

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Sottera, Inc., d/b/a/ NJOY

Intervenor-Plaintiff,

vs.

U.S. FOOD AND DRUG ADMINISTRATION,
JOSHUA M. SHARFSTEIN, M.D., **Acting**
Commissioner for Food and Drug,
MARGARET HAMBURG, M.D.,
Commissioner-Designate for Food and Drugs

and

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
KATHLEEN SEBELIUS, Secretary of the
Department of Health and Human Services

Defendants.

Civil Action No. 1:09:-cv-00771 (RJL)

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
SOTTERA, INC., D/B/A/ NJOY'S OPPOSITION TO SMOKE ANYWHERE'S MOTION
TO INTERVENE AS PLAINTIFF**

Plaintiff Sottera d/b/a NJOY ("NJOY") respectfully requests that this Court deny the Motion to Intervene as Plaintiff (Doc. 73), filed on March 18, 2011 ("Motion"), by Smoke Anywhere USA, Inc. ("Smoke Anywhere").

Smoke Anywhere seeks to intervene in this case, as of right and permissively, “to protect its interests in marketing and selling its E-cigarettes in the United States.” Mem. in Supp. of Motion at 4. The motion should be denied because (i) Smoke Anywhere’s request to intervene is untimely, coming two years after this case began and after it has been litigated nearly to completion; (ii) intervention of a new plaintiff at this late stage would prejudice NJOY by unnecessarily complicating and delaying the resolution of its case; and (iii) intervention here is not at all necessary to protect Smoke Anywhere’s interests, which would be as well protected by its intervention in a similar case recently filed in this Court, *Totally Wicked-E.Liquid, Inc. v. U.S. Food & Drug Administration*, No. 1:09-cv-00771-RJL (D.D.C.) (complaint filed on February 15, 2011).

This case began almost two years ago, and since then the parties have fully litigated the primary legal issues both in this Court and in the D.C. Circuit. On April 28, 2009, Smoking Everywhere, Inc. (“SE”) filed suit challenging the FDA’s authority to regulate customarily marketed electronic cigarettes under the drug/device provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 et seq. SE sought a preliminary injunction barring the FDA and other officials from denying its products entry into the U.S. and regulating its electronic cigarettes under the drug/device provisions of the FDCA. Shortly thereafter, NJOY joined the suit as an intervenor-plaintiff and filed its own parallel complaint and request for a preliminary injunction. On January 14, 2010, this Court granted the preliminary injunction. The FDA appealed. While the appeal was pending, SE voluntarily dismissed its complaint, and NJOY remained as the sole appellee.

On December 7, 2010, the D.C. Circuit affirmed this Court’s preliminary injunction. *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). Looking to the terms of the FDCA and the

2009 Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. §§ 378 et seq., as well as the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), the Court of Appeals held that the FDA has no authority to regulate electronic cigarettes under the FDCA's drug/device provisions unless they are marketed for therapeutic purposes. *Sottera*, 627 F.3d at 892. The Court of Appeals simultaneously recognized that NJOY's products are not marketed for therapeutic uses and that "the FDA appear[ed] not to challenge [that] claim." *Id.* at 898. The mandate issued on February 7, 2011. Unless the FDA petitions for a writ of certiorari and succeeds in persuading the Supreme Court to grant review and reverse the Court of Appeals' judgment, this case is effectively over.

Smoke Anywhere's motion to intervene in the closing stages of this case should be denied as untimely. Timely application is a threshold requirement under Federal Rule of Civil Procedure 24 both for intervention as of right and permissive intervention, and Smoke Anywhere's motion comes far too late in this case. Smoke Anywhere complains that the FDA detained its products on July 17, 2009 (Mem. in Supp. of Motion at 2). It therefore could have intervened shortly after this litigation commenced, but it waited until more than a year *after* this Court granted NJOY a preliminary injunction and *after* the D.C. Circuit affirmed that order on appeal. It is now too late in the day for intervention *in this case*, because at this point, for all practical purposes, this case is over. All that remains is for this Court to change the preliminary injunction that it ordered on January 14, 2010, to a permanent injunction, for it is settled that FDA may not regulate electronic cigarettes under the drug/device provisions of the FDCA absent therapeutic claims, and the FDA has not shown any inclination to challenge NJOY's claims as therapeutic.

Whether a motion to intervene is timely depends on the circumstances. *Associated*

Builders & Contractors, Inc. v. Herman, 166 F.3d 1248, 1257 (D.C. Cir. 1999). For example, the D.C. Circuit Court of Appeals has held that intervention within “a few weeks” after the filing of the case and before the district court ruled on a preliminary injunction motion “cannot be regarded as untimely.” *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998). This case presents the opposite pole: a delay of nearly two years until the district court has resolved the critical issue in the suit and that decision has been affirmed on appeal “cannot be regarded as [timely].” *See Hodgson v. United Mine Workers of Am.*, 473 F.2d 118, 129-30 (D.C. Cir. 1972) (intervention untimely after completion of the “critical phase” of the litigation); *see, e.g., Doe v. Duncanville Ind. School Dist.*, 994 F.2d 160, 167 (5th Cir. 1993) (district court properly denied motion to intervene as untimely when filed two days before hearing on the motion for preliminary injunction);

Smoke Anywhere’s motion to intervene should also be denied because its intervention could prejudice NJOY’s interests by complicating and delaying the resolution of the case. *See District of Columbia Hosp. Ass’n v. Heckler*, Civil Action Nos. 82-2520, 83-0223, 1984 WL 48798, at * 4 (D.D.C. Mar. 7, 1984) (recognizing that the timeliness requirement of Rule 24(a) requires a judge to “consider both the purpose for which intervention is sought and the probability of prejudice to those in the case”); Fed. R. Civ. Pro. 24(b)(3) (“In exercising its discretion, the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.”). Because the FDA obtained a stay of this Court’s preliminary injunction pending appeal, NJOY has waited almost two years since filing suit for the FDA to cease impounding its products. The intervention at this late stage of a new plaintiff, whose claims may arise from a different administrative record and might implicate different concerns, should not be allowed to complicate or delay the entry of final relief. NJOY would

unquestionably be prejudiced by such further delay.

Finally, denial of Smoke Anywhere's motion to intervene is appropriate because intervention in this case is not at all necessary to protect Smoke Anywhere's interests. To the extent NJOY's claims and Smoke Anywhere's claims address a common question of law—FDA's power to regulate e-cigarettes under its drug/device authority—NJOY has already litigated and prevailed on that critical legal issue. Far from impairing Smoke Anywhere's interests, NJOY's successful litigation is likely to have a decidedly positive *stare decisis* effect on any future suit in which Smoke Anywhere challenges FDA's detention of its products. *See Cook v. Boorstin*, 763 F.2d 1462, 1470 (D.C. Cir. 1985) (holding that the potential *stare decisis* value of construction of the governing statute and relevant findings are a "substantial" interest of an intervenor that could be impaired by the litigation). Thus, at this point in the proceedings the "practical consequences" of denying intervention will not threaten Smoke Anywhere's claims. *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 735 (D.C. Cir. 2003) (quoting *Nuesse v. Camp*, 385 F.2d 694, 702 (D.C. Cir. 1967)).

To the extent Smoke Anywhere desires to protect its interests by intervening in ongoing litigation, it should move instead to intervene in *Totally Wicked-E.Liquid, Inc. v. U.S. Food & Drug Administration*, which was filed in this Court fewer than six weeks ago and raises legal issues similar to those identified by Smoke Anywhere. Smoke Anywhere may protect its interests just as effectively in that litigation without prejudicing NJOY by threatening to complicate and delay the resolution of this case.

CONCLUSION

Smoke Anywhere's motion to intervene should be denied because it is untimely, threatens prejudice to NJOY by delaying final resolution of this case (which has already been pending for nearly two years), and is entirely unnecessary to protect Smoke Anywhere's interests.

April 4, 2011

Respectfully submitted,

/s/ Philip J. Perry

Philip J. Perry (D.C. Bar No. 434278)
LATHAM & WATKINS LLP
555 11th Street, NW, Suite 1000
Washington, DC 20004
Telephone: (202) 637-2200
Facsimile: (202) 637-2201

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2011 counsel below was served with the preceding document by notification through the court's CM-ECF system:

JOHN F. BANZHAF
Action on Smoking and Health
2013 H Street, NW
Washington, DC 20006

Drake S. Cutini
U.S. Department Of Justice
Civil Division
Office of Consumer Litigation
P.O. 386
Washington, DC 20044

Sean E. Foster
Agnew & Foster, PLLC
4314 Medical Parkway
Suite 101
Austin, TX 78756

Mitchell S. Fuerst
Robert J. Becerra
Fuerst Ittleman, PL
1001 Brickell Bay Drive
Suite 2002
Miami, FL 33131

/s/ Philip J. Perry
Philip J. Perry (D.C. Bar No. 434278)