

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

SMOKING EVERYWHERE, INC., <i>et al.</i>)	
)	
Appellees)	
)	
v.)	No. 10-5032
)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, <i>et al.</i> ,)	
)	
Appellants.)	

**UNOPPOSED MOTION OF SMOKEFREE PENNSYLVANIA,
THE AMERICAN COUNCIL ON SCIENCE AND HEALTH,
CONSUMER ADVOCATES FOR SMOKEFREE ALTERNATIVES
ASSOCIATION, NATIONAL VAPERS CLUB, MIDWEST VAPERS
GROUP, MICHAEL SIEGEL, MD, MPH, AND JOEL
NITZKIN, MD, MPH, DPA FOR LEAVE TO PARTICIPATE
AS AMICI CURIAE SUPPORTING APPELLEES**

Pursuant to Circuit Rule 29(b), Smokefree Pennsylvania, The American Council on Science and Health, Consumer Advocates for Smokefree Alternatives Association, National Vapers Club, Midwest Vapers Group, Michael Siegel, MD, MPH, Joel Nitzkin, MD, MPH, DPA respectfully move for leave to participate in the above-captioned case as *amicus curiae*. Counsel for the proposed *amici* requested consent to this Motion from counsel for Appellees and Appellants. Counsel for Appellees consents to this Motion and counsel for Appellants does not oppose this Motion.

The proposed *amici* – organizations and individuals with extensive knowledge and experience in the use of smokeless tobacco products, such as the product at issue in this case – seek leave to file an *amicus* brief, which is attached hereto as Exhibit 1.¹ The proposed *amici* are committed to reducing the harm caused by traditional cigarettes by, among other things, advocating the availability of smokefree alternatives. The proposed *amici* believe that electronic cigarettes (e-cigarettes) are a safer and preferable option to help smokers switch from using cigarettes. As such, the proposed *amici* have a significant interest in the outcome of this litigation and believe that their perspective would be helpful to the Court in evaluating the merits of this matter.

The appellants seek review of the District Court’s decision enjoining the U.S. Food and Drug Administration (“FDA”) from preventing the importation of electronic cigarettes into the United States. The District Court properly held that the FDA lacks authority to regulate these products as “drugs,” “devices” or drug-

¹ This Motion for Leave is outside the sixty (60) day period set forth in Circuit Rule 29(b) for the filing of motions for leave to participate as *amicus curiae*. However, as set forth in Circuit Rule 29(b), that period may be extended. *Amici* have endeavored to file their Motion as quickly as possible and by the July 8, 2010 deadline established by the scheduling order for the filing of *amicus* briefs on behalf of the Appellees. Moreover, Appellants would not be harmed by the filing of the attached *amicus* brief as they would have the opportunity to address the brief, should they so choose, in their Reply brief, which is not due until July 22, 2010. Moreover, as set forth herein, *amici* bring important experience and perspectives to this case.

device combinations under the Federal Food, Drug, and Cosmetics Act (“FFDCA”).

The proposed *amici* are all organizations and individuals committed to reducing tobacco use, expanding funding for smoking prevention and cessation programs, and/or informing smokers of smokefree tobacco and nicotine products that are far less hazardous alternatives to cigarettes. As such, the proposed *amici* have a strong interest in the issue of whether the FDA has authority to regulate the electronic cigarettes at issue in this case. A brief description of each of the proposed *amici* is set forth below:

1. **Smokefree Pennsylvania** was founded in 1990 by William T. Godshall, MPH, who has served continuously as its executive director. Smokefree Pennsylvania has been a pioneering advocate regarding public policies for smokefree indoor air, reducing tobacco marketing to youth, increasing cigarette taxes, preserving civil justice remedies for those injured by cigarettes, expanding funding for smoking prevention and cessation programs, and informing smokers that smokefree tobacco/nicotine products are far less hazardous alternatives to cigarettes.

Originally a statewide grass roots organization, Smokefree Pennsylvania also has been involved in many national activities to reduce smoking. During the past decade, Smokefree Pennsylvania has advocated policies to regulate the most

hazardous tobacco product (cigarettes) far more strictly than the least hazardous smokefree tobacco/nicotine products (including electronic cigarettes).

2. **The American Council on Science and Health** (ACSH) is a consumer education consortium concerned with issues related to food, nutrition, chemicals, pharmaceuticals, lifestyle, the environment, and health. ACSH is an independent, nonprofit, tax-exempt organization that was founded in 1978 by a group of scientists who were concerned that many important public policies relating to health and the environment did not have a sound scientific basis. These scientists created ACSH to add reason and balance to debates about public health issues, and to bring common sense views to the public.

The nucleus of ACSH is a board of 350 physicians, scientists and policy advisors – experts in a wide variety of fields – who review the Council’s reports and participate in ACSH seminars, press conferences, media communications and other educational activities. ACSH produces a wide range of publications, including peer-reviewed reports on important health and environmental topics (HealthFactsAndFears.com), and a semi-annual review of ACSH press coverage (Media Update).

ACSH representatives also appear regularly on television and radio, in public debates and in other forums. In addition, ACSH hosts media seminars and press conferences on a variety of public health issues. ACSH also provides an in-

house internship program for students in health science fields and participates in legislative and regulatory hearings.

3. **Consumer Advocates for Smokefree Alternatives Association**

(CASAA) is a non-profit organization that works to ensure the availability of reduced harm alternatives to smoking, and to provide smokers and non-smokers alike with truthful information about such alternatives. Its mission is to ensure the availability of effective, affordable and reduced harm alternatives to smoking by increasing public awareness and education; to encourage the testing and development of products to achieve acceptable safety standards and reasonable regulation; and to promote the benefits of reduced harm alternatives. CASAA was created in 2009 by concerned e-cigarette consumers who quit smoking by switching to e-cigarettes to protect their rights to legally access and use e-cigarettes.

4. **The National Vapers Club (NVC)** is a consumer-based activist organization established March 2009. NVC was established to protect the rights of e-cigarette consumers to access and use these products. NVC has worked closely with legislators to keep e-cigarettes available as an effective alternative to combustible tobacco cigarettes. NVC is run and funded solely by e-cigarette users. NVC evaluates businesses selling e-cigarettes in order to recommend reputable

companies who follow regulatory guidelines. NVC has produced educational multimedia tools to assist new e-cigarette users in the proper use of e-cigarettes.

NVC collaborates with international nicotine/tobacco researchers, and provides fact-based information on e-cigarettes to news media. It gathers scientific data as well as information from e-cigarette consumers and, with the help of chemists and physicians, extrapolates data to analyze efficacy, safety and physiological effects of using e-cigarettes. NVC encourages responsible regulation and testing until the FDA assumes responsibility and regulates e-cigarettes at the federal level.

5. **The Midwest Vapers Group** is a consumer-based organization whose purpose is to provide information about electronic cigarettes. Earlier this year, Midwest Vapers Group mobilized a campaign to educate Illinois legislators about e-cigarettes, and defeated proposed Illinois legislation that would have banned the sale of e-cigarettes in that state.

6. **Dr. Michael Siegel, MD, MPH** is a physician specializing in preventive medicine, and is a professor in the Department of Community Health Sciences at the Boston University School of Public Health. He has over 24 years of experience in tobacco research and policy advocacy, and has testified as an expert witness in numerous lawsuits against tobacco companies, including the

Engle and Broin cases. Dr. Siegel, who was trained as an epidemiologist, is a recognized expert in the area of cigarette smoking and health.

Dr. Siegel currently is conducting research on the safety and effectiveness of electronic cigarettes. He has been a leading critic of the FDA's misrepresentations of fact about e-cigarettes and the agency's attempt to ban the products. He has written more than a dozen posts on his blog about e-cigarettes at:

<http://tobaccoanalysis.blogspot.com/> and he has criticized CTFK, ACS, AHA, ALA, ASH and other organizations which have called for a ban on electronic cigarettes.

7. **Dr. Joel Nitzkin, MD, MPH, DPA** operates a public health and healthcare policy consulting firm, JLN, MD Associates LLC. For the past three years he has served as Chair of the Tobacco Control Task Force of the American Association of Public Health Physicians. He has served as a local health director, state health director, and President of two national public health organizations. He has been involved in tobacco control programming for over 30 years.

In February of this year, Dr. Nitzkin submitted Citizen's Petitions to the FDA on behalf of the American Association of Public Health Physicians urging the agency to reclassify and regulate e-cigarettes as tobacco products (instead of as drug-device combination products), and to truthfully inform the public about the known health risks of e-cigarettes.

Movants, the proposed *amici*, respectfully submit that their participation as *amici* would assist the Court in its consideration of this case. The proposed *amici* all possess extensive knowledge and experience in the use and benefits of smokeless tobacco products such as the product at issue in this case. The issue of whether the FDA may regulate the electronic nicotine delivery products made by the appellees directly involves the same public health issue that the proposed *amici* have dedicated themselves to addressing, and their involvement in this case would provide the Court with an important and helpful perspective on these issues.

Granting this Motion would in no way prejudice appellants or otherwise impact the current briefing schedule. This Motion is timely filed within the Court's existing scheduling order, which establishes July 8, 2010 as the deadline for filing *amicus* briefs on behalf of Appellees. Moreover, the deadline for Appellants' Reply brief is not due until July 22, 2010, so there remains ample opportunity for Appellants to consider and respond to the arguments in the proposed *amicus* brief.

A Circuit Rule 26.1 disclosure statement accompanies this Motion.

Respectfully Submitted,

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