ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 23, 2010

NO. 10-5032

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

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

*Intervenor-Plaintiff-Appellee*,

v.

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

*Defendants-Appellants*.

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On Appeal From the United States District Court For the District of Columbia
Civil Action No. 09-cv-0771 (RJL)

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# *AMICUS CURIAE* BRIEF OF WASHINGTON LEGAL FOUNDATION IN SUPPORT OF APPELLEE, URGING AFFIRMANCE

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Daniel J. Popeo
Richard A. Samp
WASHINGTON LEGAL
FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036
(202) 588-0302

Coleen Klasmeier
Rebecca K. Wood
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

*Attorneys for Amicus Curiae Washington Legal Foundation*

## CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

**A. Parties and *Amici*.** With one exception, all parties, intervenors, and *amici* appearing before the district court and in this court are listed in the Brief for Appellants. The one exception is Professor John F. Banzhaf, who filed an *amicus curiae* brief in the district court, but is not participating in this appeal.

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, the undersigned *amicus curiae*, Washington Legal Foundation ("WLF"), states that it is a nonprofit corporation organized under Section 501c(3) of the Internal Revenue Code, that it has no parent corporation, and that it has no common stock owned by a publicly owned corporation. Pursuant to Circuit Rule 26.1(b), WLF describes its general nature and purpose as follows: WLF is a public-interest law and policy center that regularly appears in this Court and others in cases raising public policy issues. WLF has no financial ties, direct or indirect, with any party to this appeal.

**B. Rulings Under Review.** The preliminary injunction under review (JA543-44) was issued on January 14, 2010, by the Hon. Richard J. Leon, United States District Court for the District of Columbia, in Civ. No. 09-771.

**C. Related Cases.** The preliminary injunction under review has been stayed by this Court. WLF is not aware of any related cases.

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## GLOSSARY

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|---|---|
| CPSC | Consumer Product Safety Commission |
| CSA | Federal Controlled Substances Act |
| DEA | Drug Enforcement Administration |
| FDA | Food and Drug Administration |
| FDCA | Federal Food, Drug, and Cosmetic Act |
| FTC | Federal Trade Commission |
| NJOY | Appellee Sottera, Inc. d/b/a NJOY |
| WLF | *Amicus Curiae* Washington Legal Foundation |

## STATEMENT OF INTEREST OF *AMICUS CURIAE*

WLF is a nonprofit public interest law and policy center founded in 1977, with supporters in all 50 States. Among other things, WLF promotes principles of limited government under the rule of law by seeking to confine federal administrative agencies, including the Food and Drug Administration ("FDA"), to their statutorily authorized powers. WLF has been a key watchdog of FDA regulation for many years and has appeared in numerous federal and state court cases involving issues similar to those presented here.

Most relevant here, WLF participated as *amicus curiae* in *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000), the landmark Supreme Court decision holding that FDA lacked authority to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act ("FDCA"). There, as here, WLF was concerned about FDA's theory of regulation, which asserted that "intended use" of a product within the meaning of Section 201(g) and (h) of the FDCA could be determined with reference to the products' actual or foreseeable use, or other non-statutory factors such as a product's inherent attributes, rather than therapeutic claims made by the manufacturer. Such a capacious interpretation would give FDA unfettered discretion to regulate virtually any consumer product as a drug or medical device, well exceeding the proper ambit of the agency's authority under the FDCA.

In addition, WLF has appeared as *amicus* in numerous other cases to urge the faithful interpretation and application of the FDCA. *See, e.g.*, *United States v. RX Depot, Inc*., 438 F.3d 1052 (10th Cir. 2006); *United States v. Lane Labs-USA*, 427 F.3d 219 (3d Cir. 2005). WLF also was the named plaintiff in the successful challenge to the constitutionality of FDA restrictions on scientific speech regarding lawful, off-label uses of FDA-approved products. *See WLF v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed sub nom. WLF v. Henney*, 202 F. 3d 331 (D.C. Cir. 2000).

Pursuant to Circuit Rule 29(b), WLF timely notified the Court on March 31, 2010, that all parties to this appeal had consented to WLF's filing of an *amicus curiae* brief in support of the appellee.

## PRELIMINARY STATEMENT

The proper interpretation of intended use is among the most important and enduring issues in food and drug law because it defines the scope of FDA's power to regulate products as drugs or medical devices under the FDCA. *See* 21 U.S.C. § 321(g)(1), (h). In the course of this litigation, the Government has advanced several broad interpretations of intended use in an effort to stretch its statutory authority to subject one category of products—electronic cigarettes—to the drug and medical device provisions of the FDCA. But the principles at stake here are much broader. WLF urges this Court to hold that a product's intended use under the FDCA can be created solely by the therapeutic or medical claims made by the product's manufacturer.

As explained below, the claims-based interpretation of intended use is the only interpretation that harmonizes the relevant jurisprudence and avoids the types of dislocations in the application of the FDCA that the Supreme Court recognized in *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000). Rather than distort the doctrine that determines the critical, threshold jurisdictional question under the FDCA for the sake of expediency, with numerous deleterious consequences, to the extent FDA wishes to regulate this product, the Government instead should invoke the appropriate alternative jurisdictional bases and political processes it has at hand.

WLF will not repeat the well-argued points made in appellee's brief. Instead, WLF invites the Court's attention to the broader body of jurisprudence on intended use under the FDCA, and to the anomalous results that would flow from the Government's erroneous interpretation.

## SUMMARY OF ARGUMENT

The FDCA authorizes FDA to regulate as "drugs" and "devices" those products that are "intended for use" in the diagnosis, cure, mitigation, treatment, or prevention of disease or "intended to affect" the structure or any function of the body. 21 U.S.C. § 321(g)(1)(B)-(C), (h)(2)-(3).[1] In order to give proper meaning and scope to these provisions in light of the overall statutory scheme, and to avoid absurd results, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [FDCA] absent manufacturer *claims* as to that product's use." *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998) (emphasis added), *aff'd on other grounds*, 529 U.S. 120 (2000); *Brown & Williamson*, 529 U.S. at 128 (recognizing argument that an

[1] FDA has not asserted jurisdiction here based on the presence of electronic cigarettes or their components in the National Formulary or United States Pharmacopeia. *See* 21 U.S.C. § 321(g)(1)(A), (h)(1). In any event, courts generally have rejected FDA's attempts to regulate any product as a drug or device merely because it is listed in these sources given that such an approach "would give the FDA virtually unlimited discretion to regulate . . . a vast range of items." *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 336-37 (2d Cir. 1977).

"intended use" under the FDCA could only be found if "the manufacturer or vendor makes some express claim concerning the product's therapeutic benefits").

It long has been accepted as a matter of statutory interpretation that "the crux of FDA jurisdiction . . . [lies] in manufacturers' *representations* . . . ." *Action on Smoking & Health v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980) (citing S. Rep. No. 74-361, at 4 (1935) (emphasis added). In this litigation, the Government has acknowledged that FDA's authority to regulate products as "drugs" or "devices" reaches products promoted with "therapeutic claims" and that no such claims have been made on this record. Gov't Br. 5 n.2, 17-18. That should end the analysis under the drug and medical device provisions of the FDCA, and the Government should now turn its focus to assessing whether these products are properly regulated under the new tobacco product provisions of the FDCA (as Appellee NJOY has acknowledged they may be), under other statutes, or not at all, in which case the proper recourse is to political processes. Unfortunately, the Government's argument does not stop there and it instead urges an array of broad alternative alleged bases for asserting its drug and device authorities, including the inherent characteristics and effects of the product, actual consumer use, and circumstances surrounding distribution. As explained below, the Government's non-claims-based interpretation of intended use conflicts with the law and threatens the effective operation of the FDCA.

## ARGUMENT

### I. THE GOVERNMENT'S INTENDED USE THEORIES CONFLICT WITH THE FDCA.

The Government advances numerous non-claims-based interpretations of intended use in an effort to enable FDA to regulate electronic cigarettes under the drug and medical device provisions of the FDCA. Although it acknowledges that therapeutic or medical claims *can* provide a basis for regulation of a product as a "drug" or "device," the Government flatly denies that such claims are *necessary* to find an intended use under the FDCA. *See, e.g.*, Gov't Br. 5 n.2, 17-18; Defs. Supp. Br. In Opp. To Pls. & Ints. Mtns. For Prelim. Inj. 8, ECF No. 41 (filed July 10, 2009) (asserting that the exclusively claims-based interpretation "is contrary to the language of the statute, FDA regulations, FDA administrative practice, and case law"); Defs. Emergency Mot. For Reconsid. of Prelim. Inj. 4, ECF No. 60 (filed Feb. 1, 2010) ("a so-called 'electronic cigarette' need not be accompanied by therapeutic claims in order to be regulated as a drug or device within the meaning of the FDCA."). The Government's approach conflicts with the law and cannot be sustained.

#### A. Intended Use Is Created By Promotional Claims Of Therapeutic Or Medical Benefit.

The scope of FDA's jurisdiction over drugs and medical devices is limited by the FDCA. "The determination that an article is properly regulated as a drug [or device] is not left to the Commissioner's unbridled discretion to act to protect

the public health but must be in accordance with the statutory definition[s]." *Nat'l Nutritional Foods Ass'n*, 557 F.2d at 334-35; *see also Am. Health Prods. Co. v. Hayes*, 574 F. Supp. 1498, 1507 (S.D.N.Y. 1983) ("[A] court's responsibility to construe the [FDCA] in accord with its protective purposes does not confer a license to ignore congressional judgments reflected in the classification scheme."), *aff'd on other grounds*, 744 F.2d 912 (2d Cir. 1984).

Nearly a century of judicial decisions, and the legislative history of the FDCA, establish that the intended use of a product under the FDCA is determined by the manufacturer's promotional claims. The statutory definitions of "drug" and "device" encompass articles that are "intended for use" or "intended to affect" within the meaning of §321(g) and (h). "Intended use" is a term of art in food and drug law that is distinct from traditional criminal or tort law notions of *mens rea* or "intent." As a former chief counsel of FDA observed:

> For decades, it generally has been understood that intended uses are established by manufacturer *statements*. It is not that intended uses are established by events in the minds of manufacturers (whatever those may be) and that the statements are merely evidence of what has occurred in those minds; rather, the statements create the intended uses, and the minds (and evidence of what has occurred in those minds) are irrelevant.

Richard M. Cooper, *The WLF Case Thus Far: Not With a Bang, But a Whimper*, 55 Food and Drug L.J. 477, 485 (2000) (emphasis added).

The doctrine of intended use, in which "intent" is irrelevant and claims are central, is based not only on the particular language of the statutory definitions of

"drug" and "device," but also on the legislative history of the FDCA. According to a seminal Senate report, whether a product is a drug or device under the legislation that would become the FDCA was to be determined by the manufacturer's "representations in connection with . . . sale" of a product. *See* S. Rep. No. 74-361, pt. 1, at 4 (1935); *see also* Foods, Drugs, and Cosmetics: Hearings on S. 2800 Before the Comm. on Commerce, 73rd Cong. 517-18 (1934) (statement of W.G. Campbell) (the categorization of a product as a "drug"—and FDA's authority to regulate it as such—hinged on the manufacturer's representations to the public). The focus on promotional claims reflects Congress's emphasis on a specific public health problem of the period: the proliferation of proprietary medicines for which fraudulent therapeutic claims were being made with impunity under prior law. *See* H.R. Rep. No. 75-2139, pt.1, at 8 (1938); 79 Cong. Rec. 4,748, 4,748 (1935) (statement of Sen. Copeland).[2]

[2] 79 Cong. Rec. at 4,748 (statement of Sen. Copeland) ("I have here a bottle of a 'medicine,' originally made for horse liniment. Now it is advertised to cure tuberculosis, pneumonia, laryngitis, bronchitis, pleurisy, influenza, la grippe, asthma, everything, indeed, from asthma to zymosis. . . . The taking of these 'remedies' for diseases which could not thus be cured or alleviated has resulted frequently in the diseases becoming incurable by reason of the delay of proper medical treatment. This is a practice which is of course inimical to health, yet it is impossible to prohibit their sale under the existing law."); *id.* ("I present here a bottle filled with a tincture made from horse-tail weed. If there is any Senator suffering from diabetes, he will be cured by taking proper doses of horse-tail weed, according to the labeling on this bottle. Unfortunately, under the law as it is at present, . . . the poor suffering citizen who has diabetes, and by modern treatment could be cured, continues to suffer when he takes horse-tail weed.").

Likewise, this Court has recognized that:

> [T]he crux of FDA jurisdiction . . . [lies] in manufacturers' representations . . . . "The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put . . . ." *Such an understanding has now been accepted as a matter of statutory interpretation*.

*Action on Smoking & Health*, 655 F.2d at 238-39 (invoking legislative history) (emphasis added); *see also United States v. Article . . . Sudden Change*, 409 F.2d 734, 739 n.3 (2d Cir. 1969); *Am. Health Prods. Co.*, 574 F. Supp. at 1506. Courts "have *always* read the . . . statutory definitions employing the term 'intended' to refer to specific marketing representations." *Am. Health Prods. Co.*, 574 F. Supp. at 1505 (emphasis added); *see, e.g.*, *Sudden Change*, 409 F.2d at 739 (explaining that a product is regulated as a drug or device "if certain promotional claims are made for it"); *V.E. Irons v. United States*, 244 F.2d 34, 44 (1st Cir. 1957) ("[W]e are entitled to utilize all of appellants' literature as well as the oral representations made by V. Earl Irons at his lectures or by authorized sales distributors."); *United States v. Nutrition Serv., Inc.*, 227 F. Supp. 375, 386 (W.D. Pa. 1964) ("The real test is how was this product being sold?"), *aff'd*, 347 F.2d 233 (3d Cir. 1965).

The concept of promotional claims is so central to intended use that promotional materials containing the requisite medical or therapeutic statements demonstrate intended use only if they are communicated to customers. *See United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995)

(holding that the materials are relevant to intended use only if they are promotional in nature and were actually distributed to customers, and if customers were currently relying on them); *see also United States v. Undetermined Quantities of an Article of Drug Labeled "Exachol*," 716 F. Supp. 787, 791 (S.D.N.Y 1989) (requiring evidence that customers continued to rely on therapeutic claims made in literature previously marketed with the product); *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219, 1225 (D. Minn. 1991) (stating that claims made in promotional materials that defendant no longer distributed were admissible only if the Government could demonstrate that defendant's customers purchased the products at issue in reliance on those materials), *aff'd*, 968 F.2d 681 (8th Cir. 1992).

Thus, under the FDCA, the proper focus of the intended use inquiry is the promotional *claims* of therapeutic or medical benefit made by the manufacturer. In the absence of such claims, no other factor can provide a basis for FDA regulation of a product as a drug or medical device, as discussed below.

**B. The Government's Theories Of Intended Use Are Incorrect.**

Although the Government's brief on appeal is not entirely clear, at various points in this litigation it has urged that a range of alternative factors may establish intended use absent promotional claims of medical or therapeutic benefit. Those alternative approaches should be rejected.

*Actual Use.* Intended use cannot be based solely on actual consumer use. Indeed, the statutory term in the definitions of "drug" and "device" is not "use" but rather "intended for use." 21 U.S.C. § 321(g)(1)(B), (h)(2). "When Congress meant to define a drug in terms of its intended use, it explicitly incorporated that element into its statutory definition." *Nutrilab Inc. v. Schweiker,* 713 F.2d 335, 337 (7th Cir. 1983) (distinguishing definition of "drug" from that of "food" under the FDCA because the "definition of food . . . omits any reference to intent"). Indeed, another FDCA provision confirms that when Congress intends to refer to the *actual* use of a drug or medical device—rather than to "intended use"—it knows how to do so. *See* 21 U.S.C. § 321(n) (referring to uses of a drug or medical device that are "customary or usual").

Given the statutory language, the courts have properly rejected FDA's prior attempts to regulate a product based on actual use. Indeed, no court has ever held that mere consumer use could support an assertion of FDA jurisdiction, and no court has ever found a product subject to drug and device regulation on that basis. In *Action on Smoking & Health*, this Court explained the difficulty—if not impossibility—of basing FDA jurisdiction on consumer use:

> In cases such as the one at hand, consumers must use the product predominantly and in fact nearly exclusively . . . before the requisite statutory intent can be inferred . . . .

655 F.2d at 240; *Ass'n of Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204, 217-18 (D.D.C. 2002) ("even the FDA has repeatedly stated that it may only regulate claimed uses of drugs, not all foreseeable or actual uses," and in the absence of claims, a use must represent the "near exclusive" use of a product to qualify as an "intended use"). If any other approach were followed, "[c]arried to its logical extreme, . . . [it] would mean that every merchant who sells carrots to the public with knowledge that some of his consumers believe that the ingestion of carrots prevents eye disease holds the carrots out for use as a drug, as that term is defined in the Act." *Millet, Pit & Seed Co. v. United States*, 436 F. Supp. 84, 89 n.4 (E.D. Tenn. 1977) (holding that apricot kernels are not drugs where manufacturer made no representations about their therapeutic use even though customers used them to prevent cancer), *vacated and remanded sub nom. United States v. Article of Food & Drug Consisting of 6,701 Cases, More or Less*, 627 F.2d 1093 (6th Cir. 1980).

*Inherent Characteristics, Actual Effects, Inherent Toxicity.* Numerous courts have recognized that a product is a drug or device because of its intended medical or therapeutic use, as demonstrated by the manufacturer's claims, and not merely because of its inherent physical or pharmacological characteristics or its actual effect on the body. For example, the Second Circuit explained that Sudden Change, a bovine albumen product marketed to provide a "Face Lift Without

Surgery," was a drug "[r]egardless of the actual physical effect" because its labeling and promotional claims referred to "face lift" and "surgery." *Sudden Change*, 409 F.2d at 738-39. Likewise, a product touted as effective in treating, mitigating, and preventing "many ailments including some of the most serious that afflict mankind" could be regulated as a drug, because "it is the intended use of an article which determines whether it is a drug, regardless of its inherent properties." *United States v. 3 Cartons More or Less "No. 26 Formula GM,"* 132 F. Supp. 569, 573 (S.D. Cal. 1952) (allowing drug regulation of products containing minute quantities of animal glands in a vegetable base despite disclaimer of no therapeutic value because totality of representations demonstrated otherwise); *see also* n.5, *infra*. Nor is inherent toxicity alone adequate to establish intended use, because "[t]oxicity is not included as an element in the statutory definition of a drug." *Nat'l Nutritional Foods Ass'n*, 557 F.2d at 335.

### C. The Government's Other Attempts To Expand The Scope Of Its Authority Cannot Be Sustained.

The Government's remaining efforts to avoid a claims-based approach and expand FDA's authority fail. The Government can take no refuge in the notion that FDA is entitled to consider "any relevant source" to determine intended use. *See* Gov't Br. 18; Defs. Mem. In Opp. To Pl.'s Mo. For Prelim. Inj. 17, ECF. No. 14 (filed May 11, 2009); *see generally United States v. Storage Spaces Designated Nos. 8 & 49*, 777 F.2d 1363, 1366 (9th Cir. 1985); *United States v. Lane Labs-*

*USA, Inc.*, 324 F. Supp. 2d 547, 567 (D.N.J. 2004), *aff'd* 427 F.3d 219 (3d. Cir. 2005); *Exachol*, 716 F. Supp. at 791. To be sure, as these cases recognize, *if* there are "drug"- or "device"-type *claims* that create the requisite intended use, then the Government is entitled to pierce a manufacturer's mere assertions that it does not intend for its product to be used for a medical or therapeutic purpose and find "intended use" within the meaning of the statutory "drug" and "device" definitions. But the "any relevant source" language does not mean that FDA is entitled to find intended use *where there are no claims*.

The Government's cited cases themselves make the point. The court in *Lane Labs-USA, Inc.* concluded that shark cartilage, rice bran, and sand brier extract products were drugs based on literature distributed with the products claiming that the products were "an effective treatment" for cancer and HIV/AIDS. 324 F. Supp. 2d at 567-68. Likewise, the court in *Exachol* determined that the product was a "drug" on the ground that the promotional materials distributed with the product claimed that it could protect against "fatty deposits" leading to a heart attack. 716 F. Supp. at 791-93. And, in *Storage Spaces*, the court concluded that the Government had properly determined that a product was a "drug" under the FDCA because of promotional materials stating that it was a "synthetic" version of

cocaine and that ingestion or inhalation of the product "may cause stimulation." 777 F.2d at 1366-67.[3]

The "other relevant source" language originated in *Hanson v. United States*, 417 F. Supp. 30 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976) (per curiam), and has been invoked in other cases since. Yet those cases, like *Hanson* itself, also involved manufacturer *claims*. *See Sudden Change*, 409 F.2d at 739 (advertisements); *United States v. Millpax, Inc*., 313 F.2d 152 (7th Cir. 1963) (letters and oral representations); *Nature Food Ctrs., Inc. v. United States*, 310 F.2d 67 (1st Cir. 1962) (speeches at public lecture hall); *V.E. Irons v. United States*, 244 F.2d 34 (1st Cir. 1957) (statements of authorized distributor); *United States v. Articles of Drug, Foods Plus, Inc.*, 239 F. Supp. 465 (D.N.J. 1965) (radio broadcast). Accordingly, absent medical or therapeutic claims, the Government cannot find an intended use by invoking the mantra of "other relevant sources." *See generally Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 531 (2005) ("On

[3] The court's analysis of the intended use in this case was somewhat unclear. *Storage Spaces* involved promotion of substances (apparently, Benzocaine, Lidocaine, Tetracaine, and Procaine) that are marketed for their therapeutic or medical benefits as anesthetics and pain relievers. 777 F.2d at 1366. The court does not appear to have parsed whether, to qualify as a "drug" in a particular case, the claim at issue must be therapeutic or medical in nature. To the extent this case can be read as *not* requiring a medical or therapeutic claim, it was wrongly decided and is inapposite for the reasons detailed in Appellee's Brief at 38-51.

occasion, a would-be doctrinal rule or test finds its way into our case law through simple repetition of a phrase—however fortuitously coined.").

Nor is it true, as the Government contended below, that other "case law further supports a far broader definition of 'drug' than [appellee] espouses." Defs. Supp. Br. In Opp. To Pls. and Ints. Mtns. For Prelim. Inj. 9; *see also* Gov't Br. 18. In the course of this litigation, the Government has relied on two cases. The first, *Action on Smoking & Health*, uses the "any relevant source" language but, as noted above, recognizes that "the crux of FDA jurisdiction . . . [lies] in manufacturers' *representations* . . . ." 655 F. 2d at 238-39 (emphasis added). The second case, on which the Government relies in its current brief, is a district court case that does not support the "broader definition" the Government seeks to establish. *See* Gov't Br. 18 (citing *United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001)).

In *Travia*, the district court reinstated criminal charges against individuals accused by the Government of violating the FDCA by distributing laughing gas (nitrous oxide) at a rock concert. 180 F. Supp. 2d at 116. The magistrate judge had dismissed the criminal complaints and informations on the ground that the laughing gas was not a "drug" and therefore the FDCA did not reach the product. *Id.* The district court rejected this conclusion, finding instead that intended use could be determined based on 21 C.F.R. § 201.128—a regulation the Government

invoked in earlier stages of this litigation, but not before this Court—that mentions the "circumstances surrounding distribution."[4] 180 F. Supp. 2d at 119.

Even if this provision were invoked or relevant here, the *Travia* court did not actually rely on the mere circumstances of distribution in the absence of claims. Instead, "the selling of balloons of laughing gas in the parking lot at a rock concert" necessarily encompassed a communication of claims. *Id.* at 118-19. Far from signaling judicial acceptance of a broad "circumstances" theory of intended use in which claims are not relevant, *Travia* actually reinforces the importance of communication from seller to buyer. Indeed, the court concluded that this "environment provided the necessary information *between* buyer and seller" about the intended use, thereby acknowledging the conveyance of claims. *Id.* at 119 (emphasis added); *see also* n.3, *supra*.

[4] The regulation states that "intended uses or words of similar import"—as employed in certain *regulatory* provisions (*e.g.*, 21 C.F.R. §§ 201.5, 201.115)—"refer to the *objective intent* of the persons legally responsible for the labeling of drugs." *Id.* § 201.128 (emphasis added). Under the plain terms of this provision, "intended use" is determined by "objective intent." *Id.* The regulation suggests various ways in which this "objective intent" may be demonstrated, including by "expressions" (such as "labeling claims, advertising matter, or oral or written statements") or by the "circumstances surrounding distribution of the article" (such as "the circumstances that the article is, with the knowledge of such persons or their representatives, *offered* and used for a purpose for which it is neither labeled nor advertised"). *Id.* (emphasis added). Even if this provision were invoked here, and it is not, because it turns on "claims" it is fully harmonious with the claims-based approach identified above. *See* § I(A)-(B), *supra*.

Thus, no court has ever found an intended use based solely on amorphous notions of "any relevant source" or "circumstances surrounding distribution" in the absence of claims.

* * * * *

In sum, there is no basis to defend FDA regulation of a drug or medical device absent a manufacturer making claims that the product will provide a therapeutic or medical benefit. Moreover, as discussed next, a non-claims-based interpretation of intended use would actually undermine the public health objectives of the FDCA by creating severe dislocations in the operation of the surrounding statutory provisions.

## II. A NON-CLAIMS-BASED INTERPRETATION WOULD LEAD TO ANOMALOUS RESULTS UNDER THE FDCA.

If intended use could be based on something other than claims about medical or therapeutic benefit, then FDA could regulate as drugs and medical devices thousands of consumer products never previously subject to the FDCA. Such a result would intrude FDA into the spheres of authority of other agencies and thwart the effective operation of the FDCA.

*First*, as Congress, the courts, and FDA itself have long recognized, if FDA were free to rely on factors other than claims of therapeutic or medical benefit in determining intended use, then FDA would have authority to regulate a vast array of products that in some sense could be said to be intended to affect the structure or

a function of the body, such as bullets, catchers' mitts, exercise equipment, bicycles, firm mattresses, hot tubs, chairs, and sunhats. Each of these ordinary items can affect body temperature, blood flow, and the like. But absent *claims* that these products produce a specific medical or therapeutic effect, clearly Congress did not intend for FDA to have plenary jurisdiction to regulate these products as drugs or devices. *See, e.g.*, § I(A), *supra*; *FTC v. Liggett & Myers Tobacco Co*., 108 F. Supp. 573, 577 n.4 (S.D.N.Y. 1952) ("a new suit of clothes has a palliative effect and the 'soothing' effect of a new bonnet purchased by the fairer sex, should not be overlooked," but soothing effects are not "the type of effect which the statute contemplates"), *aff'd*, 203 F.2d 955 (2d Cir. 1953).

*Second*, a non-claims-based theory of intended use would intrude FDA into the jurisdiction of other federal agencies. At least two statutes administered by the Consumer Product Safety Commission ("CPSC") explicitly exclude products that qualify as drugs or devices under the FDCA. *See* 15 U.S.C. § 1261(f)(2) (Federal Hazardous Substances Act); *id.* § 2052(a)(5)(H) (Consumer Product Safety Act). CPSC and FDA have determined the extent of their respective fields of regulatory authority based on the claims-based interpretation of intended use. Thus, for example, the agencies have agreed that an air cleaner is regulated by FDA if "medical claims are made for the product" and by CPSC if such claims are absent. *See* Letter from Stephen Lemberg, Ass't Gen. Counsel, CPSC to Mr. Leslie Fisher,

New York Dep't of Health 1 (Apr. 26, 1979), *available at* www.cpsc.gov/library/foia/advisory/276.pdf; *see also* 21 C.F.R. § 880.5045 (FDA medical device classification regulations for medical recirculating air cleaners). If FDA were to change its longstanding approach and interpret intended use based on something other than therapeutic or medical claims, it would strip CPSC of its longstanding jurisdiction over myriad everyday consumer products and—absent a massive expansion of FDA's oversight—leave many products subject to no federal regulation at all. *See* 15 U.S.C. § 2052(a)(5)(H) (defining consumer products to exclude drugs and devices, as those terms are defined by the FDCA).

Abandoning a claims-based approach also would frustrate the coherent operation of the FDCA with respect to products that are susceptible to abuse. The Drug Enforcement Administration ("DEA") has authority under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*., to regulate drugs that present a risk of illicit use.[5] For example, DEA has regulated khat, an amphetamine-like stimulant derived from the leaves of a plant common in East Africa, as a controlled substance. *See* 53 Fed. Reg. 17,459-60 (May. 17, 1988) (final DEA rule temporarily placing khat on Schedule IV); 58 Fed. Reg. 4,316 (Jan. 14, 1993)

[5] Among the factors the DEA is required to consider in making scheduling determinations under the CSA is the inherent "pharmacological effect" of the drug. 21 U.S.C. § 811(c)(2). The reference to "pharmacological effect," appearing in the same title of the United States Code, further indicates that Congress knows how to refer to the inherent attributes of a product when that is its intention.

(final DEA rule placing khat on Schedule I). Prior to DEA regulation, however, FDA asserted drug jurisdiction over khat in a 1982 Import Alert. 60 Fed. Reg. 41,527 (Aug. 11, 1995). FDA's actions were not based on any therapeutic claims made by the owner of the shipment, but were instead based solely on reports about khat's use and effects. *Id.* Limiting FDA regulation to products that are promoted by their manufacturers with medical or therapeutic claims assures that DEA retains the lead role in addressing abuse potential, while FDA has primary responsibility for the regulation of drugs intended for medically or therapeutically beneficial purposes.

*Third*, a non-claims-based theory of intended use would thwart the operation of the current FDA premarket review system for drugs and devices. *See generally Brown & Williamson*, 529 U.S. at 130-39 (explaining this system). For both drugs and devices, marketing authorization under the FDCA is granted based on FDA's assessment of data and information relating to safety and effectiveness *for their intended uses*. 21 U.S.C. §§ 355(d), 360, 360e; 21 C.F.R. §§ 314.125(b), 807.100. FDA uses the premarket review processes for drug and medical devices to assure that each drug and device is accompanied by labeling that bears "adequate directions for use." 21 U.S.C. § 352(f)(1). The uses for which such directions must be adequate are the "intended uses" as defined in FDA regulations, for both drugs and devices, 21 C.F.R. §§ 201.128, 801.4. Where such directions are

lacking, products are misbranded and therefore unlawful under the FDCA. *See* 21 U.S.C. § 331(a) (prohibiting "the introduction . . . into interstate commerce of any . . . drug [or] device . . . that is misbranded"); *id.* § 352(f)(1) ("A drug or device shall be deemed to be misbranded . . . [u]nless its labeling bears . . . adequate directions for use.").

If intended use could be interpreted broadly as the Government urges here, then manufacturers would be required to provide data and information demonstrating safety and effectiveness for non-claimed uses in drug and device labeling. Not only would such a requirement be incomprehensible and unworkable—as regulated entities could not possibly understand in advance the contours of what was being regulated—but it also would conflict with the FDCA, as the courts have held. *See, e.g.*, *Ass'n of Am. Physicians & Surgeons*, 226 F. Supp. 2d at 207-08 (stating that "even the FDA has repeatedly stated that it may only regulate claimed uses of drugs, not all foreseeable or actual uses"). The incongruity of the Government's approach is apparent from the circumstances of this case: if electronic cigarettes are, as the Government claims, subject to regulation as drugs or devices under the FDCA, then they could be distributed in interstate commerce only after FDA review. That review would have to assess safety and effectiveness according to some baseline, and the lack of a manufacturer

claim would mean that FDA would have no meaningful standard against which to assess whether the product should be approved.

The result would be to keep the product off the market indefinitely—as the Government apparently intends. *See generally Brown & Williamson*, 529 U.S. at 136-37 ("[t]he FDCA's misbranding and device classification provisions therefore make evident that were the FDA to regulate [tobacco products], the Act would require the agency to ban them . . . because it would be impossible to prove they were safe for their intended use"). FDA previously proposed requiring manufacturers to submit data for unclaimed uses—but abandoned that effort. *See* Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the FDA, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972). The Government should not be permitted to do indirectly, what it did not (and cannot) accomplish through more direct processes.

*Fourth*, to depart from the traditional, claims-based view of intended use would be to undermine longstanding FDA policies supporting manufacturer dissemination of non-promotional off-label use information. *See* Cooper, *supra*, at 486. As explained above, the doctrine of intended use is relevant not only to the interpretation of the statutory definitions of "drug" and "device" under the FDCA, but also to the scope of § 502(f)(1) of the FDCA, which provides that every drug and medical device must be accompanied by labeling that includes "adequate

directions for use." 21 U.S.C. § 352(f)(1). This dual applicability arises because FDA interprets the latter provision to mean "adequate directions for *intended* use." 21 C.F.R. § 201.5. For a drug or device to avoid being misbranded in violation of the FDCA, therefore, its labeling must include adequate directions for each "intended use" of the product.

If FDA were to interpret "intended use" to mean the actual use of a product, as the Government has contended in this case, then no drug or device could be used for a purpose different from the use for which it has been approved by FDA because it would not be accompanied by labeling bearing adequate directions. Yet it is well-established that drugs and medical devices may lawfully be used for such different purposes. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing that "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine") (citing 21 U.S.C. § 396).[6] Indeed, FDA has recognized that "off-label uses or treatment

[6] *See, e.g.*, 21 U. S. C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); *Sigma-Tau Pharms. v. Schwetz*, 288 F.3d 141, 147 (4th Cir. 2002) (recognizing "the longstanding practice of Congress, the FDA, and the courts not to interfere with physicians' judgments and their prescription of drugs for off-label uses"); *Rhone-*

regimens may be important and may even constitute a medically recognized standard of care." FDA, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009) at 3-4, *available at* www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm.

If "intended use" meant something other than promotional claims, then FDA could seek to commence an enforcement action against a manufacturer based on its dissemination of scientific information about uses for which a product had not been approved by FDA. Yet FDA's regulations and policies expressly allow manufacturers to provide off-label use information to health care practitioners in limited circumstances because of the importance of such information to the public health. *See* 21 C.F.R. § 312.7(a); *see also* 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994); 62 Fed. Reg. 64,074, 64,081 (Dec. 3, 1997).

In sum, the Government's capacious interpretation of the intended use doctrine would lead to numerous anomalous results and should be rejected.

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*Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514 n.3 (8th Cir. 1996) (same); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1496 (D.C. Cir. 1996) (same).

## CONCLUSION

For these reasons, WLF urges this Court to hold that a product's "intended use" under the FDCA can only be measured by the promotional claims of therapeutic or medical benefit made by the product's manufacturer and, on that basis, affirm and make final the injunction entered below.

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Respectfully Submitted,

By: /s/ Rebecca K. Wood
Coleen Klasmeier
Rebecca K. Wood
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711
Email: cklasmeier@sidley.com
rwood@sidley.com

Daniel J. Popeo
Richard A. Samp
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036
(202) 588-0302

*Attorneys for Amicus Curiae Washington Legal Foundation*

## CERTIFICATE OF COMPLIANCE

In accordance with Fed. R. App. P. 32(a)(7)(C)(i), I certify that the foregoing *Amicus* Brief of Washington Legal Foundation In Support Of Appellee, Urging Affirmance contains 6,281 words, not including the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Circuit Rule 32(a)(2), and complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B).

This brief has been prepared in proportionally spaced typeface using Microsoft Word 2007 in Times New Roman, 14 pt. typeface and complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6).

By: /s/ Rebecca K. Wood
SIDLEY AUSTIN LLP
1501 K Street, NW
Washington, D.C. 20005
(202) 736-8000

## CERTIFICATE OF SERVICE

In accordance with Fed. R. App. P. 25(d), Circuit Rule 25(c), and the Court's Administrative Order Regarding Electronic Case Filing, I hereby certify that I have, this 8th day of July, 2010, caused the foregoing *Amicus* Brief of Washington Legal Foundation In Support Of Appellee, Urging Affirmance to be filed with the Clerk, U.S. Court of Appeals for the D.C. Circuit by (i) causing eight (8) paper copies to be delivered to the Clerk's office pursuant to Circuit Rules 25 and 31 and the Clerk's Order entered in this appeal on April 12, 2010; and (ii) causing an electronic copy to be submitted to the Court's CM/ECF system, which will send notification of such filing to the following individuals:

Gregory George Garre
Richard Paul Bress
LATHAM & WATKINS LLP
555 11th Street, N.W.
Washington, D.C. 20004
202-637-2200
gregory.garre@lw.com
Rick.Bress@lw.com

*Counsel for Intevenor-Plaintiff-Appellee*
*Sottera, Inc. d/b/a NJOY*

Eric Nathan Heyer
Christopher Kip Schwartz
THOMPSON HINE LLP
1920 N Street, N.W.
Washington, D.C. 20036
(202) 331-8800
eric.heyer@thompsonhine.com
kip.schwartz@thompsonhine.com

*Counsel for Plaintiff Appellee Smoking Everywhere, Inc.*

Samantha Lee Chaifetz
Alisa B. Klein
Mark B. Stern
U.S. Department of Justice
(DOJ) Civil Division, Appellate Staff
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530
(202) 514-5000
samantha.chaifetz@usdoj.gov
alisa.klein@usdoj.gov
mark.stern@usdoj.gov

*Counsel for Defendants-Appellees Food & Drug Administration, et al.*

Drake Stephen Cutini
U.S. DEPARTMENT OF JUSTICE
(DOJ) Office of Consumer Litigation
P.O. Box 386
Washington, D.C. 20044
(202) 616-0219
drake.cutini@usdoj.gov

*Counsel for Defendants-Appellees Food & Drug Administration, et al.*

Karen Elizabeth Schifter
Office of General Counsel
HHS/FDD Division
Room WO 31-4408
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301) 796-8590
karen.schifter@fda.hhs.gov

*Counsel for Defendants-Appellees Food & Drug Administration, et al.*

William Barnett Schultz
Zuckerman Spaeder, LLP
1800 M Street, N.W.
Washington, D.C. 20036
(202) 778-1800
wschultz@zuckerman.com

*Counsel for Amici Curiae for Appellants American Academy of Pediatrics, et al.*

I further certify that I caused two (2) copies of the foregoing *Amicus* Brief of Washington Legal Foundation In Support Of Appellee, Urging Affirmance to be served upon the following individuals by Federal Express:

John F. Banzhaf
2013 H Street, N.W.
Washington, D.C. 20006

*Executive Director of Action on Smoking and Health*

Eric Michael Blumberg
FOOD & DRUG ADMINISTRATION
(FDA) Office of the Chief Counsel
5600 Fishers Lane
Rockville, MD 20857
(301) 827-5168

*Counsel for Defendants-Appellees Food & Drug Administration, et al.*

Ronald C. Machen Jr.
U.S. Attorney's Office
(USA) Appellate Division
555 4th Street, N.W.
Washington, D.C. 20530

*Counsel for Defendants-Appellees Food & Drug Administration, et al.*

By: /s/ Rebecca K. Wood
SIDLEY AUSTIN LLP
1501 K Street, NW
Washington, D.C. 20005
(202) 736-8000