ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 23, 2010

No. 10-5032

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

SMOKING EVERYWHERE, INC.,
SOTTERA, INC., d/b/a NJOY,
Intervenor-Plaintiff-Appellee,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia
Civil Action No. 09-cv-0771 (RJL)

BRIEF OF APPELLEE SOTTERA, INC. d/b/a NJOY™

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Intervenor-Plaintiff is Sottera, Inc., d/b/a NJOY ("NJOY"). The original Plaintiff was Smoking Everywhere, Inc. ("SE"). After the district court ruling on appeal, SE voluntarily dismissed its complaint against Defendants and has withdrawn from this appeal. Defendants are the United States Food and Drug Administration ("FDA"), FDA Commissioner Margaret Hamburg, the United States Department of Health and Human Services ("HHS"), and Secretary of HHS Kathleen Sebelius. Amicus briefs were filed in district court by Action on Smoking and Health and by Alliance of Electronic Smokers. The Washington Legal Foundation has filed a notice of intent to file an amicus brief on appeal. The American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the Campaign for Tobacco-Free Kids, and Public Citizen have moved for leave to file an amicus brief on appeal.

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, counsel for NJOY hereby certifies that NJOY is a privately-held Nevada corporation headquartered in Scottsdale, Arizona, engaged in the electronic cigarette industry. NJOY does not have outstanding shares or debt

securities in the hands of the public or have a parent, subsidiary, or affiliate that has issued shares or debt securities to the public.

B. Rulings Under Review

The preliminary injunction under review (JA 543-544) was issued on January 14, 2010, by the Hon. Richard J. Leon, United States District Court for the District of Columbia, in Civ. No. 09-771.

C. Related Cases

The preliminary injunction under review has been stayed by this Court. We are not aware of any related cases.

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GLOSSARY

FDA	United States Food and Drug Administration
FDCA	Food Drug and Cosmetic Act
NJOY	Appellee Sottera, Inc. d/b/a NJOY
PHSA	Public Health Service Act
SE	Smoking Everywhere, Inc.
Tobacco Act	Family Smoking Prevention and Tobacco Control Act

STATUTES AND REGULATIONS

All applicable statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

No court of appeals has ever sanctioned the expansive view of the United States Food and Drug Administration's ("FDA") jurisdiction that the agency advances in this case—that any product that affects the structure or function of the body is a drug, device or drug/device combination under the Food Drug and Cosmetic Act, ("FDCA"), 21 U.S.C. §§301 et seq. If accepted, that position would dramatically expand FDA's jurisdiction and produce absurd results that Congress never intended. This Court previously observed that Congress could not have intended such a far-reaching interpretation of FDA's drug/device authority in *Action on Smoking & Health v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980). And FDA has repeatedly rejected such an interpretation as well, making clear—as its chief counsel observed in 2002—that "it only regulates products [as a drug or device] if they are marketed with claims of medical or therapeutic utility." *See infra* 35. There is no reasoned basis to treat the products at issue here any differently.

For six decades, FDA consistently and repeatedly disavowed jurisdiction over tobacco products marketed for customary use and regulated them only when

they were sold for therapeutic purposes. In 1996, the agency abruptly changed course and claimed jurisdiction to regulate tobacco products, however marketed, as drug/device combinations under the FDCA. FDA asserted that tobacco products are "devices" because they are intended to deliver nicotine, which (under FDA's interpretation of the FDCA) is a "drug" because it affects the structure or function of the human body. The Supreme Court forcefully rejected that position in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), and held that FDA has no statutory jurisdiction over tobacco products as they are customarily marketed.

Last year, Congress passed the Family Smoking Prevention and Tobacco Control Act ("Tobacco Act"), 21 U.S.C. §§387 et seq., which amended the FDCA to provide FDA new statutory authority to comprehensively regulate—but not ban—recreational tobacco use, including by regulating the ingredients, testing, development, manufacture, labeling, packaging, advertising, promotion, distribution, and sale of tobacco products. The Tobacco Act defines "tobacco product" broadly to include "*any* product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. §321(rr)(1) (emphasis added).

This case arises from FDA's assertion of jurisdiction to regulate as a drug/device combination—and thereby ban from importation—products known as "electronic cigarettes" or "e-cigarettes." An e-cigarette delivers nicotine just "like

a traditional cigarette" but without the flame, tar, ash, or smell found in traditional cigarettes. JA512-13. Appellee NJOY imports and distributes e-cigarettes. As FDA conceded before the district court, e-cigarettes deliver nicotine "'made or derived from tobacco'" and thus would qualify under the statutory definition of "'tobacco products'" if they are not subject to drug/device jurisdiction. Defs.' Supp. Opp. Br. to Preliminary Injunction Mots. ("Opp. Br.") 5 n.3, ECF No. 41. NJOY's e-cigarettes are marketed purely for smoking pleasure and not—as FDA has acknowledged, Br. 5 n.2—for any therapeutic purpose. Since 2007, NJOY has sold at least 135,000 e-cigarettes in the United States, without any reported instance of harm to any user. Because the distribution of e-cigarettes is NJOY's sole source of revenue, FDA's continued refusal to allow the importation of these products and their components will soon destroy its business. To be clear, NJOY concedes that e-cigarettes are subject to regulation under the Tobacco Act as a tobacco product, but it challenges FDA's effort to regulate e-cigarettes as a drug/device combination under the FDCA.

After another e-cigarette company, Smoking Everywhere, Inc. ("SE"), filed suit in the United States District Court for the District of Columbia to enjoin FDA from regulating e-cigarettes as a drug/device combination and detaining or denying entry of these products into the United States, NJOY joined the suit as a co-

plaintiff and filed its own complaint and request for a preliminary injunction.[1] JA35-49. On January 14, 2010, the court granted NJOY's motion for a preliminary injunction. JA511-14.

The district court rejected FDA's claim that, unlike other tobacco products, e-cigarettes are unapproved drug/device combinations under the FDCA, and held that FDA's position was flatly inconsistent with the Supreme Court's decision in *Brown & Williamson*. The court also found that NJOY had demonstrated that it was highly likely to suffer irreparable harm from FDA's continued detention of its products. And in balancing the equities the court rejected FDA's contention that the public would be endangered if the importation ban was enjoined, noting the absence of a single reported incidence of harm from these products and FDA's unquestionable authority to comprehensively regulate them under the Tobacco Act. FDA appeals the district court's preliminary injunction order.

[1] On June 15, 2010, while this appeal was pending, SE voluntarily dismissed its complaint against FDA. *See* Notice of Voluntary Dismissal (Docket No. 70); *see also* Notice of Voluntary Dismissal and Motion for Dismissal from this Appeal (June 22, 2010). Because NJOY is a party to this case, filed its own complaint, sought a preliminary injunction below, and has participated separately in this appeal, the dismissal of SE's complaint does not affect this Court's jurisdiction.

BACKGROUND

I. STATUTORY BACKGROUND

In 1938, Congress passed the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§301 et seq., authorizing FDA to regulate certain articles including "drugs," "devices," and drug/device combinations. The statute defines "drug" to mean an "article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "articles ... intended to affect the structure or any function of the body," 21 U.S.C. §321(g)(1)(B), (C), and defines "device" along the same lines.[2] For almost six decades, FDA recognized that this language cannot be read in isolation to classify as a "drug" or "device" subject to the panoply of the FDCA's regulatory requirements everything under the sun that is intended to affect the structure or function of the human body. *See infra* Part IIA. In particular, every time the issue arose, FDA made clear that, despite nicotine's physiological effects, tobacco products are not subject to regulation under the FDCA unless they are sold for therapeutic purposes, such as weight loss or smoking cessation. FDA repeatedly disavowed jurisdiction to regulate tobacco products marketed for their customary use—i.e., without claims of therapeutic benefits. *See infra* Part IIB.

[2] 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). Articles that "constitute a combination of a drug, device, or biological product" are regulated as combination products. *Id.* §353(g)(1).

In 1996, FDA reversed course and asserted full regulatory jurisdiction over customarily marketed tobacco products. *See* 61 Fed.Reg. 44,396, 44,619-45,318 (Aug. 28, 1996). Embracing (for this purpose at least) a novel and sweeping interpretation of the FDCA's statutory definition, FDA contended that nicotine is a "drug" because it affects the structure and function of the human body, and cigarettes and smokeless tobacco, however marketed, are drug/device combination products that deliver nicotine to the body. *See id. at* 44,397. On that basis, FDA defended its authority to promulgate regulations intended to curb consumption of tobacco products by minors. *Id.* at 44,615-18.

In *Brown & Williamson*, the Supreme Court acknowledged the seriousness of the health problems associated with tobacco products but flatly rejected FDA's assertion of jurisdiction over tobacco products as plainly inconsistent with congressional intent. 529 U.S. at 131-32. The Court reasoned that, whatever the outer limits of the FDCA's structure/function language (an issue the Court was not required to reach in the case), it was clear that Congress did not intend to include tobacco products as customarily marketed within FDA's jurisdiction. Because FDA had found that tobacco products were "unsafe" and "dangerous," the Court reasoned that were FDA to regulate tobacco products "the [FDCA] would require the agency to ban them." *Id.* at 134-37. The Court recognized, however, that such a ban would contravene the premise of other statutes that recognize and expressly

contemplate that tobacco products "will continue to be sold in the United States." *Id.* at 137-39. Accordingly, the Court held that tobacco products that "cannot be used safely for any therapeutic purpose … simply do not fit" within the FDCA's regulatory scheme. *Id.* at 143.

Against that backdrop, Congress passed the Family Smoking Prevention and Tobacco Control Act ("Tobacco Act"), 21 U.S.C. §§387 et seq., in June 2009. The Tobacco Act amended the FDCA to grant FDA statutory authority to regulate comprehensively the content, testing, development, manufacture, labeling, packaging, advertising, promotion, distribution, and sale of any "tobacco product," which Congress defined broadly to include "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. §321(rr)(1).

Congress made clear that FDA's regulatory jurisdiction over tobacco products is distinct from its preexisting jurisdiction over drugs, devices, and combination products, and the provisions relating to tobacco products are contained in a separate chapter (Chapter IX) of the FDCA. 21 U.S.C. §387a(a). Thus, the definition of "tobacco product" expressly excludes any "article that is a drug …, a device …, or a combination product" within the meaning of the FDCA, 21 U.S.C. §321(rr)(2), and the Tobacco Act specifies that "tobacco products" "shall not be subject to the provisions of Chapter V [(Drugs and Devices)]", *id.*

§387a(a). Moreover, while recognizing the risks they unavoidably pose, the Tobacco Act expressly prohibits FDA from "requiring the reduction of nicotine yields of a tobacco product to zero" or "banning" cigarettes, smokeless tobacco and other tobacco products. *Id.* §387g(d)(3)(B), (A).

The Tobacco Act also covers "[m]odified risk tobacco products," which include "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* §387k(b)(1). The Act specifies that "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 governs the regulation of "drugs" and "devices." *Id.* §387a(a).

The Tobacco Act granted FDA new powers to regulate tobacco products. For example, it establishes stringent pre-market and post-market requirements for regulated tobacco products. *See* 21 U.S.C. §387e(j); 21 U.S.C. §387j. Manufacturers of tobacco products are required to register annually and are subject to FDA inspection every two years. *Id.* §387e. Tobacco product manufacturers must also provide FDA a detailed list of their products, as well as consumer information and labeling for their products. *Id.* Manufacturers must submit to FDA a list of ingredients and harmful constituents in their products, and they must provide FDA with documentation for the health effects of their products. *Id.*

§387d. FDA is authorized to issue regulations addressing the permitted constituents and nicotine content of tobacco products and requiring that the packing and storage of tobacco products conforms to "current good manufacturing practice" or other standards to protect public health. *Id.* §§387b(7), 387f(e). FDA may require testing and reporting of tobacco product constituents and adverse events. *Id.* §§387i, 387o. Finally, the Tobacco Act imposes labeling requirements and extensive advertising restrictions for tobacco products, including specific restrictions on advertising to minors. *Id.* §§387c, 387f, 387m. Congress stopped short, however, of extending FDA's drug/device jurisdiction to tobacco products.

II. FACTUAL AND PROCEDURAL BACKGROUND

NJOY imports and distributes e-cigarettes, which are products that allow smokers to inhale a nicotine vapor—distilled from tobacco leaf—in a way that simulates smoking traditional cigarettes. JA36. E-cigarettes are composed of a cartridge, a heating element or atomizer, a battery, and electronics. JA39. When the electronics sense an intake of breath, the heating element automatically vaporizes a portion of the liquid nicotine mixture for inhalation. JA39. E-cigarettes are intended to give smokers the feeling and pleasure of traditional smoking, but without the inconvenience of smoking traditional cigarettes or the flame, tar, or ash. JA96. NJOY markets, labels, and sells its products solely for adult use, as an alternative to conventional cigarettes. JA36. They are not

designed, labeled, or sold as a means to cure or treat nicotine addiction. JA39, 532.

Since 2007, NJOY has invested significant sums developing and marketing e-cigarettes in the United States. JA539. It has entered into binding contracts with suppliers and distributors for the purchase and sale of e-cigarettes, and has developed a substantial customer base. JA40. Virtually all of NJOY's revenue arises from the sale of imported e-cigarettes and their components, which are NJOY's sole product line. *Id*. For over a year and a half, NJOY imported and sold at least 135,000 e-cigarettes in the United States, without any reported instance of harm to any user. JA38.

In October 2008, without prior notice or warning, FDA began banning the import of e-cigarettes and their component parts. JA149-50. FDA issued several notices of FDA action to SE stating that its products were "subject to refusal pursuant to the [FDCA], Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded, or otherwise in violation as indicated below." JA149-52. Kevin Budich, an FDA Compliance Officer, concluded that e-cigarettes were subject to FDA's jurisdiction as drug/device combination products because they are intended to alter the structure or function of the body because they contain nicotine. JA162-63.

In response, SE offered to revise "all labels and websites to satisfy FDA that

this product is intended solely for recreational use and not as a drug or device (not intended to effect the structure or function of the body and not intended to treat, cure, mitigate or treat a disease.)." JA153-54. To no avail. Dr. James Shen, an FDA compliance officer, explained that FDA would consider e-cigarettes to be drug/device combinations no matter how they were marketed and regardless of any disclaimer of therapeutic intent. JA153. Shen stated that because "the product is intended to deliver nicotine and/or other volatized chemical substances for inhalation" and is "targeted to current and potential conventional cigarette smokers, who are knowledgeable about the effects that nicotine has on the structure and function of the body," an e-cigarette "can[not] be relabeled to make it anything other than a article which … appears to be a drug-device combination product under section 503(g)(1) of the [FDCA]." *Id*. On March 16, 2009, FDA sent SE a notice of FDA action that refused admission of the detained shipments. JA173-77. On April 20, 2009, FDA detained on the same basis a shipment of NJOY's e-cigarettes. JA55-57.

FDA's subsequent actions confirmed its determination to exercise drug/device jurisdiction over all e-cigarettes regardless of how they are marketed. Its Import Alert 66-41, with Attachment A revised in April 2009, authorized FDA field offices to detain all e-cigarettes as "unapproved new drugs" regardless of their marketing claims, and the agency's publicly available Import Refusal Reports

indicate that, since July 2008, FDA field offices have refused entry into the United States of e-cigarettes and e-cigarette components from approximately 21 different manufacturers. JA209, 293-94. FDA added e-cigarettes to Import Alert 66-41 without publishing its proposed action in the Federal Register, without notifying SE, NJOY, or others in the industry, and without seeking any public comments or input.

On April 28, 2009, SE filed suit against FDA in the United States District Court for the District of Columbia, challenging FDA's authority to regulate and ban imports of e-cigarettes under the drug/device provisions of the FDCA. JA12-17. The district court permitted NJOY to join as an intervenor-plaintiff on May 15, 2009, and NJOY filed its own complaint. JA6, 517, 35. After extensive briefing and two oral arguments, the court granted the plaintiffs' motion for a preliminary injunction on January 14, 2010. JA543-44.[3]

On the merits, the district court flatly rejected FDA's argument that, regardless of how they are marketed, because e-cigarettes include nicotine and are

[3] As a threshold matter, the district court held that SE had exhausted its administrative remedies and that NJOY's claims were "properly before the Court" given FDA's "unwavering position" that "an electronic cigarette manufacturer or distributor could [not] market its product in any other way given that electronic cigarettes are made to replicate the effects of regular cigarettes." JA 522-23 n.7. The government did not challenge the exhaustion or ripeness of SE's or NJOY's claims on appeal. And in any event, given FDA's actions and statements, the district court correctly concluded that NJOY's claims are proper. *See James v. U.S. Dep't of Health & Human Servs.*, 824 F.2d 1132, 1138 (D.C. Cir. 1987). SE's subsequent dismissal of its suit does not affect the analysis.

intended to alter the body's structure and function in the very same way as traditional cigarettes, they may be regulated as drug/device combination products. JA524-25. The court explained that the comparison to traditional cigarettes cuts conclusively against, not for, FDA's regulatory jurisdiction. JA525. It observed that the Supreme Court in *Brown & Williamson* held that FDA had no jurisdiction to regulate traditionally marketed tobacco products as an unapproved drug or device. JA529. The district court also concluded that there was no reason why e-cigarettes—which deliver nicotine derived from tobacco and are customarily marketed to have the same effects on the structure and function of the body as traditional cigarettes, JA96—should be treated differently. JA530.

The district court also analyzed the limits of FDA's drug/device jurisdiction over tobacco products with reference to the new Tobacco Act. JA527-28. The 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 is drawn. JA519 n.4. In particular, the court found that the Tobacco Act's broad definition of "tobacco product[s]" and its provisions authorizing FDA to regulate any tobacco products refuted FDA's position that nontraditional tobacco products, however marketed, are outside the

scope of the Act and instead may be regulated as "drugs" or "devices." JA527-28.

The district court also rejected FDA's alternative theory that e-cigarettes are drug/device combination products under 21 U.S.C. §321(g)(1)(B) because they are intended for use in the cure or mitigation of disease. JA531-36. The court concluded that NJOY and SE's products are sold "for 'smoking pleasure,'" and found no substantial evidence they are sold for a therapeutic purpose. JA515, 534 n.15, 535 n.17. The court explained that NJOY and SE's advertisements of "their products as a healthier alternative to traditional smoking" cannot be viewed as therapeutic claims qualifying e-cigarettes for treatment as drugs or devices because the Tobacco Act expressly regulates as a "tobacco product"—and thus expressly 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.'" JA535-36 (quoting 21 U.S.C. §387k(b)(1)).

Turning to the other elements of the preliminary injunction standard, the district court found that the harm caused by FDA's import ban is substantial and "anything but theoretical," because the loss of NJOY and SE's sole product lines "'threatens the very existence of [their] business[es].'" JA537 (citation omitted). While recognizing FDA's general interest in protecting "public health and safety," the court expressed deep skepticism that "the threat to the public interest [from e-

cigarettes] … is as great as FDA suggests." JA540. It noted that, even though NJOY and SE have "sold hundreds of thousands" of e-cigarettes in the United States, FDA "cit[ed] no evidence that those electronic cigarettes have endangered anyone" and "[no] evidence that electronic cigarettes are any more an immediate threat to public health and safety than traditional cigarettes, which are readily available to the public." JA540-41. The court pointed out, further, that FDA's undisputed authority to regulate e-cigarettes under the Tobacco Act "greatly diminished" FDA's claim of harm. JA541.

Accordingly, the district court preliminarily enjoined FDA from "detain[ing] or refus[ing] admission … of [their] electronic cigarette products on the ground that those products are unapproved drugs, devices, or drug-device combinations under the [FDCA]." JA543-44.

On March 31, 2010, this Court granted a stay pending appeal, but at the same time ordered expedition of the appeal. *See* Order (Mar. 31, 2010).

SUMMARY OF THE ARGUMENT

NJOY does not dispute that FDA may regulate e-cigarettes as tobacco products under the landmark Tobacco Act passed by Congress in 2009. The overarching question in this case is whether the district court properly rejected FDA's argument that it has jurisdiction and authority to regulate e-cigarettes as a drug/device combination under the FDCA even though FDA itself recognizes that

the e-cigarettes at issue are not sold with a therapeutic purpose. It did.

A decade ago, in *Brown & Williamson*, the Supreme Court forcefully rejected FDA's attempt to assert FDCA drug/device jurisdiction over tobacco products that are not sold with a therapeutic purpose. The Tobacco Act amended the FDCA to provide FDA distinct and separate authority to regulate (but not ban) tobacco products that are not sold with a therapeutic purpose. Despite the Supreme Court's rejection of its jurisdiction over customarily marketed tobacco products in *Brown & Williamson* and Congress's subsequent enactment of an entire statutory framework for the regulation of tobacco products, FDA asserts that it has jurisdiction to regulate e-cigarettes—a tobacco product—as a drug/device combination under the FDCA. FDA's argument is a repackaged effort to assert the same authority that the Supreme Court squarely held the agency lacks in *Brown & Williamson*. There is even less merit to FDA's argument today than there was in 2000 given that the Tobacco Act now grants FDA unquestioned authority to regulate e-cigarettes for what they in fact are—tobacco products.

As a general matter, FDA's expansive interpretation of the FDCA's drug/device definition to encompass *all* articles that affect the structure or function of the body is inconsistent with the overall text of the statute, which makes clear that FDA's drug/device jurisdiction extends only to articles that are intended to offer therapeutic benefits. Without therapeutic intent as a limiting principle, FDA

could assert jurisdiction over a universe of articles—like weapons, clothing, fitness equipment and street drugs—that Congress either chose to regulate under different statutes or never intended to regulate at all. FDA has previously acknowledged the absurdity of that position and has almost uniformly restricted its regulatory actions to articles that have a therapeutic or medicinal use. This Court has likewise recognized the untenability of this type of construction of the FDCA's definitions. *See Harris*, 655 F.2d at 240. That is enough to dispose of FDA's assertion of drug-device jurisdiction in this case.

But this Court's task is even easier because, with respect specifically to the appropriate characterization of tobacco products, it has the benefit of—and, indeed, is bound by—the Supreme Court's decision in *Brown & Williamson*. As FDA acknowledges, in invalidating FDA's 1996 rule, the Supreme Court adopted FDA's longstanding prior position that it could regulate tobacco products under the FDCA only "when sold *with therapeutic claims*, but not when sold for recreational purposes." Br. 17 (emphasis added). In this case, FDA does not dispute the district court's ruling that NJOY's e-cigarettes are *not* sold with therapeutic claims. Br. 5 n.2. As a result, FDA's regulation of e-cigarettes as a drug/device combination under the FDCA would be contrary to the interpretation of the FDCA that the Supreme Court adopted in *Brown & Williamson*.

Congress unquestionably was aware of the Court's interpretation of the

FDCA in *Brown & Williamson* when it passed the Tobacco Act to provide FDA new and distinct jurisdiction to regulate the manufacture, marketing and advertising of tobacco products. And instead of disturbing the Supreme Court's interpretation of the limits on FDA's authority to regulate tobacco products *as a drug/device combination*, Congress unambiguously provided that customarily marketed tobacco products (*i.e.*, tobacco products sold *without* therapeutic claims) should be regulated *as tobacco products* in accordance with the new regulatory regime. To the extent that FDA tries to circumvent *Brown & Williamson* by arguing that the decision was limited to "real cigarettes," Br. 9, its argument fails. The Supreme Court's holding in *Brown & Williamson* by its terms governs FDA's efforts to regulate "tobacco products," 529 U.S. at 126, 133, 161, and an e-cigarette—which delivers tobacco-derived nicotine, just like a "real cigarette," and is sold without therapeutic claims—is a tobacco product under any defensible interpretation of that term. For these reasons, FDA's assertion of drug/device jurisdiction over NJOY's e-cigarettes fails on the merits.

FDA makes little effort to contest the other elements of the preliminary injunction standard. FDA does not dispute that NJOY will be irreparably harmed absent a preliminary injunction prohibiting FDA from continuing to detain its sole product line, and it fails on several grounds to demonstrate that maintenance of the injunction threatens serious public harm. FDA's public health concerns as to e-

cigarettes are speculative and unsupported by the record below. But more to the point, even if FDA's claims had substance, FDA could comprehensively address such concerns by asserting the authority that Congress gave it under the Tobacco Act to regulate the content, testing, development, manufacture, labeling, packaging, advertising, promotion, distribution, and sale of any "tobacco product." The Tobacco Act was passed to address the very issues that FDA now raises, and confers all the authority that Congress believed appropriate to address public health risks associated with tobacco products.

Because each of the factors for evaluating a preliminary injunction weighs strongly in favor of NJOY, this Court should affirm the district court's order entering a preliminary injunction barring FDA from detaining NJOY's products.

STANDARD OF REVIEW

On a motion for a preliminary injunction, the district court must balance the four traditional equitable factors: (1) the movant's showing of a substantial likelihood of success on the merits, (2) irreparable harm to the movant, (3) substantial harm to the nonmovant, and (4) public interest. *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). "[A] district court's decision whether to grant a preliminary injunction is reviewed under the deferential standard of 'abuse of discretion.'" *Smith, Bucklin & Assocs., Inc. v. Sonntag*, 83 F.3d 476, 479 (D.C. Cir. 1996) (citation omitted); *City of Las Vegas v.*

Lujan, 891 F.2d 927, 931 (D.C. Cir. 1989). "Legal conclusions … including whether the movant has established irreparable harm, are reviewed de novo." *England*, 454 F.3d at 297; *see also O'Hara v. Dist. No. 1-PCD*, 56 F.3d 1514, 1522 (D.C. Cir. 1995).

In assessing NJOY's likelihood of success on the merits, the Court need not reach FDA's extravagant claim of deference because the statute points decisively to the conclusion that FDA lacks the authority to regulate NJOY's e-cigarettes as a drug/device combination under the FDCA. In any event, FDA's decision to regulate e-cigarettes as a drug/device combination is not entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). A reviewing court owes that deference to an agency's interpretation of its governing statutes *only* if its interpretations are reasonable, authorized by Congress, and have "the force of law." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). FDA's decisions in this case, while legally binding, were not made with the "force of law" as that phrase was understood in *Mead*.

Mead addressed the deference owed a Customs Service tariff classification ruling letter. The ruling was sent from Customs Headquarters and "'represent[ed] the official position of the Customs Service with respect to the particular transaction or issue described therein and [wa]s binding on all Customs Service personnel,'" but it was not subject to notice and comment and could equally have

been issued by "[a]ny of the 46 port-of-entry Customs offices." *Id.* at 222-24 (citation omitted). Because of the informality of the decision-making process and the relatively low level at which the decision was made, the Court concluded the ruling did not "carry the force of law" and thus "fail[ed] to qualify" for *Chevron* deference. *Id.* at 227; *see generally id.* at 230-33. That analysis also precludes *Chevron* deference here. Like the classifications rulings at issue in *Mead*, FDA's detention decisions "present a case far removed not only from notice-and-comment process, but from any other circumstances reasonably suggesting that Congress ever thought" that the decisions would "deserv[e] the deference claimed for them here." *Id.* at 231.

The district court afforded FDA's interpretation *Chevron* deference but did so without analysis, citing this Court's decision in *Citizens Exposing Truth About Casinos v. Kempthorne*, 492 F.3d 460 (D.C. Cir. 2007). *Citizens*, however, argues *against* affording *Chevron* deference here. The decision in *Citizens* was made by an Assistant Secretary of the Department of Interior and the agency formally noticed the decision in the Federal Register. Thus, the Court concluded that it had the necessary "'force of law'" to make it "'*Chevron*-worthy.'" *Id.* at 467 (citation omitted). In sharp contrast, here the decision to assert drug/device jurisdiction over and detain e-cigarettes was made by a compliance officer and memorialized in a few shipping records, comments on a hold notice, and an email exchange not

subject to the required formality of rulemaking. JA163-67, 172-73. This is not the type of considered decision-making to which *Chevron* deference is owed. Moreover, FDA has never provided an interpretation of its FDCA jurisdiction as to e-cigarettes after Congress passed the Tobacco Act apart from statements made in litigation, which of course are not entitled to deference. *See*, *e. g.*, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988).

Even if this Court determines that FDA's decision merits *Chevron* deference, however, the district court should be affirmed, because interpreted in context the FDCA unambiguously precludes FDA from regulating customarily marketed e-cigarettes as a drug/device combination rather than a tobacco product, and FDA's contrary view is unreasonable. 467 U.S. at 841-42.

ARGUMENT

I. NJOY HAS DEMONSTRATED A STRONG LIKELIHOOD OF SUCCESS ON THE MERITS

This case arises against the backdrop of a long history of Congress's and FDA's treatment of tobacco products. That history and the terms of the pertinent statutory provisions are discussed in detail below. But at the outset, the district court properly held that this case is controlled by a straightforward application of the most recent pronouncements of the Supreme Court and Congress on FDA's jurisdiction and authority with respect to tobacco products.

As FDA told the Supreme Court in *Brown & Williamson*, before 1996 "the

only instances in which the agency had found that tobacco products were drugs involved cases in which there were express market claims of therapeutic value." Brief for Petitioners, *FDA v. Brown & Williamson* (2000) (No. 98-1152), 1999 WL 503874, at *37 (emphasis added); *see id.* at *8. The agency sought to reverse course in 1996 and attempted to regulate cigarettes and smokeless tobacco as drug-delivery combination devices—nicotine being the "drug," and tobacco products the "delivery components" for that drug. 61 Fed. Reg. at 45,207, 45,208-16. As FDA has acknowledged in this case, in rejecting FDA's 1996 rule, the Supreme Court adopted FDA's prior position that it could regulate tobacco products under the FDCA only "when sold with therapeutic claims." Br. 17. That is a significant admission because FDA also has recognized that the e-cigarettes at issue in this case are *not* sold with therapeutic claims. Br. 5 n.2.

FDA seems to suggest that the Court's decision in *Brown & Williamson* was limited solely to cigarettes and smokeless tobacco. Not so. The government's petition for certiorari in *Brown & Williamson* presented the question whether "tobacco products are subject to regulation under the Act as 'drugs' and 'devices.'" Pet'rs Br., 1999 WL 503874, at Question Presented. And, the Court's holding in *Brown & Williamson* was explicitly framed in terms of "FDA's jurisdiction to regulate *tobacco products*." 529 U.S. at 133 (emphasis added); *accord id.* at 126, 143, 161. FDA also points to the fact that the agency has regulated certain nicotine

products, like nicotine gum, under the FDCA's drug and device provisions. Br. 9. But those instances involved tobacco products sold *with* therapeutic claims, namely nicotine cessation. The regulation of those products is therefore in no way inconsistent with the holding in *Brown & Williamson* or the district court's conclusion that FDA lacks jurisdiction to regulate e-cigarettes as a drug/device combination—given that NJOY's e-cigarettes are sold *without* therapeutic claims.

Of course, one thing that has changed since *Brown & Williamson* is the passage of the landmark Tobacco Act last year. That Act granted FDA power to regulate "tobacco products," but exempted from the definition any article that qualifies as a drug or device under the FDCA. FDA has stated that the Tobacco Act "'did not move the definitional line between tobacco products and drugs.'" Br. 20 (quoting JA519 n.4). The Tobacco Act does, however, eliminate any doubt that e-cigarettes are a "tobacco product" because the Act's definition of that term includes "*any* product made or derived from tobacco that is intended for human consumption, including *any* component, part, or accessory of a tobacco product." 21 U.S.C. §321(rr)(1) (emphasis added); *see United States v. Gonzales*, 520 U.S. 1, 5 (1997) ("Read naturally, the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'") (citation omitted). And FDA conceded below that the e-cigarettes in this case are "made or derived from tobacco" for purposes of that statutory definition. Opp. Br. 5 n.3 ("If these

products did not meet the definition of a drug, device or combination product, they would be subject to FDA jurisdiction under the [Tobacco Act.]").

FDA repeatedly stresses that e-cigarettes "contain no tobacco and do not burn." Br. 1; *see id.* 3, 8, 11. FDA likewise repeatedly states that e-cigarettes are not "real cigarettes." Br. 8; *see id.* at 3, 9, 13-14. But that is irrelevant under the statutory definition of "tobacco products" and simply a straw man that the agency has created to divert attention from the fact that e-cigarettes—which are designed to deliver nicotine, which is derived directly from tobacco, to humans for consumption—fall squarely within the definition of "tobacco products." Because e-cigarettes fall within the definition of "tobacco products," and because they do not constitute a drug/delivery combination under the FDCA (since they are concededly sold without therapeutic claims), FDA is authorized to regulate them *as tobacco products*. But the district court properly concluded that FDA lacks authority to regulate e-cigarettes as a drug/delivery combination.

Both *Brown & Williamson* and the Tobacco Act alone compel that result, and the Court need go no further to decide this case. As explained below, however, this conclusion is also compelled by an appreciation (usually shared by FDA) that a therapeutic-purposes limitation applies generally to the FDCA's structure/function definitions, regardless of the type of article at issue, under any reasonable construction of the statutory and regulatory scheme as a whole. FDA

has provided no reason for this Court to upset that carefully crafted scheme here by holding that FDA may regulate e-cigarettes as a drug/delivery combination. And Congress has recently granted FDA authority to regulate e-cigarettes for what they are—tobacco products.

A. FDA's Far-Reaching Structure/Function Argument Is Untenable And Leads To Absurd Results

In its broadest form, FDA urges this Court to adopt a revolutionary new conception of the FDCA's "drug" and "device" provisions. FDA argues that, regardless of the absence of any therapeutic claims in their marketing or labels, e-cigarettes nonetheless fall within its drug/device jurisdiction because they are designed to deliver nicotine, a drug with well known physiological effects. That interpretation would essentially permit FDA to regulate as a drug, device, or combination product the entire universe of articles that affect the structure or function of the human body. In *Action on Smoking & Health v. Harris*, this Court observed that such an untethered interpretation of these provisions would be untenable and "[s]urely" not what Congress intended. 655 F.2d at 240 (internal quotation marks omitted). There is no reason for a different conclusion here.

1. When Read In Context, The FDCA's Structure/Function Definitions Are Confined To Articles Intended For Therapeutic Use

As the Supreme Court reminded FDA with respect to these very same statutory provisions in *Brown & Williamson*, a "court should not confine itself to

examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme." 529 U.S. at 132. Placed in context—*i.e.*, considering the complete text of the FDCA's drug/device definitions and the nature of the FDCA's substantive regulatory provisions—the FDCA's structure/function definitions plainly treat as drugs or devices only articles intended to offer therapeutic benefits.

Although the FDCA defines as a drug or device any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. §321(g)(1)(B), or "intended to affect the structure or function of the body," *id*. §321(g)(1)(C), the two provisions are nonetheless part of a whole and should be interpreted in tandem. If the second part were interpreted in the way that FDA contends, it would swallow the first and expand the statute's reach far beyond the first provision's obvious therapeutic focus. Reading the second part of the definition to also incorporate a therapeutic or medical limitation, unrelated to "disease," would preserve a distinct role for each part and maintain statutory coherence. As the Supreme Court has admonished, "[t]he maxim *noscitur a sociis* … is often wisely applied" in this way "to avoid the giving of unintended breadth to the Acts of Congress." *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961).

That understanding of the limits and focus of the FDCA's drug/device definitions is confirmed by the statute's substantive regulatory provisions. For

example, the FDCA requires FDA in approving a new drug to ensure that the drug is "safe" and "effective" for its intended use. *See* 21 U.S.C. §393(a)(2)(A)-(D), (E). To that end, the statute requires any person filing a new drug application to submit as part of the application, among other things, "full reports of investigations which have been made to show whether or not such drug is effective in use." *See id.* §355(b)(1)(A); *see also id.* §355(b)(1)(B), (C). FDA uses this information to weigh "any *probable benefit to health* from use of the drug against any probable risk of injury or illness from such use." *Id.* §360c(a)(2)(C) (emphasis added).

The FDCA's device approval regime likewise rests on the underlying concept that FDA's regulation is limited to medical devices that purport to have some therapeutic benefit. FDA may not approve an application for premarket approval if, among other things, "there is a lack of showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended or suggested in its proposed labeling." *Id.* §360e(d)(2)(A), (B). The statute directs that FDA determine the safety and effectiveness of a device by considering the target patient population, the proposed conditions of use, and "weighing any probable *benefit to health* from the use of the device against any probable risk of injury or illness from such use."[4] *Id.* §360c(a)(2)(C) (emphasis

[4] In drafting these safety and effectiveness criteria, the drafters noted that "[t]he key concept that safety and effectiveness of a device are to be determined 'weighing any probable benefit to health from use of the device against any

added). FDA's premarket approval regulations confirm FDA's mission to balance the risks of a device against its potential benefits to health. *See* 21 C.F.R. §860.7(b). The regulations direct that there is reasonable assurance that a device is safe "when it can be determined, based on valid scientific evidence, that the *probable benefits to health* from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks." *Id.* §860.7(d)(1) (emphasis added). Likewise, the regulations hold that there is reasonable assurance of effectiveness "when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide *clinically significant results*." *Id.* §860.7(e)(1) (emphasis added).

Review of these substantive provisions demonstrates that the focus of the FDCA's drug/device scheme is on articles intended to benefit health. These provisions do not provide FDA any standards for regulating articles intended for

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probable risk of injury or illness from such use' makes clear that the proposed legislation recognizes that products having the power to be useful in the healing arts also have the potential to do harm and that the determination of safety and effectiveness is to carefully balance these considerations. Regulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits to be derived." H.R. Rep. No. 94-853, 94th Cong. 16-17 (1976).

recreational or other non-therapeutic uses for a very simple reason: FDA's drug and device jurisdiction was never intended to be applied to articles that have no therapeutic purpose. The sweeping interpretation of the structure/function definition that FDA proffers in this case does not square with the obviously more limited nature of the statute's related substantive provisions and thus fails to create "'a symmetrical and coherent regulatory scheme.'" *Brown & Williamson*, 529 U.S. at 133 (citation omitted).

2. FDA's Interpretation Defies Common Sense And Would Lead To Absurd Results

The Supreme Court also cautioned in *Brown & Williamson* that statutory interpretation "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate … policy decision[s] of … economic … magnitude to an administrative agency." 529 U.S. at 133. That principle also compels rejection of FDA's position. If accepted, FDA's interpretation of the statute's structure/function definitions would expand the agency's jurisdiction far beyond what Congress conceivably intended and what any court has ever sanctioned. If applied as FDA now insists, without therapeutic intent as a limiting principle, the FDCA's structure/function definitions would transform into drugs, devices or combination products articles like guns, bullets, mace, seat belts, air bags, and street drugs—articles that FDA never has regulated under the FDCA and that are instead regulated by other federal agencies or under different statutes that

were passed long after the FDCA was enacted.[5] More broadly, it would bring within FDA's drug/device jurisdiction a limitless scope of articles—including barbells, jump ropes, running shoes, long johns, winter coats, Jacuzzis, foam mattresses, diving equipment, and cleats, which likewise have physiological effects when used—that Congress has never sought to regulate as a drug or device. The statute cannot reasonably be interpreted to lead to such absurd results. *See, e.g,. Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 470 (1989) (Kennedy, J., concurring in the judgment) ("Where the plain language of the statute would lead to 'patently absurd consequences' that 'Congress could not *possibly* have intended,' we need not apply the language in such a fashion.") (citation omitted); *Montana v. Clark*, 749 F.2d 740, 745 (D.C. Cir. 1984) ("[I]f the 'plain' language would lead to a patently 'absurd' result, the assumption that the literal words embody legislative intent has considerably less force.") (citation omitted).

At other times and in other contexts, FDA has recognized that the FDCA's structure/function definitions cannot be applied in this counter-intuitive fashion, and it has almost always restricted its regulatory jurisdiction to articles that have a therapeutic use. For instance, in testimony before the Senate, William Goodrich, a representative of the Office of the General Counsel, Department of Health,

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[5] *See* 49 U.S.C. §§30101 et seq. (seat belts and airbags); 18 U.S.C. §922 (handguns); 18 U.S.C. §929 ("cop killer" bullets); 15 U.S.C. §§1261 et seq. (mace); 21 U.S.C. §§801 et seq. (street drugs).

Education, and Welfare, stated that FDA lacked drug/device authority over chemical sprays such as mace, because "[t]hey come properly under the Hazardous Substances Act and are not drugs." *Public Sale of Protective Chemical Sprays: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce*, 91st Cong. 37 (1969) (statement of William Goodrich). He noted that "pistols and bullets are intended to affect the function or structure of the body in the same way [mace is], but we concluded that th[os]e products could not properly be classified as drugs under the definition in the Food, Drug, and Cosmetic Act." *Id.*

FDA's usual approach to this issue is exemplified by its treatment of exercise equipment and razors. The intended use of exercise equipment such as treadmills and rowing machines is unquestionably to affect the structure or function of the human body. Yet FDA has explicitly "regulate[d] exercise equipment *only* if the equipment is intended to be used for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. FDA *does not* regulate exercise equipment intended only for general physical conditioning and/or for the development of athletic abilities in individuals who lack physical impairment." *See* FDA, *Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Exercise Equipment* 5 (July 26, 1995), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080405.

pdf (emphasis added); *see also* 21 C.F.R. §890.5360(a) (regulating as a device measuring exercise equipment, which are "manual devices intended *for medical purposes*, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity" and noting that examples "include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation") (emphasis added); 21 C.F.R. §890.5380(a) (regulating as a device powered exercise equipment, which "consist of powered devices intended *for medical purposes*, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity" and noting that examples "include a powered treadmill, a powered bicycle, and powered parallel bars") (emphasis added).

Likewise, although hair is a structure of the body, FDA has explained that "[r]azor blades and manicuring instruments *as ordinarily represented* are not devices within the meaning of the Act." *See* FDA, Compliance Policy Guide §335.500 Razor Blades, Manicuring Instruments–Not Considered Devices Under 201(h) (revised Sept. 24, 1987), www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073899.htm (emphasis added). By contrast, FDA does regulate as a device razors intended for use to prepare surgical sites. *See* 21 C.F.R. §878.4800. Similarly, FDA regulates as a device immersion

hydrobaths "intended for medical purposes" but does not regulate ordinary whirlpool baths despite their similar effects on the body. *Id.* §890.5100. FDA's regulations likewise assert jurisdiction over powered heating pads "intended for medical purposes," *id.* §890.5740(a), while leaving the Consumer Protection Safety Commission with jurisdiction over heating pads used by consumers for comfort.

FDA's own recognition that the "structure or any function" language of the statute cannot be read mechanically and is instead limited to devices with a therapeutic purpose is underscored by its section 513(g) determinations.[6] For example, in 2002, the manufacturer of an implantable chip with an intended use of storing financial and personal identification information sought a determination from FDA as to whether the chip was a device under the FDCA. FDA—through its chief legal officer, then Chief Counsel Daniel E. Troy—determined that even though the chip "will have an effect on the structure and function of the body" because "it will be permanently embedded under a person's skin," "assuming that no medical claims are made for the [chip] … FDA can confirm that it is not a medical device." Letter from Daniel E. Troy to FDA 4 (Oct. 17, 2002), *available at* http://www.fda.gov/ohrms/dockets/dailys/03/dec03/ 120503/81n-0033p-

[6] Section 513(g), 21 U.S.C. §360c(g), provides that upon a written request, "the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this chapter applicable to the device."

sup0003-vol86.pdf. Expressly disclaiming "jurisdiction" over all "articles having foreseeable physical effects," FDA explained that it "*only regulates products if they are marketed with claims of medical or therapeutic utility*. For example, FDA only regulates exercise equipment as a medical device when it is marketed with claims to prevent, treat or rehabilitate injury or disability. Otherwise it is a consumer product." *Id.* at 5 (emphasis added).

This Court has also recognized that a literal interpretation of the FDCA's structure/function definitions would lead to absurd results. *See Harris*, 655 F.2d 240. In *Harris*, this Court rejected the notion that a product falls within the "plain language of the statutory definition" of a "drug" simply because it affects bodily functions. *Id.* As the Court observed, "[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." *Id.* at 240 (*quoting FTC v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573, 576 (S.D.N.Y. 1952), *aff'd*, *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953)).

FDA nonetheless insists that, in this case, the FDCA's structure/function

definitions should be interpreted mechanically, without reference to an article's therapeutic purpose (or, apparently, any other limiting principle). It cites in support three decisions in which courts upheld FDA's position that the distribution of drugs for recreational purposes violated the FDCA. *See* Br. 18 & n.5. Those decisions do not support FDA's argument here because the defendants in those cases do not appear to have argued that, for FDCA purposes, a drug's intended effect on bodily structure or function must be therapeutic, and the courts therefore never considered that issue. FDA does not mention, moreover, that it ordinarily disavows jurisdiction over drugs used solely for recreational purposes. *See Marijuana and Medicine: The Approach for a Science-Based Approach: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources, H. Comm. on Government Reform*, 103d Cong. 25 (statement by Robert J. Meyer, M.D.) ("Pursuant to the [FDCA], FDA is responsible for the approval and marketing of drugs for medical use, including controlled substances. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the Controlled Substances Act [CSA].").

In theory, Congress could decide that the nation would be better off with a single omnipresent federal czar requiring pre-approval of and overseeing all products that affect the structure or function of the human body. But that would be a revolutionary step. And this Court should reject the agency's effort to achieve

the same result through the judicial process by advancing its unsustainable reading of the FDCA's structure/function provisions.

B. As the Supreme Court Has Held, FDA May Regulate Tobacco Products Under Its Drug/Device Provisions Only When They Are Sold For Therapeutic Purposes

Even if the FDCA's structure/function definitions could be applied to other articles, they cannot be applied without a therapeutic-intent limitation to tobacco products. As FDA told the Supreme Court in *Brown & Williamson*, "the only instances in which the agency had found that tobacco products were drugs [before its 1996 rule] involved cases in which there were express market claims of therapeutic value." Pet'rs Br., 1999 WL 503874, at *37 (emphasis added); *see id.* at *8. As FDA now acknowledges, in invalidating FDA's 1996 rule, the Supreme Court adopted that interpretation and held that FDA could regulate tobacco products under the FDCA only "when sold with therapeutic claims, but not when sold for recreational purposes." Br. 17. That interpretation is consistent with Congress's actions with respect to tobacco products and was ratified last year when Congress passed the Tobacco Act granting specific jurisdiction to regulate the manufacture, marketing and advertising of "tobacco products," defined broadly to include both enumerated traditional tobacco products and other products (like e-cigarettes) containing or derived from tobacco.

1. As It Recognized In *Brown & Williamson*, FDA Has Only Regulated Tobacco Products Under Its Drug/Device Jurisdiction If They Are Intended For Therapeutic Purposes

The government has excluded customarily marketed tobacco products from regulation as a drug or device for nearly one hundred years. As early as 1914, FDA's predecessor agency stated that it had authority to regulate tobacco products if their labeling indicated use for "the cure, mitigation, or prevention of a disease," but not if labeled or used for "smoking or chewing or as snuff and not for *medicinal* purposes." Bureau of Chemistry, U.S. Dep't of Agriculture, *Service and Regulatory Announcements* 21, 24 (Apr. 2, 1914) (C.L. Alsberg, Chief) (emphasis added). In 1929, Congress considered and rejected a bill "[t]o amend the Food and Drugs Act of June 30, 1906, by extending its provisions to tobacco and tobacco products." S. 1468, 71st Cong. 1-5 (1929); *see also* 71 Cong. Rec. 2589 (1929) (remarks of Sen. Smoot). And FDA understood that Congress did not intend to extend the law's application to tobacco products when the FDCA was passed in 1938. As FDA explained to this Court in *Harris*, in the "years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent" and "FDA repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of 'drug' absent health claims." Brief of Appellees 14-15, 16, *Harris*,

655 F.2d 236 (D.C. Cir. 1980) (No. 79-1397), attached hereto at ADD-7.

In 1963, for example, an FDA Bureau of Enforcement Guideline stated that "[t]he statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking *without accompanying therapeutic claims*, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." *Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce on S. 1454*, 92d Cong. 240 (1972) (Letter from FDA Bureau of Enforcement to Directors of Bureaus and Divisions and Directors of Districts (May 24, 1963) (emphasis added). Likewise, during debate over the 1971 amendments to the FDCA, former FDA Commissioner Dr. Charles C. Edwards testified that "[c]igarettes and other tobacco products would be drugs subject to [the FDCA] *if medical* claims are made for the product .... However, cigarettes recommended for smoking pleasure are beyond [the FDCA]." *See id*. at 239 (statement of Dr. Charles C. Edwards, former Commissioner, FDA) (emphasis added).

FDA maintained this position even when personally urged by individual Senators to assert its jurisdiction over tobacco products. *See Cigarette Labeling and Advertising: Hearings Before the S. Comm. on Commerce on S. 559 and S. 547*, 89th Cong., 1st Sess. 52 (1965) (statement of Sen. Neuberger) ("Two years ago, I went to the Commissioner of the FDA and asked him and he turned me

down. He said that this *did not affect tobacco*. It is neither a food nor a drug. I had decided according to my interpretation it would, but I did request their interpretation and I was turned down. So I figured from that additional legislation was needed.") (emphasis added).

In 1977, Action on Smoking and Health ("ASH"), a public health group, petitioned FDA to regulate cigarettes as drugs under the FDCA because they contain nicotine. Citizen Petition 4-11 (FDA Docket No. 77P-0185) (May 26, 1977). In rejecting ASH's petition, FDA cited a 1953 Second Circuit opinion, *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), for the proposition that cigarettes marketed without health claims by the vendor are not within the FDA's jurisdiction. *See* Letter from Commissioner Donald Kennedy to John F. Banzhaf, III, at 1, 4 (FDA Docket No. 77P-0185) (Dec. 5, 1977), http://www2.tobaccodocuments.org/pm/2060433107-3110.html (declining jurisdiction over the nicotine in cigarettes as drugs because "FDA can assert jurisdiction over cigarettes containing nicotine (or nicotine separately) as a drug when a jurisdictional basis for doing so exists, *e.g., health claims made by the vendors*" and noting that mere "[s]tatements" "that cigarettes are used by smokers to affect the structure or any functions of their bodies are not evidence of such intent by the manufacturers or vendors of cigarettes, as required under the provisions of [the FDCA].") (emphasis added).

Consistent with this understanding, FDA—as the agency itself advised the Supreme Court in *Brown & Williamson*—has "only" found that tobacco products could be regulated as drugs or devices in "cases in which there were express market claims of therapeutic value." Pet'rs Br., 1999 WL 503874, at *37. For example, as FDA notes, it has at various times asserted jurisdiction over "Nicotine Lollipops, Nicotine Lip Balm, and Nicotine Water." JA530 n. 13. While FDA now suggests that the regulation of those products supports its position in this case, it neglects to mention that all of those products made express *therapeutic* claims. *id*.; *see also, e.g., United States v. 354 Bulk Cartons *** Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 852-53 (D.N.J. 1959) (affirming FDA's position that cigarettes containing a substance promoted as weight-reducing were drugs under the FDCA because they made therapeutic claims); *United States v. 46 Cartons More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 337 (D. N.J. 1953) (affirming FDA's position that cigarettes accompanied by fifty-one leaflets entitled "How Cigarettes May Help You" were drugs within the meaning of the FDCA because "[i]f there be an indication of intent to use the article for the cure or mitigation, or treatment or prevention of a disease in man, then clearly the subject matter of the libel is to be considered a drug within the meaning of the act"). FDA's regulation of those products is therefore perfectly consistent with the

longstanding interpretation adopted in *Brown & Williamson*.[7]

The only possible exception that FDA cites is the regulation of Favor, a smokeless cigarette from the mid-1980s that apparently made no therapeutic claims. But that example cannot bear the weight that FDA attempts to place on it now. Indeed, FDA itself was apparently unaware of (or attached no significance to) this product when it advised the Supreme Court in *Brown & Williamson* that the "only" times it had found that tobacco products were subject to regulation as drugs or devices involved cases in which there were express therapeutic claims.

Moreover, as the district court observed, FDA's aberrant exercise of jurisdiction over Favor smokeless cigarettes not only was not subject to extensive agency review, it was never subject to judicial review. *See* JA530 n.13; *see also* JA425-26. There is no indication that Congress was ever made aware that FDA asserted jurisdiction over Favor in the 1980s, since it occurred in a single letter—not a rule—from a lower level official addressed only to Favor's manufacturer. JA425-26. And FDA never even tried to reconcile its treatment of Favor with its longstanding position on tobacco products.

[7] FDA's treatment of Nicogel is also perfectly consistent with the historical line it has drawn between traditionally marketed tobacco products and drugs. *See* JA483 (stating that Nicogel "cannot satisfy any of the sensory needs or desires associated with smoking").

2. Congress has ratified FDA's historic position that it may regulate tobacco products under its drug/device jurisdiction only when they are intended for therapeutic use

The courts—including this Court, the Fourth Circuit, and the Supreme Court—have recognized that FDA's longstanding view that it lacked authority to regulate customarily marketed tobacco products formed the backdrop for Congress's enactment of numerous statutes addressing tobacco products, and that Congress's provision for independent regulation in those statutes precludes any revisionist attempt to read tobacco product regulation back into the FDCA.

In *Harris*, this Court reviewed ASH's challenge to FDA's refusal to assert jurisdiction over cigarettes containing nicotine as a drug under the FDCA. ASH argued, as FDA does today, that "cigarettes fit within the plain language of the statutory definition." 655 F.2d at 240. This Court ridiculed that interpretation of the statutory provision as nonsensically broad, *id.*, and deferred to FDA's "long-standing interpretation of the [limited] scope of its jurisdiction over cigarettes," *id.* at 241. The Court recognized, moreover, that FDA's longstanding interpretation has effectively been codified because in passing specific tobacco legislation "Congress has been made repeatedly aware that the FDA cannot assert jurisdiction over cigarettes absent health claims made by manufacturers or vendors." *Id.*

The Fourth Circuit applied the same principle in *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1999), *aff'd*, *FDA v. Brown &*

Williamson Corp., 529 U.S. 120 (2000), in response to FDA's 1996 assertion of jurisdiction over tobacco products as customarily marketed. The Court noted that the "flaw" in FDA's position was that it "examine[d] only the literal meaning of the statutory definitions of a drug and device," without acknowledging that "[i]n the 60 years following the passage of the [FDCA], the FDA has repeatedly informed Congress that cigarettes marketed *without therapeutic* claims do *not* fit within the scope of the Act." *Id.* at 163, 168 (emphasis added). The Court observed that, "'[f]rom 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction.'" *Id.* at 168 (citation omitted). The Court appreciated that an agency is not "irrevocably bound by its prior interpretations of a statute," but concluded that the evidence of legislative ratification weigh[ed] against" FDA's turnabout in this instance. *Id.* at 170 n.18. It explained that, "[o]ver the last 60 years, Congress ha[d] enacted numerous statutes and amendments for the regulation of tobacco products …, well aware of the dangers of tobacco products and of the FDA's consistent position that it had no jurisdiction over Tobacco products." *Id.* at 175. The Court was persuaded by the absence of legislation "to overturn the FDA's interpretation of the [FDCA], that it had no jurisdiction over tobacco products as customarily used," and by Congress's "deliberate[] reject[ion of] a role for the FDA" in other proposed legislation, that "Congress never intended to give the FDA

jurisdiction over tobacco products." *Id.* at 175-76.

In affirming the Fourth Circuit's decision, the Supreme Court also recognized that in passing specific tobacco-related statutes Congress has acted "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*." 529 U.S. at 144 (emphasis added). The Court concluded that, "[u]nder these circumstances, it is evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products." *Id.* And, as explained, FDA acknowledges that when the Supreme Court rejected its 1996 rule, the Court "adopted" the agency's prior position that the agency had authority to regulate tobacco products under the FDCA only "when sold with therapeutic claims, but not when sold for recreational purposes." Br. 17.[8]

[8] It is also telling that, in its brief in *Brown & Williamson*, the government specifically argued that a holding that the agency lacked authority to regulate tobacco products as a drug or device under the FDCA would mean that "nicotine inhalers would escape FDA review as long as the manufacturer promoted them for 'breathing pleasure.'" Reply Brief of Petitioners, 1999 WL 33609281, at *3 n.1. The Supreme Court obviously was not moved by that argument in *Brown & Williamson*. And FDA's similar arguments in this case are unequally unavailing. Indeed, this argument has even less currency today, since FDA may now regulate such products as tobacco products under the Tobacco Act.

3. When it passed the Tobacco Act, Congress ratified broadly FDA's longstanding position that it lacks jurisdiction to regulate tobacco products under its drug/device jurisdiction absent therapeutic claims

Congress passed the Tobacco Act in the wake of *Brown & Williamson* to fill what it perceived as a gap in existing law. That understanding is express in the Act, which includes Congress's finding that "Federal and State governments have *lacked* the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products." Pub. L. No. 111-31, §2, 123 Stat. 1776, 1777 (2009). Congress included among the statute's express purposes "to provide authority to the Food and Drug Administration to regulate tobacco products" and "provide *new* and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, §3, 123 Stat. 1781-82 (emphasis added).

Congress's understanding of the limits of FDA's preexisting authority was informed by almost a century of consistent regulatory interpretations, punctuated by the Supreme Court's decision in *Brown & Williamson*, all teaching that FDA lacked jurisdiction to regulate tobacco products as a drug or device absent a claim of therapeutic benefit. Indeed, as discussed, the Court's opinion in *Brown & Williamson* expressly acknowledges that FDA's drug/device jurisdiction was limited to tobacco products marketed for therapeutic purposes. *See supra* 38, 46.

Congress is presumed to be aware of *Brown & Williamson* and—because there is no contrary statement—is presumed to have carried over and ratified the same understanding of FDA's authority in the Tobacco Act, continuing to treat tobacco products as drugs or devices only when marketed for therapeutic uses.

The text of the Tobacco Act confirms this understanding. The definition of "tobacco product" in the Tobacco Act specifically excludes articles that qualify as "drugs" or "devices" under the FDCA, and Congress expressly provided that the Tobacco Act should not be construed to change the established boundary between the two. 21 U.S.C. §387a(c)(1) ("Nothing in this chapter … shall be construed to affect, expand, or limit the Secretary's authority over … products under this Act that are not tobacco products under chapter V ….").

FDA appears to suggest that Congress intended to exclude from its drug/device jurisdiction only a subset of traditional tobacco products, namely, "real cigarettes" and "smokeless tobacco." Br. 13-14. But that interpretation is inconsistent both with the agency's prior recognition that FDA lacked authority to regulate tobacco products—generally—absent therapeutic claims and, more to the point, with the plain language of the Tobacco Act. That Act defines "tobacco product" to include "*any* product made *or derived from tobacco* that is intended for human consumption, including *any* component, part, or accessory of a tobacco product." 21 U.S.C. §321(rr)(1) (emphasis added). Congress's use of "any"

underscores the breadth of this definition. *See Gonzales*, 520 U.S. at 5 ("Read naturally, the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'") (citation omitted).

FDA tries to erect a straw man by repeatedly stating that e-cigarettes "contain no tobacco and do not burn," Br. 1; *see id.* 3, 8, 11, and that e-cigarettes are not "real cigarettes," Br. 8; *see id.* at 3, 9, 13. But that is irrelevant under the statutory definition of "tobacco products." And NJOY's products fall squarely within the plain meaning of that definition—the nicotine in their cartridges is naturally distilled from tobacco and intended for human consumption. JA36.

Other provisions of the Tobacco Act, moreover, confirm that Congress meant what it said when it defined "tobacco product" more broadly than just cigarettes and smokeless tobacco (on which FDA focuses). For example, whereas §387g(d)(3)(A) prohibits the Secretary from "banning" "cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products," §387g(d)(3)(B) more broadly forbids FDA from "requiring the reduction of nicotine yields of *a tobacco product* to zero." 21 U.S.C. §387g(d)(3)(A), (B) (emphasis added). That Congress omitted reference to more traditional tobacco products in its broadly worded definition of "tobacco products" demonstrates that the definition of tobacco products is broader than just cigarettes and smokeless tobacco.

Pointing to section 387a(b), FDA insists that is has the discretion to choose whether to regulate what it deems to be non-traditional tobacco products under the Tobacco Act or instead under the drug/device provisions of the FDCA. Br. 20 (citing 21 U.S.C. §387a(b)). That position cannot withstand scrutiny. That statutory provision relied on by FDA grants the Secretary authority to bring tobacco products *within* the Tobacco Act; it by no means authorizes FDA to regulate a tobacco product as a drug/device combination. FDA has not been given the discretion to pick and choose at its fancy which tobacco products will be regulated under which regulatory scheme.

The Supreme Court's reasoning in *Brown & Williamson* applies here as well. If customarily marketed e-cigarettes were "deemed" a drug/device combination, FDA would no doubt regard itself as duty-bound to ban them as unsafe under the FDCA. Indeed, although e-cigarettes do not contain the carcinogenic tars of traditional cigarettes, both FDA and its amici decry health risks they believe inherent in the nicotine that e-cigarettes deliver. *See* Br. 22.[9]

[9] Taking a page from its losing position in *Brown & Williamson*, FDA suggests that drug/device regulation of e-cigarettes and other nicotine-delivery devices may not "lead inexorably to a ban." Br. 16; *see also* Petr's Reply Br., 1999 WL 33609281, at *13 ("FDA has reasonably determined, however, that the FDCA does not require a ban on the sale of tobacco products to adults."). FDA contends that e-cigarettes are new products and have not been extensively tested or studied and that "it may well be possible" for those products "to satisfy the FDCA's safety, effectiveness, and labeling requirements and obtain FDA approval, just as FDA has approved other nicotine-containing products, such as gums or transdermal

Yet, as discussed above, the Tobacco Act prohibits FDA from "requiring the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. §387g(d)(3)(B). The Act cannot reasonably be interpreted to permit FDA to do indirectly (by "deem[ing]" e-cigarettes to be a drug/device combination rather than a tobacco product) what Congress—and the Supreme Court—has forbidden the agency to do to tobacco products directly.

As the district court noted, JA535-36, FDA's determination to impose the more onerous restrictions of the FDCA Chapter V on e-cigarettes is particularly misguided given the Tobacco Act's (*i.e.*, Chapter XI's) express provisions for "modified risk tobacco products." 21 U.S.C. §387k. These products are subject to special, detailed requirements governing their sale, distribution, and marketing. And lest there be any confusion, Congress expressly provided that these products "*shall* be regulated" under the Tobacco Act "and *shall not* be subject to" the drug/device provisions of the FDCA. *Id.* §387a(a) (emphasis added). Because NJOY's e-cigarettes could be a product "the label, labeling or advertising of which

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patches." Br. 16. But e-cigarettes are not intended for the therapeutic uses for which nicotine gums and transdermal patches have been approved by FDA, and their distributors' desire to market those products for therapeutic uses is precisely why FDA could assert drug/device jurisdiction over those products in the first place. NJOY's products are intended to be used, like traditional tobacco products, solely for smoking pleasure. JA110. Under the FDCA, drugs must be safe for their intended use, *see, e.g.*, 21 U.S.C. §393(b)(2), and just like traditional cigarettes, if regulated as a drug/device combination e-cigarettes cannot satisfy that requirement because e-cigarettes are not intended to be used in a way that provides an overriding health benefit.

represents explicitly or implicitly" that the product "contains a reduced level of a substance or presents a reduced exposure to a substance," or "does not contain or is free of a substance," *id.* §387k(b)(2)(A)(i), FDA could regulate them as modified risk tobacco products.[10] In that case, they would unquestionably be excluded from FDA's drug/device regulation. Contrary to FDA's view, it has no discretion to instead ban these "healthier" tobacco products as "unsafe" drugs or devices.

In the end, what is particularly odd about the agency's position—and what underscores its effort to upset existing law, including *Brown & Williamson* and the Tobacco Act—is that FDA has eschewed its ample authority to regulate e-cigarettes as tobacco products in accordance with the authority that Congress just gave the agency in the historic Tobacco Act and, instead, insists on attempting to shoehorn e-cigarettes into the definition of a drug/device combination under the FDCA in direct contravention of the Supreme Court's interpretation of the FDCA in *Brown & Williamson*. Some would call that Chutzpah. But this Court need only uphold the district court's conclusion that it is unlawful.

II. NJOY HAS DEMONSTRATED THAT IT WILL SUFFER IRREPARABLE HARM ABSENT A TEMPORARY INJUNCTION

FDA does not dispute that NJOY will be irreparably harmed by FDA's

[10] Of course, as the district court properly found, advertisements indicating that e-cigarettes are a "healthier alternative to traditional smoking" are not therapeutic claims qualifying e-cigarettes for treatment as drugs or devices. JA535-36 (citing 21 U.S.C. §387k(b)(1)).

continuing detention of its products absent a preliminary injunction. NJOY has invested large sums in bringing its products to market in the United States, developed a substantial customer base here, and entered into binding contracts with suppliers and distributors. *E.g.*, JA60 ¶¶4-5; Taleb Decl. (Apr. 30, 2009) ¶4, ECF No. 10-2. If it is unable to import additional e-cigarettes and components, NJOY risks breaching those contracts and irretrievably damaging relations with suppliers and distributors. More immediately, without products to sell, NJOY cannot generate the revenue it needs to pay expenses. The district court rightly found that "[b]ecause electronic cigarettes and their related components are the only product line … and because [NJOY] generate[s] all, or virtually all, of [its] revenue from the sale [thereof], the potential for economic loss … is sufficiently grave to threaten [NJOY's] very existence." JA539.

For these reasons, the district court properly found that NJOY's business would be destroyed if FDA is permitted to continue its import ban on e-cigarettes. Such enterprise-threatening harm, even though purely or primarily economic, unquestionably qualifies as irreparable injury. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (c*iting 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.")).

III. FDA HAS FAILED TO SHOW THAT THE BALANCE OF HARMS TIPS IN FAVOR OF THE INJUNCTION

As a last ditch effort, FDA and its amici insist that FDA's continued embargo of e-cigarettes is necessary to protect the public from serious harm. FDA's claims are speculative and unfounded. But in any event, Congress, which—as its express findings underscore—was deeply attuned to the public health risks stemming from the use of tobacco products, recently gave FDA all the authority it thought appropriate to combat those risks in the Tobacco Act. The fact that FDA of its own choosing has failed to avail itself of that authority provides no reason to set aside the preliminary injunction at issue in this case.

A. FDA's Concerns About Potential Public Harm Are Speculative

FDA's evidence of potential harms is paltry and entirely speculative. Indeed, FDA acknowledges that "there is little scientific data addressing the health risks" of e-cigarettes and that they "have been subject to so little testing and analysis [that] the long-term health consequences are unknown." Br. 23, 24.

Although NJOY has sold at least 135,000 e-cigarettes in the United States since 2007, FDA has not identified a single instance, either in this Court or below, of an actual reported adverse health effect. FDA's only support for its public health concerns is the declaration of Janet Woodcock, who alleges that the nicotine and potential contaminants in e-cigarettes pose risks to smokers because nicotine itself is addictive and can be harmful particularly in high doses. Even assuming

her generalized statements about nicotine are all true, they prove nothing significant, as many of the same things can be said about excessive exposure to coffee, sugar, or spicy foods—and, of course, the nicotine in traditional cigarettes and any other tobacco product. These sorts of generalized and unquantified statements fall well short of establishing imminent and serious public harm. Moreover, Woodcock's generalized allegations are undermined by the very FDA Division of Pharmaceutical Analysis study on which she relies, FDA, B.J. Westenberger, *Evaluation of e-cigarettes* (May 4, 2009) ("Westenberger study"), *available at* http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf, as the amount of nicotine required to create a significant adverse effect is considerably higher than the levels Westenberger found in e-cigarettes. JA563 ¶7.

The other "dangers" FDA alleges are similarly overstated. Woodcock declares, for example, that diethylene glycol ("DEG") was detected in one of SE's e-cigarette cartridges. JA546 ¶7. But the Westenberger study did not find *any* trace of DEG in any of NJOY's cartridges. In any event, Woodcock does not claim that the trace amounts found in SE's single cartridge posed any risk of harm. The e-cigarette cartridge itself is neither ingested directly nor handled extensively, and thus the likelihood of significant exposure to DEG found only in the cartridge is therefore very low at best. JA564 ¶9. And, although the Westenberger study also performed some aerosol and vapor tests, no tests were performed to confirm

the presence of DEG in the vapor. *Id.* Woodcock makes no attempt to explain how the Westenberger DEG findings establish any likelihood of irreparable harm from NJOY's product.

FDA notes that the Westenberger study also detected "[c]ertain tobacco-specific nitrosamines ["TSNAs"], which are human carcinogens" and some "[t]obacco-specific impurities ["TSIs"] suspected of being harmful" in cartridges casings. Br. 23. Both compounds, however, were detected "at very low levels": the TSNA levels were so low they could not even be quantified,[11] and the TSI levels were less than the specification for the cartridge of the FDA-approved smoking cessation device, Nicotrol. JA548-49 ¶¶11, 14. That e-cigarette cartridges may contain TSIs at levels lower than what FDA itself has approved as safe for inhalation hardly amounts to a significant public danger.

The evidence, moreover, demonstrates no harmful TSNAs or TSIs in the vapor that smokers actually inhale. An October 2009 vapor study by an independent testing laboratory found only trace amounts of N-nitrosoanatabine ("NAT"), which is nontoxic, noncarcinogenic, and poses no risk to public health. JA565 ¶13. Of the three TSIs cited by FDA as presenting "significant safety

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

concerns" due to potential genotoxicity,[12] only one (myosmine), a constituent of nuts, grains and fruits, *id.* ¶16, has been found in the aerosol/vapor of NJOY's products.[13] The available literature shows no harm from myosamine at the levels likely to result from the use of e-cigarettes. JA565-66 ¶15.

Finally, FDA and its amici argue that because, like pipe tobacco, e-cigarette cartridges are available in different flavors, the marketing of e-cigarettes may entice minors into nicotine dependence. Br. 10, 24. The suggestion that these electronic devices are likely to be attractive to minors has no support in the record. FDA has produced absolutely no data demonstrating that minors use these products or consider them a desirable alternative to smoking. And FDA fails to acknowledge that NJOY already prohibits the sale of e-cigarettes to minors in its contracts with its customers.

B. FDA Can Address Its Concerns By Exercising Its Undisputed Jurisdiction Over E-Cigarettes Under The Tobacco Act

FDA's public interest argument also fails for an even more fundamental reason. To the extent e-cigarettes pose any specific and imminent risk of harm—and the absence of any reported instance of harm argues strongly otherwise—the Tobacco Act authorizes FDA comprehensively to regulate their manufacture, sale,

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[12] The Riebe and Westphal (1983) study cited by Woodcock as demonstrating the genotoxicity of myosamine actually reached the opposite conclusion. JA565-66 ¶15.

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

advertising, and labeling. FDA could have exercised that authority a year ago when the Tobacco Act was passed and it could do so today. It simply has not.

For example, if FDA is actually concerned about the constituent ingredients in e-cigarettes, the Tobacco Act "authorize[s] the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products." Pub. L. No. 111-31, §3, 123 Stat. at 1782. If FDA is actually concerned about the amount of nicotine or contaminants in e-cigarettes, the Tobacco Act "vest[s] the Food and Drug Administration with the authority to regulate the levels of… nicotine, and other harmful components of tobacco products." *Id*. And if FDA is actually concerned that e-cigarettes are being marketed to minors, the Tobacco Act "ensure[s] that the Food and Drug Administration has the authority to address … the use of tobacco by young people." *Id*. at 1781. *See generally* pp. 7-9, *supra* (describing in detail the Tobacco Act's provisions regarding the content, testing, development, manufacture, labeling, packaging, advertising, promotion, distribution, and sale of tobacco products).

In short, the Tobacco Act provides FDA all the authority that Congress deemed appropriate to combat the public health and other issues presented by tobacco products—and ample authority to regulate virtually all aspects of the manufacturing, labeling, marketing and sale of e-cigarettes. Rather than exercise

its undisputed jurisdiction to regulate e-cigarettes under the Tobacco Act, FDA has spent more than a year litigating its right to regulate them under a statute that was never intended to authorize the regulation of customarily marketed tobacco products—apparently having learned nothing from its unsuccessful effort to advance the same far-reaching theories of its jurisdiction over tobacco products a decade ago in *Brown & Williamson*. That strategic choice calls into question the seriousness and urgency of FDA's public health concerns. And, as the district court observed, FDA's continuing ability at any time to assert regulatory jurisdiction over e-cigarettes under the Tobacco Act "greatly diminish[es]" its claim of "harm to the public interest." JA541.[14]

CONCLUSION

For the reasons explained above, NJOY respectfully requests that the Court affirm the District Court's decision to enter a preliminary injunction barring FDA from detaining NJOY's products.

[14] The Administrative Procedure Act ("APA") provides FDA any flexibility it needs to expedite an assertion of jurisdiction over e-cigarettes under the Tobacco Act. *See* 5 U.S.C. §553(b). FDA has used this procedure in the past. *See, e.g.*, Use of Materials Derived From Cattle in Human Food and Cosmetics, 69 Fed. Reg. 42,256 (July 14, 2004); Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals, 68 Fed. Reg. 62,353 (Nov. 4, 2003). And this procedure is more than sufficient to handle any timing concerns FDA may attempt to advance here notwithstanding its failure to invoke its Tobacco Act authority for more than a year.

Respectfully submitted,

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Dated: June 23, 2010

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Circuit Rule 32 because this brief contains 13,807 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Circuit Rule 32(a)(1). The undersigned used Microsoft Word 2003 to compute the count.

This brief also complies with the typeface requirement of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced font using Microsoft Word 2003 in 14-point Times New Roman font.

Dated June 23, 2010: /s/ Gregory G. Garre
Gregory G. Garre

CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of June, 2010, I caused the foregoing Brief of Appellee Sottera, Inc. d/b/a NJOY™ to be filed with the Clerk, U.S. Court of Appeals for the D.C. Circuit using the Court's CM/ECF system, which will send notification of such filing to the following registered users:

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I further certify that, pursuant to D.C. Circuit Rules 25 and 31 five (5) paper copies of the foregoing Brief will be hand-delivered to the Clerk of the Court.

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ADDENDUM

ADDENDUM

Regulations:

Reference Material:

21 C.F.R. §860.7

§860.7. Determination of safety and effectiveness.

* * *

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

* * *

(d)(1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

* * *

21 C.F.R. §878.4800

§878.4800. Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.

21 C.F.R. §890.5100

§890.5100. Immersion hydrobath.

(a) *Identification*. An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(b) *Classification*. Class II (performance standards).

21 C.F.R. §890.5360

§890.5360. Measuring exercise equipment.

(a) *Identification*. Measuring exercise equipment consist of manual devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes. Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.

(b) *Classification*. Class II (performance standards).

21 C.F.R. §890.5380

§890.5380. Powered exercise equipment.

(a) *Identification*. Powered exercise equipment consist of powered devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

21 C.F.R. §890.5740

§890.5740. Powered heating pad.

(a) *Identification*. A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E part 807 of this chapter subject to §890.9.

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

No. 79-1397

ACTION ON SMOKING AND HEALTH,

Appellant,

v.

PATRICIA ROBERTS HARRIS, 1/ Secretary of the Department of Health, Education, and Welfare,

JERE E. GOYAN, 2/ Commissioner of Food and Drugs,

and

THE UNITED STATES FOOD AND DRUG ADMINISTRATION,

Appellees.

ON APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLEES

1/ Patricia Roberts Harris succeeded Joseph A. Califano, Jr., as Secretary of Health, Education, and Welfare and is automatically substituted as an appellee. Rule 43(c), Fed. R. App. P.

2/ Jere E. Goyan succeeded Donald Kennedy as Commissioner of Food and Drugs and is automatically substituted as an appellee. Rule 43(c), Fed. R. App. P.

> ... The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product.

S. Rep. No. 361, 74th Cong., 1st Sess. (1935), reprinted in Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record (1938) ("Dunn"), at 240. Another example given was preparations represented for weight reduction. See, e.g., Dunn at 553. Cigarettes have been held to be a "drug" when so represented. See Trim Cigarettes, supra. 8/

Thus, the Commissioner's conclusion here -- that cigarettes are not a "drug" in the absence of health claims by the manufacturers or vendors or other evidence of the manufacturers' or vendors' intent to affect the bodily structure or functions -- accords with congressional intent in drafting the statute.

2. In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the

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8/ Accord, see the testimony of William Goodrich, FDA Chief Counsel, explaining the decision of the agency in 1970 that artificial sweeteners containing cyclamates were to be considered as drugs:

> The intention is the intention of the person who introduced that product in interstate commerce ....

Cyclamate Sweeteners: Hearing Before a Subcommittee of the House Committee on Government Operations, 91st Cong., 2d Sess. 47 (1970). Defendants' Reply Memorandum of Points and Authorities in Opposition to Plaintiff's Motion for Summary Judgment ... ("Defendants' Reply Memorandum"), Exhibit BB at 47, Jt. App. at 265.

modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor.

In construing the Food and Drugs Act of 1906, 34 Stat. 768 (the predecessor to the modern Act) 9/, FDA's predecessor agency, the Bureau of Chemistry in the Department of Agriculture, emphasized that cigarettes were beyond the scope of that Act:

9/ The relevant portion of the 1906 statute provided (Sec. 6):

> That the term "drug" as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals ....

> ... Tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof.
>
> On the other hand, tobacco and its preparations which are not so labeled and are used for smoking or chewing or as snuff and not for medicinal purposes are not subject to the provisions of the act.

Service and Regulatory Announcements, No. 13 (1914) (Memorandum of Points and Authorities in Support of Defendants' Motion for Judgment on the Pleadings and, in the Alternative, for Summary Judgment ["Defendants' Memorandum"], Exhibit 4, Jt. App. at 168) (quoted in Huddleston Memorandum, C 0834 at 13, Jt. App. at 116).

After the passage of the 1938 Act, FDA repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of the term "drug" absent health claims on behalf of the manufactuer or vendor. 10/ For example, on May 24, 1963, the FDA Bureau of Enforcement issued a guideline concerning the application of the Act and the Federal Hazardous Substances Labeling Act 11/ (then administered by FDA) to tobacco products. The guideline states:

10/ Examples of pertinent instances of agency interpretation and congressional knowledge thereof are cited infra. See also n.19, p.23, infra, and Senator Huddleston's Memorandum (C 0834, Jt. App. at 103), which provides a general discussion of congressional knowledge of agency interpretation of the definition of "drug" as applied to cigarettes and of legislation thereafter with respect to smoking and health.

11/ Pub. L. 86-613 (July 12, 1960). As amended, that Act is now the Federal Hazardous Substances Act, 15 U.S.C. § 1261, et seq.