IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC. Plaintiff-Appellee, and SOTTERA, INC., d/b/a NJOY Intervenor-Plaintiff-Appellee, vs. U.S. FOOD AND DRUG ADMINISTRATION, *et al.* Defendants-Appellants.	Appeal No. 10-5032 Civ. No. 09-cv-0771 (RJL)

JOINT OPPOSITION OF APPELLEES SMOKING EVERYWHERE, INC. AND SOTTERA, INC. d/b/a NJOY™ TO APPELLANTS' EMERGENCY MOTION FOR STAY PENDING APPEAL

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I. INTRODUCTION

Since 2007, both Plaintiff Smoking Everywhere, Inc. ("SE") and Plaintiff-Intervenor Sottera, Inc., d/b/a NJOY ("NJOY") (together "Appellees") have imported and sold electronic cigarettes ("e-cigarettes"). E-cigarettes function by vaporizing a liquid nicotine mixture derived naturally from tobacco plants. The "smoker" inhales the vaporized mixture the same way a traditional smoker inhales tobacco smoke, but without the carbon monoxide, fire, flame, smoke, ash, stub, smell, or other socially undesirable attributes of traditional cigarettes. Appellees market and sell e-cigarettes only to adults "for smoking pleasure" and not as a "smoking cessation" device to help smokers quit or for any other therapeutic purpose.

Although e-cigarettes had been on the market for over a year without any reported instance of harm to any user, in late 2008, the United States Food and Drug Administration ("FDA") began blocking their importation on the ground that they are an unapproved "drug" or "device" under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. Because FDA's policy was destroying their businesses, Appellees filed suit in the District Court to enjoin FDA from regulating e-cigarettes as a drug or device and detaining or denying entry of those products into the United States. In a thorough and well-reasoned opinion, the District Court rejected FDA's claim that e-cigarettes are an unapproved drug or device subject to its jurisdiction under the FDCA, and found that Appellees had proved that they were highly likely to suffer irreparable harm from FDA's

continued embargo of their products. On January 14, 2010, the Court therefore granted Appellees' motion for a preliminary injunction.

Appellees justifiably and irretrievably relied on the injunction by arranging to import new products and committing to millions of dollars in new customer orders. FDA took no immediate action. Two weeks later, however, FDA came to this Court seeking an "emergency" stay that would permit it to reinstate and maintain its unlawful impoundment of all e-cigarettes during the pendency of its appeal. That request is baseless. FDA will not prevail on the merits of this case, because the District Court correctly concluded that, as e-cigarettes are customarily marketed, they are no more a "drug" than traditional cigarettes; permitting the reinstatement of FDA's embargo would destroy Appellees' businesses; and FDA advances only the most conjectural and speculative public harms. If FDA believes e-cigarettes pose any risk, the 2009 Tobacco Act provides FDA authority to promulgate regulations addressing those issues. FDA's motion for a stay pending appeal should be denied.

II. BACKGROUND

Appellees import and distribute e-cigarettes, electronic products that allow consumers to inhale a nicotine vapor, distilled from tobacco leaf, in a way that simulates–physically and physiologically–smoking traditional cigarettes, but do not contain less desirable attributes of traditional cigarettes, including tar, smoke, and flame or combustion. The products, which look, feel, and taste like traditional cigarettes, are comprised of a cartridge, a heating element or atomizer, and battery and electronics. Leadbeater Decl. May 6, 2009, Attachment A, at ¶ 8. The

cartridge is a disposable plastic container that contains the liquid nicotine mixture, which the heating element vaporizes for inhalation.

Appellees have invested millions of dollars developing and marketing e-cigarettes in the U.S., and all or virtually all of their revenues arise from the sale of imported e-cigarettes and components—their only product lines. Appellees have imported and sold e-cigarettes in the United States since 2007. Until September 2008, FDA never suggested that it had authority to regulate the products and it made no attempt to do so.

In the fall of 2008 and early 2009, SE received several "Notices of FDA Action" indicating that its e-cigarettes had been detained at the port of entry, and in March 2009 FDA refused admission to one of SE's shipments. In April 2009, FDA similarly detained a shipment of NJOY's e-cigarettes. In both cases, FDA stated the products had been detained or refused because they appeared to be drugs or medical devices requiring premarket approval under the FDCA. FDA authorized U.S. Customs and Border Protection ("CBP") to detain e-cigarettes and their components as "unapproved new drugs," and since then has ensured that CBP consistently detains or refuses entry to e-cigarette products.

On April 28, 2009, SE filed a complaint against FDA in the District Court, challenging FDA's authority to regulate, and effectively ban, e-cigarettes under the drug/device provisions of the FDCA. NJOY was permitted to join as an intervenor-plaintiff on May 15, 2009. After extensive briefing and two oral arguments, the District Court granted Appellees' motion for a preliminary injunction on January 14, 2010. The District Court held that Appellees are

substantially likely to succeed on the merits of their claim that FDA lacks jurisdiction to regulate e-cigarettes as a drug or device; found that Appellees had demonstrated a high likelihood that FDA's importation ban would destroy their businesses, causing them irreparable harm; and concluded that the balance of harms "only marginally favors, *if at all*, the denial of preliminary injunctive relief." Mem. Op. at 31 (emphasis in original).

On the merits, the District Court flatly rejected FDA's justifications for regulating e-cigarettes as drugs or devices under the FDCA. The District Court first rejected FDA's argument that, because these products include nicotine and are intended to alter the body's structure and function in the very same way as traditional cigarettes, they are drugs or devices "intended to affect the structure or any function of the body" under 21 U.S.C. § 321(g)(1)(C). The Court explained that the comparison to traditional cigarettes argues conclusively against, not for, FDA's regulatory jurisdiction. The Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), had struck down FDA's attempt to assert jurisdiction over traditional cigarettes under similar theories, concluding FDA had no authority to regulate traditional cigarettes as "customarily marketed" as an unapproved drug or device. *Id.* at 156. The District Court saw no reason why e-cigarettes, customarily marketed to have the same effects on the structure and function of the body as traditional cigarettes, should be treated differently.

The District Court's understanding of the limits of FDA's drug/device jurisdiction under the FDCA was informed by the new 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Act"), passed in June 2009. The

Tobacco Act amended the FDCA in response to *Brown & Williamson* to give FDA, for the first time, express regulatory authority over "tobacco products." The District Court noted that the definitions of "tobacco product" under the Tobacco Act and "drug" or "device" under the FDCA are mutually exclusive, and concluded that, while "the Tobacco Act did not move the definitional line between tobacco products and drugs," its treatment of a particular product as a "tobacco product" "sheds considerable light" on where that line was drawn. Mem. Op. at 9 n.4. In particular, the District Court found that the Tobacco Act's broad definition of "tobacco product[s]" and its provisions authorizing FDA to regulate both traditional and non-traditional tobacco products refuted FDA's position that non-traditional tobacco products like e-cigarettes are outside the purview of the Act and are instead "drugs" or "devices" that may be regulated by FDA under its drug/device authority. Mem. Op. at 17-18.

The District Court also rejected FDA's alternative theory that e-cigarettes are drugs or devices because they are intended to have a therapeutic effect. *Id.* at 21-26. The Court concluded that Appellees' products are sold "for smoking pleasure;" and found no evidence they have been sold for a therapeutic purpose. *Id.* at 5, 24 n.15, 25 n.17. The Court also explained that Appellees' advertisement of "their products as a healthier alternative to traditional smoking" does not "mean that electronic cigarettes qualify" as a drug or device under the FDCA because the Tobacco Act expressly regulates as a "tobacco product"—and thus eliminates from consideration as a drug or device—"modified risk tobacco product[s]," which are "sold or distributed for use to reduce harm or the risk of tobacco-related disease

associated with commercially marketed tobacco products." *Id.* at 25-26 (quoting 21 U.S.C. § 387k(b)(1)).

The District Court also concluded Appellees' had amply met their burden to establish likely irreparable harm. Mem. Op. at 27-29. The Court found that Appellees' harm is substantial and "anything but theoretical," for the loss of their sole product lines "threatens the very existence of [their] business[es]." *Id.* at 29.

The District Court next considered the balance of harms. While it recognized that "FDA's interest in protecting public health and safety is, in the abstract, paramount" to purely economic interests, it was skeptical that "the threat to the public interest … is as great as FDA suggests." *Id.* at 30. The Court noted that FDA cited no evidence that the e-cigarettes already on the market have endangered anyone, *id.*, and that FDA's regulatory authority over these products under the Tobacco Act "diminished" FDA's claim of harm to the public interest, *id.* at 31.

Having concluded that Appellees satisfied the standard for relief, the District Court entered a preliminary injunction barring FDA from "detaining or refus[ing] admission … of [Plaintiffs'] electronic cigarette products on the ground that those products are unapproved drugs, devices, or drug-device combinations under the [FDCA]."[1] Jan 14, 2010 Order at 1-2. Despite that order, FDA has continued to detain Appellees' shipments.

[1] As to NJOY, the District Court conditioned this order upon absence of "a proffer of evidence . . . that NJOY's products are intended to have a therapeutic effect," because the record was less developed as to NJOY. (Order at 2.) No such proffer has since been made. As such, the district court's order stood as to both SE and NJOY.

In the immediate aftermath of the District Court's decision, FDA did nothing. Two weeks later, on Friday, January 29, 2010, FDA filed an emergency motion in the District Court to stay the injunction for three days, while the Solicitor General considered an appeal. (Dist. Ct. Dkt. No. 58.) The District Court denied FDA's motion on February 1, 2010, and FDA filed an emergency motion in the District Court for reconsideration of the injunction and/or for stay pending appeal. (Dist. Ct. Dkt. No. 60.) Within hours – before the District Court could act – FDA filed a notice of appeal and the emergency motion requesting a stay pending appeal in this Court. (Cir. Dkt. No. 4.) FDA's motion should be denied.

III. ARGUMENT

FDA's emergency request for a stay pending appeal should be denied because FDA does not remotely satisfy the standards for a stay. To justify a stay, FDA must establish that: (1) it is substantially likely to prevail on the merits of the appeal; (2) other parties will not be harmed if the court grants the stay; (3) FDA will be irreparably harmed absent a stay; and (4) the public interest supports granting the stay. *Nken v. Holder*, 129 S. Ct. 1749, 1756 (2009); *see also Wis. Gas Co. v. Fed. Energy Regulatory Comm'n*, 758 F.2d 669, 673-74 (D.C. Cir. 1985) (same). FDA has failed to meet its burden on each prong.

A. FDA Cannot Establish a Substantial Likelihood of Success on the Merits

As it did below, FDA insists that it may regulate e-cigarettes as drugs or devices because an e-cigarette is either (or both) an article "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C), or an article

"intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B). Neither argument is persuasive.

1. According to FDA, e-cigarettes are drugs or devices because they are labeled and marketed as providing the same effects as cigarettes, which contain nicotine that alters the structure and function of the body. But this Court made clear long ago that the FDCA's structure-function definitional phrase must be construed in context to refer to a therapeutic alteration of a body's structure or function. To do otherwise and deem everything that alters the structure or function of the body a drug or device would include a universe of products Congress plainly had no intent to regulate under this statute. As this Court explained, "[a]nything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article 'intended to affect the functions of the body of man' … . Surely, the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be." *Action on Smoking & Health v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980).

The District Court rightly held, moreover, that FDA's structure/function argument is inconsistent with the Supreme Court's decision in *Brown & Williamson*, because if traditional tobacco products are not subject to regulation as a drug, 529 U.S. at 134-37, then other tobacco products labeled and marketed to provide the same effects should not be treated differently. FDA criticizes at length this aspect of the analysis, arguing that the District Court improperly extended the

Brown & Williamson rationale beyond the traditional tobacco products at issue in that case. That argument is unconvincing.

As the Supreme Court recognized in *Brown & Williamson*, FDA had long disclaimed authority to regulate cigarettes and smokeless tobacco as drugs. Moreover, Congress had passed two statutes, the Federal Cigarette Labeling and Advertising Act ("FCLAA") and the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA"), in which it expressed a "policy of protecting" the commerce of the tobacco industry, long a major domestic industry, and ensured that these products "will continue to be sold in the United States." 529 U.S. at 139. The Court pointed out that, under the FDCA, if these products as customarily marketed were drugs or devices, the FDA would have to ban them, as they plainly are not safe and effective for their intended use. *Id.* at 135, 137. Because that outcome was flatly inconsistent with the intent of Congress as expressed in the FCLAA and the CSTHEA, the Court concluded that the FDCA could not be interpreted to permit FDA to regulate these traditional tobacco products as drugs or devices (except to the extent that they are marketed for therapeutic purposes). *Id.*

That reasoning extends naturally to non-traditional tobacco products, like e-cigarettes, that are marketed as providing the same effects as traditional tobacco products. It is irrelevant that e-cigarettes are not specifically addressed by the statutes cited in *Brown & Williamson*. As FDA concedes, it was the tobacco industry—not merely the cigarette or smokeless tobacco industry—that Congress expressed an interest in preserving. Indeed, the Court noted: "the marketing of *tobacco* constitutes one of the greatest basic industries of the United States with

ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare." *Id.* at 137 (emphasis added) (citing 7 U.S.C. § 1311(a), a provision not included in either the FCLAA or the CSTHEA). The Court also emphasized that "[a] ban of *tobacco* products by the FDA would … plainly contradict congressional policy." *Id.* at 139 (emphasis added). Because e-cigarettes are tobacco products derived from tobacco plants, the *Brown & Williamson* logic applies to these products as well.

FDA's attempt to limit the impact of *Brown & Williamson* on the scope of its regulatory jurisdiction is flawed as a matter of statutory jurisprudence. Although the Supreme Court's ruling was based on its appreciation that Congress could not plausibly be understood to have intended the regulation of traditional tobacco products as drugs or devices, it necessarily follows that traditional tobacco products are not articles "intended to affect the structure or any function of the body" within the meaning of 21 U.S.C. § 321(g)(1)(C). If the statute is to be interpreted coherently, other tobacco products "intended to affect the structure or any function of the body" in the very same way cannot be drugs or devices either.

As the District Court found, that conclusion is also compelled by the overall structure of the FDCA as amended by the Tobacco Act. As the District Court correctly observed, e-cigarettes marketed to provide the same structure/function effects as traditional tobacco products fall squarely within the Tobacco Act's definition of "tobacco products" and thus are expressly excluded from regulation as drugs or devices. FDA disputes that analysis. According to FDA, because the Tobacco Act expressly excludes drugs and devices from characterization as

"tobacco products," there is no need to consider whether an article that meets the FDCA's definition of a drug or device is a tobacco product under the Tobacco Act. Emergency Motion at 9-10. That is complete nonsense. Because the Tobacco Act amended the FDCA, the District Court correctly recognized that provisions of the Tobacco Act that reveal Congress's intent to regulate particular articles as tobacco products are highly relevant to, indeed, determinative of, whether FDA can regulate those products as drugs and devices.

The Tobacco Act amended the FDCA to authorize FDA to regulate "tobacco products," including cigarettes and "any product made or derived from tobacco that is intended for human consumption," including its components. Tobacco Act, Pub. L. No. 111-31, § 101(a), 123 Stat. 1776 (2009) (amending 21 U.S.C. § 321 to add subsection (rr)). FDA does not dispute that e-cigarettes are "derived from" tobacco. It argues instead that the Tobacco Act is limited to traditional tobacco products. As the District Court recognized, that argument "is not reasonable when considered in the context of the entire Tobacco Act." Mem. Op. at 18. Whereas one section of the Act 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), another prohibits "requiring the reduction of nicotine yields of a tobacco product to zero," 21 U.S.C. § 387g(d)(3)(B). Congress's express limitation of the anti-ban provision to traditional tobacco products contrasts with its unrestricted use of the term "tobacco product" in the nicotine yield provision, and that difference strongly suggests that "Congress understood the term to encompass more than traditional

tobacco products" and "intended to permit nicotine use, whether from unforeseen, non-traditional sources (like electronic cigarettes) or from … traditional sources (like regular cigarettes)." Mem. Op. at 18.

FDA's argument is also at odds with the Tobacco Act's expansive definition of the term, "tobacco product," as "any product made or derived from tobacco that is intended for human consumption." 21 U.S.C. § 321(rr)(1). Congress specifically provided that FDA's new jurisdiction 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). The District Court correctly concluded that nontraditional tobacco products like e-cigarettes marketed to produce the same effects as traditional tobacco products must be equally included within the Tobacco Act's purview, and equally excluded from regulation as a drug or device:

> 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 it 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 the Congress did not intend tobacco products to be drugs merely because they deliver nicotine. Mem. Op. at 15.

2. FDA also asserts that it has jurisdiction under the FDCA because e-cigarettes are intended to "prevent or alleviate nicotine withdrawal symptoms," and, thus, are intended for therapeutic use. The District Court rejected this claim

as a matter of fact. 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. *See id.* As the District Court found, nothing in the record supports a determination that either Appellee's promotional material is aimed at treating nicotine addiction or withdrawal. Mem. Op. at 22. Appellees do not market, label, promote, or claim that e-cigarettes "cure, mitigate, treat, or prevent ... any disease," such as the withdrawal symptoms of nicotine addiction, or that they "affect the structure or any function of the body." In fact, Appellees' packaging and labeling include disclaimers disavowing therapeutic uses of the products, noting, for instance, that its "products are not a smoking cessation product and have not been tested as such." Leadbeater Decl. (May 6, 2009), Attachment A, ¶ 9; *see also* Mem. Op. at 24, n.15. Indeed, the District Court held that Appellees' promotional materials are aimed "toward *encouraging* nicotine use." Mem. Op. at 22.[2]

Absent any express therapeutic claims, FDA must show "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." 21 C.F.R. § 201.128. Courts, including this one, have held that a

[2] FDA has pointed to its regulation of other non-traditional tobacco products containing nicotine as drugs. These products, including *inter alia*, nicotine lollipops and lip balms, were dissimilar to traditional tobacco products and were marketed with express therapeutic claims. Mem. Op. at 20 n. 13. FDA did regulate two products absent express therapeutic claims, but that conduct was not judicially reviewed and occurred either prior to *Brown & Williamson*, or was predicated on the fact that the product (nicotine hand gel) was so substantially dissimilar to traditional tobacco products. *Id.*

product may not be categorized as a drug or device absent express claims evidencing intent unless it is used "almost exclusively for therapeutic purposes." *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 703 (2d Cir. 1975). In *Harris*, 655 F.2d at 240, this Court explained that, where health-related claims are absent, there must be "near-exclusivity of consumer use . . . with the intent to affect the structure or any function of the body of man" to deem the product a drug subject to FDA's jurisdiction. FDA did not even begin to make that showing here. As the District Court found, "there is little evidence in the record that [Appellees] offer[] [their] product[s] with the knowledge that any significant number of [their] customers will use electronic cigarettes to treat nicotine addiction, even though the product is not labeled or marketed that way." Mem. Op. at 23.

To the extent FDA argues that Appellees' advertisement of their products as a "healthier alternative" to traditional smoking renders e-cigarettes a drug or device under the FDCA, this argument fails as a matter of law. As the District Court noted, the Tobacco Act includes a detailed framework for regulating "modified risk tobacco products," which are "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." 21 U.S.C. § 387k(b)(1). The existence of that framework establishes that modified risk tobacco products are within the purview of the Tobacco Act and may not be regulated as drugs or devices, but Congress also made that point expressly: "Tobacco products, *including modified risk tobacco products*, … shall be regulated by the Secretary under [new Chapter IX of the FDCA] and shall not be subject to the provisions of Chapter V" (drugs and devices). Tobacco Act, Pub.

L. No. 111-31, § 101(b) (emphasis added) (adding FDCA § 901(a)).

Appellees do not contend that their e-cigarettes are modified risk tobacco products. But if products "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" are not drugs or devices intended for therapeutic uses, then certainly products marketed as a healthier alternative to traditional tobacco products are not either. The District Court noted the absurdity of FDA's contrary position, under which, safer tobacco products would suffer the more onerous regulatory burdens applicable to drugs and devices merely because they were honestly marketed as healthier alternatives to traditional tobacco products. That could not have been Congress's intent.

B. A Stay Pending Appeal Would Inflict Irreparable Harm on Appellees

FDA does not dispute that a stay would substantially harm other parties interested in the proceedings. Nor could it. As the District Court found, Appellees' businesses would be destroyed by a stay that permitted FDA to continue its import ban on their products. It is well established that such enterprise-threatening harm, even though purely or primarily economic, qualifies as irreparable injury. *Wis. Gas Co.*, 758 F.2d at 674 (citing *Wash. Metro Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 n.2 (D.C. Cir. 1977) ("The destruction of a business is, of course, an essentially economic injury. It is not, however, one of the 'mere' economic injuries … insufficient to warrant a stay".)).

Appellees have invested millions of dollars in bringing their products to market in the United States, developed a substantial customer base here, and entered into binding contracts with suppliers and distributors. E.g., Leadbeater Decl. (May 6, 2009), Attachment A, ¶¶ 2-3; Taleb Decl. (Apr. 30, 2009), Attachment B, ¶ 4. If they are unable to import additional e-cigarettes, Appellees risk breaching those contracts and irretrievably damaging relations with suppliers and distributors. More importantly, absent imports, Appellees cannot generate the revenue they need to pay expenses. *E.g.*, Taleb Decl., (Apr. 30, 2009), Attachment B, ¶ 4. As a result of FDA's unlawful policy, SE has already lost retail outlets and any semblance of a revenue stream. As the District Court correctly determined, "[b]ecause electronic cigarettes and their related components are the only product line … and because plaintiffs generate all, or virtually all, of their revenue from the sale [thereof], the potential for economic loss … is sufficiently grave to threaten plaintiffs' very existence." Mem. Op. at 29.

In an attempt to mitigate its damages and stay in business, in the two weeks following the issuance of the preliminary injunction NJOY relied on that Order (and FDA's silence) and ordered new units from its suppliers to fulfill a significant number of new orders that it received. Leadbeater Decl. (Jan. 31, 2010), Attachment C, ¶ 2. The ability to fill those orders is critical to the survival of NJOY's business. *Id.* Granting a stay would prevent NJOY and SE from doing so and exacerbate the harm already caused by FDA's prior illegal conduct.

C. FDA Has Demonstrated No Likelihood of Irreparable Harm to the Public

Although FDA acknowledges that it has not provided this Court with the "benefit of specific evidence of the dangers posed by [e-cigarettes]," it insists that "the threat to the public health is apparent" and cannot seriously be questioned. Emergency Motion at 10. That argument is meritless. FDA cannot prevail with vague allegations of potential harm; rather, it must prove a likelihood of irreparable harm to warrant a stay.

Although e-cigarettes have been sold since 2007, FDA has not identified a single instance, either in this Court or below, of an adverse health effect from e-cigarettes. FDA's only support for its public health concerns is the declaration of Janet Woodcock, who alleges that e-cigarettes pose risks from nicotine and other constituents. In particular, Woodcock alleges that nicotine is a highly addictive pharmacological agent; nicotine in high doses can be toxic and even fatal; nicotine can cause elevations in blood pressure and heart rate; and excessive nicotine exposure may precipitate cardiovascular events in patients with cardiovascular diseases. Declaration of Janet Woodcock ("Woodcock Decl."), Attachment B to Emergency Motion, at ¶ 3, 4. She also states that the short-term side-effects from the use of e-cigarettes may include racing pulse, dizziness, slurred speech, mouth ulcers, heartburn, coughing, diarrhea, and sore throat. *Id.* at ¶ 14. Such generalized and unquantified statements—many of which could be made about coffee, sugar or spicy foods—establish no likelihood of irreparable harm. Moreover, FDA's generalized allegations regarding the potential dangers of high doses of nicotine are belied by the analyses by FDA's Division of Pharmaceutical Analysis on which Woodcock relies. B. J. Westenberger, May 4, 2009

("Westenberger study"). The amount of nicotine required to create a significant adverse effect is significantly higher than the levels Westenberger found in e-cigarettes. Declaration of F. Benjamin Thomas, III (Feb. 3, 2010) ("Thomas Decl."), Attachment D, at ¶ 7. And nicotine poisoning deaths rarely, if ever, result from nicotine inhalation. *Id.*

The other "dangers" FDA alleges are similarly belied by the Westenberger study. FDA declares, for example, that diethylene glycol ("DEG") was detected in only one of at least eighteen cartridges tested. FDA does not claim that the trace amount of DEG found posed any real risk of harm. Moreover, the cartridge itself is neither ingested directly nor handled extensively; rather, the e-cigarette user inhales an aerosol/vapor produced by the cartridge. The likelihood of significant exposure to DEG found only in the cartridge is therefore very low. Thomas Decl., Attachment D, at ¶ 9. Although the Westenberger study performed aerosol and vapor tests, no such tests were done to confirm the presence of DEG. *Id.* FDA makes no attempt to explain how the Westenberger DEG findings establish any likelihood of irreparable harm.

FDA also notes that the Westenberger study detected "certain tobacco-specific nitrosamines ["TSNAs"] which are human carcinogens" and some "[t]obacco-specific impurities ["TSIs"] suspected of being harmful." FDA fails to mention that both the TSNAs and TSIs were detected "at very low levels" in the cartridges: the TSNAs at levels that could not even be quantified,[3] and the TSIs at

[3] The level of quantitation ("LoQ") for these TSNAs are 21, 24, and 27 parts per billion ("ppb"), respectively.

levels less than the specification for the cartridge of the FDA-approved smoking cessation device, Nicotrol. Thomas Decl., Attachment D, at ¶ 11, 14. That the products contain TSIs at levels less than *what FDA has itself approved as safe for inhalation* cannot be proof of any significant danger.

In October 2009, an independent testing laboratory analyzed the vapor/aerosol from the same NJOY products in which Westenberger found TSNAs in the cartridges. N-nitrosoanatabine ("NAT"), which is nontoxic and noncarcinogenic, was the only TSNA found in the vapor/aerosol, and only at low levels. *Id*. at ¶ 13. Neither the non-quantifiable levels of TSNAs in the cartridge, nor the low levels of NAT in the vapor/aerosol pose any significant risk to human health. *Id*. at ¶ 12-13.

Of the three TSIs identified by FDA as presenting "significant safety concerns" due to potential genotoxicity,[4] only one (myosmine), a constituent of nuts, grains, and fruits, *Id*. at ¶ 16, has been found in the aerosol/vapor of Appellees' products.[5] The available literature shows that any harm from myosmine occurring *in vitro* results from levels much higher than the levels likely to result from use of e-cigarettes. *Id*. at ¶ 15.

Ultimately, FDA's case for irreparable harm fails for lack of any evidence that harm is likely at all. If FDA truly feared an imminent and serious threat, it would not have waited more than a year before asserting regulatory jurisdiction

[4] The Riebe and Westphal (1983) study cited by Woodcock as demonstrating the genotoxicity of myosmine actually reached the opposite conclusion. Thomas Decl., at ¶ 15.

[5] The Westenberger study found no myosmine in the aerosol/vapor. A later independent laboratory test found myosmine present at low levels. *Id*. at ¶ 14-15.

and it would have taken steps under the Tobacco Act to regulate the product. FDA's lack of urgency casts serious doubt on its claims of irreparable public harm.

To the extent that FDA believes e-cigarettes pose any risk, FDA does not need a stay from this Court to address that concern. The Tobacco Act provides FDA ample authority to regulate many elements of the production, labeling, and advertising of "tobacco products," while ensuring that nicotine cannot be banned entirely for recreational use. 21 U.S.C. § 387g(d)(3)(B) (the Secretary may not "requir[e] the reduction of nicotine yields of a tobacco product to zero"). Under 21 U.S.C. § 387a(b), FDA could regulate (but not ban) e-cigarettes as a tobacco product following notice and comment rulemaking.

IV. CONCLUSION

Each of the four factors to be considered by this Court in evaluating FDA's request for a stay weighs strongly in favor of Plaintiff and Plaintiff-Intervenor. Plaintiff and Plaintiff-Intervenor therefore respectfully request that this Court deny FDA's request for stay pending appeal.

Dated: February 4, 2010

Respectfully submitted,

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