No. 10-5032

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

SMOKING EVERYWHERE, INC., ,
Plaintiff-Appellee,
and

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

v.

FOOD AND DRUG ADMINISTRATION, et al.,
Defendants-Appellants.

On Appeal From The United States District Court
For The District Of Columbia

BRIEF FOR APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Plaintiff is Smoking Everywhere, Inc. Intervenor-Plaintiff is Sottera, Inc., d/b/a NJOY. Defendants are the United States Food and Drug Administration (FDA), FDA Commissioner Margaret Hamburg, the United States Department of Health and Human Services, and Secretary of Health and Human Services 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.

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

CSTHEA	Comprehensive Smokeless Tobacco Health Education Act
FCLAA	Federal Cigarette Labeling and Advertising Act
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act of 2009

JURISDICTIONAL STATEMENT

Plaintiff Smoking Everywhere and intervenor-plaintiff Sottera, Inc., d/b/a NJOY (collectively, "plaintiffs") invoked the district court's jurisdiction under 28 U.S.C. § 1331. The district court entered a preliminary injunction on January 14, 2010. Defendants filed a timely notice of appeal on February 1, 2010. This Court has appellate jurisdiction under 28 U.S.C. § 1292(a).

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that "electronic cigarettes" are exempt from regulation under the drug and device provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") unless they are intended for therapeutic use.

2. Whether, apart from this legal error, the balance of harms and the public interest require that the preliminary injunction be vacated.

STATUTORY AND REGULATORY PROVISIONS

Pertinent provisions are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

Plaintiffs seek to import devices known as "electronic cigarettes," which are battery-powered electronic devices that deliver vaporized nicotine into the user's mouth. Although they are designed to look like real cigarettes, "electronic cigarettes" contain no tobacco and do not burn. They do, however, deliver "the nicotine hit that smokers crave." JA 122 (plaintiff's promotional materials).

The Food and Drug Administration ("FDA") refused entry to inbound shipments of plaintiffs' products on the ground that they are unapproved drugs, devices, and drug-device combinations under the FDCA. In this lawsuit, plaintiffs contend that "electronic cigarettes" should be treated like real cigarettes, which, under *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000), are generally exempt from regulation under the drug and device provisions of the FDCA.

The district court accepted plaintiffs' argument and held that "electronic cigarettes" are exempt from regulation under the drugs and device provisions unless they are intended to have a therapeutic effect, such as to treat smoking addiction. The court issued a preliminary injunction that generally bars FDA from denying entry to plaintiffs' products as unapproved drugs, devices, or drug-device combinations. JA 543-544.

On the government's emergency motion, this Court granted an administrative stay. *See* 2/2/2010 Order (Ginsburg, Henderson, Rogers, JJ.). After further briefing, this Court dissolved the administrative stay and granted a stay pending appeal. *See* 3/31/2010 Order (Ginsburg, Griffith, Kavanaugh, JJ.).

STATEMENT OF FACTS

A. Background

1. A so-called "electronic cigarette" is a battery-powered device that allows the user to inhale nicotine vapor. Smoking Everywhere Complaint ¶¶ 8-9 (JA 14-15). It is made up of three basic parts — the cartridge, the heating element or atomizer, and the battery and electronics. *Id*. ¶ 9 (JA 15). The cartridge is a disposable plastic container that contains a mixture of propylene glycol and liquid nicotine and serves as the mouthpiece. *Ibid*. The heating element vaporizes the nicotine mixture. *Ibid*. The battery and electronics power the heating element and monitor air flow. *Ibid*. When a user inhales, the air flow is detected by the device's electronics and activates the heating element. *Id*. ¶ 10 (JA 15). When the heating element is activated, the mixture containing liquid nicotine is vaporized and the user inhales the nicotine vapor. *Ibid*.; *see also* NJOY Complaint ¶¶ 13-16 (JA 38-39).

Although "electronic cigarettes" are designed to look like real cigarettes, they contain no tobacco and do not burn. Thus, plaintiff's promotional materials emphasize that "it's NOT a real cigarette, there is NO real smoke, flame, tar or tobacco." JA 96. The claimed purpose of the device is to "deliver the nicotine hit that smokers crave." JA 122. They are promoted to deliver a range of nicotine doses including "High Nicotine (16mg), Medium Nicotine (11mg) or Low Nicotine (6mg)."

JA 96 (Smoking Everywhere products); *see also* NJOY Complaint ¶ 13 & Exh. A (JA 38, 53) (similar nicotine doses for NJOY products).

2. In October 2008, FDA detained inbound shipments of Smoking Everywhere's "electronic cigarettes" imported from China because the product appeared to be an unapproved drug, device, or combination product. JA 149-152, 185, 128. In March 2009, after administrative proceedings, FDA issued "Refusal of Admission" notices for the shipments. JA 173-177. In April 2009, FDA detained an inbound shipment of NJOY's "electronic cigarettes." JA 55-57.[1]

B. The District Court Opinion And Order

Plaintiff Smoking Everywhere filed this lawsuit in April 2009, after its products were refused entry into the United States. NJOY subsequently joined as an intervenor-plaintiff. Plaintiffs contended that "electronic cigarettes" are exempt from regulation under the drug and device provisions of the FDCA unless they are intended for therapeutic use. They urged that the reasoning of *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000), which held that FDA lacked authority to regulate cigarettes and smokeless tobacco products as customarily marketed, applies equally to "electronic cigarettes."

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[1] In May 2009, FDA added "electronic cigarettes" manufactured by three Chinese companies to an Import Alert that authorizes detention by FDA district offices. JA 207.

The district court accepted this argument and, on January 14, 2010, issued a preliminary injunction. The order provides that "FDA shall not detain or refuse admission into the United States of Smoking Everywhere's electronic cigarette products on the ground that those products are unapproved drugs, devices, or drug-delivery combinations under the Food, Drug, and Cosmetic Act." JA 543-544. A similar injunction was entered with respect to NJOY's products. JA 544.[2]

In the accompanying opinion, the district court recognized that "electronic cigarettes" contain no tobacco and are thus not subject to the "tobacco-specific" legislation discussed in *Brown & Williamson*. *See* JA 526-527 (discussing the Federal Cigarette Labeling and Advertising Act (FCLAA) and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA)). Nonetheless, the court dismissed as "too clever by half" the argument that the Supreme Court's holding could not be extended to nicotine-delivery devices such as "electronic cigarettes." JA 527.

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[2] The NJOY injunction applies absent a proffer of evidence that the products are "intended to have a therapeutic effect." JA 544. The Smoking Everywhere injunction does not allow for such a proffer because the court concluded, based on the administrative record, that Smoking Everywhere products are not intended for therapeutic use. JA 531-535. In reaching this conclusion, the district court improperly discounted Smoking Everywhere's therapeutic claims (as well as their other drug claims). However, as discussed below, Smoking Everywhere's products would be subject to FDCA regulation even in the absence of the therapeutic claims.

The district court also acknowledged that FDA has long exercised jurisdiction over nicotine products such as "Favor Smokeless Cigarettes," "Nicogel Tobacco Hand Gel," Nicotine Lollipops, Nicotine Lip Balm, and Nicotine Water — including products marketed for "recreational, non-therapeutic" nicotine use. JA 530 n.13. The court believed, however, that FDA should have revisited its regulation of recreational nicotine products in light of *Brown & Williamson*, concluding that such regulation was "not in step with the reasoning of that case." *Ibid*. The court held that "[b]ecause plaintiffs sell their electronic cigarette products for customary recreational use, those products (just like traditional cigarettes) are properly excluded from the meaning of drug or device under the FDCA." JA 531.

The court noted that the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act") authorizes FDA to regulate "tobacco products," 21 U.S.C. § 387a(a), and suggested that any authority to regulate "electronic cigarettes" could derive only from this statute. JA 530. The court acknowledged, however, that the 2009 statute excludes from the definition of "tobacco product" any article that is a drug, device, or combination product under the FDCA, and provides that such articles shall be subject to regulation under the preexisting FDCA provisions. JA 520 (citing 21 U.S.C. § 321(rr)(2)-(3)). The court thus recognized

that the Tobacco Control Act "did not move the definitional line between tobacco products and drugs." JA 519 n.4.

The district court concluded that the balance of harms and the public interest favored entry of a preliminary injunction. The court believed that an injunction would not threaten the public health because "FDA cites no evidence that" the "electronic cigarettes" previously imported into this country "have endangered anyone." JA 540. The court also noted that plaintiffs claim to derive virtually all of their revenue from the importation of "electronic cigarettes" into the United States. JA 537-539.

The government sought reconsideration and a stay pending appeal. In support of its motions, the government submitted the declaration of Janet Woodcock, M.D., Director of FDA's Center for Drug Evaluation and Research, addressing the threat to the public health posed by electronic cigarettes. JA 545-559.

The district court denied a stay by minute order, *see* 2/1/2010 Order (JA 10), and did not act on the reconsideration motion. This Court granted an administrative stay of the preliminary injunction and, subsequently, a stay pending appeal.

SUMMARY OF ARGUMENT

1. Plaintiffs seek to import battery-powered devices that deliver vaporized nicotine into the user's mouth. Although described as "electronic cigarettes," the products contain no tobacco and are not "cigarettes" within the meaning of federal law. They do, however, deliver "the nicotine hit that smokers crave," JA 122, and are promoted to provide nicotine in a range of specified doses.

The district court concluded that "electronic cigarettes" should be treated as though they were real cigarettes for purposes of the FDCA, and thus under *Brown & Williamson* not subject to regulation as a drug or device when sold for recreational use. The ruling is premised on a fundamental misunderstanding of the Supreme Court's decision in *Brown & Williamson*. The Supreme Court explained that Congress had specifically regulated cigarettes under various statutes, all of which made clear that Congress did not intend to ban the sale of cigarettes. It observed that FDA had never, before 1996, regulated cigarettes as customarily marketed under the FDCA. And it explained that application of that statute would logically have resulted in a complete ban on cigarette sales, a result directly at odds with express congressional intent as reflected in the statutes regulating cigarettes. Accordingly, the Court concluded that the FDCA could not properly be construed to apply to cigarettes as customarily marketed.

The Supreme Court's analysis has no application to "electronic cigarettes." Unlike real cigarettes, "electronic cigarettes" are not subject to the federal statutes invoked in *Brown & Williamson*, and a restriction on their importation would not contravene a declared congressional policy. Nor does the regulation of plaintiffs' products mark an extension of FDA's interpretation of the drug and device provisions of the FDCA. The agency has, for years, regulated nicotine products ranging from "smokeless cigarettes" to nicotine lollipops under the FDCA's drug and device provisions.

As the district court recognized, the new authority to regulate "tobacco products" vested in FDA by the Tobacco Control Act does not constrict FDA's preexisting authority under the FDCA. The Tobacco Control Act expressly excludes from its definition of "tobacco product" any article that is a drug, device, or combination product under the FDCA, and expressly provides that such articles shall be subject to regulation under the preexisting FDCA provisions. FDA's decision to regulate "electronic cigarettes" under the FDCA's drug and device provisions rather than under its new authority is plainly a reasonable interpretation of the statutes it is charged with administering.

2. Because the injunction rests on legal error, reversal would be required even if the district court had not also erred in assessing the public health concerns created

by its order. Plaintiffs seek to import and distribute large quantities of products containing toxic and addictive chemicals, and the district court incorrectly disregarded the public health risks that these untested and unregulated products present. "Electronic cigarettes" are subject to none of the manufacturing controls required for FDA-approved nicotine-delivery products. Nor are they subject to the warning requirements and other protections that govern the marketing of real cigarettes, including the federal restrictions on sales to children. The district court's cursory dismissal of these serious concerns would warrant reversal even apart from the legal errors underlying its ruling.

STANDARD OF REVIEW

The legal ruling on which preliminary injunction rests is subject to *de novo* review in this Court. *Davis v. Pension Benefit Guarantee Corp*., 571 F.3d 1288, 1291 (D.C. Cir. 2009). The district court's balancing of harms and the public interest is reviewed for abuse of discretion. *Ibid*. FDA's interpretation of the statutes it is charged with administering is entitled to *Chevron* deference. *Brown & Williamson*, 529 U.S. at 132 (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837 (1984)).

ARGUMENT

I. FDA Has Properly Regulated "Electronic Cigarettes" Under The FDCA's Drug And Device Provisions.

A. The reasoning of *Brown & Williamson* does not extend to "electronic cigarettes."

1. Plaintiffs seek to import so-called "electronic cigarettes," which are battery-powered devices with a heating element that vaporizes a liquid nicotine mixture that is inhaled by the user. JA 14-15, 38-39. It is undisputed that "electronic cigarettes" contain no tobacco and are not, in fact, cigarettes. *See* 15 U.S.C. § 1332(1) (FCLAA definition); 21 U.S.C. § 387(3) (Tobacco Control Act definition). Indeed, plaintiff's promotional materials emphasize that "it's NOT a real cigarette, there is NO real smoke, flame, tar or tobacco." JA 96. The claimed purpose of the device is to provide a user with specified doses of nicotine without having to smoke a real cigarette. JA 53, 96.

Although "electronic cigarettes" are incontrovertibly *not* cigarettes, the district court ruled that they cannot be regulated under the "drug" or "device" provisions of the FDCA in light of the Supreme Court's decision in *Brown & Williamson*, which held that *real* cigarettes as customarily marketed cannot be regulated under the FDCA.

The Supreme Court's reasoning has no application to plaintiffs' products. In *Brown & Williamson*, the Court reviewed an FDA rule that, for the first time, asserted jurisdiction under the FDCA to regulate cigarettes and smokeless tobacco products as customarily marketed. *See* 529 U.S. at 127. In invalidating that rule, the Court stressed that cigarettes and smokeless tobacco were specifically addressed in several federal statutes, including the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 *et seq.*, and the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4401 *et seq*. *See Brown & Williamson*, 529 U.S. at 143-144.

As the Court emphasized, these statutes were enacted against the background of a long held FDA position that it lacked authority to regulate cigarettes and smokeless tobacco as customarily marketed. The Court declared: "As the FDA concedes, it never asserted authority to regulate tobacco products as customarily marketed until it promulgated the regulations at issue here." *Id*. at 146. The Court found it "clear that Congress' tobacco-specific legislation has effectively ratified the FDA's previous position that it lacks jurisdiction to regulate tobacco." *Id*. at 156.

Noting the FCLAA's express policy to protect the commerce of the cigarette industry – long a major domestic industry – the Court concluded that "the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States." *Id*. at 137, 139. The Court reasoned that "Congress'

decisions to regulate labeling and advertising and to adopt the express policy of protecting 'commerce and the national economy ... to the maximum extent' reveal its intent that tobacco products remain on the market." *Id*. at 139.

In contrast, the Court explained, if FDA were to regulate cigarettes and smokeless tobacco under the FDCA, "the Act would require the agency to ban them." *Id*. at 137. Because Congress had not meant to ban these products, the Court reasoned, Congress could not have intended that they be subject to regulation under the FDCA. *Id*. at 137-139.

2. "Cigarettes" and "smokeless tobacco" are defined terms under the federal statutes discussed by the Supreme Court, and these terms incontrovertibly do not encompass plaintiffs' "electronic cigarettes."[3] Thus, unlike real cigarettes, they are

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[3] Under FCLAA, the term "cigarette" means —

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

15 U.S.C. § 1332(1); *see also id*. § 4408(1) & Historical Note (CSTHEA) (providing the current and pre-2009 definitions of "smokeless tobacco"). The FDA rule that was the subject of *Brown & Williamson* contained substantially the same definitions of "cigarette" and "smokeless tobacco" as were found in the FCLAA and the CSTHEA. *See* 21 C.F.R. § 897.3(a) & (i) (1997).

not required to bear Surgeon General warnings, *see* 15 U.S.C. §§ 1333, 4402; they are not subject to the ban on television and radio advertising, *see id*. §§ 1335, 4402(f)); and they are not subject to the federal provision that makes receipt of certain block grants by states contingent on restricting sales to minors, *see* 42 U.S.C. § 300x-26(a)(1).

The rationale of *Brown & Williamson* does not extend to nicotine-delivery devices that have never been the subject of any specific federal legislation. Regulation of devices such as "electronic cigarettes," nowhere mentioned in *Brown & Williamson*, is not at odds with any congressional policy and would not mark a change from longstanding FDA practice. To the contrary, FDA has long used its drug and device authority to regulate nicotine products such as "Favor Smokeless Cigarettes," "Nicogel Tobacco Hand Gel," Nicotine Lollipops, Nicotine Lip Balm, and Nicotine Water. JA 530 n.13.

For example, in 1987, a decade before the rule at issue in *Brown & Williamson*, FDA exercised jurisdiction over a product indistinguishable in all relevant respects from the products at issue here. The "Favor Smokeless Cigarette" was a small tube containing "a plug impregnated with nicotine solution" that allowed the user to inhale nicotine vapor, and it was marketed to provide "cigarette satisfaction without smoke." JA 425-426; *see also* JA 416-424 (promotional materials). Although the

manufacturer made no express therapeutic claims, FDA advised the company that the product was "a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body" and therefore an unapproved new drug. JA 426. FDA explained that it would take legal action if the company did not discontinue its marketing. *Ibid*.

Similarly, in 2008, FDA refused to allow the importation of "Nicogel," a nicotine hand gel that was made from liquified tobacco and touted to provide "cigarette satisfaction" for use "when you are unable or it is inconvenient to smoke." JA 478. In finding that Nicogel was an unapproved drug, FDA rejected the argument that *Brown & Williamson* foreclosed regulation under the FDCA. JA 487-492. FDA explained that, unlike the cigarettes and smokeless tobacco products at issue in *Brown & Williamson*, Nicogel was not subject to any alternative regulatory scheme. JA 487. It explained that "the statute on which Nicogel USA chiefly relies, the Comprehensive Smokeless Tobacco Health Education Act, plainly does not apply to Nicogel, and Nicogel USA concedes as much." *Ibid*.

By contrast, FDA concluded in 2003 that it lacked jurisdiction to regulate "Ariva," a tablet that was made from compressed powdered tobacco and that met the definition of "smokeless tobacco" in the CSTHEA. JA 491-492. FDA thus denied a citizen petition requesting that the agency regulate "Ariva" as a drug. JA 492.

Thus, unlike in *Brown & Williamson*, FDA's regulatory practice does not support exempting "electronic cigarettes" from regulation under the FDCA. Nor does FDCA regulation of "electronic cigarettes" and other nicotine-delivery devices lead inexorably to a ban. The Supreme Court concluded, based on well established scientific evidence, that cigarettes as traditionally marketed would be banned as unsafe if regulated as drugs under the FDCA — a result that could not be squared with the existing statutes regulating cigarettes as traditionally marketed. *See Brown & Williamson*, 529 U.S. at 135-37, 143. By contrast, "electronic cigarettes" are newer products and have not been extensively tested or studied. JA 548-549. Thus, it may well be possible for a manufacturer of "electronic cigarettes," upon the submission and review of an appropriate application, 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 and transdermal patches. Furthermore, if upon review of an appropriate application FDA were to conclude that the application should not be approved, that decision would not run afoul of the existing statutes regulating cigarettes as traditionally marketed.

3. The district court noted that, under *Brown & Williamson*, cigarettes are subject to regulation under the FDCA when marketed with therapeutic claims.[4] Before the 1996 rule, FDA had "repeatedly informed Congress that cigarettes are beyond the scope of the [FDCA] absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor." *Brown & Williamson*, 529 U.S. at 146 (quoting FDA's brief in *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980)); *see also id*. at 145 (quoting a 1963 FDA letter stating 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"). In invalidating the 1996 rule, the Supreme Court adopted the prior FDA position that it could regulate cigarettes under the FDCA when sold with therapeutic claims, but not when sold for recreational purposes. 529 U.S. at 131-32.

The district court concluded that, in light of this reasoning, FDA should have abandoned its regulation of *all* recreational nicotine products after *Brown & Williamson*, because, in the district court's view, such regulation was "not in step with the reasoning of that case." JA 530 n.13. This pronouncement reflects the central error of the district court's analysis. *Brown & Williamson* recognized that

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[4] *See, e.g.*, *United States v. 46 Cartons ... Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953) (sustaining FDA regulation of cigarettes claimed to prevent respiratory and other diseases).

even cigarettes can be regulated under the FDCA when accompanied by therapeutic claims. 529 U.S. at 131-32. The Court's reasoning did not suggest that FDA should reconsider its existing regulation of other nicotine products that do not contain tobacco and that were not subject to any alternative regulatory regime.

As the reasoning of *Brown & Williamson* reflects, the FDCA definitions of "drug" and "device" include articles "intended to affect the structure or any function of the body" as well as articles "intended for use in the ... mitigation, treatment, or prevention of disease." 21 U.S.C. §§ 321(g)(1), (h). In general, a product meeting either prong of this definition is properly regulated as a drug or device. *See United States v. Storage Spaces*, 777 F.2d 1363, 1366 & n.4 (9th Cir. 1985) (sustaining regulation of recreational drugs).[5] With respect to cigarettes, however, *Brown & Williamson* concluded that it would contravene congressional intent to regulate cigarettes as customarily marketed because such regulation would inevitably lead to a ban, a result foreclosed by other legislation. By contrast, "electronic cigarettes" are not carved out from the normal operation of the FDCA.[6]

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[5] *See also, e.g.*, *United States v. Undetermined Quantities of Articles of Drugs*, 145 F. Supp. 2d 692, 698-700 (D. Md. 2001) (street drug alternatives); *United States v. Travia*, 180 F. Supp. 2d 115, 118-119 (D.D.C. 2001) (recreational nitrous oxide).

[6] In opposing a stay, plaintiffs relied on this Court's decision in *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). But unlike in that case, the evidence of the "intended use" of plaintiffs' products is not "derived from

B. The Family Smoking Prevention and Tobacco Control Act does not constrict FDA's preexisting authority under the FDCA.

The Family Smoking Prevention and Tobacco Control Act grants FDA new authority to regulate tobacco products. 21 U.S.C. § 387a(a). This grant of authority applies to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." *Id*. § 387a(b).

The Act defines "tobacco product" to include a product "derived from" tobacco as well as a product made from tobacco. *Id*. § 321(rr)(1). Congress made explicit, however, that it was not altering FDA's authority to regulate drugs or devices under the preexisting FDCA provisions. As the district court acknowledged (JA 520), the Tobacco Control Act expressly excludes from the definition of "tobacco product" any article that is a drug, device or combination product under the FDCA, 21 U.S.C. § 321(rr)(2), and expressly provides that such articles shall continue to be regulated

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consumer use alone," *id*. at 239. For example, plaintiffs' product labeling and promotional materials expressly claim that the devices will deliver specified doses of the drug nicotine, which creates and sustains addiction by altering the structure of the brain. JA 438-439; JA96 (Smoking Everywhere promotional materials offering cartridges in "High Nicotine (16 mg), Medium Nicotine (11 mg) or Low Nicotine (6 mg)"); JA53 (NJOY promotional materials offering cartridges in 18 mg, 12 mg, and 6 mg); *see also, e.g.*, JA 122 (Smoking Everywhere products deliver "the nicotine hit that smokers crave"); JA 127 (Smoking Everywhere products "satisfy … smoking addiction").

under the FDCA provisions that govern drugs, devices, and combination products, *id*. § 321(rr)(3). Accordingly, the district court itself recognized that the Tobacco Control Act "did not move the definitional line between tobacco products and drugs." JA 519 n.4.[7]

In any event, if there were doubt as to whether "electronic cigarettes" should be regulated under FDA's new authority to regulate "tobacco products" or under FDA's preexisting FDCA authority, FDA's determination to regulate these products under its drug and device authority is entitled to deference. *See Brown & Williamson*, 529 U.S. at 132 (holding that FDA's interpretation of the FDCA is governed by *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837 (1984)). This case concerns the intersection of two statutes that FDA is charged with administering, and the Tobacco Control Act expressly vests FDA with the responsibility to determine which tobacco products it "by regulation deems to be subject to" the new provisions. 21 U.S.C. § 387a(b). FDA's determination reflects a reasonable interpretation of the statutes it is charged with implementing.

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[7] For the same reason, a product that is a drug, device or combination product is not a "modified risk tobacco product" within the meaning of the Tobacco Control Act. *See* 21 U.S.C. § 387k(b)(1) (defining "modified risk tobacco product" as any "tobacco product" sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products).

II. The Harm Caused By The Importation Of "Electronic Cigarettes" Is Immediate, Irreparable, And Contrary To The Public Interest.

As discussed above, the preliminary injunction rests on an error of law and should be vacated on that basis alone. The district court's failure to consider the significant public health concerns raised by its ruling constitutes an independent abuse of discretion.

The danger posed by the unrestricted sale of products containing toxic and addictive chemicals cannot seriously be questioned. As discussed above, "electronic cigarettes" are not subject to the array of federal restrictions applicable to cigarettes, including warning requirements, advertising restrictions, and federal restrictions on sales to minors. Even without the benefit of specific evidence of the dangers these products pose, the threat to the public health is apparent.

In light of the district court's expressed concern about the absence of such specific evidence, *see* JA 540-541, the government, in seeking reconsideration and a stay, also called to the district court's attention findings made after FDA's decision to refuse entry to the particular shipments at issue in this case. Insofar as the preliminary injunction extends beyond the shipments addressed in the administrative record, it is particularly appropriate to consider all available evidence of harm. These findings, summarized in the Declaration of Janet Woodcock, M.D., Director of FDA's

Center for Drug Evaluation and Research, confirm that the importation of "electronic cigarettes" poses a serious and imminent threat to the public health.

Nicotine in high doses can be toxic and even fatal, and the amount of nicotine that will have a toxic effect is lower for children than for adults. Woodcock Decl. ¶ 4 (JA 546). Even in lower doses, nicotine can cause elevations in blood pressure and heart rate. *Id*. ¶ 14 (JA 549). Short-term side-effects reported from use of "electronic cigarettes" include racing pulse, dizziness, slurred speech, mouth ulcers, heartburn, coughing, diarrhea, and sore throat. *Ibid*. Excessive nicotine exposure may precipitate cardiovascular events in patients with preexisting cardiovascular disease such as coronary artery disease, peripheral vascular disease, and hypertension. *Ibid*. Thus, FDA-approved nicotine replacement therapies – unlike "electronic cigarettes" – currently have precautions for patients with cardiovascular disease. *Ibid*.

A new drug application for a nicotine replacement product must include nicotine safety data and information regarding manufacturing controls to ensure that each individual product contains an identified and accurately calibrated amount of nicotine. *Id*. ¶ 7 (JA 547). Pharmaceutical grade nicotine is also tested for the presence of pesticides and herbicides. *Ibid*.

By contrast, "electronic cigarettes" are not subject to the manufacturing controls or other requirements applicable to FDA-approved nicotine replacement

products. FDA has not received any applications to approve an "electronic cigarette" product and there is little scientific data addressing the health risks these products pose. *Id*. ¶ 8 (JA 547). The findings announced by FDA in July 2009 underscore the potential risks. *Id*. ¶ 9 (JA 547-548). Those findings reflect the results of FDA's laboratory analysis of a small sample of cartridges sold by Smoking Everywhere and NJOY. *Ibid*. In the samples analyzed, the "electronic cigarettes" labeled as containing no nicotine in fact had low levels of nicotine present. *Id*. ¶ 10 (JA 548). Three different "electronic cigarette" cartridges with the same label each provided a markedly different amount of nicotine with each puff. *Ibid*. The nicotine levels per puff ranged from 26.8 to 43.2 mcg nicotine/100 mL. *Ibid*.

In the same samples, diethylene glycol was detected in one cartridge at approximately 1%. *Id*. ¶ 11 (JA 548). Diethylene glycol is a solvent and is toxic to humans. *Ibid*. This solvent, when used in pharmaceuticals (often as a substitute for propylene glycol), has resulted in significant numbers of fatalities. *Ibid*. Certain tobacco-specific nitrosamines, which are human carcinogens, were detected in half of the samples tested. *Ibid*. Tobacco-specific impurities suspected of being harmful to humans were detected in a majority of the samples tested. *Ibid*.

Because no appropriate studies about the safety of "electronic cigarette" products have been submitted to FDA, consumers and FDA currently have no way to

know what types or concentrations of potentially harmful chemicals or what dose of nicotine are being inhaled when these products are used. *Id*. ¶ 13 (JA 548-549). They have no way to know whether the vapor contains harmful contaminants. *Ibid*. (JA 549). Because "electronic cigarettes" have been subject to so little testing and analysis, the long-term health consequences are unknown. *Id*. ¶ 14 (JA 549).

The unregulated distribution of "electronic cigarettes" — which plaintiffs offer in candy flavors, JA 53, 99 — also presents a serious risk of addicting new users, including children. Woodcock Decl. ¶ 5 (JA 546). To the extent that young people and other non-smokers are attracted to "electronic cigarettes," their use of these products can lead to nicotine addiction and eventual use of other tobacco products, including cigarettes. *Ibid*. Based on perceptions of these products that are unsupported by scientific evidence, non-smokers may begin nicotine use through these products, former smokers may resume nicotine use, and current smokers may attempt use these products for smoking-cessation instead of FDA-approved products proven effective for this use. *Ibid*. The threat to public health is paramount.

CONCLUSION

For the foregoing reasons, the preliminary injunction should be vacated.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)(7)(B)

I hereby certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: the type face is fourteen-point Times Roman font, and number of words is 5164.

/s/ Alisa B. Klein
_____
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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of May, 2010, I caused the foregoing brief to be filed with the Court in hard copy and electronically and served through the Court's ECF system. In addition, I caused the accompanying two-volume joint appendix to be filed in hard copy and served on the following by hand delivery:

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ADDENDUM

15 U.S.C. § 1332

As used in this chapter–

(1) The term "cigarette" means–

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

15 U.S.C.A. § 4408 (as amended in 2009)

For purposes of this chapter:

(1) The term "smokeless tobacco" has the meaning given such term by section 387(18) of Title 21.

21 U.S.C. § 387

In this subchapter:

***

(3) Cigarette

The term "cigarette"–

(A) means a product that–

> (i) is a tobacco product; and
> (ii) meets the definition of the term "cigarette" in section 1332(1) of Title 15; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

***

(18) Smokeless tobacco

The term "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

21 U.S.C. § 321

For the purposes of this chapter–

***

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). ***

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is–

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

***

(rr) (1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title.

(3) The products described in paragraph (2) shall be subject to subchapter V of this chapter.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this chapter (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

21 U.S.C. § 387a

(a) In general

Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V of this chapter.

(b) Applicability

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

(c) Scope

(1) In general

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under subchapter V of this chapter or any other subchapter.

(2) Limitation of authority

(A) In general

The provisions of this subchapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) Exception

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this subchapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) Rule of construction

Nothing in this subchapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) Rulemaking procedures

Each rulemaking under this subchapter shall be in accordance with chapter 5 of Title 5. This subsection shall not be construed to affect the rulemaking provisions of section 387a-1(a) of this title.

(e) Center for Tobacco Products

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

***

21 U.S.C. § 387k(b)(1)

The term “modified risk tobacco product” means 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.