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

---

Brief of *Amici Curiae* American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Legacy Foundation, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, and Public Citizen Supporting Appellants

---

William B. Schultz
Carlos T. Angulo
Zuckerman Spaeder LLP
1800 M Street, N.W., Suite 1000
Washington, D.C. 20036-5802
(202) 778-1800 (telephone)
(202) 822-8106 (facsimile)
email: wschultz@zuckerman.com

CERTIFICATE OF PARTIES, RULINGS, AND RELATED CASES

All parties, intervenors and *amici* appearing in this case are listed in the Appellants' brief, as are all rulings and related cases.

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

On April 29, 2010, the *amici* – the American Academy of Pediatrics, American Cancer Society, American Cancer Society Cancer Action Network, American Heart Association, American Legacy Foundation, American Lung Association, American Medical Association, Campaign for Tobacco-Free Kids, and Public Citizen – moved for leave to participate in this case and represented that they would file their brief on May 24, 2010, the day that Appellants' brief is due. That motion is currently pending before this Court. *Amici* respectfully submit this brief since the Court may not act in its motion until after its brief would be due.

The *amici* are all national organizations committed to preserving the public health and have each been at the forefront of efforts to regulate the use of cigarette and other tobacco and nicotine-delivery products in the United States in order to reduce the morbidity and mortality caused by tobacco use. The *amici* have a strong interest in the question of whether FDA may regulate the electronic nicotine-delivery products at issue in this case. A brief description of each of the amici follows.

a. **The American Academy of Pediatrics** ("AAP") was founded in 1930 and is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of AAP has grown from the original group of 60 physicians specializing in children's health to 60,000 primary care physicians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 79 years, AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to working with hospitals and clinics, as well as with state and federal governments to protect the well-being of America's children. AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to second-hand tobacco smoke.

b. **The American Cancer Society** ("ACS") has more than three million volunteers nationwide, including 50,000 physicians. The organization works to eliminate cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, advocacy and service. Since its founding in 1913, ACS has conducted groundbreaking research to identify the use of tobacco products as a major cause of cancer and worked to educate the public about its deadly effects. The **American Cancer Society Cancer Action**

Network is the advocacy affiliate of ACS, helping to educate government officials on cancer as a public policy issue, and has almost half a million grassroots advocates.

c. The American Heart Association ("AHA") is a voluntary health organization founded in 1924 to reduce death and disability from cardiovascular diseases and stroke – two of the top three causes of death among Americans. AHA is one of the world's premier health organizations, with 22.5 million volunteers and supporters in nearly 2,000 community organizations in the 50 states as well as in Washington, D.C., and Puerto Rico. The association invested more than $473.5 million in fiscal year 2004-05 for research, professional and public education, community service and advocacy so people across America can live stronger, longer lives. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters.

d. The American Legacy Foundation ("Legacy") is dedicated to building a world where young people reject tobacco and anyone can quit. Legacy was established in March 1999 as a result of the Master Settlement Agreement reached between the attorneys general in 46 states and five U.S. territories and the tobacco industry. Legacy develops programs that address the health effects of tobacco use through grants, technical assistance and training, youth activism, strategic partnerships, counter-marketing and grass roots marketing campaigns, research,

public relations and outreach to populations disproportionately affected by the toll of tobacco.

e. **The American Lung Association** ("ALA") is the nation's oldest voluntary health organization, with volunteers in all 50 states and the District of Columbia, and a total of nearly 400,000 volunteers. ALA is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research.

f. **The American Medical Association** ("AMA"), an Illinois non-profit corporation founded in 1847, is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all United States physicians, residents, and medical students are represented in the AMA's policy making process. Its objects are to promote the science and art of medicine and the betterment of public health. The AMA has long had an interest in the regulation of tobacco products and the tobacco industry. As an institution, it has developed expertise in the pharmacology of nicotine, the toxic effects of cigarette smoke, and the societal implications of tobacco usage. For many years, the AMA has been one of the leading anti-smoking organizations in the United States.

g. **The Campaign for Tobacco-Free Kids** ("Tobacco-Free Kids") works to raise awareness that cigarette smoking is a public health hazard by advocating public policies to limit the marketing and sales of tobacco to children, and altering the environment in which tobacco use and policy decisions are made. Tobacco-Free Kids has over 100 member organizations, including health, civic, corporate, youth, and religious groups dedicated to reducing children's use of tobacco products.

h. **Public Citizen** is a consumer advocacy organization founded in 1971, with more than 200,000 members and subscribers nationwide. Public Citizen has long been active before Congress, regulatory agencies, and the courts in matters relating to public health in general and regulation by the Food and Drug Administration (FDA) in particular. Concerned about the severe health risk posed by tobacco products, Public Citizen has long advocated for increased regulation of these products and of the promotional efforts of the tobacco industry.

The *amici* are all non-profit institutions. No publicly-held corporation has an ownership stake of greater than 10% in any of the *amici*. No counsel or party to this case has made a monetary contribution intended to fund the preparation or submission of this brief, nor has any counsel or party to this case authored this brief in whole or in part.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITY

* Authorities on which we chiefly rely are marked with an asterisk.

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief of Appellants.

GLOSSARY

CDC	Centers for Disease Control and Prevention
CDER	FDA's Center for Drug Evaluation and Research
FDA	Appellant U.S. Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040.
HHS	U.S. Department of Health and Human Services
NDA	New Drug Application
NRT	Nicotine Replacement Therapy
SAMHSA	Substance Abuse and Mental Health Services Administration
Smoking Everywhere	Appellee Smoking Everywhere, Inc.
Tobacco Act	Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776.

SUMMARY OF ARGUMENT

Amici agree with the Appellant Food and Drug Administration (FDA) that Appellees' "electronic cigarettes" meet the Federal Food Drug and Cosmetic Act's (FFDCA's) definitions of "drugs" and "devices," and are therefore subject to regulation by FDA under that statute, notwithstanding the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). The District Court, however, disagreed, enjoining FDA from regulating these products – which, though characterized as "recreational,"[1] deliver the addictive drug nicotine into the bloodstream and are touted and used as alternatives to cigarettes.[2]

As explained in Section I, the effort to reduce the mortality and morbidity associated with tobacco use is one of the great public health challenges of our time, and safe and effective nicotine substitute products are needed to help meet that challenge. As explained in Section II, the lower court decision, if upheld, would have serious adverse impacts on the public health, for four reasons.

First, under that decision, electronic cigarettes and products like it would not need to be deemed safe or effective by FDA before marketing, and would be

---

[1] Joint Appendix ("JA") 530 (Dist. Ct. Memorandum Opinion, January 14, 2010, ("Op.") at 20).

[2] JA 514 (Op. at 4) (noting that Appellee Smoking Everywhere "markets its electronic cigarettes as a healthier alternative to traditional cigarettes" and citing company promotional materials and customer testimonials praising product as, *inter alia*, "a great alternative to help . . . stop smoking cigarettes" and "healthier than real cigarettes").

available without any objective evaluation or control over the level or potency of the nicotine in the products, or the quantity or quality of other ingredients. Because electronic cigarettes have not been subject to the kind of objective, rigorous scientific study FDA requires, the evidence is inadequate to conclude that electronic cigarettes are either safe or effective – and there is data suggesting that these products could present real dangers to the public health. Thus, their unregulated presence on the market must be viewed as a threat to the public health. Moreover, the injunction, if upheld, will also encourage other companies to end-run the regulatory process, leading to the marketing of other potentially unsafe and/or ineffective products used and advertised as tobacco alternatives.

Second, the injunction could also result in *increases* in tobacco use, especially among children, by introducing non-smokers to smoking behaviors and nicotine through use of unregulated products like electronic cigarettes. The problem is exacerbated by the fact that these products are not currently subject to the advertising restrictions to which cigarettes and other conventional tobacco products are subject and therefore can be manufactured and marketed in ways that appeal to children – *e.g.,* by using flavors that appeal to children and that Congress banned in cigarettes precisely because of that appeal.

Third, the injunction could cause reductions in the use of already-approved tobacco cessation products. Safe, effective alternative nicotine products are a key

part of the fight against tobacco use, and FDA has approved several nicotine drug products that meet its rigorous requirements. These FDA-approved products have been determined to work safely in helping persons quit tobacco use, but the presence on the market of unapproved nicotine alternatives of uncertain safety and effectiveness is likely to cause many tobacco users to either (1) use unapproved products instead of approved ones that have been screened for safety and effectiveness, or (2) stop using smoking cessation products altogether because of a misapprehension that they are *all* of unproven safety and effectiveness.

Fourth and finally, FDA regulation provides a needed incentive for companies working to develop the next generation of tobacco cessation products to ensure that their products are safe and more effective than products currently on the market. Notwithstanding the presence on the market of several FDA-approved nicotine substitutes, tobacco quit rates remain low, and *more and better* safe and effective nicotine products could substantially benefit many people. An injunction permitting certain nicotine products to sidestep safety and effectiveness evaluation will encourage other manufacturers of nicotine products to follow suit, avoiding FDA review and resulting in additional risks to the public health.

In short, the District Court's decision will make it substantially more difficult to address the problem of tobacco use in America and will have serious adverse consequences for the public health. This case is not about whether

electronic cigarettes are in fact safe and effective within the meaning of the governing law. Rather, it is about whether this product, which mimics smoking behaviors, may have a particular appeal to children, and presents potential dangers to its users should be allowed on the market without being subject to scientifically rigorous standards applicable to other nicotine delivery products.

ARGUMENT

I. Reducing tobacco use is one of the great public health challenges of our time, and safe and effective nicotine substitute products are needed to help meet that challenge.

Tobacco use accounts for 435,000 deaths each year in America and is widely regarded as the chief preventable cause of illness and death worldwide.[3] About 21 percent of U.S. adults – approximately 45 million Americans – smoke cigarettes,[4] and millions of additional adults use smokeless tobacco.[5] A 2004 Surgeon General Report, supported by more than 16,000 reports and studies, concluded that "[s]moking harms nearly every organ of the body" and causes cancer, cardiovascular disease, respiratory disease, reproductive harms, and many other

---

[3] U.S. Department of Health and Human Services, Public Health Service, "Treating Tobacco Use and Dependence: Clinical Practice Guideline" (2008 Update). (hereafter, "Treating Tobacco Use"), at 11 (citing, *inter alia*, data from the Centers for Disease Control and Prevention (CDC)).

[4] *Id.* (citing, *inter alia*, CDC, "Cigarette smoking among adults – United States 2006" (2007)).

[5] *Id.* at 163 (citing CDC data that the use of smokeless tobacco was reported among 4 percent of U.S. adult men in 2005).

health problems.[6] Tobacco use also represents a huge drain on the nation's economy. Health-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.[7] If all smokers covered by State Medicaid programs were to quit, annual Medicaid savings after five years would be $9.7 billion.[8]

Pediatric use of tobacco is a particular concern.[9] In America, about 4,000 people under 18 smoke their first cigarette each day, and approximately 1,200 children and adolescents become daily smokers each day.[10] In 2006, an estimated 3.3 million Americans aged 12 to 17 were current users of tobacco products.[11] Among adults who smoke daily, 90 percent tried their first cigarette before age 21.[12] Quit rates among children and adolescents are far lower than among adults, with the result that many tobacco users begin early, never quit, and suffer health

---

[6] "The Health Consequences of Smoking: A Report of the Surgeon General," May 27, 2004, at 8. Meanwhile, health risks from smokeless tobacco include abrasion of teeth, gingival recession, periodontal bone loss, leukoplakia, and oral and pancreatic cancer. Treating Tobacco Use at 163.

[7] Treating Tobacco Use, at 11 (citing, *inter alia*, CDC, "Best Practices for Comprehensive Tobacco Control Programs – 2007").

[8] *Id.* (citing American Legacy Foundation, "Saving lives, saving money: tobacco-free states spend less on Medicaid").

[9] *See* Family Smoking Prevention and Tobacco Control Act ("Tobacco Act"), Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009) (Finding 1) ("The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.").

[10] Treating Tobacco Use, at 158 (*citing*, *inter alia*, 2005 and 2006 data from the Substance Abuse and Mental Health Services Administration (SAMHSA)).

[11] *Id.*

[12] *Id.* (citing American Lung Association, "Adolescent smoking statistics 2003").

consequences throughout the remainder of their (often-shortened) lives.[13] Congress has estimated that reducing tobacco use by minors would save three million lives and would result in $75 billion in reduced health care costs.[14]

While millions of Americans are addicted to tobacco and nicotine, more than 70 percent of American adult smokers, approximately 30 million persons, want to quit.[15] There is therefore a clear demand and need for products and services to aid smoking and tobacco use cessation. Several such products have been deemed safe and effective by FDA and are on the market today, including "nicotine replacement therapies" (NRTs), which deliver a carefully calibrated amount of nicotine into the body without the damaging effects of smoking or other tobacco use.[16] These products, and others still in development, are an important component of the fight against tobacco use: existing FDA-approved NRTs have been shown to increase by 50-70% the likelihood of success of a tobacco quit attempt.[17]

---

[13] *Id.* (noting that "the rate of failed adolescent quit attempts exceeds that of adult smokers" and citing, *inter alia*, CDC, "Use of cessation methods among smokers aged 16-24 years" (2003)).
[14] Tobacco Act, 123 Stat. at 1777 (Finding 14).
[15] Treating Tobacco Use, at 15 (citing CDC, "Cigarette smoking among adults – United States 2006" (2007)).
[16] These products include nicotine gum, the transdermal patch, nicotine inhaler, nicotine lozenges, and nicotine nasal spray.
[17] L. Stead, et al., *Nicotine replacement therapy for smoking cessation*, Cochrane Database of Systematic Review, Issue 4 (January 23, 2008).

II. The District Court's injunction would hinder efforts to reduce the mortality and morbidity associated with tobacco use and harm the public health.

If upheld, the District Court's decision enjoining FDA regulation of electronic cigarettes and permitting the marketing of these products without an agency determination of safety and effectiveness would have serious public health consequences.

a. The District Court's injunction would allow the marketing of potentially dangerous and ineffective nicotine products.

The District Court's decision, if upheld, facilitates and encourages companies' efforts to end-run the strict FDA regulatory requirements for nicotine products and to market products that are of unknown safety and effectiveness and quite possibly dangerous and ineffective.

As noted above, FDA has approved as drugs nicotine replacement products that meet its regulatory standards, including products containing nicotine derived from tobacco, such as nicotine patches and nicotine gum.[18] FDA approved these products as safe and effective after rigorous agency review. Such strict review is compelled not

[18] In general, FDA has long regulated as drugs nicotine products other than products it deemed to be traditional tobacco products – even when the nicotine was derived from tobacco. As Appellants have explained, the Tobacco Act expressly provides for FDA regulation under the agency's preexisting authority over products that meet the definition of "drugs" or "devices" and states that once FDA determines a product meets one or both of those definitions, it shall not be treated as a "tobacco product" under the Act. Appellees' products meet the definition of "drug" or "device."

only by the great public need for such products, discussed above, but also by the risks associated with the use of nicotine itself, an "addictive drug"[19] that is "dangerous or even fatal" when administered in large doses.[20] A declaration in this case from Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), details the health risks related to nicotine use:

> [U]pon entering the bloodstream, nicotine is a stimulant that increases blood pressure, respiration, and heart rate. Symptoms of nicotine poisoning include vomiting, diarrhea, abdominal cramping, confusion and convulsions, tachycardia, and hypertension . . . . [N]icotine can cause elevations in blood pressure and heart rate. Excessive nicotine exposure may precipitate cardiovascular events in patients with cardiovascular disease such as coronary artery disease, peripheral vascular disease, and hypertension.[21]

There can be no question, therefore, that nicotine products deserve close scrutiny from the FDA, which is charged with assessing the safety and effectiveness of new drug products, to protect the public health. As with all new drugs, the standards governing FDA approval of NRTs are rightly strict ones. A New Drug Application (NDA) for an NRT must include detailed safety data, as well as manufacturing controls to ensure that each individual product contains an identified and accurately calibrated amount of nicotine. Pharmaceutical grade nicotine used in FDA-approved products – whether or not tobacco-derived – is

---

[19] Tobacco Act, 123 Stat. at 1777 (Finding 3).
[20] JA 546 (Declaration of Janet Woodcock. M.D. ("Woodcock Decl."), at ¶ 4).
[21] JA 546, 549 (Woodcock Decl. at ¶ ¶ 4, 14).

also tested for the presence of pesticides and herbicides. Finally, product labels for FDA-approved NRTs must contain precautions for patients that have cardiovascular disease: specifically, patients with coronary artery disease, serious cardiac arrhythmias, or other vasospastic disease are advised to consult their physicians before nicotine replacement therapy is prescribed.[22]

If the injunction in this case is upheld, however, products like electronic cigarettes, despite having undergone no FDA review, will be available to recreational users, including youth, and to consumers seeking help in quitting tobacco. As a result, a non-tobacco user or a smoker who turns to electronic cigarettes because they have been touted as "a great alternative to help . . . stop smoking cigarettes" or "healthier than real cigarettes" (*supra* n. 4) will have no way of knowing whether the product contains harmful contaminants, whether the product contains a dangerous level of nicotine or, alternatively, a wholly ineffective level of nicotine, or whether the person should forgo using the product because he or she suffers from another medical condition – much less whether the product will actually help the smoker quit.

While the long-term health consequences of electronic cigarettes are unknown, due to the minimal review they have undergone, FDA's limited testing

[22] JA 547, 549 (Woodcock Decl. at ¶¶ 7, 14).

of a small sample of electronic cigarettes in July 2009 has already revealed numerous potential safety problems with electronic cigarettes, including:

- The presence of low levels of nicotine in certain electronic cigarettes labeled as containing no nicotine;
- the wide variability in the amount of nicotine emitted with each puff, from 26.8 to 43.2 mcg nicotine/mL;
- the presence of diethylene glycol – a solvent that is toxic to humans and has resulted in "significant fatalities" when used in pharmaceuticals – in one of the tested electronic cigarette cartridges;
- the presence of tobacco-specific nitrosamines, which are human carcinogens, in half the samples tested; and
- the presence of tobacco-specific impurities suspected of being harmful to humans – anabasine, myosmine, and B-nicotine – in a majority of the samples tested.[23]

These are precisely the kinds of safety issues that FDA review of nicotine products has historically been designed to identify and address, and that electronic cigarette manufacturers ought to be required to resolve before they are allowed to market their products for use by the tens of millions of Americans looking for recreational drug use or alternatives to tobacco.

[23] JA 547-548 (Woodcock Decl. at ¶¶ 9-12). FDA has also received reports of short-term side effects caused by electronic cigarettes, including racing pulse, dizziness, slurred speech, mouth ulcers, heartburn, coughing, diarrhea, and sore throat. JA 549 (Woodcock Decl. at ¶ 14).

b. The District Court's injunction would likely lead to greater nicotine use and, eventually, to tobacco use among children.

Unregulated nicotine products like electronic cigarettes not only may fail to help address the problem of tobacco use; they may also exacerbate that very problem – for example, by introducing non-tobacco users, especially children, to smoking behaviors and nicotine products for the first time.

As noted above, youth tobacco use is a particularly significant public health issue – one that Congress most recently tackled in the Tobacco Act, which contains numerous findings regarding the impact and prevalence of tobacco advertising aimed at young persons[24] and has as a goal the restriction of such advertising. If the District Court's decision is upheld, however, electronic cigarettes would not be subject to any regulatory restrictions covering "drugs" or "medical devices," nor are they currently subject to any regulation applicable to tobacco products, such as warning labels, advertising restrictions or restrictions on sales to minors.

Consequently, electronic cigarettes do not carry any mandated health warnings, and may be – and are – sold in flavors such as strawberry, chocolate, and mint that appeal to children and teenagers, and in places like shopping malls frequented by young people.[25] Thus, the lack of regulation over these products enables them to be manufactured, sold and marketed in a manner that, rather than

---

[24] *See, e.g.,* Tobacco Act, 123 Stat. at 1777-1778 (Findings 14-27)
[25] JA 546 (Woodcock Decl. at ¶ 5).

helping people quit smoking, could actually *introduce* non-smokers – in particular children – to smoking behaviors and nicotine and, potentially, lead them eventually toward tobacco use. As noted by Dr. Woodcock, "FDA is concerned that this novel nicotine product, to the extent it remains an unapproved and unregulated product, will attract new constituencies to nicotine use . . . ."[26]

c. The District Court's decision would discourage tobacco users from using FDA-approved smoking cessation products to help them quit.

The presence of unregulated nicotine products on the market will also exacerbate the problem of tobacco use by creating competition for and discouraging the use of FDA-approved smoking cessation products, for two reasons.

First, "current smokers may attempt to use these [unregulated nicotine] products instead of products proven effective for smoking cessation."[27] Second, the confusion caused by the presence on the market of unregulated nicotine products viewed by the public as unsafe or ineffective may lead consumers to forgo all smoking cessation products, even those FDA has actually found to be safe and effective. This possibility is of particular concern because an already-common hurdle to the use of FDA-approved nicotine products is the misperception that they

[26] JA 549 (Woodcock Decl. at ¶ 15). *See also id.* (expressing FDA's concern that "non-smokers may initiate nicotine use through these products").
[27] JA 549 (Woodcock Decl. at ¶ 15).

are no safer than conventional tobacco products. For example, according to a recent FDA citizens petition, "[t]he most persistent and pernicious belief among smokers that interferes with their interest in using NRT is the belief that heart attack risk is greater or the same for NRT as for cigarette use."[28] Misperceptions about the safety or effectiveness of smoking cessation products generally will be reinforced by the presence on the market of nicotine products that have yet to be proven safe and effective and may well be dangerous and ineffective.

d. The District Court's injunction would undermine the incentive to develop new, better alternative nicotine products.

Although, as noted above, existing FDA-approved NRTs have been shown to increase the likelihood of success of a tobacco quit attempt, quit rates remain low: only 44% of U.S. adult smokers even attempt to quit (although 70% want to do so) each year, and each year only a small percentage are successful – in 2005, for example, a mere 4-7 percent.[29] There are many reasons for these low quit rates, but the numbers nonetheless highlight the potential need for more – and more effective – NRTs on the market.

---

[28] FDA Citizen Petition filed by the Association for the Treatment of Tobacco Use and Dependence and the Society for Research on Nicotine and Tobacco, February 12, 2010, FDA Docket No. FDA- 2010-P-0089, at 18 and n.59. *See also id.* at 18 n.62 (noting survey in which 66 percent of smokers or ex-smokers agreed somewhat with the statement that "stop-smoking products with nicotine are just as harmful as cigarettes").

[29] Treating Tobacco Use at 15 (citing, *inter alia*, CDC data).

In the recently-enacted Tobacco Act, Congress underscored the importance of developing new safe and effective products to help tobacco users quit, providing in section 918(a) of that legislation that a sponsor of a new smoking cessation device, including an NRT, may petition FDA for fast-track consideration of its application.[30] The Tobacco Act further provides in section 918(b) that the Secretary of Health and Human Services (HHS) shall report to Congress on:

> how best to regulate, promote and encourage the development of innovative products and treatments . . . to better achieve, in a manner that best protects and promotes the public health -
>
> (A) total abstinence from tobacco use;
> (B) reductions in consumption of tobacco; and
> (C) reductions in the harm associated with continued tobacco use.[31]

To meet this need, however, the incentive for companies to undertake the critically important process of securing an FDA safety and effectiveness determination must be maintained. The District Court's injunction, however, has the opposite effect, weakening the incentive for nicotine product makers to undertake the rigorous testing needed to secure FDA approval. Some companies interested in developing nicotine products for FDA approval to assist tobacco users to quit may, as a result of this decision, opt not to conduct the safety and efficacy tests needed to bring new products to market. And other companies that currently

---

[30] Tobacco Act, 123 Stat. at 1825.
[31] *Id.* at 1825-26.

abide by FDA requirements may be inclined to avoid investing in the development of more effective nicotine replacement products altogether if they perceive that they will be competing with less expensive, unregulated products.

* * *

Electronic cigarettes may or may not be a safe and effective alternative to tobacco (although, as noted above, there is evidence raising significant safety concerns). The rigorous FDA approval process is designed to answer that question. FDA's effort to regulate electronic cigarettes is not a pre-judgment as to these products' approvability, but an essential step in the process of determining whether the products are part of the solution to one of the greatest public health problems of our time.

CONCLUSION

For the foregoing reasons, this Court should vacate the preliminary injunction entered by the District Court.

Respectfully submitted,

/s/ William B. Schultz
William B. Schultz
Carlos T. Angulo
Zuckerman Spaeder LLP
1800 M Street, N.W., Suite 1000
Washington, D.C. 20036-5802
(202) 778-1800 (telephone), (202) 822-8106 (fax)
email: wschultz@zuckerman.com

Counsel for Amici

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 4,632 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the type style requirements of Fed. R. App. 32(a)(6). It has been prepared in a proportionally spaced typeface using Microsoft Word in size 14 font and Times New Roman style.

/s/ William B. Schultz May 24, 2010
Counsel for *Amici*

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of May, 2010, I caused the foregoing brief to be filed with the Court in hard copy and electronically, and served through the Court's ECF system on the following:

Christopher Kip Schwartz, Esq.
Eric Nathan Heyer, Esq.
Thompson Hine LLP
1920 N Street, N.W., Suite 800
Washington, D.C. 20036
tel: 202-263-4157

Richard Paul Bress, Esq.
David A. Becker, Esq.
Latham & Watkins
555 11th St., N.W., Suite 1000
Washington, D.C. 20004
tel: 202-637-2200

Richard A. Samp, Esq.
Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036-0000
tel: 202-588-0302

Alisa Klein, Esq.
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave., NW Room 7235
Washington, D.C. 20530
Tel: 202 514-1597

/s/ William B. Schultz
William B. Schultz

Counsel for *Amici*