UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' SUPPLEMENTAL BRIEF IN OPPOSITION TO PLAINTIFF'S AND INTERVENOR'S MOTIONS FOR A PRELIMINARY INJUNCTION

At the preliminary injunction hearing on May 15, 2009, the Court inquired about the effect that the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"), which was signed into law on June 22, 2009, might have on the legal issues before the Court. *See* FSPTCA, Public Law No: 111-31, H.R. 1256, 111th. Cong. (2009) (available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1256enr.txt.pdf. The parties were unable to fully address the Court's questions at that time because the bill was still pending. The government now submits this summary of provisions that may be relevant to FDA's authority over electronic cigarettes, and responds to plaintiff's and intervenor's supplemental briefs on the same subject.

Through this legislation, Congress confirmed its intention that *some* nicotine- and tobacco-containing products were already properly subject to FDA's existing regulatory authority

under the Federal Food, Drug, and Cosmetic Act ("FDCA") before this recent enactment. The new law also expands FDA's jurisdiction by granting it the authority to regulate *additional* nicotine- and tobacco-containing products that previously were not within FDA's jurisdiction. Accordingly, the question for products such as the electronic cigarettes distributed by plaintiff Smoking Everywhere, Inc. ("SE") is no longer whether Congress intends for FDA to regulate electronic cigarettes derived from tobacco, but, for each product, under which authorities – as drugs, devices, and combination products, or as tobacco products.

The answer with respect to the products at issue in this action is still the same: FDA's original conclusion – that the two shipments of E-cigarettes that were referenced in the complaint are combination products regulated under FDA's drug and device authorities – remains correct. In the administrative proceeding documented in the administrative record provided to this Court, FDA found, after examining the product, the claims made in the product labeling, and information SE submitted to FDA, that SE's product met the definition of both a drug and device under the FDCA. Nothing in the FSPTCA alters or affects that conclusion.

DISCUSSION

I. IN THE FSPTCA, CONGRESS RECOGNIZED THAT TOBACCO PRODUCTS MAY BE DRUGS, DEVICES, AND COMBINATION PRODUCTS

In enacting the FSPTCA, Congress confirmed its understanding that certain tobacco products are properly regulated as drugs, devices, and combination products under the FDCA. The FSPTCA amended the FDCA by adding the new term "tobacco product," defined as follows:

> (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 [21 U.S.C. § 321](g)(1), a device under [21 U.S.C. § 321](h), or a combination product described in [21 U.S.C. § 353](g).
> (3) The products described in paragraph (2) shall be subject to chapter V of this Act.[1]

FSPTCA, Sec. 101(a). Accordingly, under paragraph (2) of this definition, any product that is a drug, device, or combination product under the FDCA will not be considered a "tobacco product" whether or not it contains ingredients derived from tobacco.

By excluding drugs, devices, and combination products from the definition of "tobacco product," Congress confirmed its intention that tobacco-containing products that are subject to FDA's pre-existing jurisdiction are still subject to that jurisdiction. Congress made clear that nothing in the FSPTCA "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 Act that are not tobacco products under chapter V or any other chapter." FSPTCA, Sec. 901(c)(1). In this manner, the FSPTCA established parallel tracks for FDA regulation of nicotine- and tobacco-containing products depending on whether or not they are drugs/devices/combination products. Any nicotine- or tobacco-containing product, whether or not previously marketed, that meets the definition of "drug" or "device" under the FDCA (for example, because drug claims are made for the product), will continue to be regulated under the drug/device/combination product authorities of the FDCA. *See* FSPTCA, Sec. 101(a)(3).[2]

For products derived from tobacco that are *not* subject to the drug/device/combination

---

[1]Chapter V of the FDCA includes the substantive provisions governing drugs/devices/combination products and is codified at 21 U.S.C. §§ 351-360ccc.

[2]Congress also made a series of findings that demonstrate that Congress recognizes the drug-like attributes of tobacco products, including that "[n]icotine is an addictive drug" and that "[t]obacco dependence is a chronic disease." FSPTCA, Sec. 2, ¶¶ (3) & (33).

product authorities of the FDCA, the FSPTCA provides that those products are subject to regulation under the provisions of the FSPTCA and not under the existing drug/device/combination product authorities. *See* FSPTCA, Sec. 901(a). Section 901(a) of the FSPTCA provides that tobacco products "shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V." As noted, chapter V of the FDCA includes the substantive provisions governing drugs, devices, and combination products and is codified at 21 U.S.C. §§ 351-360ccc.

The FSPTCA similarly defines "modified risk tobacco product" as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease." *See* FSPTCA, Sec. 911(b)(1). By including the defined term "tobacco product" within the definition of "modified risk tobacco product," Congress incorporated the limitation of the former definition into the latter definition, so that drugs, devices, and combination products are excluded from "modified risk tobacco product" as well. Congress confirmed this construct in explicitly stating that products intended to be used to treat tobacco dependence and approved as drugs or devices would be regulated under the FDA's existing drug and device authorities and are not "modified risk tobacco products" under the FSPTCA. *See* FSPTCA, Sec. 911(c).

II. THE FSPTCA DOES NOT AFFECT THE OUTCOME OF THIS CASE

The FSPTCA does not provide any basis for FDA to change its original conclusions with respect to the products in this action. As the administrative record shows, FDA properly found, based on its examination of the evidence, that the shipments of E-cigarettes referenced in the complaint are combination products that are regulated under FDA's drug and device authorities. *See* Defendants' Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction

("U.S. Mem.") at 10-11, 16-21. As the government explained in its opposition brief, SE's E-Cigarette vaporizes nicotine, a recognized pharmacological agent, for inhalation by consumers. U.S. Mem. at 18. The promotional material connected with the refused shipments contained claims that represent and suggest that the product will provide the same drug effects on the structure and function of the human body as cigarettes. *Id*. at 19-21. Based on this evidence, FDA properly concluded that these products meet the definitions of drug and device under the FDCA. Because the products are excluded from the definition of "tobacco product" pursuant to Section 101(2) of the FSPTCA, FDA's original conclusion remains correct even after the enactment of the FSPTCA.

Plaintiff, in its supplemental brief, acknowledges the existence of the second part of the definition of tobacco products, which excludes drugs, devices, and combination products, Pl. Supp. Mem. at 3, but then proceeds to ignore it in its analysis. The intervenor completely ignores the exclusion altogether. This Court, however, cannot disregard Section 101(a)(2) of the FSPTCA. When a term is defined as "A but not B," one cannot simply ignore the "but not B" portion of the definition.

Instead, plaintiff assumes that its product is a "tobacco product" that would be regulated under the new provisions of the FSPTCA, *id*. at 5, and the intervenor appears to contend that its product is a modified risk tobacco product. Int. Supp. Br. at 4-5.[3] It is both premature and

[3] There appears to be no dispute among the parties that SE's E-cigarettes satisfy the first prong of the definition of "tobacco products," in that they are "made or derived from tobacco [and] intended for human consumption." FSPTCA, Sec. 101(1). *See* Pl. Supp. Mem. at 5 ("the electronic cigarette falls within the definition of 'tobacco product'"); Int. Supp. Br. at 3. In addition, the intervenor has alleged that its product allows "users to inhale liquid nicotine vapor distilled from natural tobacco plants." Intervenor Complaint ¶ 1. Hence, if these products did not meet the definition of a drug, device, or combination product, they would be subject to FDA

unnecessary for FDA to opine (or for the Court to consider) how these authorities would specifically be applied to any electronic cigarettes that did not meet the definition of drug or device. Because that issue is not presented by the administrative action challenged in this case as reflected in the administrative record before the Court, neither plaintiff nor the intervenor has a ripe claim with respect to FDA's application of the FSPTCA to electronic cigarettes.

III. PLAINTIFF AND THE INTERVENOR MISCHARACTERIZE THIS CASE

In its supplemental brief, plaintiff seeks to recast its complaint as embodying the issue of "whether the FDA exceeded its authority by declaring, without opportunity for public notice and comment, that E-cigarettes were drug-device combination products that could not enter the country unless approved by the FDA," as well as imposing an "import ban" on E-cigarettes. Pl. Supp. Mem. at 4; *see also id.* at 5-6. This statement does not fairly represent the posture of this case.

There is no evidence in the record of any categorical declaration by FDA that it is imposing an "import ban" on all electronic cigarettes. FDA's determination regarding SE's E-cigarettes that were detained and refused was based on the administrative record regarding those products. *See* U.S. Mem. at 9-11; 16-21. There is nothing that requires public notice and comment in connection with this administrative decision.

Nor is plaintiff's contention regarding notice and comment appropriate at this juncture. The complaint referred to Import Alert 66-41 ("IA 66-41"), which contains a list of drug products that are not approved for distribution in the United States and that may be detained by FDA field personnel pending the submission of testimony or other evidence by the importer and a final

---

jurisdiction under the FSPTCA.

decision whether the products should be released into commerce or refused admission. Included on that list are electronic cigarettes manufactured by three Chinese firms. As discussed in the government's opposition memorandum, the import alert is a mechanism for FDA headquarters to communicate information and provide guidelines to FDA field personnel and the regulated industry. U.S. Mem. at 31. Further, the import alert pertains only to detention, not the ultimate refusal of entry. In addition, upon detention, importers have the opportunity, after detention but before the ultimate decision regarding admission or refusal, to present evidence to the agency. *Id.* at 31-32. FDA makes admissibility decisions with respect to electronic cigarettes based on evidence related to the specific products in question and has not declared an industry-wide "ban."[4] For this reason, the import alert is not a substantive rule that requires notice-and-comment rulemaking. *Id.* at 30-35. Plaintiff failed to argue that point either at the hearing or in its reply brief, and thereby essentially conceded it. Plaintiff offers no authority to support its argument that FDA must engage in notice-and-comment rulemaking related to its individual import detention decisions – or with respect to IA 66-41.

The intervenor similarly mischaracterizes the issues before the Court. The intervenor asserts that FDA "contend[s] that E-cigarettes are 'drug-device' combination products simply because they contain nicotine." Int. Supp. Br. at 1. That is not an accurate description of the case before this Court. As the administrative record demonstrates, FDA made its determination regarding the shipments of SE's E-cigarettes based on an examination of the product and its

[4]Plaintiff further suggests that this alleged import "ban" contradicts the FSPTCA's prohibition on a complete ban of all cigarettes. Pl. Supp. Mem. at 3, 5. Plaintiff, however, is using the term "ban" loosely. FDA's position with regard to cigarette alternatives that meet the definition of "drug" is that there must be an approved new drug application before the product is marketed. That position is not the equivalent of a "ban."

labeling and promotional material, and concluded that the nature of the product together with its claims supported the conclusion that the products were drug-device combination products. U.S. Mem. at 16-17. The intervenor's sole support for its assertion that FDA has made a categorical determination regarding e-cigarettes is a selective quotation from an email by an FDA Compliance Officer in which he expressed a "belie[f]" that it would not be possible to relabel the product to avoid FDA's drug/device/combination product authority. Int. Supp. Br. at 2 n.2. *See* AR DET 92. The Compliance Officer, however, continued by explaining that the importer may make a written proposal to the agency to obtain a more official response. Further, an email from an FDA employee does not constitute an authoritative binding statement by the agency. *See* 21 C.F.R. § 10.85(k) (informal communications by FDA employees are not binding).

The intervenor also incorrectly asserts that a product is not a "drug" within the meaning of the FDCA unless the manufacturer makes "medical or therapeutic claims . . . on the product's labeling or promotional materials." Int. Supp. Br. at 2. Such a restrictive definition is contrary to the language of the statute, FDA regulations, FDA administrative practice, and case law. The FDCA defines "drug" to include, among other things, "articles (other than food) intended to affect the structure or any function of the body," as well as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B) & (C). Thus, whether an article is a drug depends on its "intended use." The "intended use" of a product refers, in turn, "to the objective intent of the persons legally responsible for the labeling of drugs," which "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or

their representatives. . . ." 21 C.F.R. § 201.128.

The case law further supports a far broader definition of "drug" than the intervenor espouses. *See, e.g., Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) ("[I]t is well established that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.") (internal citations and quotation marks omitted); *United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (Despite the absence of labeling, "the surrounding circumstances of the sales" demonstrated that the intended use of the nitrous oxide product was to affect the structure or any function of the body of man). *See also* U.S. Mem. at 4-5, 16-21.

The intervenor also asserts that FDA has made no effort to specify how NJOY's E-cigarettes, without claims, could be considered a "drug or device." Int. Supp. Br. at 5. The intervenor, however, chose to seek to intervene in this case even though there had been no final agency action with respect to its product, or an administrative record for the Court to review. Having obtained permission to express its views despite its failure to await the completion of the administrative process, it cannot be now heard to complain about the lack of an administrative record regarding its product. Additionally, for this reason, NJOY does not present a ripe injury or case or controversy, and its complaint should be dismissed.

CONCLUSION

For the reasons stated above and in the government's original opposition brief, the motions for preliminary injunction should be denied.

Of Counsel:

DAVID S. CADE
Acting General Counsel

MICHAEL M. LANDA
Acting Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

KAREN E. SCHIFTER
Associate Chief Counsel, Litigation
U.S. Dept. of Health & Human Services
Office of the General Counsel
5600 Fishers Lane
Rockville, MD 20857
301-827-1152

July 10, 2009

Respectfully submitted,

TONY WEST
Assistant Attorney General

ANN M. RAVEL
Deputy Assistant Attorney General

EUGENE M. THIROLF
Director

/s/
DRAKE CUTINI
Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
202-307-0044
drake.cutini@usdoj.gov