REPLY IN SUPPORT OF MOTION FOR STAY PENDING APPEAL

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

The district court concluded that the FDA could not regulate plaintiffs' so called "electronic cigarettes" as a drug or device under the Food Drug and Cosmetics Act ("FDCA"), and that the FDA could not deny entry of these products into the United States on this basis. Although styled a preliminary injunction, the order squarely holds that the agency lacks authority "to regulate electronic cigarettes as a drug-device combination" (1/14/10 Order 2), and it contemplates no further proceedings regarding that determination. Accordingly, the district court's order turns on an error of law, even apart from the court's abuse of discretion in considering the balance of harms.

1. The district court erred in concluding that the reasoning of FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000), precludes the FDA's regulation of plaintiffs' nicotine-delivery device under the FDCA. Plaintiffs' opposition identifies no basis for extrapolating that conclusion from the Supreme Court's decision. The Court in Brown & Williamson invalidated a rule that would have, for the first time, asserted FDA jurisdiction over cigarettes and smokeless tobacco as customarily marketed. As plaintiffs do not dispute, the selling point of their product is precisely that it is "NOT a real cigarette, there is NO real smoke, flame, tar or tobacco." DET 25 (promotional materials by plaintiff Smoking Everywhere, Inc.) (Docket Entry 15).

It is a high-tech device constructed with a metal casing, lithium battery, atomizer, microprocessor, and a cartridge containing various chemical substances. Other than its superficial appearance, it is a "cigarette" only in the sense that it orally delivers "the nicotine hit that smokers crave." DET 51 (Docket Entry 15). As plaintiffs acknowledge (Opp. 9), these "electronic cigarettes" are not "cigarettes" within the meaning of federal law and do not fall within the scope of any of the several statutes that the Supreme Court found relevant in Brown & Williamson in determining FDA authority to regulate cigarettes and smokeless tobacco. Plaintiffs' products are not subject to the provisions that

"require that health warnings appear on all packaging and in all print and outdoor advertisements," Brown & Williamson, 529 U.S. at 143 (citing Federal Cigarette Labeling and Advertising Act 15 U.S.C. §§ 1331, 1333 and the Comprehensive Smokeless Tobacco Health Education Act,15 U.S.C. §§ 4401, 4402); they are not covered by the prohibitions on "advertising of tobacco products through 'any medium of electronic communication' subject to regulation by the Federal Communications Commission," id. at 144 (citing 15 U.S.C. §§ 1335, 4402(f)); they were not addressed in the triennial reports of the Secretary of HHS on the "addictive property of tobacco," ibid. (citing 42 U.S.C. § 290aa-2(b)(2)); and, in contrast 2 to cigarettes and smokeless tobacco products, federal law does not require States to outlaw the sale or distribution of "electronic cigarettes" to minors as a condition on the receipt of block grants, ibid. (citing 42 U.S.C. § 300x-26(a)(1)).

Indeed, until very recently, no State regulated the sale of "electronic cigarettes," which plaintiffs offer in child-friendly flavors such as chocolate, vanilla, strawberry, apple, and cherry. E.g., DET 28 (Docket Entry 15).3 Plaintiffs shrug off as "irrelevant" (Opp. 9) the panoply of regulations to which their product is not subject, even though it was crucial in Brown & Williamson that those regulatory schemes applied to cigarettes and smokeless tobacco. As the Court explained, "the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States." Brown & Williamson, 529 U.S. at 137, 139. Accordingly, the Court reasoned, Congress could not also have meant to subject cigarettes and smokeless tobacco to potential removal from the market as unapproved drugs under the FDCA. 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. 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. In contrast, in 1987, a decade before the rule at issue in Brown & Williamson, the FDA had asserted

jurisdiction over a nicotine product indistinguishable in all relevant respects from the products at issue here. The "Favor Smokeless Cigarette" was a small plastic 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." AR NIC 10-11, 1 (Docket Entry 17). Although the manufacturer made no therapeutic claims, FDA advised that these products were unapproved new drugs and that FDA would take action if the company did not discontinue their marketing. Id. at 10-11.4 Plaintiffs suggest (Opp. 13 n.2) that Brown & Williamson called this regulation into question. As the decision makes clear, however, the Court and the FDA understood that regulation of such devices stood on an altogether different footing than regulation of real cigarettes and smokeless tobacco products. Brown & Williamson is explicit that the "tobacco products" at issue were those over which the FDA had not previously asserted jurisdiction. Those products were the subject of other regulatory statutes that Congress had enacted "to address the issue of tobacco and health." Brown & Williamson, 529 U.S. at 156. As the Supreme Court declared, Congress had "created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA." Ibid. Brown & Williamson addressed a new assertion of jurisdiction over cigarettes and smokeless tobacco "as customarily marketed -- that is, without manufacturer claims of therapeutic benefit." Id. at 127. The Court did not question FDA's authority to regulate even cigarettes and smokeless tobacco products if manufacturers asserted therapeutic benefits. Plaintiffs draw the mistaken inference (adopted by the district court) that the Supreme Court thereby called into question the FDA's authority to regulate other products, such as the "Flavor Smokeless Cigarette," unless their manufacturers made "therapeutic" claims. Under the plain terms of the FDCA, "drug" and "device" are defined to include articles that are either "intended to affect the structure or any function of the body" or "intended for use in the ... mitigation, treatment, or prevention of disease." 21 U.S.C. §§ 321(g)(1), (h). The Supreme Court did not purport to constrain the application of those criteria to products over which the FDA had already exercised jurisdiction and that did not fall within the scope of the regulatory statutes

cited by the Court in determining the intended scope of the FDCA with regard to cigarettes and smokeless tobacco.5 Plaintiffs point to no federal statutes analogous to those cited in Brown & Williamson that regulate their product and reflect a "collective premise" that electronic nicotine-delivery devices "will continue to be sold in the United States." This Court's decision in Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980), did not, as appellees suggest (Opp. 8), eliminate from the FDCA's "drug" and "device" definitions the provisions that include articles "intended to affect the structure or any function of the body." In that case, the Court sustained FDA's refusal to assert jurisdiction over cigarettes, citing FDA's repeated disavowals to Congress of such authority. See id. at 241; see also Brown & Williamson, 529 U.S. at 146 (quoting FDA brief's in Action on Smoking and Health). The Court also found inadequate the evidence presented of intended product use "to affect the structure or any function of the body of man," concluding that the Commissioner had not acted arbitrarily or capriciously in determining "that this [was] not the proper case in which some evidence of consumer use, even if demonstrating the appropriate intent, may suffice to establish the requisite statutory intent[.]" Action on Smoking and Health, 655 F.2d at 246. Brown & Williamson, 529 U.S. at 137, 139. Nor, of course, does regulation of such devices impinge on "one of the greatest basic industries of the United States." Id. at 137.6

In sum, as plaintiffs recognize, "the Supreme Court's ruling was based on its appreciation that Congress could not plausibly be understood to have intended the regulation of traditional tobacco products as drugs or devices." Opp. 10 (emphasis added). And plaintiffs identify no basis for extending the Court's reasoning to a battery-powered device for nicotine inhalation.

2. Plaintiffs' reliance on the 2009 legislation (Opp. 10) is equally misplaced. As explained in our stay motion, the 2009 legislation vests FDA with authority to regulate "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," and permits the Secretary to regulate "any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). Congress contemplated that the Secretary might exercise this discretion to regulate "cigars," "little cigars," and "pipe tobacco," and thus provided that the

Secretary may not ban these products. Id. § 387g(d)(3)(A). At the same time, Congress recognized that its new definition of "tobacco product" — which includes products "derived from tobacco" as well as products that contain tobacco, id. § 321(rr)(1) — would potentially reach nicotine drugs and devices already subject to regulation under the FDCA, and made clear that it was not altering the FDA's authority to regulate such drugs and devices under the preexisting provisions. Congress thus excluded from the definition of "tobacco product" any article that is a drug, device or combination product under the FDCA, id. § 321(rr)(2)); provided that such articles shall continue to be regulated under the FDCA provisions that govern drugs, devices, and

6 As plaintiffs recognize, "there is no domestic manufacturer of electronic cigarettes." 1/14/10 Op. 28 (citing Complaint ¶ 12). They thus rely entirely on overseas manufacturers. Ibid.

Combination products, id. § 321(rr)(3)); and provided 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. § 387a(c)(1). 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 the FDA's preexisting authority under the FDCA, FDA's determination to regulate these products under its drug and device authority is plainly entitled to deference. This case concerns the intersection of two statutes that FDA is charged with administering, and the 2009 legislation expressly vests FDA with the responsibility to determine which tobacco products it "deems by regulation to be subject to" the new provisions. Id. § 387a(b). At a minimum, the FDA's determination reflects a reasonable interpretation of the statutes it is charged with implementing.

B. The Balance Of Harms And The Public Interest Strongly Militate In Favor of A Stay To Permit Review By This Court. As plaintiffs observe, "the District Court held that Appellees' promotional materials are aimed "toward encouraging nicotine use." Opp. 13 (quoting Mem. Op. at 22). Plaintiffs acknowledge, as they must, that "'[n]icotine in high doses can be dangerous and even fatal,'" Thomas Decl. ¶ 7, although they seek to allay fears by declaring that "[d]eath from nicotine inhalation alone is extremely rare," ibid. They admit that the

nicotine yield in the cartridges sampled by FDA varied widely from the doses marked on the labeling, id. ¶ 8, but assert that the amounts were not high enough to have a "significant adverse toxicological effect," ¶ 7. They concede that the toxic chemical diethylene glycol was detected, id. ¶ 9, but declare that it was found in "only one" of 18 cartridges tested and that the "likelihood of a significant exposure" is "very low." Ibid. They acknowledge that "various Tobacco-Specific Impurities" were identified, but insist that "only one, myosmine," is "potentially genotoxic, `raising significant safety concerns.'" Id. ¶ 14; see also id. ¶ 15. These responses do not reassure. As plaintiffs do not dispute, they seek to import and distribute large quantities of cartridges containing toxic chemicals in unknown amounts that are subject to none of the manufacturing controls required for FDA-approved nicotine-delivery products. As our motion explained, a manufacturer of an FDA-approved nicotine product must have in place manufacturing controls to ensure that each individual product contains an identified and accurately calibrated amount of nicotine, and must test for the presence of contaminants. Woodcock Decl. ¶ 7. Moreover, FDA approved nicotine therapies must bear precautions for patients with cardiovascular disease. Id. ¶ 14. By contrast, the "electronic cigarettes" made in China and other countries are subject to none of these manufacturing controls and bear no warnings. Nor are they subject to the array of requirements and restrictions that federal law imposes on real cigarettes, including Surgeon General warnings, advertising restrictions, and restrictions on sales to children. The danger posed by the unrestricted distribution of unregulated products containing toxic chemicals cannot seriously be questioned. Even apart from the acute health risks that these products pose, there is no dispute that the nicotine is "a highly addictive pharmacological agent." Opp. 17. Indeed, plaintiff Smoking Everywhere proclaims that the express purpose of its "electronic cigarettes" is to deliver "the nicotine hit that smokers crave." DET 51 (Docket Entry 15). The distribution of these nicotine-delivery devices — which are offered in candy flavors, DET 28 (Docket Entry 15)— thus presents a serious risk of addicting new users, including children. Woodcock Decl. ¶ 5. Plaintiffs' paid consultant does "not believe that the results of the [FDA] study demonstrate any significant risk to consumers of e-cigarettes from nicotine poisoning, or exposure to" the other

toxins identified in the sampled cartridges. Thomas Decl. ¶ 17. But the purpose of the sample analysis was not to determine whether plaintiffs' products are safe. That is the purpose of the scientific studies required to support an application to market a new drug. See 21 U.S.C. § 355. Nor could a court discount the health risks associated with "electronic cigarettes" even if the FDA had identified not a "single instance" of "an adverse health effect" from "electronic cigarettes," (Opp. 17)– although, in fact, short-term side effects including racing pulse, dizziness, slurred speech, mouth ulcers, heartburn, coughing, diarrhea, and sore throat have been reported, see Woodcock Decl. ¶ 14. The long-term health consequences are unknown precisely because "electronic cigarettes" have been subject to so little testing and analysis. Ibid. Moreover, adverse health effects are under-reported even for approved drugs, and are particularly under-reported for products that are not FDA approved. Id. ¶ 8. The safety of an unapproved drug is not determined on the basis of anecdotal reports; it is determined through an evaluation of clinical studies or comparable scientific evidence. Id. ¶¶ 6, 8.7 Plaintiffs do not claim that their products have any redeeming social value. To the contrary, they disavow any "therapeutic" uses and proclaim that their products are "aimed toward encouraging nicotine use." Opp. 13. They assert a right to profit from the immediate importation of their products into the United States, claiming that "in the two weeks following the issuance of the preliminary injunction NJOY relied on that Order (and FDA's silence) and ordered new units from its suppliers to fulfill a significant number of new orders." Opp. 16. Even if FDA had been "silent" for the two weeks following issuance of the injunction, plaintiffs could not manufacture irreparable injury by swiftly committing Although intervenor-p 7 laintiff Sottera Inc., which does business under the name NJOY, claims that it has imported and sold "electronic cigarettes" in the United States since February 2007, see Leadbeater Decl. ¶ 2-3, that claim is inconsistent with FDA's records and with the records of the State of Arizona Corporation Commission, which show that Sottera Inc. was not incorporated until March 2007.
See www.starpas.azcc.gov(Corporate Records). to fill new orders. The injunction did not purport to require the immediate importation of any products. To the contrary, the district court expressly reserved judgment as to whether appellees' products

could be detained under other sources of authority, 1/14/10 Op. 26 n.18, and further indicated that NJOY's products could be detained under the drug and device authority if supported by evidence that the products are intended to have a therapeutic effect. 1/14/10 Order at 2.

In any event, as the government explained in its district court motion, government counsel contacted counsel for plaintiff and intervenor-plaintiff on January 22, the week after the injunction issued, to seek consent for an administrative stay. See Docket Entry 58. A full week later, on January 29, counsel for plaintiff Smoking Everywhere advised the government that it would oppose. Counsel for the intervenor-plaintiff did not respond even at that time. Thus, the government moved for an administrative stay, and filed a notice of appeal the day that motion was denied. Plaintiffs' maneuvers in this period cannot be cited as a basis for frustrating meaningful review by this Court.

CONCLUSION

The injunction of January 14, 2010, should be stayed pending appeal.