

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

SMOKING EVERYWHERE, INC.,

Plaintiff,

and

SOTTERA, INC., d/b/a NJOY,

Intervenor-Plaintiff,

v.

U.S. FOOD AND DRUG
ADMINISTRATION, et al.,

Defendants.

No. 10-5032

Civ. No. 09-cv-0771 (RJL)

**EMERGENCY MOTION FOR STAY PENDING APPEAL
AND FOR IMMEDIATE TEMPORARY STAY PENDING
THIS COURT'S CONSIDERATION**

INTRODUCTION AND SUMMARY

Defendants-appellants respectfully ask this Court for a stay pending appeal of the district court's injunction of January 14, 2010, and ask that the Court enter an immediate temporary stay to permit consideration of this stay motion. This morning the district court denied the government's emergency motion for a temporary administrative stay. *See* 2/1/2010 Minute Order. Accordingly, **we respectfully request that the Court issue an administrative stay today, February 1, 2010.**¹

¹ A notice of appeal has been filed. *See* Docket Entry 61. Pursuant to Local Rule 8, counsel for plaintiff and intervenor have been given advance notice, by telephone and email, of the filing of this motion. If the district court acts on the government's pending motion for reconsideration or stay pending appeal, we will promptly notify this Court.

The order on review enjoins the Food and Drug Administration (FDA) from preventing the importation of certain nicotine-delivery devices from overseas. These battery-powered devices deliver vaporized nicotine into the user’s mouth on inhalation. 1/14/10 Op. 2-3 (Attachment A); *see also* Woodcock Decl. ¶ 3 (Attachment B). Although described as an “electronic cigarette,” the product contains no tobacco and does not burn. Its chief purpose, as touted by plaintiff, is to deliver “the nicotine hit that smokers crave.” DET 51.² Although plaintiff’s device is incontrovertibly *not* a cigarette, the district court concluded that FDA lacks authority to regulate the “electronic cigarettes” sold for recreational use as a “drug” or “device” under the Federal Food Drugs and Cosmetics Act (FDCA), finding the Supreme Court’s reasoning in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), with respect to real cigarettes, to be equally applicable to so-called “electronic cigarettes.”

The injunction is premised on legal error. *Brown & Williamson* concluded that permitting the regulation of cigarettes and smokeless tobacco, as customarily marketed, as drugs or devices would logically result in their prohibition — a result that Congress clearly did not intend. The Court also found that permitting regulation as a “drug” or “device” would be at odds with provisions of several other federal statutes that specifically regulated “cigarettes” and “smokeless tobacco.” The Court did not suggest that its ruling would preclude regulation of *any* product designed to provide its user with nicotine, and the FDA has, for years, regulated products ranging from nicotine patches to nicotine lollipops under the drug and device provisions of the FDCA.

The district court mistakenly concluded that FDA could regulate “electronic cigarettes” sold for recreational use only under provisions of the Family Smoking

² Excerpts from the administrative record are reproduced in Attachment C.

Prevention and Tobacco Control Act of 2009, if at all. The 2009 legislation, unlike the FDCA, provides a definition of “tobacco products.” The very broad definition set out in the 2009 legislation would potentially encompass some products that have been or could have been regulated as “drugs” or “devices.” Congress was thus at pains to ensure that it would not inadvertently constrict FDA’s authority under the drug and device provisions. The 2009 legislation expressly 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. 1/14/10 Op. 10 (quoting 21 U.S.C. § 321(rr)(2)-(3)).

The district court’s balancing of the harms in granting an injunction and (implicitly) in denying an administrative stay gives extraordinarily little weight to public health concerns protected by the FDCA and extraordinary deference to plaintiff’s claim of immediate economic harm. The injury resulting from the importation and distribution of plaintiff’s products is irreparable. As discussed below, the court was quite wrong to believe that no injury would result from the use of these harmful and addictive products. Nor is this harm offset by any immediate significant irreparable harm to plaintiff. FDA issued a “Refusal of Admission” for plaintiff’s shipments in March 2009, and this suit has been pending since April 2009. It is entirely proper that this Court be afforded the opportunity to consider the legal basis of the district court’s invalidation of FDA’s regulatory authority.

STATEMENT

Plaintiff Smoking Everywhere imports battery-powered devices that deliver vaporized nicotine into the user’s mouth on inhalation. 1/14/10 Op. 2-3 (Attachment A); *see also* Woodcock Decl. ¶ 3 (Attachment B). The product contains no tobacco and does not burn. Thus, as plaintiff’s promotional material

explains, “it’s NOT a real cigarette, there is NO real smoke, flame, tar or tobacco.” DET 25. These so-called “electronic cigarettes” do, however, deliver “the nicotine hit that smokers crave,” DET 51, offering users a range of nicotine doses including “High Nicotine (16mg), Medium Nicotine (11mg) or Low Nicotine (6mg).” DET 25.

FDA first detained shipments of “electronic cigarettes” imported by plaintiff in 2008 because the product appeared to be an unapproved drug, device or combination product. 1/14/10 Op. 5-6. In March 2009, after administrative proceedings, FDA issued “Refusal of Admission” notices for both shipments. *Id.* at 6. A short time later, FDA added “electronic cigarettes” manufactured by three Chinese companies to an Import Alert that authorizes detention by FDA district offices. *Id.* at 6-7. Intervenor NJOY, another importer, alleges that from June 2008 to May 2009, FDA district offices denied entry to more than thirty-five shipments of such devices produced by 20 other manufacturers, including one of NJOY’s inbound shipments. *Id.* at 7.

After shipments of its products were refused admission into the United States, plaintiff brought this lawsuit in April 2009, contending that electronic cigarettes imported for recreational purposes are exempt from regulation under the drug and device provisions of the FDCA. Plaintiff urged that “electronic cigarettes” should be treated in the same way as real cigarettes under the reasoning of *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), which held that the FDA lacked authority to regulate cigarettes and smokeless tobacco as customarily marketed as drugs or devices.

On January 14, 2010, the court issued what it styled as a “preliminary” injunction that adopts plaintiff’s reasoning and 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.” 1/14/10 Order (Attachment A). A similar injunction was entered with respect to products imported by intervenor NJOY. *Ibid.* The court recognized that electronic cigarettes contain no tobacco and are thus not subject to the “tobacco-specific” legislation cited by the Supreme Court in *Brown & Williamson*, 529 U.S. at 143. *See* 1/14/10 Op. 16-17. 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. *Id.* at 17.

The 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. *Id.* at 20 n.13. The court noted that regulation of nicotine products marketed for “recreational” purposes predated *Brown & Williamson*. *Ibid.* The court believed, however, that the FDA should have revisited its regulation of such nicotine products in light of *Brown & Williamson*, concluding that such regulations are “not in step with the reasoning of that case.” *Ibid.*

The court concluded 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.” *Id.* at 21. The court suggested the FDA jurisdiction over such products would derive, if at all, from provisions of the Family Smoking Prevention and Tobacco Control Act of 2009. That statute contains a definition of “tobacco products,” 21 U.S.C. § 387a(a), that includes “any product made or derived from tobacco that is intended for human consumption,” *id.* § 321(rr)(1). As the district court acknowledged, however, when Congress vested the FDA with this new regulatory authority, it did not thereby constrict its regulatory powers under the drug and device provisions of the FDCA. 1/14/10 Op. 9 n.4, 10. As the court

noted, the 2009 legislation expressly 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. *Id.* at 10 (quoting 21 U.S.C. § 321(rr)(2)-(3)). Thus, the court acknowledged that the 2009 legislation “did not move the definitional line between tobacco products and drugs.” *Id.* at 9 n.4.

The court concluded that the balance of harms and the public interest favored entry of a preliminary injunction. It noted that plaintiff and intervenor claim to derive virtually all of their revenue from the importation of electronic cigarettes into the United States. *Id.* at 27-29. The court believed that importation of these products poses no significant threat to public health, stating that plaintiff and intervenor have already sold hundreds of thousands of electronic cigarettes in the United States “yet FDA cites no evidence that those electronic cigarettes have endangered anyone.” *Id.* at 30.

ARGUMENT

A. The Preliminary Injunction Rests On An Error Of Law.

This case concerns the scope of FDA’s authority to regulate drugs and devices under the Federal Food, Drug, and Cosmetic Act, and the intersection of that authority with FDA’s authority to regulate tobacco products under the Family Smoking Prevention and Tobacco Control Act of 2009. The district court concluded, based on its reading of *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), that FDA might regulate electronic nicotine-delivery devices sold for recreational use under the 2009 legislation, but that its ability to regulate them as drugs under the FDCA is extremely limited. That ruling incorrectly expands *Brown & Williamson* far beyond the subject matter of that decision, and fails to give effect to Congress’ determination in the 2009 legislation to leave

FDA's existing regulatory authority under the FDCA intact with regard to products that might otherwise be subject to regulation under the new statute.

In *Brown & Williamson*, the Supreme 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 Supreme Court stressed that cigarettes and smokeless tobacco were specifically addressed in several federal statutes, including the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. §§ 1331 *et seq.*, and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), 15 U.S.C. §§ 4401 *et seq.* *See Brown & Williamson*, 529 U.S. at 133-134. Noting the FCLAA's express policy of protecting 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. Because FDA's assertion of jurisdiction over cigarettes and smokeless tobacco would then have required that those products be banned, *id.* at 134-135, the Court found the assertion of jurisdiction to be inconsistent with the intent of Congress. *Id.* at 137. It 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.

“Cigarettes” and “smokeless tobacco” are defined terms under the federal statutes discussed by the Supreme Court. *See* 15 U.S.C. § 1332(1) (FCLAA definition of “cigarette”); 15 U.S.C. § 4408 (CSTHEA definition of “smokeless tobacco”). It is undisputed that the FCLAA and the CSTHEA do not apply to the electronic nicotine-delivery devices at issue here, which contain no tobacco.

1/14/10 Op. 16-17.

The rationale of *Brown & Williamson* cannot properly be extended beyond the cigarettes and smokeless tobacco products that were the subject of its holding to products that have never been the subject of any specific federal legislation. Regulating nicotine-delivery devices such as “electronic cigarettes,” not 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 regulated products such as “Favor Smokeless Cigarettes,” “Nicogel Tobacco Hand Gel,” Nicotine Lollipops, Nicotine Lip Balm, and Nicotine Water, *id.* at 20 n.13, and has approved nicotine replacement therapies in the form of gums, transdermal patches, nasal sprays, inhalers, and lozenges.³

These FDA-regulated nicotine products — like electronic cigarettes — have never been subject to the scheme of warnings and restrictions that Congress had imposed on cigarettes and smokeless tobacco even prior to the 2009 legislation. They are 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 made the receipt of certain block grants by states contingent on restricting sales to minors, *see* 42 U.S.C. § 300x-26(a)(1). Instead, as noted above, these nicotine-delivery products have long been regulated under the FDCA, which requires pre-market FDA review for safety and effectiveness. *See* 21 U.S.C. §§ 355(d), 360(c).

It should be stressed that a product such as a nicotine lollipop or a so-called “electronic cigarette” need not be accompanied by therapeutic claims in order to be regulated as a drug or device within the meaning of the FDCA. 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 ...

³ [Http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm198176.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm198176.htm).

mitigation, treatment, or prevention of disease.” 21 U.S.C. §§ 321(g)(1), (h). Nothing in *Brown & Williamson* suggests that such drugs and devices may be imported and sold without the FDA approval required to ensure safety and effectiveness.

In this regard, the district court misunderstood the significance of the distinction drawn in *Brown & Williamson* between tobacco products as “customarily” marketed and tobacco products marketed with “therapeutic” claims. The Supreme Court held that *even* cigarettes and smokeless tobacco could be regulated under the FDCA’s drug and device provisions if they were sold with therapeutic claims. 529 U.S. at 131-32. In other words, the Court recognized an exception to its general holding that cigarettes and smokeless tobacco lay outside FDA’s jurisdiction under the FDCA. That observation did not purport to circumscribe the FDA’s authority to regulate products other than cigarettes and smokeless tobacco simply because they deliver nicotine.

In enacting the 2009 legislation, Congress adopted a definition of “tobacco products” that extends far more broadly than the cigarettes and smokeless tobacco products at issue in *Brown & Williamson*. As the district court noted, the new statute contains a definition of “tobacco product” that includes a product “derived from” tobacco as well as a product made with tobacco. 1/14/10 Op. 18 (citing 21 U.S.C. § 321(rr)(1)). That definition would potentially subject an electronic nicotine-delivery device to regulation under the newly enacted provisions because the nicotine is “derived from tobacco.” Congress also clearly understood, however, that the broad definition in the new legislation would encompass drugs and devices already subject to regulation under the FDCA, and it was at pains to make explicit that it was not altering the FDA’s authority to regulate such drugs and devices under the preexisting FDCA provisions. As the district court recognized, the new statute excludes from the definition of “tobacco product” any article that is a drug,

device or combination product under the FDCA, *id.* at 10 (citing 21 U.S.C. § 321(rr)(2)); provides that such articles shall continue to be regulated under the FDCA provisions that govern drugs, devices, and combination products, *ibid.* (citing 21 U.S.C. § 321(rr)(3)); and provides that nothing in the new legislation shall be construed to limit FDA’s authority under the drug and device provisions to regulate products that are not tobacco products, *id.* at 9 n.4 (citing 21 U.S.C. § 387a(c)(1)). Thus, as the district court acknowledged, the 2009 legislation “did not move the definitional line between tobacco products and drugs.” *Ibid.*

In sum, an electronic nicotine-delivery device does not fall within the scope of the “cigarettes” and “smokeless tobacco” products at issue in *Brown & Williamson*, and nothing in the Supreme Court’s reasoning or the 2009 legislation calls into question FDA’s authority to regulate such products under the drug and device provisions of the FDCA. Contrary to the district court’s holding, *id.* at 14, FDA’s position rests on a reasonable interpretation of the statutes it is charged with administering and is entitled to deference. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

B. The Harm Caused By The Importation Of “Electronic Cigarettes” Is Immediate, Irreparable, And Contrary To The Public Interest.

The danger posed by the unrestricted sale of addictive products containing toxic chemicals cannot seriously be questioned. As discussed above, “electronic cigarettes” are not subject to the array of federal restrictions applicable to cigarettes and smokeless tobacco, including warning requirements, advertising restrictions, and federal restrictions on sales to minors. Even without the benefit of specific evidence of the dangers posed by electronic cigarettes, 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* 1/14/10 Op. 30-31, the government, in seeking a stay, also

called to the district court's attention findings made after FDA's decision to refuse to entry to the particular shipments at issue in this case. Insofar as the preliminary injunction extends beyond the shipments addressed in the administrative records submitted to the district court, 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 (Attachment B). A new drug application for a nicotine replacement product thus 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. 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. However, the findings announced by FDA in July 2009 underscore the potential risks. *Id.* ¶ 9.⁴ Those findings reflect the results of FDA's laboratory analysis of a small sample of cartridges sold by plaintiff Smoking Everywhere and intervenor NJOY. *Ibid.* In the samples analyzed, the electronic cigarettes labeled as containing no nicotine in fact had low levels of nicotine present. *Id.* ¶ 10. Three

⁴ See also *FDA Warns of Health Risks Posed by E-Cigarettes* (July 23, 2009), available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm.

different electronic cigarette cartridges with the same label each emitted 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. Diethylene glycol is a solvent and is toxic to humans. 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 currently have no way to know what types or concentrations of potentially harmful chemicals (or what dose of nicotine) they are inhaling when they use these products. *Id.* ¶ 13. They have no way to know whether the vapor contains harmful contaminants. *Ibid.* Because electronic cigarettes have been subject to so little testing and analysis, the long-term health consequences are unknown. *Id.* ¶ 14. It is known, however, that nicotine can cause elevations in blood pressure and heart rate. *Ibid.* Short-term side-effects reported from electronic cigarette use 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.*

To the extent they remain unapproved and unregulated products, electronic cigarettes may attract new nicotine users and increase nicotine dependence. *Id.*

¶ 15. 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.* 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.*

The danger posed by the unrestricted sale of addictive products containing toxic chemicals is not diminished by the possibility, raised by the district court, that FDA could regulate electronic cigarettes under the 2009 legislation. Even if electronic cigarettes were “tobacco products” within the meaning of that legislation, it appears that they would not be subject to FDA regulation at this time because the authority vested in FDA by the 2009 legislation extends only to “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.*” 21 U.S.C. § 387a(b) (emphasis added). Electronic cigarettes are not “cigarettes, cigarette tobacco, roll-your-own tobacco, or smokeless tobacco” within the meaning of the 2009 legislation. *See* 21 U.S.C. §§ 387(3), (4), (15), (18) (definitions). Thus, it appears that electronic cigarettes would not be subject to FDA’s new authority absent a rulemaking. In any event, for the reasons already discussed, electronic cigarettes are not “tobacco products” within the meaning of the 2009 legislation, which carves out from the definition of “tobacco product” any product that is a drug, device or combination product. *Id.* § 321(rr)(2)-(3)). Thus, they are properly regulated under the drug and devices provisions of the FDCA rather than as “tobacco products.”

CONCLUSION

This Court should issue a stay pending appeal of the district court's injunction of January 14, 2010, and an immediate temporary stay to permit consideration of this stay motion.

Respectfully submitted,

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FEBRUARY 2010

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of February, 2010, I caused the foregoing motion, with attachments, to be filed with this Court in hard copy and through the ECF system and served on the following counsel by electronic mail:

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