, e-cigarettes fall within the definition of tobacco product, despite the fact that they do not contain any tobacco.

Two other essential definitions create impediments for the FDA in the context of e-cigarettes. A "cigarette" is defined as a tobacco product that meets the definition of the term "cigarette" in the FCLAA and "includes tobacco, in any form, that is functional in the product, which, because of its

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[95] *Id.* §201(rr)(2).

[96] A combination product is a product having multiple mechanisms of action and is regulated according to the "primary mode of action." 21 C.F.R. § 3.2 (2011).

[97] 21 U.S.C. § 201(rr)(1) (2006).

[98] *Smokeless Tobacco Facts*, CDC, http://web.archive.org/web/20121105192631/http://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/smokeless_facts/index.htm (last updated Aug. 4 2011) (accessed by searching for http://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/smokeless_facts/index.htm in the Internet Archive index).

appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco."[99] The FCLAA defines a cigarette as

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).[100]

This limits cigarettes to products that actually contain tobacco. Thus, the term electronic cigarette is a misnomer—according to the TCA, it is not a cigarette.

Smokeless tobacco is "any product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity."[101] Thus, although e-cigarettes are smokeless in that the atomizer vaporizes the nicotine, they are not a smokeless tobacco product within the meaning of the statute. These three core definitions—tobacco product, cigarette, and smokeless tobacco—position e-cigarettes as tobacco products as a general matter, but remove them from the realm of either cigarettes or smokeless tobacco. This definitional positioning is significant, as many of the core provisions of the TCA apply only to cigarettes and smokeless tobacco.[102]

2. New and Modified Risk Products

There are also heightened requirements in the TCA for "new" and "modified risk" products. Essentially, any product falling into either category will require a premarket review prior to entering the market. A "new tobacco product" is defined as any tobacco product that was not commonly marketed in the United States as of February 15, 2007 or any modification of a tobacco product, including a change in design or any component, part, or constituent, where the portion modified was commercially marketed in the United States after February 15, 2007.[103] The

[99] 21 U.S.C. § 387(3) (2006).

[100] 15 U.S.C. § 1332(1) (2006).

[101] 21 U.S.C. § 387(18) (2006).

[102] *See generally* CTR. FOR TOBACCO PRODS., supra note 55.

[103] 21 U.S.C. § 387j(a)(1) (2006).

FDA has published a draft guidance that lists the types of evidence a manufacturer can produce to establish that a product was marketed prior to February 15, 2007, including copies of advertisements, catalog pages, promotional material, trade publications, bills of lading, and freight bills.[104] The statute also allows a showing of substantial equivalence to a product that was commercially marketed prior to the critical date,[105] though the FDA has not yet provided any guidance on how this is to be accomplished by the manufacturer. Congress borrowed the phrase and concept of substantial equivalence from the medical device provisions.[106]

A "modified risk tobacco product" is "any tobacco product that is sold or distributed for use to reduce the harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[107] The FDA has further clarified the scope of "sale or distribut[ion]" by a guidance document providing that prohibited representations can be found on the label,[108] labeling,[109] or any advertising, can be implicit or explicit, and can be directed to consumers through any type of media.[110] Previously, such products were identified with descriptors such as light, low tar, or mild. The use of such descriptors or any representations that the tobacco product offers a reduced risk is prohibited unless manufacturers satisfy all scientific data and comparative study requirements set out by the FDA. [111] The FDA has actively begun to enforce these provisions.[112]

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[104] CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH AND HUMAN SERVS., ESTABLISHING THAT A TOBACCO PRODUCT WAS COMMERCIALLY MARKETED IN THE UNITED STATES AS OF FEBRUARY 15, 2007, at 3 (2011) (noting that any and all materials produced as evidence must be dated).

[105] The definition of substantial equivalence is a tobacco product that "has the same characteristic as the predicate tobacco products" or "has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health." 21 U.S.C. § 387j(a)(3) (2006).

[106] *Id.* § 360c(i)(1)(A).

[107] *Id.* § 387k(b)(1).

[108] *Id.* § 321(l).

[109] *Id.* § 321(m).

[110] CTR. FOR TOBACCO PRODS., U.S. DEP'T OF HEALTH & HUMAN SERVS., MODIFIED RISK TOBACCO PRODUCT APPLICATIONS 6 (2012).

[111] *Id.* The Institute of Medicine published a special report identifying appropriate scientific measures for modified risk tobacco products. Inst. of Med., Scientific Standards for Studies on Modified Risk Tobacco Products (2012).

[112] *See* CTR. FOR TOBACCO PRODS., *supra* note 110.

3. Therapeutic Claims

Any claim by a manufacturer or distributor that a tobacco product has a therapeutic effect, such as claims that a product is a smoking cessation product or nicotine addiction treatment, will prompt regulation under the drug and device frameworks. This requires rigorous premarket requirements, including clinical trials, detailed product information, and FDA review. Examples of FDA-approved drug and device smoking cessation products include pharmaceuticals (*e.g.,* Zyban and Chantix), nicotine lozenges, nicotine nasal sprays, nicotine inhalers, nicotine skin patches, and nicotine gums.[113]

Figure 1 depicts the relationship among these definitions in the form of a Tobacco Product Decision Tree. As an initial matter, any representations about the product that signal a drug or medical device intended use, or therapeutic claims, such as use in smoking cessation, reduction, or as a healthy alternative to smoking, will trigger the drug or medical device provisions.[114] If no such representations exist, the next determination is whether it is a "tobacco product." For tobacco products that entered the market after February 15, 2007, the failure to verify substantial equivalence triggers heightened premarket requirements.[115] Likewise, products marketed as modified risk are subject to premarket requirements as well,[116] including comparison studies to existing products and submission of chemical composition information.[117]

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[113] For information regarding FDA approved products, see *FDA 101: Smoking Cessation Products,* FDA (Dec. 2012), http://www.fda.gov/forconsumers/consumerupdates/ucm198176.htm.

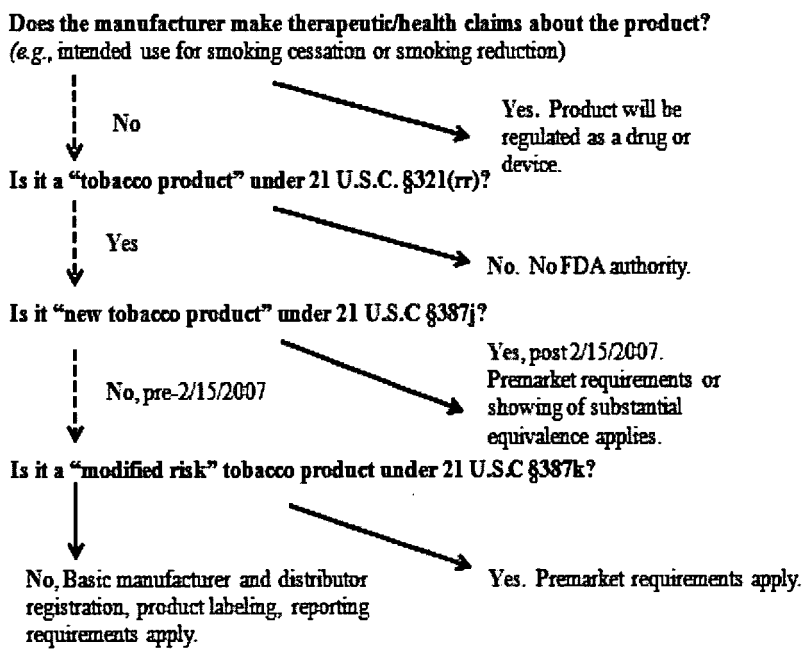
[114] 21 U.S.C. § 201(rr)(2)-(3) (2006).

[115] *Id.* § 387j(a)(1).

[116] *Id.* § 387k(b)(1).

[117] CTR. FOR TOBACCO PRODS., *supra* note 110, at 6.

Figure 1: Tobacco Product Decision Tree



4. Ban on Cigarette Additives

There is an explicit ban on flavoring additives for cigarettes,[118] a provision chiefly targeted to curb the appeal of cigarettes to youth:

[A] cigarette or any of its component parts...shall not contain, as a constituent...or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.[119]

[118] 21 U.S.C. § 387g(a)(1)(A) (2006).
[119] *Id.* § 387g(a)(1)(A).

The FDA has already carried out this ban, issuing warning letters notifying cigarette manufacturers and distributors that any product in violation would be subject to immediate enforcement action.[120] However, the scope of this ban and the regulations supporting it do not cover e-cigarettes because of the scope of the definition of "cigarette" contained in the TCA.

C. Industry-Launched Legal Challenges

Not surprisingly, the tobacco industry has lashed out against the FDA, filing lawsuits challenging provisions of the TCA as violating the First Amendment[121] and challenging FDA enforcement actions over e-cigarettes.[122] Litigation had been ongoing regarding the placement of graphic warnings on cigarette packaging and restrictions on various promotional activities.[123] However, Attorney General Eric Holder and the FDA are reportedly not pursuing an appeal to the Supreme Court.[124] FDA officials have stated they would "undertake research to support a new rulemaking consistent with the Tobacco Control Act."[125] As for e-cigarettes, a 2010 decision of the D.C. Circuit in *Sottera v. FDA* dealt squarely with questions about the definition of tobacco product as opposed to drug or medical device, the scientific and technical aspects of e-cigarettes, and the scope of intended use as it relates to therapeutic claims made by the manufacturer.[126] The *Sottera* case and its implications are discussed in detail in Part V.

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[120] Consumer information, press releases, transcripts of media briefings, and warning letters are available on the FDA's website. *See Flavored Tobacco*, FDA, http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/default.htm (last updated Mar. 21, 2013) (last visited Apr. 5, 2013).

[121] *See, e.g.*, R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266 (D.D.C.), *aff'd*, 696 F.3d 1205 (D.C. Cir. 2012); Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

[122] Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

[123] *Overview: Cigarette Health Warnings*, FDA, http://www.fda.gov/TobaccoProducts/Labeling/ucm259214.htm (last updated Feb. 24, 2012).

[124] Michael Felberbaum, *U.S. Won't Appeal Ruling Blocking Graphic Cigarette Warnings*, AUGUSTA CHRON. (March 19, 2013), http://chronicle.augusta.com/news/business/2013-03-19/us-wont-appeal-ruling-blocking-graphic-cigarette-warnings.

[125] *Id.*

[126] *Sottera*, 627 F.3d 891.

IV. ELECTRONIC CIGARETTES GO VIRAL

The e-cigarette industry is booming—approximately 3.5 million Americans now regularly use e-cigarettes.[127] CDC studies show that e-cigarette use quadrupled in a single year from 2009 to 2010.[128] Based on 2011 numbers, 21% of adult smokers in the United States have used e-cigarettes, 6% of all adults have tried e-cigarettes, and general awareness of e-cigarettes rose to 60% of all adults, up from 40% in 2010.[129] The co-founder of the Tobacco Vapor Electronic Cigarette Association stated in March 2012 that nearly 20 million e-cigarette cartridges are sold in the United States. per week;[130] the chief financial officer of the Association recently estimated that the market will exceed $1 billion in U.S. sales by December 2014.[131]

A. From Atomizers to Vaping: A Product Overview

Popular media and public health literature alike attribute the invention of the e-cigarette to Hon Lik, a Chinese pharmacist, in early 2000.[132] Hon patented his invention first in the European Union[133] and then in the United States.[134] By the mid-2000s, the e-cigarette was marketed widely in China by the Ruyan Company and made its way to an international market by the

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[127] Mary Diduch, *North Jersey Companies See Growth Along with E-cigarette Industry*, RECORD (Jan. 18, 2013, 7:24 AM), http://www.northjersey.com/news/187414911_North_Jersey_companies_see_growth_along_with_e-cigarette_industry.html.

[128] John Tierney, *A Tool to Quit Smoking Has Some Unlikely Critics*, N.Y. TIMES (November 8, 2011), http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html.

[129] About One in Five Adult Cigarette Smokers Have Tried an Electronic Cigarette, CDC (February 28, 2013), http://www.cdc.gov/media/releases/2013/p0228_electronic_cigarettes.html.

[130] *E-Cigarettes Are Here to Stay*, CONVENIENCE STORE DECISIONS (Mar. 22, 2012, 11:21 AM), http://www.csdecisions.com/2012/03/22/e-cigarettes-are-here-to-stay.

[131] Diduch, *supra* note 127.

[132] Jonathan Foulds et al., *Electronic Cigarettes (E-Cigs): Views of Aficionados and Clinical/Public Health Perspectives*, 65 INT'L J. CLINICAL PRAC. 1037, 1037 (2011).

[133] Improved Atomizing Electronic Cigarette, European Patent No. 2,404,515 (filed Jan. 28, 2010) (issued Jan. 11, 2012); An Aerosol Electronic Cigarette, European Patent No. 1,736,065 (filed Mar. 18, 2005) (issued June 3, 2009); Flameless Electronic Atomizing Cigarette, European Patent No. 1,618,803 (filed Mar. 8, 2004) (issued Dec. 3, 2008).

[134] Electronic Atomization Cigarette, U.S. Patent No. 7,832,410 (filed Mar. 18, 2005).

year 2006.[135] Despite the renown of the Hon Lik invention, an examination of patent resources reveals numerous issued patents claiming smokeless delivery methods of nicotine, the earliest granted in 1965.[136] While these patents share various features and functions with the Ruyan e-cigarette and various similar products, they do not fully encompass the current mass-marketed form of the e-cigarette. The technology rapidly developed during the first decade of the 21st century.

The present day e-cigarette is a smokeless, battery-powered device that vaporizes liquid nicotine for delivery via inhalation by the user. The e-cigarette does not contain tobacco, only nicotine derived from the tobacco plant and trace amounts of several secondary chemical ingredients. It is composed of three parts that screw together: the nicotine cartridge; the atomizer (which vaporizes the nicotine); and the rechargeable battery that powers it.[137] Many products are also equipped with a light-emitting diode (LED) indicator at the end that is activated when the user draws in air. The cartridge contains liquid nicotine and is sealed either with an aluminum foil lid or with a plastic cork. A single cartridge can hold the nicotine equivalent of an entire pack of traditional cigarettes.[138] The composition, strengths,[139] and flavoring[140] of the nicotine liquid appear highly variable across different products.[141] Sottera doing business as NJOY, identifies the ingredients

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[135] Joan Lowy, *Ban Proposed on Electronic Cigarettes on Planes*, MSNBC (Sept. 14, 2011 3:25 PM), http://www.msnbc.msn.com/id/44518729/ns/travel-news/t/ban-proposed-electronic-cigarettes-planes.

[136] Smokeless Non-Tobacco Cigarette, U.S. Patent No. 3,200,819 (filed Apr. 17, 1963) (issued Aug. 17, 1965); *see also, e.g.*, Electronic Smoking System, U.S. Patent No. 5,934,289 (filed Oct. 20, 1997) (issued Aug. 10, 1999); Artificial Smoke Cigarette, U.S. Patent No. 7,845,359 (filed Mar. 22, 2007) (issued Dec. 7, 2010); Aerosol Electronic Cigarette, U.S. Patent No. 8,156,944 (filed May 15, 2007) (issued Apr. 17, 2012); Electronic Cigarette, U.S. Patent Application No. 10/886,508, (published Jan. 27, 2005).

[137] Legacy for Longer Healthier Lives, *supra* note 1.

[138] *See Smoking Everywhere E-Cigarette Cartridges 2.0*, SMOKING EVERYWHERE, http://www.smokingeverywhere.com/cartridges.php (last visited July 25, 2012) ("Each cartridge is equivalent to aprox [sic] 20 traditional cigarettes (100-200 puffs).").

[139] *Id.*

[140] *See Smoking Everywhere E-Cigarette Comes in Different Flavors*, SMOKING EVERYWHERE, http://www.smokingeverywhere.com/flavors.php (last visited July 25, 2012) (advertising flavors such as apple, cherry, strawberry, and chocolate).

[141] Letter from B.J. Westenberger, Deputy Dir., Div. of Pharmaceutical Analysis, FDA to Michael Levy, Supervisor Regulatory Counsel, Office of Compliance, Div. of New Drugs and Labeling Compliance, FDA (May 4, 2009), *available at* http://www.fda.gov/downloads/Drugs/ ScienceResearch/UCM173250.pdf [hereinafter Westenberger Memo].

(though not the concentrations) on its website as: propylene glycol, nicotine, ethanol, glycerol (glycerin), acetylpyrazine, guaiacol, myosmine, cotinine, and vanillin.[142]

The atomizer, which converts the nicotine liquid into a fine mist, consists of a metal wick and a heating element. When screwed onto the cartridge, the nicotine liquid from the cartridge comes in contact with the atomizer unit and is carried to the metal coil heating element. When one draws air inwards at the end of the e-cigarette cartridge, it triggers a current from the battery through the metal coil element in the atomizer which heats up the nicotine liquid.

B. An Industry Profile and Marketing Tactics

The vast share of companies distributing e-cigarettes and nicotine cartridges (also called "e-juice") market and sell their products utilizing both the internet and in-store purchasing. Notably, e-cigarettes have begun advertising on television, as the ban on television and radio cigarette commercials does not apply to them.[143] The cost of e-cigarettes range from about $20 to $150 for the starter kits; the replacement nicotine cartridges vary in price by retailer and location but seem to average about $12 for a 5 pack refill; and disposable e-cigarettes are now available for about $3 each.[144] While the typical e-cigarette is sold in the shape of a cigarette, many products are sold in the shape of discreet objects such as pipes,[145] pens,[146] and lipstick.[147]

Brands such as Smoking Everywhere,[148] NJOY,[149] and blu eCigs[150]

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[142] NJOY, *supra* note 10.

[143] "After January 1, 1971, it shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission." 15 U.S.C. § 1335 (Supp. 2011).

[144] These numbers were derived from online searches of e-cigarette websites, point-of sale advertisements, and pricing at retail outlets in March 2013.

[145] *E-CIG E-PIPE*, E-CIG.COM, http://www.e-cig.com/shopping/products/54-ecig-E-Pipe/ (last visited Apr. 5, 2013).

[146] *Pen Style e-Cigarette,* E-CIGS UNLIMITED, http://www.ecigsunlimited.com/kits/pen-style-e-cigarette (last visited Apr. 5, 2013).

[147] *Lipstick E Cigarette*, ALIBABA.COM, http://www.alibaba.com/product-gs/501751147/Lipstick_E_Cigarette.html (last visited Apr. 18, 2013).

[148] SMOKING EVERYWHERE, http://www.smokingeverywhere.com (last visited June 8, 2012). The website boasts: "Smoking Everywhere Electronic Cigarette looks like a traditional cigarette, feels like a traditional cigarette, tastes like a traditional cigarette, but it isn't a traditional cigarette. It's just a a [*sic*] tar-free way to enjoy smoking!"

have a prominent market presence. The industry is dominated by small, independent companies, with the exception of blu eCigs, which was acquired in April 2012 by Lorilland Tobacco Company for $135 million.[151]

Internet-based marketing of e-cigarettes commonly utilizes affiliate marketing schemes that enable users to distribute products and generate profits by recruitment of customers.[152] Some companies claim to have policies that require those seeking affiliate status to agree not to sell e-cigarettes to individuals under the age of 18 or to market the products as a smoking cessation product.[153] However, e-cigarettes are available for purchase from websites that do not verify age,[154] raising concerns about accessibility to minors. The strong internet presence of e-cigarettes can also be attributed to online communities of users[155] and frequent podcasts by sellers.[156] The tactics are working: Google has labeled "electronic cigarettes" as an online search term that has experienced a growth of over 5,000%.[157] Search trends are becoming a focus of study for researchers.[158]

Advertisements typically emphasize one or more of the following features of their e-cigarette products: freedom to smoke anywhere; no adverse smell, tar, smoke, or toxic chemicals; no social stigma; cost savings; and health advantages over traditional cigarettes, with several specifically reaching out to smokers aiming to quit or cut down.[159] Some companies and

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[149] NJOY, http://www.njoy.com (last visited Apr. 5, 2013).

[150] BLU ECIGS, http://www.blucigs.com (last visited Apr. 5, 2013).

[151] Diduch, *supra* note 127.

[152] *Id.*

[153] *See* Cyrus K. Yamin et al., *E-Cigarettes: A Rapidly Growing Internet Phenomenon*, 153 ANNALS INTERNAL MED. 607, 608 (2010).

[154] *See id.*

[155] *See, e.g.*, E- CIGARETTE FORUM, http://www.e-cigarette-forum.com/forum (last visited Apr. 5, 2013) (describing itself as the "world's largest electronic cigarette website").

[156] Yamin et al., *supra* note 153, at 607.

[157] *Id.*

[158] *See generally* John W. Ayers et al., *Tracking the Rise in Popularity of Electronic Nicotine Delivery Systems (Electronic Cigarettes) Using Search Query Surveillance*, 40 AM. J. PREVENTIVE MED. 448 (2011); Annice E. Kim et al., *Smokers' Beliefs and Attitudes About Purchasing Cigarettes on the Internet*, 121 PUB. HEALTH REP. 594 (2006); Annette K. Regan et al., *Electronic Nicotine* Delivery Systems: Adult Use and Awareness of the "E-Cigarette" in the USA, 22 Tobacco Control 19 (2013).

[159] The University Medical and Dental School of New Jersey (UMDNJ) has amassed an impressive collection of cigarette and tobacco advertising and marketing. UMDNJ, TRINKETS AND TRASH: ARTIFACTS OF THE TOBACCO EPIDEMIC, http://www.trinketsandtrash.org. Visitors to the website can search by category; selecting "e-cigarettes" will generate 40 results of e-

distributors advertise their products as not emitting secondhand smoke and as ecologically friendly.[160] The accuracy of these claims is unclear and hotly contested.[161] Premium Electronic Cigarette, which claims to be "one of the largest retailers of electronic cigarette systems and kits" states on its website that "[o]ne of the most important reasons why smokers are switching to electronic cigarettes is because they allow users to determine their nicotine intake, which is a great way to reduce their smoking habit without resorting to either quitting abruptly or to nicotine patches and gum."[162] American Blue Tip products are advertised as "a healthier, convenient alternative to cigarettes" and "so effective as a substitute for cigarettes."[163] It also directs consumers to "feed the hand to mouth habit."[164] In an ironic, almost inspiring twist, actor Stephen Dorff (for blu) tells consumers to "[r]ise from the ashes."[165]

Many celebrities have also touted the smoking cessation use of e-cigarettes publicly.[166] For example, in a 2010 interview with David Letterman, Katherine Heigl raved about her e-cigarette, stating that she had tried everything—the nicotine patch, gum, and prescription medication before turning to the e-cigarette.[167] She stressed to Letterman that her goal

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cigarette advertising from the past three years. These features of product claims were identified by the author using those 40 advertisements, television commercials, and direct email advertisements.

[160] Yamin et al., *supra* note 153, at 607.

[161] *Id.*

[162] PREMIUM VAPES, http://www.premiumecigarette.com (last visited Apr. 5, 2013).

[163] *See* Sch. of Pub. Health, *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, UNIV. OF MED. & DENTISTRY OF N.J., http://www.trinketsandtrash.org/detail.php?artifactid=7002 (last visited Apr. 5, 2013).

[164] *Id.*

[165] *See* Sch. of Pub. Health, *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, UNIV. OF MED. & DENTISTRY OF N.J., http://www.trinketsandtrash.org/detail.php?artifactid=7410 (last visited Apr. 5, 2013).

[166] *See, e.g.*, Celebrities Smoking Electronic Cigarettes: Leo DiCaprio, Katherine Heigl, JWoww Puff Away, HUFFINGTON POST (May 8, 2012, 4:46 PM), http://www.huffingtonpost.com/2012/05/08/celebrities-smoking-electronic-cigarettes-photos_n_1500814.html.

[167] CanadaVapes, *Katherine Heigl & David Letterman Vape Electronic Cigarettes*, YOUTUBE (Sept. 29, 2010) http://www.youtube.com/watch?v=ysGyfLwwr1s. One excerpt is particularly interesting:

> Katherine: "So I started to quit. . . . I tried everything; I did the patch, I did the gum, I did the Chantix, twice. . . . But now I do this. . . . Now I do the electronic cigarette."

was that she would eventually wean herself off of the e-cigarette entirely after utilizing it to quit smoking.[168] Charlie Sheen was named the face of a new e-cigarette called the NicoSheen in 2011.[169] OK! Magazine recently discussed Catherine Zeta-Jones being gifted Smokestik electronic cigarettes by a company representative to "support her quitting the bad habit."[170] A recently publicized celebrity endorsement for e-cigarettes came from Elliott Storm, a high profile disabled Vietnam veteran and author.[171]

Despite industry exhortations that e-cigarettes are not intended to be used in smoking cessation, public impressions reflect a majority of users who either rely on e-cigarettes to quit or reduce smoking, or who believe that e-cigarettes are a safer alternative to traditional cigarettes. Survey research indicates efforts to quit smoking were the most frequently cited reason for use of e-cigarettes.[172] The draw of the e-cigarette for smokers is that it delivers nicotine to counter nicotine withdrawal symptoms, it evokes the psychological response to cigarette smoking because of its shape, and it supports the familiar behavioral aspects of smoking.[173] The behavioral and physical stimuli alone (such as that associated with merely holding an unlit cigarette) are capable of reducing the craving to smoke.[174]

A number of studies have investigated public and user perceptions about e-cigarettes.[175] In a 2011 survey of 104 e-cigarette users, "[t]hree

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David: "and then you wean yourself off eventually and you'll be just fine."
Katherine: "Yeah that's the idea."

[168] *Id.*

[169] *Charlie Sheen Unveiled as the Face of New Electronic Cigarette*, DAILY MAIL (Apr. 30, 2011, 5:47 PM), http://www.dailymail.co.uk/tvshowbiz/article-1382270/Charlie-Sheen-unveiled-face-new-electronic-cigarette.html.

[170] Laura Lane, *Catherine Zeta-Jones Trying to Quit Smoking*, OK! MAGAZINE, (Aug. 5, 2011, 7:28 PM), http://www.okmagazine.com/news/catherine-zeta-jones-trying-quit-smoking.

[171] PRWeb, 21 Century Smoking Electronic Cigarette Company Gets Celebrity Endorsement, NEWSON6.COM, (July 2, 2012 10:07 AM), http://www.newson6.com/story/18931593/21-century-smoking-electronic-cigarette-company-gets-celebrity-endorsement.

[172] Yamin et al., *supra* note 153, at 607 (citing a study showing that 65% of respondents indicated that use of e-cigarettes was to quit smoking).

[173] Michael B. Siegel et al., *Electronic Cigarettes as a Smoking-Cessation Tool: Results from an Online Study*, 40 AM. J. PREVENTIVE MED. 472, 474 (2011).

[174] *Id.* at 472.

[175] *See, e.g.*, Ayers et al., *supra* note 158; Jean-François Etter, *Electronic Cigarettes: A Survey of Users*, 10 BMC PUB. HEALTH 231 (2010); Foulds et al., *supra* note 132; Regan et al., *supra* note 158.

quarters started using e-cigs with the intention of quitting smoking and almost all felt that the e-cig had helped them to succeed in quitting smoking."[176] One study reports that among 3,037 users of e-cigarettes, 77% of respondents said that they used them to quit smoking or to avoid relapse and 20% said that they used them to reduce consumption of tobacco with no intent to quit smoking.[177] In a larger survey involving 3,587 participants, over three quarters of respondents likewise stated
that one reason for their use of e-cigarettes was to quit smoking or avoid relapse.[178]

C. Public Perceptions, Public Health Perspectives, and a Dearth of Scientific Data

Several core concerns about e-cigarettes have been identified. The first concern is the uncertainty: the FDA and public health advocates seek conclusive studies as to the actual constituents of the products on the market in terms of nicotine levels, toxins, and other chemicals.[179] The FDA has directed extensive coverage to the risks of e-cigarettes, providing consumers with information on its website.[180] The second concern is the particular risk to youth: product flavorings such as grape, vanilla, and chocolate are being flagged as chiefly appealing to youth, encouraging them to use flavored e-cigarettes because popular flavorings in traditional cigarettes have now been banned.[181] The third concern is the misconception about the health benefits of e-cigarettes: claims made by manufacturers and distributors related to utility in smoking cessation or reduction in cigarette use, and statements

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[176] Foulds et al., *supra* note 132.

[177] *Id.* at 1040-41.

[178] Jean-François Etter & Chris Bullen, *Electronic Cigarette: Users Profile, Utilization, Satisfaction and Perceived Efficacy,* 106 ADDICTION 2017 (2011).

[179] *See, e.g.*, Bridget M. Kuehn, *FDA: Electronic Cigarettes May Be Risky*, 302 J. AM. MED. ASS'N 937, 937 (2009); *see also* Kuschner et al., *supra* note 22; Sungkyu Lee et al., *Public Health Challenges of Electronic Cigarettes in South Korea*, 44 J. PREVENTIVE MED. & PUB. HEALTH 235 (2011); Anna Trtchounian et al., *Conventional and Electronic Cigarettes (E-Cigarettes) Have Different Smoking Characteristics*, 12 NICOTINE & TOBACCO RESEARCH 905 (2010); Constantine I. Vardavas et al., *Short-Term Pulmonary Effects of Using an Electronic Cigarette: Impact on Respiratory Flow Resistance, Impedance, and Exhaled Nitric Acid*, 141 CHEST 1400 (2012).

[180] *Electronic Cigarettes (e-Cigarettes)*, FDA, http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm (last updated Oct. 9, 2012).

[181] Kuehn, *supra* note 179.

about the healthfulness of e-cigarettes are under close scrutiny.[182] The fourth concern is the risk of overconsumption: there is some attention directed to the lack of finality to an e-cigarette as being a potential problem, as smokers who have turned to the e-cigarette no longer have the butt of the cigarette as a cue to stop smoking. Unlike a traditional single cigarette that is typically smoked in its entirety and then discarded, use of an e-cigarette can be extended[183] in that a nicotine cartridge can contain up to twenty times the amount of nicotine of a single cigarette.[184] While a cigarette smoker has the ability to keep track of how many cigarettes in a pack he or she consumes, a nicotine cartridge has no such measure.

Little is known about the safety or adverse effects of e-cigarettes.[185] The popular medical information website, WebMD, recognizes the widespread use of e-cigarettes for smoking cessation purposes and urges clinical trials to determine safety.[186] Scientific and clinical publications have only begun to target issues related to e-cigarette use. An FDA study of two e-cigarette products revealed tobacco-associated chemicals, trace amounts of toxic chemicals, and varying levels of nicotine present in identically-labeled products.[187] Only one existing product, the Ruyan e-cigarette, has undergone

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[182] *See, e.g.*, 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 (2011); Pasquale Caponnetto et al., *Successful Smoking Cessation with Electronic Cigarettes in Smokers with a Documented History of Recurring Relapses: A Case Series*, 5 J. MED. CASE REP. 585 (2011); Riccardo Polosa et al., *Effect of An Electronic Nicotine Delivery Device (E-Cigarette) on Smoking Reduction and Cessation: A Prospective 6-Month Pilot Study*, 11 BMC PUB. HEALTH 786 (2011); Siegel et al., *supra* note 173. In fact, the California Attorney General filed suit against Smoking Everywhere in early 2010 for misleading claims. Office of the Attorney Gen., *Brown Sues Electronic Cigarette Maker for Targeting Minors and Misleading Advertising Claims*, CAL. DEP'T JUSTICE (Jan. 13, 2010), http://oag.ca.gov/news/press-releases/brown-sues-electronic-cigarette-maker-targeting-minors-and-misleading.

[183] Respondents of one survey of e-cigarette users indicated an estimated median of twenty uses per day (where a single use was defined as 10-20 puffs). Foulds et al., *supra* note 132, at 1039.

[184] Electronic Cigarette Frequently Asked Questions (FAQ's), EPUFFER, http://www.epuffer. com/eshop/faqs-frequently-asked-questions.html (last visited Apr. 5, 2013). The website provides that "[o]ne regular cigarette would be equivalent to 10-15 epuffs," with the "Elite Classic" ePuff cartridge containing the nicotine of 18-20 cigarettes and the "Eaze [sic] Magnum" ePuff cartridge containing the nicotine of 20-25 cigarettes.

[185] Siegel et al., *supra* note 173, at 472.

[186] Daniel J. DeNoon, *Survey: E-Cigarettes May Help Smokers Quit*, WEBMD (Feb. 8, 2011), http://www.webmd.com/smoking-cessation/news/20110208/survey-e-cigarettes-may-help-smokers-quit.

[187] Kuehn, *supra* note 179.

a rigorous scientific study regarding safety using a risk-benefit methodology, though Ruyan funded the study.[188]

General questions about the overall safety of the products are being posited in light of several reports of death or serious injury resulting from e-cigarettes. In the United States, there have been at least two reports of e-cigarettes exploding in users' faces and hands causing severe injuries including blown out teeth, extensive burns and tissue damage to lips and tongue, burns to the hands, and hearing and vision loss.[189] Furthermore, a British doctor attributed the death of a patient from severe lipoid pneumonia, a lung disease, to e-cigarette use.[190] He posited (and continues to assert) that the inhalation of the oil in the e-cigarettes caused a similar result to those who are overexposed to oil inhalation over the course of their lifetime.[191]

V. FDA ACTION AND JUDICIAL REVIEW IN SOTTERA V. FDA

The FDA has begun testing the bounds of the statutory framework for regulation of tobacco products through enforcement actions against e-cigarette products. Although ultimately an unsuccessful attempt by the FDA to regulate e-cigarettes as drug-device products, the *Sottera* case is instructive in beginning to delineate the operative regulatory framework for the FDA as it faces a proliferating e-cigarette market.

A. Product Detention and Preliminary Injunction

The FDA has asserted its jurisdiction over e-cigarettes in two instances. In September 2008, the FDA detained several import shipments of e-

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[188] Murray Laugesen, *Second Safety Report on the Ruyan E-Cigarette*, HEALTH NEW ZEALAND LTD, (Apr. 9, 2008), http://www.mlm-infos.com/files/2ndsafetyreport_9apr08_930.pdf.

[189] Mikaela Conley, *Man Suffers Severe Injuries After E-Cigarette Explodes in His Mouth*, ABC NEWS (Feb. 15, 2012), http://abcnews.go.com/Health/electric-cigarette-explodes-fla-mans-face/story?id=15645605; *Electronic Cigarette Explodes in Muskogee Woman's Hand*, FOX23.COM (Apr. 18, 2012, 8:35 PM), http://www.fox23.com/mostpopular/story/Electronic-cigarette-explodes-in-Muskogee-womans/ek2x6P6rvkyLu5cMrvGwVQ.cspx; *Update: Was Exploding E-Cigarette a "Mod"?*, CSP DAILY NEWS (Feb. 20, 2012), http://www.cspnet.com/news/tobacco/articles/update-was-exploding-e-cigarette-mod.

[190] *Gateshead Doctor Calls for Research into "E-Cigarettes,"* BBC NEWS (Mar. 28, 2011, 4:27 PM), http://www.bbc.co.uk/news/uk-england-12887335.

[191] *Id.*

cigarettes manufactured by Smoking Everywhere, Inc. and subsequently issued notices of detention for violation of the FDCA.[192] A December 2008 correspondence establishes the asserted basis of jurisdiction: e-cigarettes and component parts are "intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction,"[193] thereby subjecting them to pre-market requirements under the FDCA as drug-device products. In March 2009, the FDA issued a refusal of admission notice and directed the detained products be exported or destroyed within 90 days.[194] In April 2009, the FDA also detained Sottera's shipment of e-cigarettes.[195] Smoking Everywhere and Sottera filed complaints on April 28, 2009 and May 15, 2009, respectively, seeking to enjoin the FDA from regulating e-cigarettes as drug-device combinations under the FDCA. The district court determined that the balance of harms favored Sottera and Smoking Everywhere and issued a preliminary injunction against the FDA.[196]

After detaining the imports, the FDA analyzed samples of the two products, including nicotine cartridges of various proclaimed amounts. Although the analysis was not a basis for the original detention of the products and not at issue in the case, the FDA has used the findings to support its position that e-cigarettes pose serious health risks. A May 2009 memorandum generated by the Deputy Director of the Division of Pharmaceutical Analysis within the Center for Drug Evaluation and Research at the FDA reported harmful volatile components in tests of both products, including tobacco-specific nitrosoamines and impurities, and even traces of diethylene glycol, a poisonous organic compound.[197] The tests also found that identically labeled cartridges contained varying amounts of nicotine.[198]

B. Appellate Review

On appeal to the D.C. Circuit, the court addressed whether the NJOY e-

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[192] Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 64 (D.D.C.), *aff'd sub nom.* Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

[193] *Id.* at 65.

[194] *Id.*

[195] *Id.*

[196] *Id.* at 78-79. Smoking Everywhere did not continue as a party on appeal.

[197] Westenberger Memo, *supra* note 141.

[198] *Id.*

cigarette, marketed by Sottera, could be regulated as a drug or medical device or merely as a tobacco product.[199] Affirming the judgment of the lower court to grant a preliminary injunction against the FDA, the D.C. Circuit also held that the FDA's authority over the NJOY e-cigarette was limited to the provisions covering tobacco products.[200] Though the court noted a weak factual record on the marketing of e-cigarettes,[201] it found that without evidence that the company was making therapeutic claims, the "definitional line laid down in *Brown & Williamson* . . . leaves the FDA without jurisdiction over these products under the FDCA's drug/device provisions."[202]

The NJOY product itself was labeled for smoking pleasure rather than as a therapeutic or smoking cessation product,[203] which was critical to the court's decision. In reaching its conclusion, the majority read *Brown & Williamson* to exclude *all* tobacco products from the drug and device provisions (not just those products on the market at the time of the holding, *i.e.*, cigarettes and smokeless tobacco) as long as the manufacturer, NJOY, did not make drug-like claims.[204] The court determined that Congress had consciously developed a broader statutory scheme that distinguished customarily marketed tobacco products, including more than just cigarettes and chewing tobacco, from those tobacco products marketed for therapeutic purposes.[205]

C. Forgoing Further Appeal

The FDA ultimately decided to forgo appeal and issued a letter to the public setting forth its reasoning.[206] The letter assured adherence to the jurisdictional lines drawn by the *Sottera* court, while also indicating the relevance of other provisions of the statute that are implicated by e-

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[199] Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).

[200] *Id.* at 897. This authority includes restrictions on sale, advertising, manufacture, and the establishment of standards. *Id.* at 898.

[201] *Id.* at 898.

[202] *Id.*

[203] *Id.* at 893.

[204] *Id.*

[205] *Id.* at 897.

[206] Letter from Lawrence R. Deyton, Dir., Ctr. for Tobacco Products & Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to stakeholders (Apr. 25, 2011), http://www.fda.gov/ newsevents/publichealthfocus/ucm252360.htm.

cigarettes.[207] For example, the FDA included requirements covering new tobacco products and a portion of the definition of tobacco product that includes those tobacco products marketed in combination with other FDA-regulated products.[208] The letter also emphasized that the FDA may issue a guidance document regarding therapeutic claims and triggers for regulation as a drug or medical device.[209]

The decision in *Sottera* and the FDA's subsequent decision not to appeal are woefully unsatisfying. The remainder of this Article is premised on two complementary positions. The first is that the TCA is inadequate for oversight of e-cigarettes, which are novel nicotine delivery devices for which the FDA ought to have the authority to assess safety and efficacy. E-cigarettes are not typical cigarettes consisting of tobacco grounds rolled in paper. Compared to a traditional tobacco product, e-cigarettes deliver a purer form of nicotine without the tobacco, the intake of nicotine is more rapid, and the user does not have the behavioral cue of a cigarette butt to signal the completion of a normal dose. Surely, the FDA safety assessment in the context of new drugs and devices deals with this phenomenon exactly, where novel delivery of excessive levels of active ingredients produce uncertain effects on the body.

The second position responds to the FDA's announcement that it will regulate e-cigarettes under the framework created by the TCA rather than pursue jurisdiction under the drug and medical device provisions. Going forward, the FDA will need to assess the industry as a whole to identify those claims, representations, and uses that do in fact trigger the drug-medical device requirements. This will require a prime focus not only on the explicit claims and representations of intended use of the product by both the original manufacturer and distributors, but also on implicit representations and actual consumer use.

VI. GOING FORWARD: STRENGTHENING REGULATION OF ELECTRONIC CIGARETTES

Absent a change in position from the FDA, e-cigarettes will be regulated under the framework espoused in *Sottera*. This Part informs the process of deciphering whether a manufacturer or distributor is making therapeutic claims or whether customary use implies an intended therapeutic

[207] *Id.*
[208] *Id.*
[209] *Id.*

use as a drug-device product. Despite the problematic analysis presented by the court in *Sottera*, particular claims, representations, and actual consumer use of e-cigarette products for smoking cessation or reduction do in fact trigger drug-medical device provisions. Even if the FDA takes the stance that actual consumer use fails to trigger drug-device provisions, various product features may trigger heightened requirements for new tobacco products and modified-risk tobacco products. The FDA may also rely on broad statutory authority from Congress to promulgate product-specific regulations and guidance.

A. Triggering Drug-Device Regulation Through Marketing, Promotion, and Consumer Use

Where the manufacturer of a tobacco product makes any claims or statements about the intended use of the product that fall within the drug or medical device definition, those statutory and regulatory provisions will apply. The FDA has clarified the scope of intended use by regulation:

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.[210]

This regulation makes clear that intended use extends beyond explicit claims and representations by the original manufacturer and the subsequent marketer. In fact, intended use includes representations by those affiliated with the product and actual consumers, if the distributor has knowledge of actual consumer use.

Claims made by the manufacturer on the product label and in marketing and promotion are the primary indicators of intended use. The FDA and Federal Trade Commission have made clear that company and manufacturer websites are also a source of promotional claims for purposes of enforcement. Increased monitoring and surveillance of manufacturer and distributor claims on labels and in advertising and promotion by the FDA and the CTP would assist in identifying problematic claims.

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[210] 21 C.F.R. § 201.128 (2011).

The FDA confronts challenges in several product realms by definitional lines demarcated by intended use.[211] For example, a cosmetic[212] is also regulated as a drug if claims are made that the product affects the structure or function of the human body or that the product will improve health or treat a health or disease-related condition.[213] The FDA has struggled with this line between a drug and a cosmetic for decades, as reflected by a litany of warning letters to industry[214] as well as informational materials on its website.[215] Even absent manufacturer claims, a cosmetic with a drug or drug-like intended use gleaned through customary consumer use or consumer perception may be regulated as a drug.[216] Unlike cosmetics, e-cigarette claims will not involve structure-function aspects, such as "lifting" wrinkles, "rebuilding" cells, or "repairing" imperfections.

With e-cigarettes, the challenge will likewise be policing the definitional lines. If a tobacco product manufacturer or distributor makes drug or medical device claims, it will be subject to the related requirements. For tobacco products, the traditional cigarette and smokeless tobacco manufacturers are careful to avoid marketing claims that sound therapeutic in nature, such as cessation or addiction treatment (triggering the drug requirements) or risk reduction (triggering the modified-risk requirements). The FDA will need to discern what claims made by e-cigarette manufacturers will similarly trigger heightened requirements. Given the novelty of e-cigarette technology (which means that the FDA is facing a rapid learning curve), coupled with aggressive marketing campaigns requiring vigilant watchdogging on the part of an already stressed administrative agency, manufacturers and distributors of e-cigarettes are currently thriving because of statutory and regulatory gaps and the

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[211] *See* Jordan Paradise & Ethan Fitzpatrick, Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?, 117 PENN ST. L. REV. 53 (2012).

[212] A cosmetic is another definition in the FDCA hinging on intended use, defined as "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance . . . ." 21 U.S.C. § 321(i) (Supp. 2011).

[213] *See id.* § 321(g)(1)(C). Foods and dietary supplements can make structure-function claims as long as they do not venture into unallowable health or disease-prevention claims.

[214] *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics*, FDA, http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm081086.htm (last updated Nov. 26, 2012).

[215] *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, FDA (July 8, 2002, updated Apr. 30, 2012),http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm [hereinafter *Is It a Cosmetic?*].

[216] *Id.*

inadequate enforcement. It will be years before the FDA can catch up with the claims targeted to consumers, though recent statements from the FDA indicate that this is a priority area following the outcome of *Sottera*.[217] Aside from direct representations made in marketing and promotion, any representation from the manufacturer or distributor in any public forum technically constitutes providing evidence of intent. Communications and reports to other administrative agencies within the federal government are readily available to the FDA to glean an intended use from representations contained within those sources. The FDA and other regulatory agencies often rely on these representations to support enforcement actions. For example, in framing a 1987 Regulatory Letter, the Department of Health and Human Services (DHHS) relied on the statements that Advanced Tobacco Products, Inc. made in labeling and promotional literature and in reports to the Securities and Exchange Commission (SEC) to support the finding that the FAVOR smokeless cigarette product[218] was a nicotine delivery system.[219] Accordingly, the letter stated that as a nicotine delivery system intended to affect the structure or function of the body through pharmacologic action, the FAVOR cigarette had violated the new drug provisions under the FDCA and its marketing should be discontinued.[220] The letter heavily referenced statements made by the company in its annual report to the SEC, including references to medical literature regarding the effects of nicotine on the nervous system and its addictive qualities.[221] The company responded with a letter indicating that distribution of the product had been curtailed pending preparation of a detailed response,[222] and the company ultimately removed the product from the market voluntarily without enforcement action by the DHHS. Given the voluntary withdrawal

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[217] Letter from Lawrence R. Deyton, *supra* note 206.

[218] Conceptually similar to present day e-cigarettes, when air is drawn through the tube over the nicotine solution, a small amount of nicotine is inhaled by the user. However, it contains no heating element or battery and operates simply by drawing air over the nicotine solution. U.S Patent No. 4,284,089 col. 3 ll. 25-30, (filed Apr. 2, 1980). The specific amount of nicotine inhaled during each draw of air is dictated by how constricted the passageway through the nicotine chamber is and by alteration of the surface area of the absorbent material. *Id.* col. 5 ll. 10-20.

[219] Regulatory Letter from Daniel L. Michels, Dir., DHHS, Office of Compliance, Ctr. for Drugs & Biologics (Feb. 9, 1987), http://www.legacy.library.ucsf.edu/documentStore/h/e/b/ heb65e00/Sheb65e00.pdf.

[220] *Id.* at 2.

[221] *Id.* at 1.

[222] Letter from James E. Turner, Chief Operating Officer, Advanced Tobacco Products, Inc. (Mar. 9, 1987) (on file with author).

of the product, reliance on these representations has not been tested in the courts.[223]

Patent filings with the U.S. Patent and Trademark Office or other international patent bodies are another useful resource. Any information provided to support a patent application and subsequent patent is made public and becomes part of the public domain, accessible to anyone via the internet. As a means to satisfy utility and novelty requirements in patent law, inventors support their invention description with reasons that their invention is useful and new for a particular application.[224] Patents for e-cigarettes may house a wealth of statements relevant to whether the manufacturer is representing the product as a smoking cessation or reduction product or is making claims of therapeutic benefit as compared to smoking risks.

For example, the inventor of the FAVOR smokeless cigarette described above was granted a patent in 1981 for a smokeless cigarette consisting of "a container defining a passageway therethrough and having a mouthpiece; means containing a source of vaporizable nicotine in fluid communication . . . [and] means for preventing the evaporation of said nicotine during periods of non-use . . . ."[225] The invention was "designed to reduce or eliminate the disadvantages associated with conventional smoking habits using combustible cigarettes"[226] and to "eliminate or ameliorate the adverse consequences" of smoking.[227]

The Lik Hon patent (assigned to Best Partners Worldwide Limited, reportedly acquired by Ruyan Investments) makes representations such as:

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[223] In the litigation leading up to *Sottera*, the FDA argued that the assertion of jurisdiction over the FAVOR smokeless cigarette is relevant for purposes of e-cigarette regulation. The district court noted that such an action was not judicially reviewed, it predated the Supreme Court's decision in *Brown & Williamson*, and it was "not in step with the reasoning of that case." Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62, 72 (D.D.C.), *aff'd sub nom.* Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010). However, the treatment of the FDA's assertion of jurisdiction over the FAVOR product is not satisfactorily discussed in the lower court decision, is relegated to a footnote, and is premised on a seemingly inaccurate framing of the reasoning of *Brown & Williamson*. Specifically, the district court states that the reasoning in *Brown & Williamson* was "based in part on FDA's representations to Congress that customarily-marketed tobacco products are not subject to FDA jurisdiction absent therapeutic claims." *Id.* Notably, the case does not address other aspects of the FAVOR history, namely the FDA's reliance on the SEC filings, to construe intended use of the product.

[224] *See* 35 U.S.C. §§ 101-102 (2006).

[225] U.S. Patent No. 4,284,089, *supra* note 217, at col. 14 ll. 52-59.

[226] *Id.* at col. 1 ll. 9-11.

[227] *Id.* at col. 2 ll. 4-5.

"only contain[ing] nicotine without the harmful tar;"[228] "provide[s] an electronic atomization cigarette that may function as a substitute for smoking cessation products or as a cigarette substitute;"[229] and "[the] advantages of the present invention include smoking without tar, significantly reducing the cancerogenic risk."[230] The patent also generally points out that "some cigarette substitutes" such as "nicotine patch, nicotine mouthwash, . . . nicotine chewing gum, nicotine drink" have a "major disadvantage"[231] and that the invention "overcome[s] the above-referenced drawbacks."[232] A Li Han patent (assigned to Ruyan Investments) provides that the invention "has been designed to provide an aerosol electronic cigarette that substitutes for cigarettes and helps the smokers to quit smoking."[233] The representations present within each of these patents strongly support a finding of an intended therapeutic use as a cessation or at least a modified risk product. However, it is unclear whether the FDA will succeed in using a patent claim as evidence of intended use for a particular e-cigarette product given complicated licensing arrangements that may exist between the inventor, patent assignee, and industry.

In tandem with increased general monitoring of marketing and promotion to mine for product claims, the FDA could search SEC filings and product-related patents in connection with manufacturer and distributor registration. The FDA could require submission of such materials at the time of registration, and on an annual basis through regulation or a guidance document.

B. Application of New and Modified Risk Provisions

Even where no drug or medical device claims are present, the FDA has at its disposal regulatory authority over the categories of new tobacco products and modified-risk products. Reports detailing the history of e-cigarettes identify a general presence in the U.S. market in the mid-2000s, with many sources pinpointing the exact date as some time in 2007. The FDA ought to determine when the various e-cigarette products entered the U.S. market and whether and to what extent changes in design are amenable to being grandfathered in as substantially equivalent to products already on

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[228] U.S. Patent No. 7,832,410, at [57] (filed Mar. 18, 2005).
[229] *Id.* at col. 1 ll. 53-55.
[230] *Id.* at col. 2 ll. 62-64.
[231] *Id.* at col. 1 ll. 35-41 (internal quotation marks omitted).
[232] *Id.* at col. 1 ll. 52.
[233] U.S. Patent No. 8,156,944 col. 1 ll. 58-60 (filed May. 15, 2007).

the market. The guidance to industry regarding new tobacco products is scant except to provide sources of evidence of market presence prior to the critical date.[234] Thus, elaboration on the role of substantial equivalence ought to be a priority for the FDA.

Future direction from the FDA on the new tobacco provisions will be important as the agency examines e-cigarettes and the timing of market entry for the various products and their progeny. The TCA appears to give the FDA the requisite authority to interpret the definition of substantial equivalence as applied to tobacco products. The FDA should consider interpreting the term strictly, not allowing incremental product changes without pre-market assessment. In the realm of devices, the FDA's inconsistent interpretation of substantial equivalence has raised significant safety concerns despite strong countervailing policy goals such as encouraging innovation and rapid introduction of new products.[235] Setting clear guidance is imperative.

Perhaps more useful for regulation and enforcement against e-cigarettes are the modified-risk products provisions contained in the TCA. Those products sold or distributed as reducing the harm or risk of disease associated with traditional cigarettes are subject to heightened requirements prior to marketing, including scientific data and comparative studies.[236] The FDA can use statements about risk reduction made in marketing, promotional materials, and SEC and patent filings to support regulation of e-cigarettes as modified risk tobacco products. Any label, marketing and promotional material, website, or other manufacturer representations about the product will likewise support heightened requirements. As noted in Part III, the FDA is also in the process of implementing these provisions of the TCA; guidance should focus on specific e-cigarette claims triggering heightened requirements.

C. E-Cigarette-Specific Regulations and Guidance for Standardization, Reporting, and Labeling

Alongside scrutiny of product claims, actual consumer use, and application of the new and modified-risk provisions, the FDA should also begin to gather information and impose standards on the e-cigarette industry. Additional efforts to regulate e-cigarettes should be directed

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[234] *See* Ctr. for Tobacco Prods., *supra* note 104.

[235] *See* Paradise, *supra* note 60, at 488.

[236] *See* 21 U.S.C. § 387k(b)(1) (2006); CTR. FOR TOBACCO PRODS., *supra* note 110.

toward the development of requirements to force uniformity and standardization across the industry, provide consumers with information regarding ingredients and nicotine levels, and create quality control mechanisms and product standards. This is not as daunting a task as it may seem.

The broad authority granted to the FDA, coupled with detailed statutory provisions, provides groundwork for the development of regulations and guidance regarding e-cigarette manufacturing and sale. Most relevant are provisions mandating manufacturer registration,[237] disclosure to the FDA of ingredients,[238] and manufacturing practice requirements.[239] The statute requires every owner or operator engaged in the manufacture, preparation, and processing of tobacco products to register the name, place of business, and a list of all tobacco products.[240] The statute also requires the FDA to promulgate regulations requiring testing and reporting of ingredients, constituents, and additives by brand and sub-brand requisite to protect the public health.[241] All ingredients, including tobacco substances, compounds, and additives, as well as a description of the milligram content, delivery, and form of nicotine in each tobacco product, must be reported.[242] Harmful and potentially harmful constituents (HPHCs) in tobacco products must be reported by brand and quantity;[243] the FDA has already developed a list of 93 HPHCs.[244] At a minimum, the FDA may require e-cigarette manufacturers and distributors to register and file a list of all tobacco products, ingredients, and HPHCs.[245]

The FDA has issued several nonbinding guidance documents for industry explaining the agency's current plans to interpret and develop the statutory requirements for filing and reporting.[246] The agency provides that as it moves forward with full implementation and enforcement of the

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[237] 21 U.S.C. § 387e (2006).

[238] *Id.* § 387d.

[239] *Id.* § 387e(e).

[240] *Id.* § 387e.

[241] *Id.* § 387o(a).

[242] *Id.* § 387d.

[243] *Id.* § 387d(a)(3).

[244] *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List*, FDA (Mar. 2012), http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm.

[245] *See* REGISTRATION AND PRODUCT LISTING, *supra* note 88.

[246] *See id.*; Reporting Harmful Constituents, *supra* note 88.

reporting requirements via rulemaking it will revise or withdraw the guidelines accordingly.[247] While these guidance documents signal movement from the FDA, priority should be given to spell out these requirements to the e-cigarette industry and make it clear that the filing and reporting requirements apply to them.

Aside from the these actions covering filing and reporting, the FDA should require mandatory listing of all e-cigarette ingredients for labeling and packaging, similar to nutrition facts for foods[248] and supplement facts for dietary supplements.[249] The ingredients should be listed on each starter kit, nicotine cartridge, and disposable product in addition to all accompanying labeling and packaging for the product. The format and requirements for this information should issue through notice and comment rulemaking.

The TCA also grants the FDA authority to establish product standards.[250] Uniformity and standardization are also vital for the entire e-cigarette industry to assure consumer comprehension and industry accountability. This includes clearly conveyed nicotine levels for initial and refill nicotine cartridges; FDA-cleared design, mechanisms, and parts for the atomizer, battery, and nicotine cartridge; and, ideally, some notification to the user of the amount of nicotine consumed. This could possibly be built into the LED system as a changing color notification as more nicotine is consumed.

Quality control mechanisms are also necessary as part of manufacturing practices. The FDA has effectively implemented these in various other contexts, including food production[251] and drug[252] and device development.[253] These manufacturing practices would identify general constructs for personnel, grounds, facilities, equipment, processes, and controls, warehouse conditions, and distribution. The FDA would rely on these when investigating and inspecting a particular e-cigarette facility, and they would support enforcement action against violations.

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[247] Reporting Harmful Constituents, *supra* note 88, at 2.

[248] *See* 21 C.F.R. § 101.9 (2011).

[249] *Id.* § 101.36 (2011).

[250] 21 U.S.C. § 387g (2006).

[251] 21 C.F.R. § 110 (2011).

[252] *Id.* §§ 210-211.

[253] *Id.* § 820. This is called Quality System Regulation (QSR) in the device realm.

D. Congressional Additive Amendments

In order to address concerns about the allure of e-cigarettes to children under the age of 18, Congress should consider amending provisions in the TCA that ban additives in cigarettes by broadening their coverage to encompass e-cigarettes.[254] As written, the ban applies only to cigarettes, leaving e-cigarettes and various other products free to incorporate flavoring that may attract younger users. Likewise, legislation targeted toward e-cigarette marketing and advertising would also assist to curb the appeal and availability to adolescents and youth. However, the political will must exist to make such a change at the legislative level. Based on the nearly ten years it took Congress to enact the TCA, legislative fixes are not the primary or ideal means of enhancing regulation.

E. A Role for State and Local Authorities to Restrict Use and Sale

States and local governments can play a role as well, in parallel with FDA efforts to bolster regulation of e-cigarettes. A distinctive feature of the TCA is the broad latitude expressly preserved to state and local authority to regulate tobacco products.[255] Congress took pains not to limit authority of federal agencies, states, or Indian tribes to "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure" that "is in addition to, or more stringent than, requirements [under the TCA], including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco."[256] The preemption clause directly following the preservation clause does set bounds to this, in that federal requirements regarding product standards, pre-market review, adulteration, misbranding, labeling, registration, good manufacturing standards, and modified-risk tobacco products preempt state and local requirements that are different from, or in addition to, the federal requirements.[257]

This preservation will be essential to the states and localities as the FDA rolls out regulations. It leaves much room for restrictions crafted more

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[254] 21 U.S.C. § 387g(a)(1)(A) (2006).

[255] 21 U.S.C. *Id.* § 387p(a)(1) (2006).

[256] *Id.* § 387p(a)(1).

[257] *Id.* § 387p(a)(2)(A).

specifically to the geographic location and local political environment.[258] State and local regulatory efforts will likely continue to focus on smoking bans and restrictions on promotional activities.[259] Proactively assessing and characterizing e-cigarette use, distribution, and promotion as part of state and local efforts would be a valuable step. Specifically, authorities should take care in drafting smoking bans to include e-cigarettes.

Thirty-nine states and 3,671 municipalities already have laws in place restricting or prohibiting smoking in public places and workplaces.[260] However, the laws were drafted with cigarettes and traditional tobacco products in mind. Many specifically use the word "smoke" or "smoking" to define the restricted or prohibited action. States must be careful to draft relevant laws to explicitly include e-cigarettes if the intent is to prohibit or restrict that action in addition to traditional means of smoking. For example, New Jersey has become the first state to amend its public smoking laws to include electronic cigarettes. The New Jersey Smoke-Free Air Act (amended in 2010) prohibits smoking in indoor public places, workplaces, and in buildings or grounds of any public or nonpublic elementary or secondary school.[261] It defines "smoking" as encompassing "the inhaling or exhaling of smoke or vapor from an electronic smoking device"[262] and defines "electronic smoking device" as "an electronic device that can be used to deliver nicotine or other substances to the person inhaling from the device, including, but not limited to, an electronic cigarette, cigar, cigarillo, or pipe."[263] Likewise, Somerset, Massachusetts; King County, Washington; Madison County, Kentucky; Suffolk County, New York; Cattaraugus County, New York; Savannah, Georgia; and San Francisco, California have passed ordinances explicitly including e-cigarettes within the scope of their

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[258] For a discussion of state and local oversight opportunities under the TCA, see Leslie Zellers & Ian McLaughlin, *State and Local Policy as a Tool to Complement and Supplement the FDA Law*, 2 HASTINGS SCI. & TECH. L.J. 117 (2010).

[259] *See, e.g., id.*

[260] *Overview List—How Many Smokefree Laws?*, AM. NONSMOKERS' RIGHTS FOUND., http://www.no-smoke.org/pdf/mediaordlist.pdf (last updated Apr. 5, 2013). For a discussion of state and local laws regarding smoking and their lack of application to electronic cigarettes, see Daniel F. Hardin, *Blowing Electronic Smoke: Electronic Cigarettes, Regulation, and Protecting the Public Health*, 2011 U. ILL. J.L. TECH. & POL'Y 433.

[261] N.J. STAT. ANN. § 26:3D-58 (West 2011).

[262] N.J. STAT. ANN. § 26:3D-57 (West 2011).

[263] *Id.*

smoking bans.[264]

Various jurisdictions, both states and municipalities, have also enacted laws requiring licenses to sell e-cigarettes and banning sales to minors.[265] Others are under consideration.[266] States and local governments should assess their current smoking bans and other restrictions and decide whether to amend the language to include e-cigarettes. The political will and regional differences in views on smoking will drive these efforts.

CONCLUSION

The ever-rising hype and consumption of e-cigarettes is an opportunity to examine, interpret, and apply legislation governing tobacco products, as well as reassess the scope of drug and medical device regulation. The success of the e-cigarette industry signals the proliferation of a product containing a highly addictive chemical that currently evades regulation in light of recent case precedent and confusion regarding the scope of recently enacted legislation. If the public health is to be adequately protected, the FDA must initiate widespread investigations of product claims and representations made by the manufacturers that frame e-cigarettes as therapeutic products, as well as utilize the arsenal of statutory authority provided in the TCA. This Article, through historical exploration, comparative assessment, and statutory, regulatory, and case law interpretation and analysis argues that there is a feasible approach to strengthening regulation of e-cigarettes under the current statutory framework. This approach includes increased scrutiny of manufacturer and distributor claims for therapeutic intent triggering drug or medical device provisions, examination of actual consumer use of e-cigarette products, application of the new tobacco product and modified-risk tobacco product provisions, and additional regulatory movements from the FDA to foster uniformity and standardization, quality control, and access to product information.

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[264] Karen Blumenfeld, *Electronic Cigarettes (E-Cigarettes)*, GLOBAL ADVISORS ON SMOKEFREE POLICY (Feb. 1, 2013) 1-2, http://www.njgasp.org/E-Cigs_White_Paper.pdf.

[265] *Id.* New York recently enacted such a law, which also bans e-cigarettes use within 100 feet of a public or private school. Glenn Bain, *Gov. Cuomo Signs Two Laws to Protect Children from Nicotine Addiction; One of the Measures Bans the Sale of Electronic Cigarettes to Youth Under the Age of 18*, N.Y. DAILY NEWS (Sept. 5, 2012, 6:01 PM), http://www.nydailynews.com/new-york/gov-cuomo-signs-laws-protect-children-nicotine-addiction-measures-bans-sale-electronic-cigarettes-youth-age-18-article-1.1152718.

[266] *See, e.g., id.*