UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' OPPOSITION TO MOTION OF
SMOKE ANYWHERE USA, INC., TO INTERVENE AS PLAINTIFF

Defendants oppose the motion by Smoke Anywhere USA, Inc., to intervene as plaintiff. The motion and the proposed intervenor complaint are premised on two mistaken assumptions. First, Smoke Anywhere assumes that defendant United States Food and Drug Administration ("FDA") is continuing to exercise drug and device regulatory authority over electronic cigarettes without therapeutic claims. *See, e.g.*, Proposed Intervenor Complaint ("Prop. Compl.") ¶¶ 11, 28, 33, 56. That assumption is wrong. The D.C. Circuit held in this case that FDA can regulate tobacco products under the drug/device provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") only if the products are "marketed for therapeutic purposes." *Sottera, Inc. v FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010). To comply with that holding, FDA has changed its import policy, and no longer refuses shipments of e-cigarettes that do not make therapeutic claims. Declaration of Domenic J. Veneziano, Director, Division of Import Operations and Policy ("Veneziano Decl.") ¶ 5 (attached hereto).

Second, Smoke Anywhere asserts that this litigation is in an "early stage" because there is no answer filed, no trial date, and no schedule for further proceedings. Memorandum of

Points and Authorities in Support of Smoke Anywhere's Motion to Intervene as Plaintiff ("Interv. Mem.") at 13. That statement fails to acknowledge the current status of the case: there have been extensive proceedings to date, including briefing and oral argument in both this Court and the D.C. Circuit spanning almost two years. At present, the government has until April 25, 2011, to determine whether to petition the United States Supreme Court for a writ of *certiorari*, and has therefore sought an extension on the time to file an answer. Once the appeal is resolved, it is not likely that there will be much in the way of further proceedings. By the time proceedings resume in the district court, the fundamental legal question underlying the original case will be resolved, and this litigation will likely be entering a *concluding* stage.

For these reasons, Smoke Anywhere cannot establish the requirements for intervention. Its claims are moot, it lacks standing, and its attempt to intervene is untimely. Accordingly, the Court should deny the motion to intervene.

BACKGROUND

I. History of this Litigation

The original plaintiff, Smoking Everywhere, Inc. ("SE") filed this lawsuit on April 28, 2009, and was joined shortly thereafter by plaintiff-intervenor Sottera, Inc. d/b/a NJOY ("Sottera"). SE and Sottera, distributors of imported electronic cigarettes, cigars, and their accessories ("e-cigarettes"), challenged FDA's decision to refuse entry of SE's products into the United States as unapproved drug-device combinations under the FDCA.

The FDCA and FDA's implementing regulations provide that, if an imported drug or device is adulterated, misbranded, or an unapproved new drug, FDA may detain it and, after notice and an opportunity for a hearing, refuse admission of the product into the United States.

21 U.S.C. § 381(a); 21 C.F.R. § 1.94. SE complained of two specific FDA refusals of shipments of its e-cigarettes and components. SE's primary allegation was that, in light of the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), FDA has no drug or device jurisdiction over e-cigarettes, and therefore FDA's refusal of the shipments was unlawful.

SE also claimed that Import Alert 66-41 ("IA 66-41") was a rule that should have been published for notice and comment rulemaking. IA 66-41 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 decision whether the products should be released into commerce or refused admission. In late March and early April 2009, FDA amended IA 66-41, adding electronic cigarettes manufactured by three Chinese firms.

After the enactment in June 2009 of the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act"), Pub. L. No. 111-31, 123 Stat. 1776, the Court requested further briefing on the relevance of that law to the questions before it. On January 14, 2010, the Court granted SE's and Sottera's motions for preliminary injunction. *Smoking Everywhere, Inc. v. United States,* 680 F. Supp. 2d 62 (D.D.C. 2010). The Court enjoined FDA from detaining or refusing admission to SE's and Sottera's e-cigarettes unless the products were intended to have a therapeutic effect, and stated as follows:

> [A]bsent substantial evidence of the manufacturer's objective intent that its electronic cigarettes affect the structure or function of the body in a way distinguishable from "customarily marketed" tobacco products or that its electronic cigarettes have the therapeutic purpose of treating nicotine withdrawal, there is no basis for FDA to treat electronic cigarettes, as they are marketed by the plaintiffs in this case, as a drug-device combination when all they purport to do is

offer consumers the same recreational effects as a regular cigarette.

Id. at 75. The Court did not address or grant any relief with respect to the claim that IA 66-41 was an improperly promulgated rule.

The government appealed and obtained a stay of the injunction pending appeal. While the appeal was pending, SE withdrew from the case, leaving Sottera as the sole plaintiff. On December 7, 2010, the D.C. Circuit issued a per curiam judgment affirming this Court's decision. The D.C. Circuit held that nicotine-containing products with therapeutic claims can be regulated as "drugs" and "devices" under the FDCA, but that other customarily marketed nicotine-containing products can be regulated only as "tobacco products" under the Tobacco Control Act. 627 F.3d at 898. On December 15, 2010, the D.C. Circuit, on its own motion, dissolved the stay of this Court's preliminary injunction order. On December 20, 2010, the government filed a motion to reinstate the stay and petitions for rehearing and rehearing *en banc*. On January 24, 2011, the D.C. Circuit denied the government's petitions for rehearing and rehearing *en banc*, and denied the motion to reinstate the stay as moot.

After the D.C. Circuit issued its decision, FDA directed its field operations not to detain or refuse any shipments of e-cigarettes without therapeutic claims. Veneziano Decl. ¶ 5. When the D.C. Circuit denied the government's petitions for rehearing on January 24, 2011, FDA reissued its directive that e-cigarettes should not be detained or refused unless they are accompanied by labeling that makes therapeutic claims, including electronic cigarettes imported specifically by Sottera, Inc. d/b/a NJOY. *Id.*

II. Smoke Anywhere's Proposed Complaint

Smoke Anywhere alleges that it imports and distributes e-cigarettes. Its proposed complaint – filed nearly two years after the original complaint, 18 months after its alleged injury, and more than a year after this Court's injunction – largely mimics the original complaint filed by SE. The counts and the prayer for relief are essentially the same. It claims that FDA's assertion of jurisdiction over e-cigarettes is *ultra vires* (Count I); that the addition of e-cigarettes to IA 66-41 violated the Administrative Procedure Act (APA) (Count II); and that Smoke Anywhere is entitled to declaratory relief (Count III).

In terms of injury, Smoke Anywhere alleges that FDA detained, on July 17, 2009, and refused, on October 22, 2009, a shipment of its e-cigarettes on the ground that the products were unapproved new drugs. Prop. Compl. ¶ 27. There are no allegations of more recent FDA action against Smoke Anywhere or its products. Smoke Anywhere alleges that it fears that FDA will continue to refuse and detain its e-cigarettes as unapproved new drugs, *id*. ¶ 28, but it cites nothing to substantiate that fear.

ARGUMENT

Smoke Anywhere has not and cannot establish the requirements for either intervention of right or by permission. Rule 24 of the Federal Rules of Civil Procedure governs the ability of a non-party to intervene as a party in an existing lawsuit. Unless a right to intervene is unconditionally granted by federal statute (which is not the case here), a non-party has a right to intervene in a case only if it shows that (1) its motion to intervene was timely filed; (2) it has an interest relating to the property or transaction that is the subject of the action; (3) it is so situated

that without intervention the disposition of the action may as a practical matter impair or impede its ability to protect its interest; and (4) its interest is not adequately represented by existing parties. See Fed. R. Civ. P. 24(a); *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003). A prospective intervenor must satisfy all four elements of Rule 24(a) to intervene as of right. *Jones v. Prince George's County*, 348 F.3d 1014, 1019 (D.C. Cir. 2003). In addition to these requirements of Rule 24, in order to intervene as of right, a prospective intervenor must establish that it has Article III standing. *Fund for Animals, Inc.*, 322 F.3d at 731-32.

Permissive intervention is governed by Rule 24(b), and requires that the prospective intervenor show: "(1) an independent ground for subject matter jurisdiction; (2) a timely motion; and (3) a claim or defense that has a question of law or fact in common with the main action." *Equal Emp't Opportunity Comm'n v. Nat'l Children's Ctr.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998); *In re Endangered Species Act Section 4 Deadline Litig.*, 270 F.R.D. 1, 6-7 (D.D.C. 2010). "[P]ermissive intervention is an inherently discretionary enterprise." *Nat'l Children's Ctr.*, 146 F.3d at 1046.

Mootness prevents Smoke Anywhere from establishing the elements for either type of intervention. Because Smoke Anywhere is challenging a now-defunct policy, it cannot establish standing, subject matter jurisdiction, or an interest that would be impaired by this litigation. After the D.C. Circuit held that nicotine-containing products can be regulated as "drugs" and "devices" under the FDCA only if they contain therapeutic claims, *Sottera, Inc.*, 627 F.3d at 898, FDA changed its policy to comply with that ruling. *See* Veneziano Decl. ¶ 5. Similarly, FDA is no longer following the portion of IA 66-41 related to three e-cigarette manufacturers because that portion of the import alert is superseded by FDA's new e-cigarette policy. *Id.* ¶ 6.

Thus, Smoking Anywhere's complaint challenges policies that FDA no longer follows, and cannot follow unless the D.C. Circuit's decision is reversed. For this reason, Smoke Anywhere cannot establish the elements of Article III standing, as required of a prospective intervenor as of right. *United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1146 (D.C. Cir. 2009). The only injury that Smoke Anywhere alleges is FDA's October 2009 refusal to admit a shipment of its e-cigarettes. That old injury cannot establish present-day standing because standing requires that the "injury will be 'redressed by a favorable decision.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 38 (1976)). The proposed complaint seeks injunctive and declaratory relief to force FDA to change its policy regarding imported e-cigarettes. Given that FDA has already changed its policy to comply with the D.C. Circuit's decision in this case, Smoke Anywhere's alleged injury is already redressed.

Similarly, Smoke Anywhere cannot show that, without intervention, the disposition of the action may as a practical matter impair or impede its ability to protect its interest. *See* Fed. R. Civ. P. 24(a). Smoke Anywhere asserts that it meets this requirement because the "crippling effects of an import ban" will "affect the viability of Smoke Anywhere's future business." Interv. Mem. at 10. Again, this argument assumes that FDA is continuing its old policy in defiance of the decision of the D.C. Circuit. Because that assumption is incorrect, Smoke Anywhere cannot establish that any further proceedings in this case will impede its ability to protect its interest. In addition, because "the issues presented are no longer 'live,'" Smoke Anywhere cannot establish subject matter jurisdiction, *see County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979) (quotation omitted), as required for permissive intervention. *Nat'l*

Children's Ctr., 146 F.3d at 1046.[1]

Smoke Anywhere's motion also fails as untimely. For both intervention as of right and permissive intervention, timeliness is required. Timeliness under Rule 24 takes into account "all the circumstances, especially weighing the factors of time elapsed since the inception of the suit, the purpose for which intervention is sought, the need for intervention as a means of preserving the applicant's rights, and the probability of prejudice to those already parties in the case." *United States v. British Am. Tobacco Austl. Servs.*, 437 F.3d 1235, 1238 (D.C. Cir. 2006) (citation omitted). The district court has considerable latitude in making this determination. *Smoke v. Norton*, 252 F.3d 468, 471 (D.C. Cir. 2001).

Smoke Anywhere moved to intervene nearly two years after this case began (and eighteen months after its alleged injury), and after the parties, this Court, and the Court of Appeals have engaged in extensive proceedings. As a result of those proceedings and the decisions already issued, intervention at this stage is unnecessary and pointless as a means to protect Smoke Anywhere's rights. Smoke Anywhere's eleventh hour intervention would also

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[1] Count III of Smoke Anywhere's proposed complaint (declaratory judgment) cannot save it. Declaratory relief is only permitted if jurisdiction otherwise exists. 28 U.S.C. § 2201 ("In a case of actual controversy within its jurisdiction . . any court . . . may declare the rights . . ."); *Public Service Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 242 (1952) (Declaratory Judgment Act "applies . . . only to 'cases and controversies in the constitutional sense.'") (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)); *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-72 (1950) (in the Declaratory Judgment Act, "Congress enlarged the range of remedies available in the federal courts but did not extend their jurisdiction. . . . [T]he requirements of jurisdiction – the limited subject matters which alone Congress had authorized the District Courts to adjudicate – were not impliedly repealed or modified."). The Declaratory Judgment Act does not establish a right of action. *See Vaden v. Discover Bank*, 129 S. Ct. 1262, 1278 n.19 (2009); *Walpin v. Corp. for Nat'l, & Cmty. Serv.*, 718 F. Supp. 2d 18, 24 (D.D.C. 2010) ("In general, a count for a declaratory judgment 'is not cognizable as a separate cause of action, but is more properly included in the[] prayer for relief.'") (citation omitted).

likely prejudice the existing parties by complicating the final resolution of any remaining issues in the present litigation. *See, e.g., Tripp v. Executive Office of the President*, 194 F.R.D. 344, 348 (D.D.C. 2000) (denying motion for intervention where intervention would raise "collateral issues and undue complications" that would "unreasonably frustrate and prolong" the case).

CONCLUSION

For the reasons states above, the Court should deny the motion to intervene.

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