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"),[1] 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,

[1] 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).[2]

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).

---

[2] 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).[3] Because electronic cigarettes, as marketed by

[3] 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.[4] 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

---

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.

[4] 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).[5] 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

---

[5] 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).[6] 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.

---

[6] 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).

Plaintiffs seek review under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*. The APA requires a court to set aside final agency action that it finds to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id.* § 706(2)(A), (C).[7] Because plaintiffs invite the Court to review FDA's construction

---

[7] There is some question about whether FDA's decision to detain NJOY's shipment without a "Refusal of Admission" notice is a final agency action. (*See* FDA Supp. Br. [#41] at 9). NJOY contends that because further resort to the administrative process would be futile, it need not fully exhaust its administrative remedies. I agree. Exhaustion does not apply where it "would be futile because of certainty of an adverse decision." *James v. U.S. Dep't of Health & Human Servs.*, 824 F.2d 1132, 1138 (D.C. Cir. 1987) (internal quotation marks and emphasis omitted). "Resort to administrative remedies is 'futile' and adverse action certain," if the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider." *Id.* at 1139. FDA has taken the sweeping position in this litigation that if an electronic cigarette product claims to "provide the same drug effects on the structure or function of the human body as cigarettes," then that product meets the definition of a drug or device under the FDCA. (FDA Supp. Br. [#41] at 5). On that basis, FDA denied entry to Smoking Everywhere's electronic cigarettes because, for instance, they claimed to "provide smokers the same delight, physical and emotional feelings" as traditional cigarettes. (AR DET 49). NJOY's product makes a similar claim. For example, NJOY markets its electronic cigarettes as providing "all the pleasures of smoking without all the problems." (Leadbeater Decl. [#24-1] at Ex. A). It is unlikely that an electronic cigarette manufacturer or distributor could market its product in any other way given that electronic cigarettes are made to replicate the effects of regular cigarettes. An FDA official suggested as much when he advised a representative of Smoking Everywhere that FDA did not believe Smoking Everywhere's product could be "relabeled to make it anything other than an article which . . . appears to be a drug-device combination." (AR DET 82). Given FDA's refusal to allow entry of Smoking Everywhere's products, given its unwavering position in this litigation (even after passage of the Tobacco Act), and given the manner in which NJOY has marketed its electronic cigarettes, there is no reason to believe that FDA would treat NJOY's products any differently than Smoking Everywhere's products. Indeed, as NJOY points out, FDA has already refused entry to as many as thirty-five shipments of electronic cigarettes from twenty manufacturers. (NJOY Supp. Reply [#44] at 6). Accordingly, the Court concludes that exhaustion would be

and application of the FDCA, FDA is entitled to deference under *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Brown & Williamson Tobacco*, 529 U.S. at 132 (stating that *Chevron* is the appropriate framework for analyzing FDA's claim of authority to regulate tobacco products).[8] *Chevron* deference is appropriate in this case because FDA's interpretation and application of the relevant statutory provisions forms the basis of its decision to detain or to refuse entry of plaintiffs' products and thus carries the force of law. *See Citizens Exposing Truth About Casinos v. Kempthorne*, 492

---

futile and that NJOY's claims, like Smoking Everywhere's, are now properly before the Court.

[8] Even more boldly, FDA also argues that its import decisions are committed to agency discretion and thus are not subject to any judicial review. Judicial review is not permitted under the APA where "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). FDA contends that the authority to refuse imports is committed to its discretion by 21 U.S.C. § 381(a)(3), which authorizes FDA to refuse admission of a drug or device if it "appears" from examination or "otherwise" that the drug or device is "adulterated, misbranded, or in violation of section 355." For FDA, Congress's use of the term "appears" is dispositive. By authorizing FDA to refuse admission to any product that "appears" misbranded or adulterated, "Congress empowered the agency to exercise its discretion in a broad and flexible manner." (FDA Opposition [#14] at 29). FDA's argument goes much too far. Agency action is committed to agency discretion by law only where "the statute is drawn so that a court would have *no meaningful standard* against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985) (emphasis added). Here, there is such a standard: whether the article under inspection is "adulterated, misbranded, or in violation of section 355." 21 U.S.C. § 381(a)(3). The statute's use of the term "appears" affords the agency, at best, some degree of deference in close cases, but it certainly does not permit the agency unfettered discretion to refuse an article that obviously is beyond the scope of the FDCA. Furthermore, the issue in this case is not whether a particular drug appears adulterated or misbranded, but whether a particular product is even a drug subject to the FDCA. FDA might well be entitled to *Chevron* deference on this threshold legal question, but it is certainly not entitled to *unreviewable* discretion.

F.3d 460, 466 (D.C. Cir. 2007) (holding that *Chevron* deference applies, even in the absence of formal rulemaking or adjudication, where an agency action has the force of law).

The first step in the *Chevron* analysis requires a reviewing court to inquire "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. If so, the court must give effect to Congress's "unambiguously expressed intent." *Id.* at 843. If, however, Congress has not spoken unambiguously, the court must defer to the agency's construction of the statute so long as that construction is "permissible." *Id.*

The relevant statutory provisions, particularly the Tobacco Act's amendments to the FDCA, hardly constitute the kind of direct statement by Congress that would satisfy the first step of the *Chevron* analysis. Thus, the real issue under *Chevron* is whether FDA's position is a "permissible"—that is, reasonable—construction or application of those provisions. For the following reasons, I believe it is not.

A. Structure Or Function Claims

FDA says that the electronic cigarettes marketed by plaintiffs are a drug-device combination and should therefore be excluded from the Tobacco Act's definition of "tobacco product" because the labeling and promotional materials "represent and suggest that the product will provide the same drug effects as cigarettes." (FDA Opposition [#14] at 19). Because plaintiffs' electronic cigarettes are to be used, like conventional cigarettes, as a means for delivering nicotine and because consumers and scientists widely

believe that nicotine has drug-like effects, (*id.* at 18-19), FDA contends that plaintiffs' electronic cigarettes are intended to affect the structure or function of the body, (FDA Supp. Br. [#41] at 5). As a result, they qualify as a drug-device combination, not as a tobacco product. (*Id.*). Put simply, this argument is bootstrapping run amuck.

That electronic cigarettes are devices for delivering nicotine and are intended to have the same effect on the structure and function of the body as cigarettes is hardly a basis for classifying electronic cigarettes as a drug-device combination, thereby excluding them from the definition of "tobacco product." If it were, then traditional cigarettes would be excluded as well. Indeed, any tobacco product containing nicotine and claiming to have some pharmacological effect would be excluded. Because this result would effectively dismantle the existing regulatory wall Congress erected between tobacco products and drug-device combinations, I can easily infer that Congress *did not* intend tobacco products to be drugs merely because they deliver nicotine.[9]

---

[9] Another provision of the Tobacco Act supports this inference as well. If Congress intended that FDA regulate tobacco products as drugs merely because they deliver nicotine, then it is certainly possible, if not likely, that FDA would have to ban those products as unsafe if the manufacturer intended that they be used, like traditional cigarettes, solely for the enjoyment of their pharmacological effects. Approval of a new drug is contingent on clinical tests that show the drug to be safe and effective for its intended use. 21 U.S.C. § 355(b)(1), (d). FDA acknowledges, and the administrative record shows, that nicotine causes addiction, which is a harmful disease. (*See, e.g.*, Administrative Record of Nicotine Background ("AR NIC") 23, 49-50, 66). Congress has also issued findings that "[n]icotine is an addictive drug" and that "[t]obacco dependence is a chronic disease." Pub. L. No. 111-31, 123 Stat. at 1777, 1779. At high doses, nicotine exposure can even be fatal. (AR NIC 54). Nevertheless, whatever health implications nicotine might have, the Tobacco Act expressly forbids FDA from "requiring the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. §

Not surprisingly, FDA does not contend that *traditional* tobacco products like cigarettes are drug-device combinations. FDA accepts, as it must, that those products are exempt from such regulation by the Supreme Court's decision in *Brown & Williamson Tobacco*. Instead, FDA contends that only *non-traditional* tobacco products can be drug-device combinations. According to FDA, by excluding drugs or devices from the Tobacco Act's definition of "tobacco product," Congress merely "confirmed its intention that tobacco-containing products that [were] subject to FDA's *pre-existing* jurisdiction are still subject to that jurisdiction." (FDA Supp. Br. [#41] at 3 (emphasis added)). I disagree.

FDA attempts to avoid the full implications of its rationale for treating electronic cigarettes as drug-device combinations by limiting the meaning of "tobacco product" (at least as applied to products containing nicotine) to those specific products at issue in *Brown & Williamson Tobacco*. In that case, the Supreme Court acknowledged that if FDA classified traditional tobacco products, like cigarettes, as drugs or devices under the FDCA, it would have to *ban* those products as unsafe for their intended use. *Brown & Williamson Tobacco*, 529 U.S. at 134-37. To do so, however, would run afoul of congressional intent as revealed in subsequent tobacco-specific legislation—such as the Federal Cigarette Labeling and Advertising Act ("FLCAA"), Pub. L. No. 89-92, 79 Stat.

387g(d)(3)(B). It is apparent, therefore, that Congress did not intend tobacco products delivering nicotine for recreational use to be classified as a drug-device combination and thus subject to a potential ban on nicotine yields.

282 (1965), and the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30—which regulates certain tobacco products but does not ban them. *Id.* at 137-39. The FLCAA applies only to "cigarettes" and "little cigars," 15 U.S.C. § 1331 *et seq.*,[10] and the CSTHEA applies to "smokeless tobacco" products, 15 U.S.C. 4401 *et seq.*[11] Because neither act encompasses electronic cigarettes, FDA contends that those products, at least as they are marketed by plaintiffs, are beyond the scope of *Brown & Williamson Tobacco* and are therefore regulable as a drug or device under the FDCA. This argument is too clever by half.

FDA's interpretation of "tobacco product" is not reasonable when considered in the context of the entire Tobacco Act. For instance, one provision of the Act specifically prohibits FDA from "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products." 21 U.S.C. § 387g(d)(3)(A). Yet another provision prohibits FDA from "requiring the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. § 387g(d)(3)(B). That Congress would single-out "traditional" products for specific

---

[10] The FLCAA defines "cigarette" as "any roll of tobacco wrapped in paper or in any substance not containing tobacco" or "any roll of tobacco wrapped in any substance containing tobacco which . . . is likely to be offered to . . . consumers as a cigarette." 15 U.S.C. § 1332(1). It defines "little cigar" as "any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco . . . and as to which one thousand units weigh not more than three pounds." *Id.* § 1332(7).

[11] The CSTHEA defines "smokeless tobacco" as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." 21 U.S.C. § 387(18).

protection but use the broader term "tobacco product" when denying FDA the power to eliminate nicotine yields suggests that Congress understood the term to encompass more than traditional tobacco products and that Congress intended to permit nicotine use, whether from unforeseen, non-traditional sources (like electronic cigarettes) or from well-established, traditional sources (like regular cigarettes).

More importantly, it is apparent from Congress's broad definition of "tobacco product" that it intended the Tobacco Act's regulatory scheme to cover far more than the fixed array of traditional tobacco products at issue in *Brown & Williamson Tobacco*. Both the FLCAA and the CSTHEA only apply to "cigarettes," "little cigars," and "smokeless tobacco," which Congress defined with considerable specificity, yet the Tobacco Act applies to "tobacco products," which Congress defined expansively as "any product made or derived from tobacco that is intended for human consumption." 21 U.S.C. § 321(rr)(1). Furthermore, Congress made clear that FDA's new jurisdiction over tobacco products applies, not only "to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," but "to any other tobacco products" as well. *Id.* § 387a(b). Simply put, the Court cannot accept that Congress defined "tobacco product" in this manner when it knew all along that the only tobacco products beyond FDA's drug-device jurisdiction were the traditional products governed by the FLCAA and CSTHEA (with the possible exception of any nicotine-free tobacco products).

This conclusion is particularly warranted given that the line FDA attempts to draw between traditional tobacco products and non-traditional tobacco products is based on a

flawed reading of *Brown & Williamson Tobacco*. FDA contends that the logic and reasoning of that case is limited to the traditional tobacco products covered by the FLCAA and CSTHEA. This reading of the case is defective, however, because it ignores that the Supreme Court understood Congress's enactment of that tobacco-specific legislation, not as a narrow exception to the FDCA, but as a ratification of "the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products." *Brown & Williamson Tobacco*, 529 U.S. at 144. Because Congress was acting "against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco *absent claims of therapeutic benefit by the manufacturer*," *id.* (emphasis added), the Supreme Court had little choice but to conclude that Congress had "effectively ratified" FDA's position that it lacked authority over tobacco products as "customarily marketed," *id.* at 156. Thus, the line drawn by the Supreme Court was not between traditional and non-traditional tobacco products, as FDA suggests, but between tobacco products as customarily marketed and those that claim therapeutic benefits.[12] Against this backdrop, the Tobacco Act reflects Congress's intent

---

[12] Although the Supreme Court noted that it was not deciding the larger question of whether any product could be classified as a drug or device absent claims of therapeutic or medical benefit, it made clear nevertheless that FDA's assertion of jurisdiction over customarily-marketed tobacco products contradicted Congress's clear intent, *Brown & Williamson Tobacco*, 529 U.S. at 131-32, which the Supreme Court found to be based on FDA's repeated representations that it lacked authority under the FDCA to regulate tobacco products "absent claims of therapeutic benefit by the manufacturer," *id.* at 144-56. *See also id.* at 156 ("Congress has affirmatively acted to address the issue of tobacco and health, *relying* on the representations of the FDA that it had no authority to regulate tobacco." (emphasis added)).

to undo what it had earlier ratified. No longer will FDA lack jurisdiction over tobacco products as customarily marketed. Congress enacted the Tobacco Act to confer FDA jurisdiction over any tobacco product—whether traditional or not—that is sold for customary recreational use, as opposed to therapeutic use. As such, the Tobacco Act, in effect, serves as an implicit acknowledgment by Congress that FDA's jurisdiction over drugs and devices does not, and never did, extend to tobacco products, like electronic cigarettes, that are marketed in customary fashion for purely recreational purposes.[13] Furthermore, the Tobacco Act's broad definition of "tobacco product" is also an implicit admission by Congress that the existing tobacco-specific legislation, such as the FLCAA and CSTHEA, failed to cover the full array of tobacco products that were beyond FDA's jurisdiction under the FDCA.

This conclusion does not mean that tobacco products can *never* be classified as a drug or device in the absence of therapeutic claims. A case might arise, for instance,

---

[13] Although FDA has in the past asserted jurisdiction over "Favor Smokeless Cigarettes" and "Nicogel Tobacco Hand Gel," both of which purported to be recreational, non-therapeutic nicotine products (*see* AR NIC 1-11, 58-80), those actions were not judicially reviewed. In any event, FDA's decision on smokeless cigarettes came before *Brown & Williamson Tobacco* and is not in step with the reasoning of that case, which was based in part on FDA's representations to Congress that customarily-marketed tobacco products are not subject to FDA jurisdiction absent therapeutic claims. Furthermore, FDA predicated its decision to assert jurisdiction over Nicogel on the dissimilarity between that product and traditional tobacco products. (*See* AR NIC 68 (stating that Nicogel "cannot satisfy any of the sensory needs or desires associated with smoking")). Other products cited by FDA—such as Nicotine Lollipops, Nicotine Lip Balm, and Nicotine Water—are not "customarily marketed" tobacco products because they too are dissimilar from traditional tobacco products, and more importantly, because they make express therapeutic claims. (*See* AR NIC 12-13, 20).

where a manufacturer markets its tobacco product as having a non-therapeutic effect on the structure or function of the body that is different from nicotine. In that circumstance, the product might properly be classified as a drug or device because it is not a tobacco product as "customarily marketed." But that is not the case here. FDA does not contend that the electronic cigarettes marketed by plaintiffs are intended to affect the structure or function of the body in any way materially different from traditional cigarettes. Indeed, by FDA's own admission, Smoking Everywhere markets its product as providing "the same drug effects on the structure and function of the human body as cigarettes." (FDA Supp. Br. [#41] at 5). Likewise, NJOY markets its product as providing "all the pleasures of smoking." (Leadbeater Decl. [#24-1] at Ex. A). Because plaintiffs sell their electronic cigarette products for customary recreational use, those products (just like traditional cigarettes) are properly excluded from the meaning of drug or device under the FDCA.

B. Therapeutic Claims

FDA also contends that the electronic cigarettes marketed by Smoking Everywhere are drug-device combinations, not only because they contain nicotine and are intended to affect the structure or function of the body in the same way as traditional cigarettes, but because they are intended "to prevent or alleviate nicotine withdrawal symptoms." (FDA Opposition [#14] at 21).[14] According to FDA's "Correspondence" issued on December

[14] The Tobacco Act certainly contemplates that tobacco products marketed for the therapeutic purpose of treating nicotine addiction might constitute a drug-device combination excluded from the Tobacco Act's definition of "tobacco product." The Act specifically provides that products "intended to be used for the treatment of tobacco

23, 2008, FDA found that "'Smoking Everywhere E-Cigarette' and its component parts appear to be intended . . . to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction." (AR DET 97-98, 100-01).

Unfortunately for FDA, however, this finding is "unsupported by substantial evidence" in the record. *See* 5 U.S.C. § 706(2)(E). The "intended use" of a product is determined by "the objective intent of the persons legally responsible" for labeling the product. 21 C.F.R. § 201.128. Objective intent may be shown, for example, "by labeling claims, advertising matter, or oral or written statements" by the labeler. *Id.* It may also 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." *Id.* Here, the overwhelming sum of Smoking Everywhere's promotional material is aimed, not toward preventing, mitigating, or treating nicotine addiction and the effects of withdrawal, but toward *encouraging* nicotine use. Just a sampling of the promotional claims reveals, for instance, that Smoking Everywhere intends its electronic cigarettes to provide "the nicotine hit that smokers crave," to "refresh smokers and satisfy their smoking addiction," and to provide "the same pleasures of smoking a traditional cigarette." (AR DET 51, 56). The brand name itself is evidence that the product is not intended to prevent, treat, or mitigate nicotine use and addiction but to promote "the

---

dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of subchapter V of this chapter." 21 U.S.C. § 387k(c).

freedom to smoke everywhere." (AR DET 49). Not only does Smoking Everywhere offer low nicotine dosages, it offers high dosages as well. (AR DET 25, 28). It even offers its product in assorted flavors. (AR DET 28). Indeed, the overarching theme of the marketing campaign, from the pictures to the promotional claims, is that smoking electronic cigarettes is fun and exciting. One certainly does not get the impression from the advertising materials in the record that nicotine addiction is something that Smoking Everywhere intends its product to treat and cure. Moreover, there is little evidence in the record that Smoking Everywhere offers its product with the knowledge that any significant number of its customers will use electronic cigarettes to treat nicotine addiction, even though the product is not labeled or marketed that way.

FDA references only three claims made in Smoking Everywhere's literature: (1) electronic cigarettes offer "smokers a chance of smoking in a much healthier way," (2) electronic cigarettes are "a great alternative to help . . . stop smoking real cigarettes," and (3) "I've been smoking real cigarettes for over 20 years and really wanted to stop . . . I've been using it for 3 weeks now and feel great." (AR DET 49, 21; FDA Opposition [#14] at 21). The latter two claims are customer testimonials posted on the Smoking Everywhere website. None of these claims, on their face, suggests an objective intent to treat nicotine addiction and withdrawal. At best, these claims demonstrate that Smoking Everywhere markets its electronic cigarettes as an alternative—albeit a healthier

alternative—to traditional cigarettes.[15] FDA does not point to any representation by Smoking Everywhere that its product is intended to help wean smokers off of nicotine. Nor does FDA identify any product labeling that includes instructions about how to overcome nicotine addiction using electronic cigarettes. The clear import of Smoking Everywhere's advertising is that it wants consumers to use its electronic cigarettes for the same recreational purposes and with the same frequency as traditional cigarettes.[16] Thus, FDA's finding that the electronic cigarettes marketed by Smoking Everywhere appear to

---

[15] To the extent that smoking cessation is a therapeutic claim distinct from the treatment of nicotine addiction and withdrawal, the Court is aware that the two customer testimonials referenced above suggest that electronic cigarettes are intended for smoking cessation, if not for treating nicotine dependence (as suggested by FDA). Given Smoking Everywhere's express *disclaimer* that its electronic cigarettes are not intended as a smoking cessation device, (AR DET 1), and given the overwhelming evidence in the record that its electronic cigarettes are intended merely as a recreational alternative to traditional cigarettes (and not necessarily as a therapeutic replacement for traditional cigarettes), the Court concludes that the two testimonials cited by FDA are not alone sufficient to support a finding that the product appears to be intended to help customers quit smoking.

[16] In this respect, Smoking Everywhere's electronic cigarettes are different from other nicotine products regulated by FDA that bear no similarity to traditional tobacco products and make express therapeutic claims. For instance, Nicotine Lollipops claim to help smokers quit "by *suppressing the symptoms of nicotine withdrawal*" and by allowing "the individual to control the amount of nicotine taken based on the body's need at the time." (AR NIC 12 (emphasis added)). Nicotine Lip Balm represents that it helps "*relieve* the craving for nicotine" and is "*designed* to help a person quit." (AR NIC 13 (emphasis added)). Similarly, Nicotine Water claims that it is a "[m]ethod of delivering Nicotine *to reduce use of tobacco products*" and is "more *effective*" than other products for treating addiction, like nicotine patches or gum. (AR NIC 20 (emphasis in original)).

be intended to prevent, mitigate, or treat nicotine addiction is simply not supported by substantial evidence in the administrative record.[17]

Nor does the fact that plaintiffs advertise their products as a healthier alternative to traditional smoking mean that electronic cigarettes qualify as a drug-device combination under the FDCA. Smoking Everywhere advertises, for instance, that its product poses "less health risk." (AR DET 21). Along similar lines, NJOY markets its product as having "all the pleasures of smoking without all the problems." (Leadbeater Decl. [#24-1] at Ex. A). A product qualifies as a "drug" if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). The Court has already concluded based on the information before it that the electronic cigarettes marketed by plaintiffs are not intended for treating the disease of nicotine addiction. To the extent those products are marketed as providing the same experience as traditional cigarettes but without the negative health consequences associated with tar and smoke, they fall within the plain meaning of "modified risk tobacco product," which the Tobacco Act defines as any tobacco product "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco

---

[17] With respect to NJOY, FDA provides no factual basis at this point for the Court to conclude that NJOY's electronic cigarettes are intended to treat nicotine addiction or to facilitate smoking cessation. Indeed, NJOY represents that it has always labeled its products with a disclaimer stating that the products are not for smoking cessation. (Leadbeater Decl. [#24-1] at ¶ 9). The Court is mindful that the factual record relating to NJOY is sparse. In the course of this litigation, FDA may produce evidence from an administrate record that NJOY's products in fact make therapeutic claims. Absent such evidence, however, FDA may not detain those products on that basis.

products." *Id.* § 387k(b)(1). To treat as a drug any tobacco product that merely claims to be a healthier alternative would effectively nullify the provisions relating to modified risk tobacco products, which represent Congress's implicit acknowledgment that those products were outside of FDA's jurisdiction prior to the Tobacco Act. Moreover, it would create the absurd result that certain tobacco products—like low tar cigarettes or electronic cigarettes—would be exposed to the more onerous regulatory burdens for drugs and devices merely because they claim to be healthier alternatives to traditional tobacco products. Because the relevant statutory provisions do not compel this result, it is easy to conclude that Congress did not intend it.

In sum, absent substantial evidence of the manufacturer's objective intent that its electronic cigarettes affect the structure or function of the body in a way distinguishable from "customarily marketed" tobacco products or that its electronic cigarettes have the therapeutic purpose of treating nicotine withdrawal, there is no basis for FDA to treat electronic cigarettes, as they are marketed by the plaintiffs in this case, as a drug-device combination when all they purport to do is offer consumers the same recreational effects as a regular cigarette. Thus, the plaintiffs are substantially likely to succeed on their claim that FDA cannot regulate and thereby exclude their electronic cigarettes from the United States on the basis that those products are an unapproved drug-device combination under the FDCA.[18]

---

[18] The Court takes no position on whether there is some other basis for FDA (or any other agency) to exclude electronic cigarettes from entry into the United States.

II. Irreparable Harm

Plaintiffs contend that they will suffer irreparable harm because FDA has disallowed entry into the United States of their electronic cigarettes—their only product line—and will continue to do so. To constitute irreparable harm, the claimed injury "must be both certain and great; it must be actual and not theoretical." *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). To say the least, the harm to plaintiffs in this case is anything but theoretical. FDA has refused admission of Smoking Everywhere's electronic cigarette products and has ordered that they be exported or destroyed. In NJOY's case, FDA has detained its inbound shipment of electronic cigarettes and, by all accounts, will continue to do so. FDA justifies its decision to detain or refuse entry to these products because the products are intended to provide the same drug effects on the structure and function of the body as cigarettes. Because the point of electronic cigarettes is to provide the same effects as regular cigarettes, there is little reason to believe that FDA will not exclude future shipments of plaintiffs' products on the same basis.

The question then is whether the claimed injury—an economic one—is likely to be irreparable absent a preliminary injunction. The law is well-settled "that economic loss does not, in and of itself, constitute irreparable harm" unless, of course, the loss "threatens the very existence of the movant's business." *Id.* Both Smoking Everywhere and NJOY represent that the inability to import their electronic cigarettes into the United

---

Certainly, FDA now has jurisdiction to regulate tobacco products like electronic cigarettes in any manner it wishes consistent with the Tobacco Act and the APA.

States for domestic and international distribution will deprive them of needed revenue and thus threaten the continued viability of their respective enterprises. I agree.

Since its founding over a year ago, Smoking Everywhere has imported and sold more than 600,000 electronic cigarette kits. (Smoking Everywhere Complaint [#1] at ¶ 7). It derives all of its revenue from the sale of these products, which are its sole product line. (*Id.* at ¶ 12). Smoking Everywhere claims that there is no domestic manufacturer of electronic cigarettes, so it relies entirely on overseas manufacturers. (*Id.*). Smoking Everywhere further represents that it must import the products into the United States before it can sell them here or abroad. (Second Declaration of Elicko Taleb [#20-1] at ¶ 3). Because its electronic cigarette products are manufactured abroad and must first be imported into the United States *before* they can be distributed or sold, Smoking Everywhere will have no source of revenue once its inventory is exhausted, if FDA continues to refuse admission of its products on the ground that those products are unapproved drug-device combinations. To obtain approval as a drug under the FDCA is undoubtedly a long and expensive process, and according to Smoking Everywhere, its inventory is already near depletion. (Declaration of Elicko Taleb [#10-1] at ¶ 4). Furthermore, Smoking Everywhere currently has binding contracts with overseas suppliers as well as approximately 120 independent distributors that would be jeopardized if Smoking Everywhere were delayed indefinitely in bringing its products to market. (*Id.*). Based on these representations, it is clear that the potential economic loss and loss

of good will are substantial, especially for a fledgling company like Smoking Everywhere that has only one product line.

NJOY raises similar concerns. It has been selling electronic cigarettes since early 2007 and has now sold at least 135,000 units in the United States. (NJOY Complaint [#22] at ¶ 13). Like Smoking Everywhere, NJOY's sole business line is electronic cigarettes. (Leadbeater Decl. [#24-1] at ¶ 6). As a result, "[v]irtually all of NJOY's revenues are derived from the importation of E-Cigarettes into the United States." (*Id.* at ¶ 4). Because electronic cigarettes and their related components are the only product line for both companies and because plaintiffs generate all, or virtually all, of their revenue from the sale of imported electronic cigarettes, the potential for economic loss absent preliminary injunctive relief is sufficiently grave to threaten plaintiffs' very existence. Therefore, the Court is satisfied that plaintiffs have shown the necessary irreparable harm.[19]

---

[19] It is also worth noting that even if the claimed economic injury did not threaten plaintiffs' viability, it is still irreparable because plaintiffs cannot recover money damages against FDA. Where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, "any loss of income suffered by [the] plaintiff is irreparable *per se*." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008); *see also Clarke v. Office of Fed. Housing Enter. Oversight*, 355 F. Supp. 2d 56, 65 (D.D.C. 2004) (Leon, J.) (noting that "courts have recognized that economic loss may constitute 'irreparable harm' where a plaintiff's alleged damages are unrecoverable"). Absent a waiver, sovereign immunity shields the federal government and its agencies, like FDA, from suit. *FDIC v. Meyer*, 510 U.S. 471, 475 (1994). The APA, of course, waives sovereign immunity for federal agencies but only in actions "seeking relief other than money damages." 5 U.S.C. § 702. Even though the Federal Tort Claims Act ("FTCA") waives immunity for damages in some instances, it does not do so here. Claims "based upon an act or omission of an employee of the Government . . . in the execution of a

III. Harm To Third Parties And The Public Interest

Having concluded that the likelihood of success on the merits and the likelihood of irreparable harm weigh in favor of plaintiffs, only a brief comment is warranted as to the two remaining elements of the preliminary injunction inquiry. FDA contends that the public interest in health and safety weighs in favor of denying preliminary relief because, by enforcing the FDCA as it sees fit, FDA protects the public from unsafe and ineffective drugs. FDA further contends that the potential harm to other interested parties or to the public interest, should the court grant the preliminary injunction and allow the unapproved electronic cigarettes into the market, would far outweigh the economic harm to plaintiffs, should the court deny the preliminary injunction. I disagree. While FDA's interest in protecting public health and safety is, in the abstract, paramount to plaintiffs' purely economic interests, given the particular facts and circumstances of this case, I am not convinced that the threat to the public interest in general or to third parties in particular is as great as FDA suggests. Together, both Smoking Everywhere and NJOY have already sold hundreds of thousands of electronic cigarettes, yet FDA cites no evidence that those electronic cigarettes have endangered anyone. Nor has FDA cited any evidence that electronic cigarettes are any more an immediate threat to public health and

---

statute or regulation, whether or not such statute or regulation be valid," as well as claims arising out of "interference with contract rights," both of which would most likely apply in this case, are excluded from the FTCA's general waiver of sovereign immunity for torts. 28 U.S.C. § 2680(a), (h). There being no apparent avenue for obtaining damages against FDA, any economic loss suffered by plaintiffs due to the detention or refused admission of their products can never be recovered and is therefore irreparable.

safety than traditional cigarettes, which are readily available to the public. Furthermore, now that FDA has regulatory power over electronic cigarettes through the Tobacco Act, any harm to the public interest or to third parties caused by an injunction that merely forbids FDA from regulating electronic cigarettes as a drug-device combination is greatly diminished. At best, therefore, the potential harm to the public interest or to other interested parties only marginally favors, *if at all*, the denial of preliminary injunctive relief. To the extent the balance of harms and the public interest favor FDA, those factors are overcome nevertheless by the likelihood of success on the merits and the likelihood of irreparable harm, both of which strongly favor plaintiffs. Consequently, plaintiffs have, in my judgment, met their burden for establishing entitlement to a preliminary injunction.

CONCLUSION

This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices under the FDCA. Ironically, notwithstanding that Congress has now taken the unprecedented step of granting FDA jurisdiction over those products, FDA remains undeterred. Unfortunately, its tenacious drive to maximize its regulatory power has resulted in its advocacy of an interpretation of the relevant law that I find, at first blush, to be unreasonable and unacceptable. I am mindful, however, that the purpose of preliminary injunctive relief is merely "preventative, or protective; it seeks to maintain the status quo pending a final determination of the merits of the suit." *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977). Because I have concluded that plaintiffs

are substantially likely to succeed on the merits and are likely to suffer irreparable harm if I do not return the parties to the status quo ante, their respective motions for preliminary injunction are GRANTED pending a final disposition of this case. An Order consistent with this opinion is attached herewith.

RICHARD J. LEON
United States District Judge