EXHIBIT 1

No. 10-5032

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

SMOKING EVERYWHERE, INC.,
Plaintiff-Appellee,

and

SOTTERA, INC., D/B/A NJOY,
Intervenor-Plaintiff-Appellee,

v.

FOOD AND DRUG ADMINISTRATION, *et al*.,
Appellants.

On Appeal from the U.S. District Court for the District of Columbia

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BRIEF OF *AMICI CURIAE* 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 SUPPORTING APPELLEES AND AFFIRMANCE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties And Amici: Plaintiff-Appellee is Smoking Everywhere, Inc. Intervenor-Plaintiff-Appellee is Sottera, Inc., d/b/a NJOY ("NJOY"). Defendants-Appellants are the United States Food and Drug Administration ("FDA"); FDA Commissioner, Margaret Hamburg; the United States Department of Health and Human Services (HHS); and HHS Secretary, Kathleen Sebelius. *Amici* are the American Academy of Pediatrics, the Washington Legal Foundation, the American Cancer Society Cancer Action Network, the American Heart Association, the American Legacy Foundation, the American Lunch Association, the American Medical Association, the Campaign for Tobacco-Free Kids, and Public Citizen.

B. Ruling Under Review: The preliminary injunction under review was issued on January 14, 2010, by the Hon. Richard J. Leon of the United States District Court for the District of Columbia, in Civ. No. 09-771.

C. Related Cases: *Amici* are not aware of any related cases.

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GLOSSARY

ACSH	The American Council on Science and Health
CASAA	Consumer Advocates for Smokefree Alternatives Association
Council	The American Council on Science and Health
E-Cigarettes	Electronic cigarettes
FDA	Food and Drug Administration
FDCA	Food Drug and Cosmetic Act
MVG	Midwest Vapers Group
NJOY	Appellee Sottera, Inc., d/b/a NJOY
NVC	National Vapers Club
Tobacco Act	2009 Family Smoking Prevention and Tobacco Control Act
Vapers	E-cigarette users

IDENTITY AND INTEREST OF THE *AMICI*, AND THE SOURCE OF AUTHORITY TO FILE THIS BRIEF

On July 8, 2010, the *amici*—American Council on Science and Health, Smokefree Pennsylvania, Consumer Advocates for Smokefree Alternatives Association, National Vapers Club, Midwest Vapers Group, Michael Siegel, MD, MPH, and Joel Nitzkin, MD, MPH, DPA—moved for leave to participate in this case. A copy of this brief was submitted as an exhibit to the motion for leave because the Court likely would not rule on the motion until after the deadline to file the brief had passed.

The *amici* are organizations (national and regional) and individuals committed to reducing the harm caused from traditional cigarettes by, among other things, advocating the availability of smokefree alternatives. The *amici* have a strong interest in the question of whether, instead of regulating the electronic cigarettes at issue in this case as tobacco products, the FDA may regulate them under the more onerous standards governing drugs, devices, and combination products. A brief description of each of the *amici* follows.

A. The American Council on Science and Health ("ACSH" or "Council") is a consumer education consortium concerned with issues relating to food, nutrition, chemicals, pharmaceuticals, lifestyle, the environment, and health. ACSH is an independent, nonprofit, and tax-exempt organization. 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 was founded in 1978 by a group of scientists who had become concerned that many important public policies related to health and the environment did not have a sound scientific basis. These scientists created the organization to add reason and balance to debates about public health issues and to bring common sense views to the public. With these goals in mind, ACSH produces a wide range of publications, including peer-reviewed reports on important health and environmental topics and a semi-annual review of ACSH press coverage. ACSH representatives 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.

B. Smokefree Pennsylvania was founded in 1990 by William T. Godshall, MPH, who has served as its executive director since that time. Smokefree Pennsylvania has been a pioneering advocate for the public policy favoring smokefree indoor air. It has campaigned to reduce tobacco marketing to youth, increase cigarette taxes, preserve civil justice remedies for those injured by cigarettes, expand funding for smoking prevention and cessation programs, and inform 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 e-cigarettes).

C. Consumer Advocates for Smokefree Alternatives Association ("CASAA") is a non-profit organization that works to ensure the availability of reduced-harm alternatives to smoking traditional cigarettes and to provide smokers and nonsmokers 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, encouraging the testing and development of products to achieve acceptable safety standards and reasonable regulation, and promoting the benefits of reduced-harm alternatives. CASAA was created last year by a group of concerned consumers who, after switching from traditional cigarettes to e-cigarettes, now endeavor to protect their right to legally access and use e-cigarettes.

D. National Vapers Club ("NVC") is a consumer-based activist organization, established March 2009, run and funded solely by e-cigarette users ("vapers"). NVC evaluates businesses selling e-cigarettes in order to recommend

to its members reputable companies who follow regulatory guidelines. NVC has produced educational multimedia tools to assist new e-cigarette users in the proper use of the product. NVC also collaborates with international nicotine/tobacco researchers to provide 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 this data to analyze the efficacy, safety, and physiological effects of using e-cigarettes. 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.

E. Midwest Vapers Group ("MVG") is a consumer-based organization whose purpose is to provide information about e-cigarettes. It was founded and is run by Julie Woessner, JD and Patricia Clewell, both of St. Louis, MO. Earlier this year, MVG mobilized a campaign to educate Illinois legislators about e-cigarettes, and defeated Illinois legislation that would have banned the sale of e-cigarettes in that state.

F. Michael Siegel, MD, MPH (an individual) is a physician specializing in preventive medicine. He is also a professor in the Department of Community Health Sciences at the Boston University School of Public Health. Dr. Siegel 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. Dr. Siegel, who was trained as an epidemiologist, is a recognized expert in the area of cigarette smoking and health. He is currently conducting research on the safety and effectiveness of e-cigarettes. Dr. Siegel has been a leading critic of the FDA's misrepresentations of fact about e-cigarettes and its attempt to ban the products.

G. Joel Nitzkin, MD, MPH, DPA (an individual) runs 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 also 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, he 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 provide consumers with accurate information about e-cigarettes.

SUMMARY OF ARGUMENT

This case arises in the aftermath of the U.S. Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000), that the FDA lacks authority under the Food, Drug, and Cosmetic Act ("FDCA") to

regulate tobacco products sold without therapeutic claims, and Congress's subsequent passage of the 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Act"), which gives the FDA broad authority to regulate (but not ban) tobacco products.

Amici agree with NJOY that electronic cigarettes ("e-cigarettes") are "tobacco products" that can be regulated only under the Tobacco Act. The FDA's effort to exercise FDCA jurisdiction over e-cigarettes (in order to ban them) is fundamentally incompatible with the regulatory framework established by Congress and would unnecessarily upset the reasonable expectations of e-cigarette consumers.

The FDA and its *amici* attempt to overcome the defects in their merits argument by reciting a laundry list of potential health risks associated with e-cigarettes that they contend would go unaddressed if the district court's injunction were affirmed. But there is no recorded evidence that e-cigarettes pose any risk to the public health. Moreover, all of the potential health risks cited by the FDA and its *amici* with respect to e-cigarettes apply doubly to traditional cigarettes, which (despite their confirmed risks) unquestionably fall outside the scope of the FDCA. Finally, to the extent that the FDA is genuinely concerned about the potential risks of e-cigarettes, it should exercise its authority under the Tobacco Act. The Tobacco Act gives the FDA broad authority to regulate the production, sale,

distribution, advertising and promotion of tobacco products. While the FDA would rather ban e-cigarettes outright, Congress has clearly and unambiguously foreclosed that possibility, and the FDA cannot chart a different policy course.

ARGUMENT

I. THE *AMICI* AGREE WITH APPELLEE ON THE MERITS OF ITS LEGAL ARGUMENT.

The *amici* agree with NJOY and with the district court that e-cigarettes are not "drugs," "devices," or "combination products" under the FDCA. A decade ago, in *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court held that the FDA does not have jurisdiction to regulate tobacco products. 529 U.S. at 161. In support of this conclusion, the Court cited the FDA's long-held position that it "lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer." *Id.* at 144; *see also* Appellant's Br. at 17. In this case, the district court enjoined the FDA from regulating NJOY's e-cigarettes "absent a proffer of evidence that the products are 'intended to have a therapeutic effect.'" *See* Appellant's Br. at 5 n.2. The FDA has failed to proffer any such evidence. It nevertheless asserts that e-cigarettes are subject to regulation as a drug-device combination under the FDCA.

The *amici* agree with the district court that the FDA's interpretation of "tobacco products" is unreasonably narrow, particularly when considered in light

of the Tobacco Act, which defines "tobacco product" expansively as "any product made or derived from tobacco that is intended for human consumption . . . ." *See* 21 U.S.C. § 321(rr)(1). The notion that NJOY's e-cigarettes, which undisputedly contain nicotine distilled from tobacco plants, are not "tobacco products," and thus exempted from regulation under the FDCA, is both illogical and contrary to the unambiguous intent of Congress. The FDA's novel and far-reaching theory of FDCA jurisdiction should be rejected.

II. THE FDA'S GENERALIZED HEALTH CLAIMS REGARDING E-CIGARETTES ARE SPECULATIVE AND MUST BE PUT IN PERSPECTIVE.

The FDA and its *amici* attempt to overcome the plain import of *Brown & Williamson* and the Tobacco Act by engaging in vague speculation about the purported health risks associated with e-cigarettes. The FDA concedes, however, that it has no evidence of any demonstrated health consequences related to e-cigarettes by acknowledging that e-cigarettes "have been subject to so little testing and analysis [that] the long-term health consequences are unknown." *See* Appellant's Br. at 23-24. Indeed, the evidence of record is that e-cigarettes have been sold in the United States since 2007 without one identified instance of an adverse health effect. Nor does the record substantiate the claims asserted by the FDA and its *amici* (i) that e-cigarettes will addict new nicotine users (including children); (ii) that former smokers may resume nicotine use through e-cigarettes,

or; (iii) that current smokers may attempt to use e-cigarettes for smoking cessation instead of FDA-approved products proven effective for this use. But in any event, the FDA could address all of those concerns pursuant to the authority conferred upon it by the Tobacco Act, rather than by trying to force e-cigarettes into the ill-fitting drug/ device framework. *See infra* Part III.

In sharp contrast to the FDA's speculation about the potential risks of e-cigarettes, the parties agree—and, indeed, it is virtually beyond dispute—that traditional cigarettes are one of the greatest health concerns of our time. The FDA's *amici* rightly note that roughly 21 percent of adult Americans smoke traditional cigarettes and that "'[s]moking harms nearly every organ of the body and causes cancer, cardiovascular disease, respiratory disease, reproductive harms, and many other health problems." *See* Brief of Amici Curiae Supporting Appellants ("Appellant *Amici* Br.") at 4-5 (quoting "The Health Consequences of Smoking: A Report of the Surgeon General," May 27, 2004, at 8). In addition to these human costs, traditional cigarettes strain our national economy and health care system. As the FDA's *amici* observe, "[h]ealth-care costs attributable to smoking are estimated at $96 billion per year in direct medical costs and an additional $97 billion per year in lost productivity." *See* Appellant *Amici* Br. at 5.

Despite the unquestioned personal risk and colossal national burden associated with traditional cigarettes, Congress has declined to ban them and,

indeed, has passed a panoply of tobacco-specific statutes that expressly recognize and contemplate that tobacco products "will continue to be sold in the United States." *See Brown & Williamson*, 529 U.S. at 137-39. Most recently, in the wake of *Brown & Williamson*, Congress enacted the Tobacco Act, which permits the FDA to regulate, but not ban, tobacco products—including traditional cigarettes. *See* 21 U.S. C. § 387a(a) (specifying that "tobacco products" "shall not be subject to the provisions of Chapter V ("Drugs and Devices")); *id*. § 387g(d)(3)(A)-(B) (prohibiting the FDA from "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products" and from "requiring the reduction of nicotine yields of a tobacco product to zero").

Against this backdrop, the FDA's relentless attempt to ban the import of e-cigarettes as unlawful drug-device combination products is nothing less than a derogation of its mission to protect the public health. The FDA knows that it cannot ban traditional cigarettes—indisputably one of the chief preventable causes of illness and death worldwide—so instead it seeks to regulate (and ban) what must surely be a safer alternative.[1] In the context of a regulatory regime that

[1] The FDA's allegations of harm logically imply that, if e-cigarettes were drug-device combinations under the FDCA, the FDA would be required to remove them from the market. *See Brown & Williamson*, 529 U.S. at 134-35 (noting that the FDCA requires the FDA to prevent the marketing of any drug or device "where the

contemplates the continued legality of traditional cigarettes, the *amici* believe that safer substitutes should be embraced, not abolished.

III. IN THE TOBACCO ACT, CONGRESS GAVE THE FDA ALL AUTHORITY IT THOUGHT APPROPRIATE TO ADDRESS THE HEALTH CONCERNS PRESENTED BY TOBACCO PRODUCTS, INCLUDING E-CIGARETTES.

Both the FDA and its *amici* insist that the district court's injunction would leave tobacco products, like e-cigarettes, unregulated and would hinder efforts to reduce mortality and morbidity associated with tobacco use. This assertion is false. In the Tobacco Act, Congress gave the FDA broad authority to comprehensively address the public health and societal problems caused by the use of tobacco products.

Congress passed the Tobacco Act with the express purpose of "ensur[ing] that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." *See* 21 U.S.C. §387 (Sec. 3. Purpose (2)). Other purposes of the Tobacco Act were to "authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products" and to "vest the [FDA] with the authority to

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potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit" and observing that the FDA could not regulate cigarettes under the FDCA without removing them from the market).

regulate the levels of tar, nicotine, and other harmful components of tobacco products." *Id*. § 387 (Sec. 3. Purposes (3), (5)).

Consistent with these congressional goals, the Tobacco Act specifically authorizes the FDA to promulgate regulations (i) requiring restrictions on the sale, distribution, advertising and promotion of tobacco products, *id*. § 387f(d)(1); (ii) requiring manufacturers to ensure that their packing and storage of tobacco products conforms to "current good manufacturing practice" or other standards to protect public health, *id*. §§ 387b(7), 387f(e); (iii) requiring testing and reporting of tobacco product constituents and adverse events, *id*. §§ 387i, 387o; and (iv) imposing any other tobacco product standard that it finds appropriate for the protection of the public health, *id*. § 387g(a)(3)(A). In addition to this broad delegation of regulatory authority, the Tobacco Act:

- imposes branding and labeling requirements and a number of stringent advertising restrictions on tobacco products, including restrictions on advertising to minors, *id*. §§387c, 387f(d)(2), 387m;
- requires manufacturers and importers to submit to the FDA a list of ingredients and constituents in their products and to provide the FDA with documentation of the health effects of their products, *id*. §387d;
- requires manufacturers of tobacco products to register annually and subjects them to FDA inspection every two years, *id*. §387e;

- requires product manufacturers to provide to the FDA a detailed list of their products and to submit consumer information and labeling for their products, *id*. §387e, and;
- establishes stringent pre-market and post-market requirements for regulated tobacco products, *see id.* §§ 387e(j); 387j.

In short, the Tobacco Act gives the FDA all the tools it needs to address each of the health concerns raised by the FDA and its *amici* with respect to e-cigarettes.

What the Tobacco Act does *not* permit is for the FDA to impose an outright ban on e-cigarettes (or other more harmful tobacco products). The FDA and its *amici* may disagree with this policy choice, but the FDA may not delegate to itself more authority than Congress thought appropriate.

CONCLUSION

For the foregoing reasons, the *amici* respectfully request that the Court affirm the district court's decision to enter a preliminary injunction barring the FDA from detaining NJOY's products.

Respectfully Submitted,

/s/

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Dated: July 8, 2010

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of July, 2010, I caused copies of the foregoing Brief of *Amicus Curiae* Supporting Appellees to be served by electronic filing and first class mail, postage prepaid on the following counsel:

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