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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC.,

Plaintiff,

and

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

Intervenor-Plaintiff,

v.

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

Defendants.

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

ALLIANCE OF ELECTRONIC SMOKERS' MOTION FOR LEAVE TO PARTICIPATE AND FILE BRIEF AS *AMICUS CURIAE*

The Alliance of Electronic Smokers ("AES"), as an interested nonparty, by and through undersigned counsel, respectfully moves the Court for leave to participate and file a brief as *amicus curiae* in this litigation in support of Plaintiff's and Intervenor-Plaintiffs' Motions for Preliminary Injunction.

ARGUMENT

As set forth in greater detail in the accompanying Brief of *Amicus Curiae*, AES is an *ad hoc* group consisting of current consumers of electronic cigarettes (e-cigarettes) that would like to preserve their current choice of tobacco products – a right that is being eliminated by the efforts of the U.S. Food and Drug Administration (FDA) to improperly to exert regulatory authority over e-cigarettes. AES and its members are concerned that their right to choose a

preferred vehicle for smoking pleasure could be infringed based on the outcome of the present case. Accordingly, AES and its members have significant interests in the outcome of this litigation. Moreover, AES believes that its perspective would be helpful to the Court in evaluating the merits of this matter. In particular, AES responds to points raised in the submissions by Action on Smoking and Health (ASH), which this court has granted permission to appear as *amicus curiae*. A copy of AES's proposed *amicus* brief is attached hereto as Exhibit A to this Motion.

Because the proposed *amicus* brief responds to points raised in ASH's previous submissions in this matter, AES believes its participation will not prejudice any party. Pursuant to Local Rule 7(m), undersigned counsel has conferred by telephone with counsel for Plaintiff and Intervenor Plaintiff, and they do not oppose this Motion. Also, AES conferred with counsel for Defendants regarding their consent and, as of the time of this filing, was still waiting for a response.

Respectfully Submitted,

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Dated: September 9, 2009

Counsel for The Alliance of Electronic Smokers

CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of September, 2009, I caused a true a correct copy of the foregoing Motion for Leave to File Brief as *Amicus Curie*, Entries of Appearance, and proposed Order to be served via first-class mail, postage prepaid, upon the following:

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Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC., Plaintiff, and SOTTERA, INC., d/b/a/ NJOY, Intervenor-Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	Civil Action No. 1:09-cv-00771 (RJL)

BRIEF OF *AMICUS CURAE*
ALLIANCE OF ELECTRONIC SMOKERS

The Alliance of Electronic Smokers is an ad hoc group of adult smokers who use and enjoy electronic cigarettes ("e-cigarettes") for recreational purposes and wish to continue to do so. E-cigarettes have been available to smokers since 2007 and, until recently, the U.S. Food and Drug Administration ("FDA") had made no effort to restrict their use. We wish to bring several points to the Court's attention, and to comment on various issues raised by *amicus* Action on Smoking and Health ("ASH") in its recent filings:

I. THE NEW TOBACCO ACT

If FDA wishes to regulate e-cigarettes, it now has an avenue to do so—through the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"), Public Law No: 111-31, H.R. 1256, 111th. Cong. (2009). FDA acknowledges that e-cigarettes would fit the statutory

definition of a "tobacco product" under the FSPTCA. *See* Defendants' Supplemental Brief In Opposition to Plaintiff's and Intervenor's Motions For A Preliminary Injunction, filed July 10, 2009, at 5 n.3. The FSPTCA reflects a legislative compromise. The Act allows FDA to regulate many elements of the production, labeling and advertising of "tobacco products," while ensuring that *nicotine cannot be banned for recreational use*. FSPTCA Section 907(d)(3) (the Secretary may not "requir[e] the reduction of nicotine yields of a tobacco product to zero."). Under section 901(b), FDA could regulate (but not ban) e-cigarettes following notice and comment rulemaking. Indeed, there is no statutory or other legal reason why FDA could not issue a notice promptly and complete this type of rulemaking in a matter of months.[1]

Congress recognized expressly in the FSPTCA that FDA did not previously have drug jurisdiction over tobacco products. FSPTCA, Sec. 2(7) & (12), Sec. 3 (1-7). The term "tobacco products" in the FSPTCA was drawn from the Supreme Court's decision in *FDA v. Brown & Williamson*. 529 U.S. 120, 131, 158-59 (2000). In that case, the Supreme Court held that "Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products." 529 U.S. at 126. Just as it has in this case, the FDA argued in *Brown &Williamson* that tobacco products were within its drug jurisdiction because they are intended "to deliver the pharmacological effects of satisfying addiction, stimulation and tranquilization. . . ." 529 U.S. at 131. But the fact that tobacco products deliver nicotine with stimulative pharmacological effects failed to persuade the Supreme Court that FDA had jurisdiction to regulate tobacco as a drug as

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[1] In contrast, it takes, on average, approximately eight years to obtain FDA approval of a drug, from the initiation of clinical trials through the FDA approval process. *See* Tufts Center for the Study of Drug Development, Outlook 2009, *available at* http://csdd.tufts.edu/InfoServices/OutlookPDFs/Outlook2009.pdf.(last visited September 8, 2009). During this time, the unapproved drug cannot be marketed or sold.

customarily marketed for tobacco pleasure. *Id.* at 158-59. Indeed, the Supreme Court only noted one possible exception to its conclusion that FDA lacked drug jurisdiction over tobacco products – "with respect to the well-established exception of when the manufacturer makes *express claims of therapeutic benefit*." *Id.* at 158-59 (emphasis supplied). As the Plaintiff and Plaintiff-Intervenor have argued in this litigation, there are no such claims of "therapeutic benefit" in the record in this case; nothing in the record shows such products were offered to help smokers them quit smoking (*i.e.* for smoking cessation) or for any other medical purpose.

II. FDA's PRIOR VIEWS ON *BROWN & WILLIAMSON*

Until recently, FDA agreed that *Brown & Williamson, supra*, precluded it from exercising drug jurisdiction over "tobacco products" offered for sale for non-therapeutic purposes, *i.e.* as customarily marketed for "tobacco pleasure." Indeed, in 2003 FDA considered a citizen petition requesting that FDA classify as a drug a new non-cigarette "tobacco product" named "Ariva" – a tablet consisting of "cigalett" pieces of compressed powdered tobacco, mint flavoring and other ingredients. Like e-cigarettes, Ariva's labeling indicated that it would deliver nicotine to its users "***When you can't smoke***," and indicated that the product "***contains nicotine, an addictive substance***." *See* Attachment A hereto, August 29, 2003, letter from John M. Taylor, III, Associate Commissioner for Regulatory Affairs, FDA, at 2 (emphasis added). The FDA concluded that it did not have drug jurisdiction over Ariva and explained very clearly that it viewed the *Brown & Williamson* decision to cover this new "tobacco product:"

> The Court [in *Brown & Williamson*] concluded that FDA has no jurisdiction over "tobacco products as customarily marketed" because they simply do not fit within FDCA's regulatory scheme. The Court recognized that "customarily marketed" tobacco products do not include products for which claims of therapeutic benefit, including "drug claims" or "health claims" are made. . . .
>
> * * *

> ***...FDA believes that, based on the information available to it at this time, it is precluded from asserting jurisdiction over Ariva as currently marketed because it is a "customarily marketed" tobacco product within the meaning of* Brown & Williamson.**

Id. at 2-3 (citations omitted and emphasis added).

III. RESPONSE TO ASH'S AMICUS ARGUMENTS

ASH has filed an *amicus* brief, and apparently has also sent the court a letter with a ten-page single-spaced commentary on the August 17th hearing, dated August 24, 2009 (the "August 24 letter"). Notably, much of the *amicus* material is not relevant here or part of the administrative record compiled by FDA. For example, neither of the e-cigarette manufacturers acting as plaintiffs here have advertised or market their products as delivery mechanisms for approved drugs with therapeutic effects, like Cialis or Viagra, as ASH's August 24 letter misleadingly suggests. Similarly, ASH purports to identify certain other relevant products containing nicotine, but none are relevant here, because: (1) those products made specific claims about therapeutic purposes, (2) they predated the Supreme Court's holding in *Brown & Williamson*; and/or (3) they were not ever the subject of a judicial challenge. Moreover, ASH fails to mention the one post-*Brown & Williamson* precedent that actually *is* relevant here – Ariva, as discussed above, another unconventional nicotine product for which FDA received citizen petitions requesting that it assert jurisdiction – a request that FDA flatly rejected in 2003, finding that it lacked jurisdiction over "customarily marketed" tobacco products.

In addition, ASH cites *Harris v. Action for Smoking & Health*, 655 F.2d 236 (1980), a case it lost in the D.C. Circuit, to support its position that explicit manufacturer representations regarding drug claims are not necessary. To the contrary, however, in that case, the D.C. Court

of Appeals actually affirmed the lower court's holding that FDA's refusal to assert jurisdiction over cigarettes as a "drug" was not arbitrary, capricious, or contrary to law.

Far from supporting ASH's argument, *Harris* made clear that:

> . . . the crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent . . . . Such an understanding has now been accepted as a matter of statutory interpretation.

655 F.2d 236, 238-39. And to the extent that manufacturer's objectively manifested intent can be inferred, the D.C. Court of Appeals explained:

> . . . consumers must use the product predominately and in fact *nearly exclusively* with the appropriate intent before the requisite statutory intent can be inferred.

655 F.2d at 240.[2] That is certainly not the case here. There is no evidence to suggest that consumers have used e-cigarettes predominantly, much less nearly exclusively, for purposes of therapeutic benefit. Our choice to use e-cigarettes over traditional cigarettes is instead influenced by social stigmas and inconveniences associated with traditional smoking. But practical concerns are also important: the e-cigarette leaves no tar stains on the roof of our cars or in our homes, and does not leave our skin, breath, or clothes smelling like an ashtray. Also, we are able to "smoke" in places that traditional smoking is prohibited because second-hand smoke is not an issue. And the electronic cigarette gives the user the same smoking pleasure as traditional cigarettes, including by mimicking the physical activity of smoking.

E-cigarettes are very different from products offered to help smokers quit. The nicotine patch and gum for example are meant to gradually assist users to eliminate their nicotine addiction. Those products describe in detail how to eliminate nicotine addiction in multiple

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[2] ASH also cites *U.S. v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001) for the proposition that a written label is not required to infer a seller's intent. But *Travia* is readily distinguishable – there, undercover agents presented evidence of the oral representations made to customers about the purpose of the product sold, and the case had no bearing at all on tobacco products.

steps. E-cigarettes are not marketed for that purpose, and the product labeling does not include directions or any other statements concerning how to quit smoking.

There are other nontraditional nicotine products, such as "Snus" and dissolvable tobacco products such as Ariva, that have no purpose other than to deliver nicotine for recreation. By attempting to eliminate our access to the electronic cigarette, the FDA is depriving us of our right as consumers to make an informed choice to use vaporized nicotine products.

IV. CONCLUSION

The Alliance of Electronic Smokers respectfully requests that the Court consider the consumer as an intelligent force and provide consumers the right to choose to use and enjoy electronic cigarettes, or personal vaporizers, for recreational purposes. Accordingly, for the reasons set forth in this case by Plaintiff Smoking Everywhere, Inc. and Plaintiff-Intervenor Sottera Inc. d/b/a NJOY, and for the additional reasons set forth herein, the Alliance of Electronic Smokers respectfully requests that the Court hold that the FDA lacks the authority to interfere with that choice, and to grant the requested preliminary injunctions.

Respectfully Submitted,

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Dated: September 9, 2009

Counsel for The Alliance of Electronic Smokers

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

ENTRY OF *AMICUS CURIE* APPEARANCE

Please enter my appearance as counsel in this case for *amicus curie* Alliance of Electronic Smokers. I certify that I am admitted to practice in this court.

Respectfully Submitted,

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ORDER

Having reviewed and considered the Motion for Leave to Participate and File Brief as *Amicus Curie* of the Alliance of Electronic Smokers ("AES"), and all other pleadings and documents properly before the Court, it is hereby

ORDERED that AES' Motion for Leave is GRANTED; and it is further

ORDERED that AES' Brief of *Amicus Curiae* shall be filed.

Dated this ____ day of _____, 2009.

BY THE COURT:

_____
JUDGE RICHARD J. LEON

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