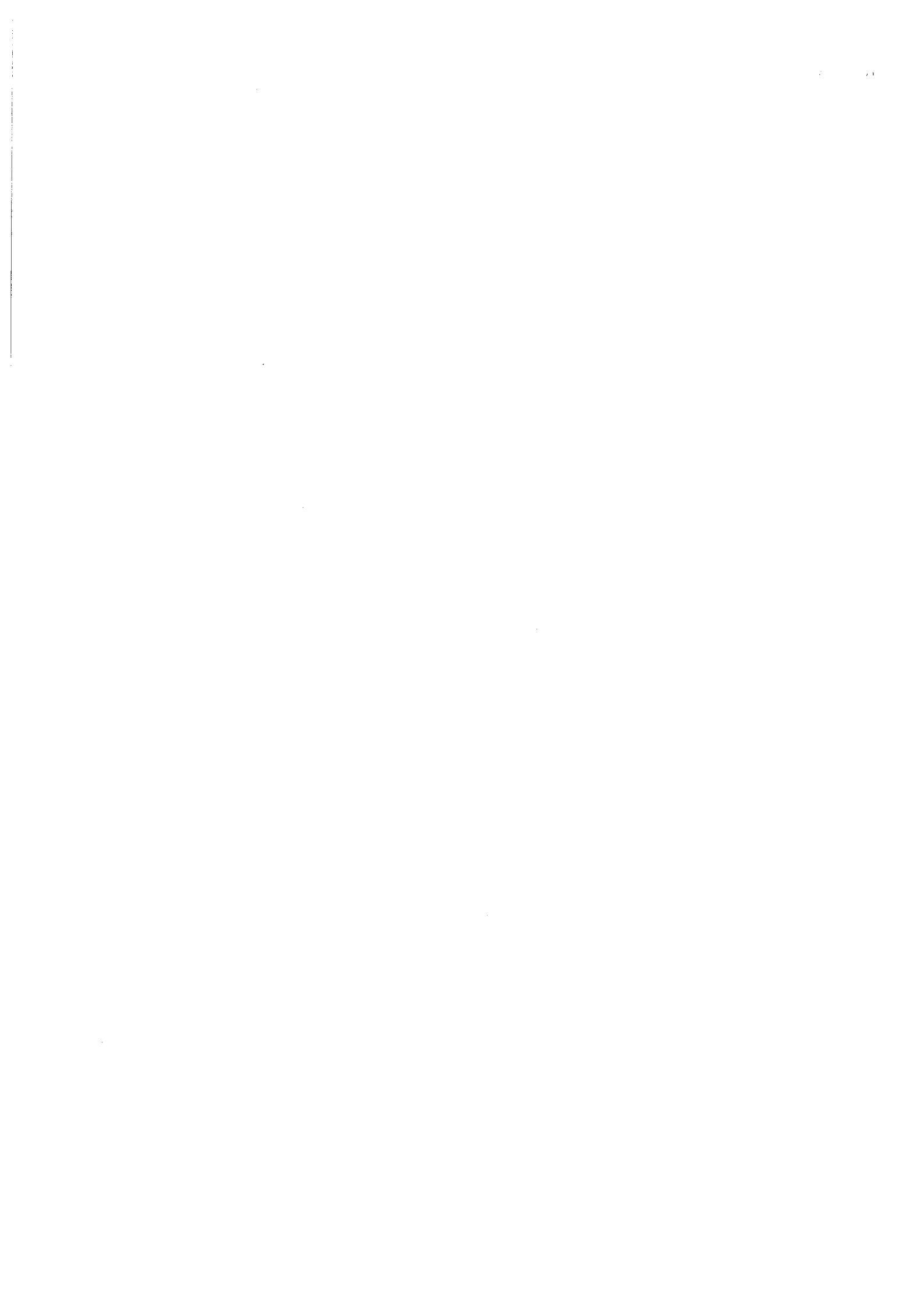



## **ANNEX 2**

***Smoking Everywhere Inc and Sottera Inc, d/b/a NJoy v. U.S. Food  
and Drug Administration [Civil Case No. 09-771 (RJL)]***



UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC., )  
 )  
 Plaintiff, )  
 )  
 and )  
 )  
 SOTTERA, INC., d/b/a NJOY, )  
 )  
 Intervenor-Plaintiff, )  
 )  
 v. ) Civil Case No. 09-771 (RJL)  
 )  
 U.S. FOOD AND DRUG )  
 ADMINISTRATION, *et al.*, )  
 )  
 Defendants. )

  
MEMORANDUM OPINION  
(January 14, 2010) [# 2 and 24]

Plaintiff, Smoking Everywhere, Inc. (“Smoking Everywhere”), and intervenor-plaintiff, Sottera, Inc., which does business as “NJOY” (“NJOY”) (collectively, “plaintiffs”), are distributors of a product known as “electronic cigarettes” or “E-cigarettes.” They claim that inbound shipments of their products from overseas manufacturers have been denied entry into the United States, or have otherwise been detained, by order of the Food and Drug Administration (“FDA”) on the ground that electronic cigarettes are an unapproved drug-device combination under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.* Plaintiffs seek a preliminary

injunction against the FDA and Commissioner Margaret Hamburg, as well as the U.S. Department of Health and Human Services and Secretary Kathleen Sebelius (collectively, “FDA”),<sup>1</sup> enjoining FDA from regulating electronic cigarettes as a drug-device combination and from denying entry of those products into the United States. As such, this case raises for the first time the issue of whether FDA has the authority under the FDCA to regulate electronic cigarettes as a drug-device combination. For the following reasons, the Court concludes that it does not and therefore GRANTS plaintiffs’ motions.

## FACTUAL BACKGROUND

### I. Electronic Cigarettes

Smoking Everywhere describes “electronic cigarettes” as “an alternative to traditional smoked tobacco products” that is “designed to replicate the adult experience of smoking without combustion or the use of cancerous by-products.” (Smoking Everywhere Complaint [#1] at ¶ 8). They function by vaporizing a liquid nicotine mixture that is derived naturally from tobacco plants. (*Id.*). Once the nicotine mixture is vaporized, the user inhales the vapor in much the same way that a traditional smoker would inhale tobacco smoke, except “without the fire, flame, tar, carbon monoxide,

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<sup>1</sup> Among the original named defendants in this suit were Joshua M. Sharfstein, Acting Commissioner of the FDA, and Charles E. Johnson, Acting Secretary of Health and Human Services. Pursuant to Federal Rule of Civil Procedure 25(d), if a public officer named as a party to an action in his official capacity ceases to hold office, the Court will automatically substitute that officer’s successor. In this case, Joshua Sharfstein and Charles Johnson no longer serve as the acting heads of their respective agencies. Accordingly, the Court removes them as defendants in this lawsuit.

known cancerous substances, ash, stub, or smell found in traditional cigarettes.” (*Id.*)

Electronic cigarettes have three basic components that are designed to resemble an actual cigarette: the cartridge, the heating element (also known as the atomizer), and electronics plus a battery. (*Id.* at ¶ 9). The cartridge, a plastic container that holds a mixture of propylene glycol and liquid nicotine, serves as the mouthpiece of the electronic cigarette. (*Id.*) The heating element vaporizes the liquid nicotine mixture, and the electronics power the heating element and monitor the air flow. (*Id.*) When a user inhales from the cartridge, the electronics detect the flow of air and then activate the heating element, which vaporizes the nicotine mixture. (*Id.* at ¶ 10). The vapor, which the user inhales, contains a flavor that simulates the taste and feel of tobacco. (*Id.*) Simply stated, the electronic cigarette is designed to look and to be used just like a traditional cigarette.

Smoking Everywhere is a distributor that imports electronic cigarettes from overseas manufacturers. (*Id.* at ¶¶ 7, 12). It derives all of its revenue from the importation and sale of electronic cigarettes, its sole product line. (*Id.* at ¶ 12). Since its founding over a year ago, it has imported and sold more than 600,000 units. (*Id.* at ¶ 7). Smoking Everywhere markets its electronic cigarettes as an alternative to traditional cigarettes that delivers the same sensation as smoking. Its promotional materials state, for example: “[e]ach cartridge is equivalent to 20 traditional cigarettes”; “[t]he taste of the Smoking Everywhere cartridge resembles that of tobacco”; “Smoking Everywhere E-Cigarette has been designed to look and feel like a traditional cigarette”; “[i]t looks like a

real cigarette, feels like a real cigarette and tastes like a real cigarette, yet it isn't a real cigarette"; "Smoking Everywhere E-Cigarette . . . gives the users the feeling they get when they smok[e] real cigarette[s]"; "Smoking Everywhere E-Cigarette will provide smokers the same delight, physical and emotional feelings they get in smoking traditional cigarettes"; "[t]his is what the smoker gets, the nicotine hit that smokers crave"; and "[e]lectronic cigarette' is a kind of non-flammable electronic cigarette with similar functions to those of a common cigarette which is to refresh smokers and satisfy their smoking addiction, thus making them happy and relaxed." (Administrative Record of Detention and Refusal ("AR DET") 28, 35, 39, 41, 49, 51, 56). Smoking Everywhere also markets its electronic cigarettes as a healthier alternative to traditional cigarettes. For example, customer testimonials on its website proclaim: "I thought [E-cigarette] was a great alternative to help me stop smoking real cigarettes"; "I've been smoking real cigarettes for over 20 years and really wanted to stop because it was damaging my lungs . . . I've been using [E-cigarettes] for 3 weeks now and feel great"; and "[t]here is less health risk, and I can smoke anywhere and everywhere." (AR DET 21). Smoking Everywhere's promotional materials also state that E-cigarettes are "cheaper and healthier than real cigarettes," that they offer "smokers a chance of smoking in a much healthier way," and that "smokers still get their nicotine, but don't get any harmful side effects of smoking traditional cigarettes." (AR DET 39, 49).

NJOY, an intervenor-plaintiff in this case, is also in the business of importing and distributing electronic cigarettes. (NJOY Complaint [#22] at ¶ 1). Since it began selling electronic cigarettes in early 2007, NJOY has sold at least 135,000 units in the United States. (*Id.* at ¶ 13). NJOY markets its electronic cigarettes only for “smoking pleasure” as an alternative to conventional cigarettes. (NJOY Complaint [#22] at ¶ 1). It claims not to make therapeutic representations. (*Id.*). Indeed, NJOY labels its products with a disclaimer that states, for instance: “NJOY products are not a smoking cessation product and have not been tested as such.” (Declaration of John Leadbeater (“Leadbeater Decl.”) [#24-1] at ¶ 9 (internal quotation marks omitted)).

## **II. The Refused Shipments**

This action arises from FDA’s decision to detain multiple inbound shipments of electronic cigarettes belonging to Smoking Everywhere and NJOY. In the case of Smoking Everywhere, FDA issued a “hold” on two shipments that arrived at Los Angeles International Airport in late September 2008. (AR DET 59-60). On October 29, 2008, FDA issued notices of “Detention” on the ground that the shipments “appear to be adulterated, misbranded or otherwise in violation” of the FDCA. (AR DET 78-79, 80-81). After an exchange of information about the shipments between FDA and Smoking Everywhere, FDA issued a “Correspondence” on December 23, 2008, stating its conclusion that “‘Smoking Everywhere E-Cigarette’ and its component parts appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat

the withdrawal symptoms of nicotine addiction.” (AR DET 97-98, 100-01). Thus, according to FDA, the product appears to be an unapproved drug-device combination under the FDCA. (*Id.*). FDA reiterated this view in follow-up correspondence from a compliance officer to a representative of Smoking Everywhere:

We believe that when originally offered for importation, this product was explicitly labeled and promoted for “drug” use. In addition, . . . this product is clearly intended for “drug” use by “the circumstances surrounding the distribution of the article.” These circumstances include the product’s conventional cigarette appearance; its design, formulation, and function to deliver to the body through inhalation of a smoke-like aerosol (resembling conventional cigarette smoke) various volatile chemical substances, including nicotine, produced by the article; and how the product is intended to be manipulated and used like conventional cigarettes to affect the body’s structures and functions and/or to treat/mitigate the symptoms of nicotine addiction.

(AR DET 82). Based on this conclusion, FDA issued “Refusal of Admission” notices on March 16, 2009, for both shipments and directed that the “products must be exported or destroyed under Customs supervision within 90 days.” (AR 102-04, 105-06).<sup>2</sup>

A short time later, FDA added electronic cigarettes manufactured by three Chinese companies to Import Alert 66-41, a directive that authorizes FDA district offices to “detain without physical examination any [u]napproved and/or misbranded drug listed in the attachment.” (Administrative Record of Import Alert 66-41 (“AR IA”) 3, 85-86).

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<sup>2</sup> Smoking Everywhere also alleges that another inbound shipment of its electronic cigarettes was detained at FDA’s request on April 13, 2009, at the Port of Miami in Miami, Florida (Smoking Everywhere Complaint [#1] at ¶ 28), but FDA reports that it has been unable to find any record of this shipment (FDA Opposition [#14] at 11).

Between March 30 and April 7, 2009, FDA listed electronic cigarettes and electronic cigarette components manufactured by Shenzhen Kanger Technology Co. Ltd., Desonic Industrial, and Loong Totem Science & Technology as unapproved or misbranded drugs. (AR IA 85-86). NJOY claims, however, that even though the import alert only applies to the three named manufacturers, FDA's publicly available Import Refusal Reports show that, from June 2008 to May 2009, FDA district offices have denied entry to more than thirty-five shipments of electronic cigarettes and their components from twenty other manufacturers. (NJOY Supp. Reply [#44] at 6; Declaration of David A. Becker in Support of Motion for Preliminary Injunction [#44-1, -2] at ¶¶ 3-4).

In NJOY's case, an inbound shipment of its electronic cigarettes arrived in Phoenix, Arizona on April 15, 2009. (NJOY Complaint [#22] at ¶ 27, Ex. B). Five days later, FDA issued a notice of "Detention" on the ground that NJOY's products "appear to be intended to both affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction." (*Id.* at ¶¶ 27-28, Ex. B). Arguing that FDA intends to deny entry to NJOY's electronic cigarettes based on FDA's conclusion (evident in *Smoking Everywhere's* case) that electronic cigarettes are unapproved drug-device combinations under the FDCA, NJOY requested leave to intervene in this case, which the Court granted.

## DISCUSSION

Plaintiffs seek a preliminary injunction barring FDA from refusing entry of their electronic cigarette products on the basis that those products are unapproved drug-device

combinations. The factors that a court must weigh in deciding whether to grant preliminary injunctive relief are, of course, well-known: (1) whether “the plaintiff has a substantial likelihood of success on the merits”; (2) whether “the plaintiff would suffer irreparable injury were an injunction not granted”; (3) whether “an injunction would substantially injure other interested parties”; and (4) whether “the grant of an injunction would further the public interest.” *Ark. Dairy Co-op Ass’n, Inc. v. U.S. Dep’t of Agric.*, 573 F.3d 815, 821 (D.C. Cir. 2009). The party seeking a preliminary injunction need not prevail on each factor. “If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak.” *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995). Having weighed the relevant factors, the Court concludes that plaintiffs have made a sufficient showing of success on the merits and irreparable harm to warrant preliminary injunctive relief.

#### **I. Likelihood Of Success On The Merits**

In *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court held that tobacco products, like traditional cigarettes, are not subject to FDA regulation as a drug or device. 529 U.S. 120, 160-61 (2000).<sup>3</sup> Because electronic cigarettes, as marketed by

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<sup>3</sup> Because FDA had found that tobacco products were “unsafe” and “dangerous,” the Supreme Court reasoned “that were the FDA to regulate cigarettes and smokeless tobacco, the [FDCA] would require the agency to ban them.” *Brown & Williamson Tobacco*, 529 U.S. at 134-37. The Supreme Court noted, however, that a ban on tobacco products pursuant to the FDCA would contravene congressional intent because Congress “has foreclosed the removal of tobacco products from the market.” *Id.* at 137. Given that Congress had passed legislation specifically aimed at tobacco on six occasions since 1965, the Supreme Court inferred that “the collective premise of these statutes is that

plaintiffs, are the functional equivalent of traditional cigarettes, plaintiffs contend that FDA cannot regulate their products. They further contend that Congress's recent enactment of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("Tobacco Act"), supports their argument.<sup>4</sup> Under the Tobacco Act, FDA may now regulate tobacco products, which the Act defines as "any product made or derived from tobacco that is intended for human consumption," 21 U.S.C. § 321(rr)(1), but it cannot regulate those products as it would a drug or device under the

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cigarettes and smokeless tobacco will continue to be sold in the United States." *Id.* at 137-39. To the extent that tobacco products are unsafe and yet cannot be banned, the Supreme Court concluded that "they simply do not fit" within the FDCA's regulatory scheme. *Id.* at 143.

<sup>4</sup> Even though Congress did not enact the Tobacco Act until after the agency action under review in this case, it is significant because it reflects Congress's understanding of the state of the law at the time of the agency action. Enacted against the backdrop of the Supreme Court's decision in *Brown & Williamson Tobacco*, the Tobacco Act reflects Congress's intent to confer FDA jurisdiction where it did not previously exist. One of the enumerated purposes of the Act is "to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act . . . , by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." Pub. L. No. 111-31, 123 Stat. at 1781. Thus, to the extent that a particular product satisfies the Tobacco Act's definition of "tobacco product" and is exempt from regulation as a drug or device under the terms of the Act, the Court can assume that the product would have been exempt from FDA jurisdiction prior to passage of the Tobacco Act. Indeed, the Act itself provides that it is not intended to "affect, expand, or limit [FDA's] authority over (including the authority to determine whether products may be regulated), or the regulation of, products . . . that are not tobacco products under [the drug-device subchapter]." 21 U.S.C. § 387a(c)(1). The parties seem to agree that the Tobacco Act did not move the definitional line between tobacco products and drugs; they simply disagree about where the line is drawn. Undoubtedly, Congress's passage of the Tobacco Act sheds considerable light on that issue.

FDCA, *id.* § 387a(a).<sup>5</sup> There being no dispute that the nicotine in plaintiffs' electronic cigarettes is naturally distilled from actual tobacco and is intended for human consumption (FDA Supp. Br. [#41] at 5 n.3), plaintiffs assert that their electronic cigarettes qualify as a tobacco product and are therefore exempt from regulation as a drug-device combination.

Not surprisingly, FDA contends that the Tobacco Act supports its argument that electronic cigarettes fall beyond the scope of *Brown & Williamson Tobacco* and, as a result, are subject to regulation under the FDCA as a drug-device combination. To make its case, FDA points to a provision of the Tobacco Act that excludes from the meaning of "tobacco product" any "article that is a drug under [21 U.S.C. § 321(g)(1)], a device under [21 U.S.C. § 321(h)], or a combination product described in [21 U.S.C. § 353(g)]." 21 U.S.C. § 321(rr)(2)-(3). FDA contends that the labeling and promotional materials for Smoking Everywhere's products "represent and suggest that the product[s] will provide the same drug effects on the structure and function of the human body as cigarettes." (FDA Supp. Br. [#41] at 5). Because of those effects, FDA claims that the electronic cigarettes marketed by Smoking Everywhere qualify as a drug-device combination, which the FDCA defines as an article "intended to affect the structure or any function of the

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<sup>5</sup> The Tobacco Act provides that "[t]obacco products, including modified risk tobacco products . . . , shall be regulated by the [Secretary of Health and Human Services] under this subchapter and shall not be subject to the provisions of subchapter V of this chapter," which pertains to the regulation of "drugs" and "devices." 21 U.S.C. § 387a(a).

body.” 21 U.S.C. § 321(g)(1)(C).<sup>6</sup> FDA also argues that Smoking Everywhere’s promotional materials suggest that its electronic cigarettes are intended to have a therapeutic effect. According to FDA, “[t]he assertion that E-Cigarettes provide a ‘healthier way’ to obtain the effects of nicotine establishes that E-Cigarettes are intended to prevent or alleviate nicotine withdrawal symptoms.” (FDA Opposition [#14] at 21). Consequently, FDA claims that Smoking Everywhere’s products also satisfy the FDCA’s other definition of a drug-device combination as an article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” 21 U.S.C. § 321(g)(1)(B). Based on the totality of the labeling and promotional materials, FDA contends that Smoking Everywhere’s electronic cigarettes either are intended to affect the structure or function of the body or are intended for use in the mitigation of disease. Thus, FDA concludes that those products fall well within the FDCA’s definition of a drug-device combination and should be regulated as such.

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<sup>6</sup> The Court notes that the FDCA defines a “device” along the same lines as a “drug.” For instance, a “device” is defined as “an instrument, apparatus, . . . or other similar or related article, including any component, part, or accessory,” that is “intended for use in the diagnosis . . . cure, mitigation, treatment, or prevention of disease” or that is “intended to affect the structure or any function of the body.” 21 U.S.C. § 321(h)(2)-(3). Unlike a drug, however, a device “does not achieve its primary intended purposes through chemical action within or on the body” and “is not dependent upon being metabolized for the achievement of its primary intended purposes.” *Id.* § 321(h). Articles that “constitute a combination of a drug, device, or biological product” are regulated as combination products. *Id.* § 353(g). FDA understands this provision as giving it the discretion to regulate combination products as drugs, as devices, or as both. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,400 (1996).

