ORAL ARGUMENT NOT YET SCHEDULED
Case No. 14-5226

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

LORILLARD, INC., *et al.*,
Plaintiffs-Appellees,

v.

U. S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia
No. 11-440 (RJL) (Hon. Richard J. Leon, District Judge)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES, URGING AFFIRMANCE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES AND CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Amicus curiae Washington Legal Foundation (WLF) certifies as follows:

1. Parties and Amici

All parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief for Appellees.

Pursuant to Circuit Rule 29(b), Fed.R.App.P. 26.1, and Circuit Rule 26.1, *amicus curiae* Washington Legal Foundation states that it is a non-profit corporation; it has no parent corporation, and no publicly-held company has a 10% or greater ownership interest. Pursuant to Circuit Rule 26.1(b), WLF describes its general nature and purpose as follows. It is a public-interest law firm and policy center that regularly appears in this Court in cases raising public policy issues.

2. Ruling Below

References to the rulings at issue appear in the Brief for Appellants.

3. Related Cases

This case was not previously before this or any other Court.

/s/ Richard A. Samp
Richard A. Samp

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GLOSSARY

APA	Administrative Procedure Act
Challenged Members	Drs. Neal Benowitz, Jack Henningfield, and Jonathan Samet
FACA	Federal Advisory Committee Act, 5 U.S.C. App. §§ 1 *et seq.*
FDA	U.S. Food and Drug Administration
Labeling Act	Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 15 U.S.C. §§ 1331-1341
TCA	Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 21 U.S.C. §§ 387 *et seq.*
TPSAC	Tobacco Product Scientific Advisory Board
WLF	Washington Legal Foundation

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES, URGING AFFIRMANCE

INTERESTS OF *AMICUS CURIAE*

Washington Legal Foundation (WLF) is a non-profit public interest law firm and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise principles, individual rights, a limited and accountable government, and the rule of law.

WLF believes strongly that public support for the work of federal government agencies can be maintained only so long as the public perceives that their proceedings are administered fairly. An essential ingredient of any fair administrative system is the presence of impartial decision-makers.

To that end, WLF has a decades-long record of litigating in support of strict enforcement of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, § 1 *et seq.*, a statute designed to ensure regularity in the proceedings of committees appointed to provide advice to the federal government. *See, e.g., Public Citizen and Washington Legal Found. v. U.S. Dep't of Justice*, 491 U.S. 440 (1989);

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[1] All parties have consented to the filing of this brief. On April 23, 2015, WLF filed with the Court its consented-to notice of intent to participate as *amicus curiae*. Pursuant to Fed.R.App.P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

Citizen Petition No. FDA-2011-P-0497 (docketed June 30, 2011) (petition seeking to bar use of report of advisory committee on medical devices because committee's composition violated FACA's "fair balance" requirement).

WLF is concerned that the federal government's position in this case, if adopted by the Court, would effectively end all meaningful judicial enforcement of federal statutes designed to ensure impartial federal decision-making. Based on a largely uncontested factual record, the district court found that three individuals appointed to a federal advisory committee have financial interests that conflict with their ability to serve impartially on that committee, and that the Food and Drug Administration (FDA) was fully apprised of those conflicts at the time of the appointments. Despite those findings, the federal government takes the position that those adversely affected lack standing to challenge the appointments; that the courts are not authorized to hear such challenges; and that even if the courts are so authorized and ultimately determine that the appointments were illegal, they are powerless to enter the very relief that could effectively redress the violation. WLF takes issue with that crabbed vision of judicial review.

STATEMENT OF THE CASE

The facts of this case are set out in detail in Appellees' brief. WLF wishes to highlight several facts of particular relevance to the judicial review issues on

which this brief focuses.

Throughout the past 50 years, Congress has adopted a series of statutes designed to address the adverse health effects of smoking. In 1965, it adopted the Federal Cigarette Labeling and Advertising Act (the "Labeling Act"), Pub. L. No. 89-92, 15 U.S.C. §§ 1331-1341, a "comprehensive Federal program to deal with cigarette labeling and advertising." *Id.* § 2. Since adoption of the Labeling Act, all cigarette labels and advertising have been required to bear increasingly strong health warnings. In 2009, Congress adopted the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, 21 U.S.C. §§ 387 *et seq.*, which for the first time authorized FDA to regulate the manufacture, marketing, and distribution of tobacco products. Among Congress's purposes in adopting the TCA were to provide FDA with "regulatory authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," *id*. § 3(1), and "to promote cessation to reduce disease risk associated with tobacco related diseases." *Id.* § 3(9).

Although Congress granted FDA no regulatory authority over tobacco products before 2009, FDA officials nonetheless have sought to exercise such authority for the past several decades. In 1996, FDA adopted a final rule that sought to regulate tobacco products as "drug delivery devices" and the nicotine

contained in tobacco products as a "drug." 61 Fed. Reg. 44418 (1996). The practical effect of the regulation would likely have been to ban the sale of tobacco products because the Food, Drug, and Cosmetic Act prohibits the sale of unsafe drugs and devices, and all agree that there is no safe level of smoking. The Supreme Court struck down the regulation, concluding that FDA lacked authority to regulate tobacco products as customarily marketed. *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000).

In adopting tobacco-control legislation over the past half-century, Congress has sought to promote public health while at the same time ensuring that adults who wish to smoke may continue to do so. *See, e.g.*, TCA § 3(7) (one purpose of TCA is "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers."). While Congress "has known about the dangers of cigarettes for many years" and has taken significant steps designed to minimize their adverse impact on public health, "it has never banned them. Indeed, regulation of cigarettes rests on the assumption that they will still be sold and that consumers will maintain a right to choose to smoke or not to smoke." *Graham v. R.J. Reynolds Tobacco Co.*, _ F.3d _, 2015 WL 1546522 (11th Cir., April 8, 2015) (citations omitted).

While Congress in 2009 was deliberating the scope of new tobacco control legislation, a number of anti-smoking activists were calling on Congress to ban the use of menthol flavoring in cigarettes. The TCA as ultimately adopted did not include a menthol ban. The TCA authorizes FDA to adopt "tobacco product standards" that require the elimination from tobacco products of any additive (including menthol) if FDA determines that such elimination is "appropriate for the protection of the public health." 21 U.S.C. § 387g(a)(3)(A).

Congress did not, however, want FDA to take any action with respect to menthol without obtaining advice from independent, outside experts regarding whether including menthol flavoring in tobacco products has any adverse health effects. The TCA required FDA to refer to the TPSAC[2] "for report and recommendation . . . the issue of the impact of the use of menthol in cigarettes on the public health." 21 U.S.C. § 387g(e)(1). The TCA mandated that the menthol report was to be the TPSAC's number one priority: it required the Committee to submit its report within one year after its establishment. 21 U.S.C. § 387g(e)(2).

All parties agree that appointments to the TPSAC are subject to numerous conflict-of-interest and fair-balance provisions set forth in federal statutes. In

[2] The TCA mandated the creation of the 12-member Tobacco Product Scientific Advisory Committee to provide advice and recommendations to FDA on a variety of tobacco-related health issues. 21 U.S.C. § 387q(a) & (c).

addition to the conflict-of-interest provision set forth in the TCA itself, 21 U.S.C. § 387q(b)(1)(C), these provisions include:

- 18 U.S.C. § 208, the federal government's broadly applicable conflict-of-interest statute, which bars service in the executive branch by individuals in any matter in which they have a financial interest;

- 21 U.S.C. § 379d-1(c)(2)(A) (2010), which bars participation on an FDA advisory committee by individuals in any matter in which they have "a financial interest that could be affected by the advice given to the Secretary with respect to such matter";[3] and

- FACA § 5(b)(2)-(3) and (c), 5 U.S.C. App. 2, § 5(b)(2)-(3), (c), which require agency heads to ensure that the membership of advisory committees is "fairly balanced in terms of the point of view represented" and that "the advice and recommendation of the advisory committee will not be inappropriately influenced by the appointing authority or any special interest."

Appellants (collectively, "FDA") in 2010 appointed three members to the TPSAC who have close ties to plaintiffs' attorneys who specialize in tort litigation filed against cigarette manufacturers. All three "Challenged Members"—Drs. Neal Benowitz, Jack Henningfield, and Jonathan Samet—have received substantial compensation for providing expert testimony against tobacco company defendants in product liability tort suits, regarding the effects on public health of cigarette smoking and of menthol cigarettes in particular. Moreover, they are scheduled to

[3] Congress substantially amended § 379d-1 in 2012. Those amendments are not relevant to this lawsuit, which focuses on events in 2009-2011.

provide expert testimony in hundreds of similar pending lawsuits that have not yet come to trial. Although cigarette manufacturers repeatedly objected that the three doctors had financial conflicts that barred them from service on the TPSAC, FDA concluded that no disqualifying conflicts existed and went ahead with their appointments.

In February 2011, well before the TPSAC completed its menthol study, Appellees (collectively, "Lorillard and Reynolds") filed suit to prevent the TPSAC from moving forward with the study while the three Challenged Members remained on the Committee. The TPSAC devoted most of its resources in 2010-11 to completing the study; it finally issued its Menthol Report on July 21, 2011. Among the report's conclusions: (1) there is insufficient evidence to support a conclusion that menthol cigarettes are more harmful to public health than non-menthol cigarettes; (2) there are no public health benefits of menthol compared to non-menthol cigarettes; (3) "[m]enthol cigarettes have an adverse health impact on public health in the United States"; and (4) "[r]emoval of menthol cigarettes from the marketplace would benefit the public health of the United States." Slip op. at 17.

In July 2014, the district court granted summary judgment to Lorillard and Reynolds, concluding that FDA's decision to permit the three Challenged

Members to serve on the TPSAC was arbitrary and capricious, in violation of the Administrative Procedure Act (APA). *See* 5 U.S.C. § 706(2)(A) (requiring a federal court to set aside agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."). The court concluded that the three had financial conflicts of interest within the meanings of both the general conflicts statute (18 U.S.C. § 208) and the FDA-specific conflicts statute (21 U.S.C. § 379d-1(c)(2)(A) (2010)) and that FDA should not have appointed them to the TPSAC in light of those conflicts. Slip op. at 25-34. It said that the conflicts "undermine the public's confidence in the agency's decision-making process and render its final product suspect, at best." *Id.* at 34.

As a remedy, the court barred FDA from using the Menthol Report and required FDA "to reconstitute TPSAC's membership so that it complies with the applicable ethics laws." *Id.* at 35. In light of its conflict findings, the court deemed it unnecessary to address Appellees' additional claims that FDA violated FACA by: (1) appointing an advisory committee that was not "fairly balanced in terms of the point of view represented" and that was "inappropriately influenced" by a "special interest"; and (2) allowing the TPSAC to operate in a manner inconsistent with FACA procedural requirements. *Id.* at 4 n.7.

SUMMARY OF ARGUMENT

That the Challenged Members have a financial conflict is obvious to any reasonable observer. Indeed, FDA's continued denial of a conflict calls into question its impartiality in assessing the public health effects (if any) of menthol flavoring in cigarettes.

Of greater ultimate concern to WLF, however, is the ability of the judiciary to police compliance with the conflicts statutes. FDA takes the position that non-compliance is essentially unreviewable in the courts, asserting that: (1) tobacco companies—the entities most adversely affected by the agency's actions—lack standing to challenge the TPSAC appointments; (2) a federal court is not authorized to hear such challenges because they are nonjusticiable; and (3) even if the courts are so authorized and ultimately determine that the appointments were illegal, they are powerless to enter the very relief that could effectively redress the violation. None of those assertions is well taken.[4]

FDA claims that Lorillard and Reynolds lack standing because they have

[4] WLF agrees with all of the district court's rulings. It does not separately address other district court rulings, including that: (1) the Challenged Members' financial interests in the development of nicotine replacement therapy products as a substitute for cigarette smoking created an additional set of financial conflicts; and (2) the financial conflicts created an appearance of conflict of interest, and private litigants are entitled to file suit to enforce the appearance standards set forth in 5 C.F.R. pt. 2635.

failed to demonstrate that they were injured by Drs. Benowitz, Henningfield, and Samet's service on the TPSAC. It makes this claim despite uncontested evidence that: (1) the Challenged Members, prior to joining the TPSAC, had publicly opined that removal of menthol cigarettes from the market would have a beneficial impact on public health; (2) the TPSAC adopted that position in the Menthol Report; and (3) the Menthol Report's conclusion has been cited repeatedly (by the Challenged Members and others) in cigarette product liability litigation, which has resulted in numerous large verdicts against Lorillard and Reynolds. FDA argues that there is no evidence that the Challenged Members "impermissibly influenced TPSAC's deliberations" in order to bolster their future expert testimony in such litigation. FDA Br. at 27. But Lorillard and Reynolds need not demonstrate that the Challenged Members acted "impermissibly" during TPSAC deliberations in order to demonstrate injury directly traceable to FDA's decision to place them on the TPSAC. It is enough to demonstrate that the Challenged Members played at least some role in shaping the Menthol Report's conclusions and that those conclusions have injured them.

FDA fares no better with its assertion that the claims are nonjusticiable. It asserts that agency review of financial conflict claims "is committed to agency discretion by law," 5 U.S..C. § 701(a)(2), and thus is excepted from review under

the APA. FDA Br. at 31-38. That assertion is inconsistent with numerous court decisions holding that agency action is *presumptively* subject to judicial review under the APA.

FDA's nonjusticiability argument focuses principally on the agency's claim that the applicable statutes are drawn in such broad terms that courts "have no meaningful standard against which to judge the agency's exercise of discretion." FDA Br. 31. That argument is not well taken. Both 18 U.S.C. § 208 and 21 U.S.C. § 379d-1(c)(2)(A) (2010) spell out in some detail when a current or prospective federal advisory committee member should be deemed to have a financial conflict. Courts have considerable experience in applying financial conflict rules, particularly in the closely related context of disqualification (under 28 U.S.C. § 455(a)) of judges based on financial conflicts.

Finally, having found that FDA violated the APA by appointing the Challenged Members to the TPSAC, the district court did not abuse its discretion in barring FDA from using the Menthol Report and requiring FDA "to reconstitute TPSAC's membership so that it complies with the applicable ethics laws." *Id.* at 35. An order barring use of the Menthol Report is the only relief that will effectively remedy FDA's statutory violation. Moreover, the order to reconstitute TPSAC's membership was the only means by which the district court could ensure

that the Challenged Members would not play a future role in the drafting and issuance of an unconflicted TPSAC menthol report—a report that of necessity will be the TPSAC's top priority given that Congress's deadline for completing the report expired more than four years ago.

ARGUMENT

I. LORILLARD AND REYNOLDS HAVE ARTICLE III STANDING TO CHALLENGE FDA's NONCOMPLIANCE WITH THE APA

Lorillard and Reynolds may not invoke the jurisdiction of the federal courts under Article III of the Constitution unless they can establish standing to complain of FDA's conduct. As the district court determined, they have established standing on multiple grounds.

Article III standing contains three requirements:

> First, and foremost, there must be alleged (and ultimately proven) an "injury in fact"—a harm suffered by the plaintiff that is "concrete" and "actual and imminent, not 'conjectural' or 'hypothetical.'" . . . Second, there must be causation—a fairly traceable connection between the plaintiff's injury and the complained of conduct of the defendant. . . . And third, there must be redressability—a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 102-103 (1998) (citations omitted).

The district court upheld standing based on four distinct injuries asserted by

Lorillard and Reynolds in support of their standing claim:

> (1) the Challenged Members' access to plaintiffs' confidential information, which can influence their consulting advice and expert testimony adverse to plaintiffs; (2) the Challenged Members' shaping of TPSAC reports to aid such testimony; (3) the Challenged Members' influence, through the TPSAC, on FDA to take regulatory actions adverse to plaintiffs' economic interests; and (4) an adverse effect on the stock price of Lorillard, Inc. due to the composition of the TPSAC.

Slip op. at 20 n.18. WLF agrees that Lorillard and Reynolds have established standing on the basis of all four categories of injury. We focus solely on the second of the four injuries, both because it is so clearly established and because it is yet another example of the extent to which FDA decision-makers have fallen under the influence of those who specialize in filing tort actions against businesses that are subject to FDA regulation. *See* Section III.B, *infra*.

The evidence is uncontested that the Challenged Members are deeply involved in efforts to obtain billions of dollars in damages from tobacco companies in product liability lawsuits. Drs. Benowitz, Henningfield, and Samet have received hundreds of thousands of dollars for their expert testimony against tobacco company defendants in product liability tort suits; their testimony focuses on the public health effects of cigarette smoking and of smoking menthol cigarettes in particular. More importantly for purposes of establishing standing, as of June 30, 2010, the Challenged Members were scheduled to provide expert testimony in

at least 937 (!) pending lawsuits that had not yet come to trial. There is no serious question that Lorillard and Reynolds are injured when expert witnesses testify against them in product liability lawsuits, nor that the injury increases when the witnesses can take steps to bolster their credibility with additional evidence. The Menthol Report's principal conclusions—that "[m]enthol cigarettes have an adverse health impact on public health in the United States" and that "[r]emoval of menthol cigarettes from the marketplace would benefit the public health of the United States"—are just such additional evidence. Indeed, as FDA concedes, FDA Br. 27, at least one of the Challenged Members has cited the Menthol Report in support of his subsequent testimony against tobacco manufacturers.

That injury is directly traceable to FDA's appointment of the Challenged Members to the TPSAC. Both before and during their service on the TPSAC, they were outspoken critics of cigarette manufacturers and of the marketing of menthol cigarettes. All three supported the TPSAC's decision to issue the Menthol Report and its conclusions that removal of menthol cigarettes from the marketplace would benefit public health. Moreover, the relief granted by the district court redresses Lorillard's and Reynolds's injuries. By concluding that conflicts tainted the Menthol Report and prohibiting its use by FDA, the district court has significantly undermined the report's credibility and thus mitigated the injury that the report was

causing to cigarette manufacturers in product liability litigation.

FDA's appointments of the Challenged Members to the TPSAC also inflicted a second injury in connection with pending litigation. Their appointments to a prestigious federal advisory committee added a significant credential to their resumes, a credential that they have regularly highlighted during their testimony against tobacco companies. Lorillard and Reynolds are harmed by actions that increase the credibility of expert witnesses designated to testify against them. The district court's decision redresses that injury by undermining the value of the credential and demonstrating that FDA should not have appointed the Challenged Members to the TPSAC in light of their financial conflicts.

FDA argues that there is no evidence that the Challenged Members "impermissibly influenced TPSAC's deliberations" in order to bolster their future expert testimony in such litigation. FDA Br. at 27. But Lorillard and Reynolds need not demonstrate that the Challenged Members acted "impermissibly" during TPSAC deliberations in order to demonstrate injury directly traceable to FDA's decision to place them on the TPSAC. It is enough to demonstrate that the Challenged Members had financial conflicts, that they played at least some role in shaping the Menthol Report's conclusions, and that those conclusions have injured the companies.

Moreover, the Challenged Members were not mere potted plants who passively acceded to the views of other TPSAC members regarding the effects of menthol on public health. As Lorillard and Reynolds note:

> FDA put the challenged members in positions to shape the Menthol Report, and they did. Dr. Samet chaired TPSAC and its Menthol Report Subcommittee. FDA advisory-committee chairs have report-shaping powers [*see* FDA, *Policy and Guidance Handbook for FDA Advisory Committees* 64-67 (1994)]. Drs. Samet and Benowitz were lead authors of chapters of the Menthol Report. Dr. Samet drafted Chapter 8 (containing the report's conclusions and recommendations), on which he received non-public "suggestions" from Dr. Henningfield, and which Dr. Henningfield reviewed.

Appellees Br. 17 (footnotes omitted). In sum, Lorillard and Reynolds have adequately demonstrated that they have suffered injury due to FDA's appointment to the TPSAC of three individuals who: (1) regularly testify against tobacco companies in product liability litigation; (2) are highly paid by plaintiffs' attorneys for their testimony; (3) actively supported Menthol Report conclusions/ recommendations that damage tobacco companies' ability to defend against product liability claims; and (4) can point to their service on the TPSAC as an additional credential that bolsters their credibility as witnesses in such litigation.

II. LORILLARD's AND REYNOLDS's FINANCIAL CONFLICT CLAIMS ARE JUSTICIABLE UNDER THE APA

Lorillard and Reynolds assert that they were injured by FDA's wrongful

action in appointing the Challenged Members to the TPSAC despite their financial conflicts of interest. The APA creates a right of action for just such claims:

> A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

APA § 10(a), 5 U.S.C. § 702.

Indeed, this Court has explained that only "[v]ery rarely has Congress withheld judicial review from those who have suffered an Article III injury at the hands of an administrative agency." *PDK Laboratories Inc. v. U.S. Drug Enforcement Administration*, 362 F.3d 786, 792 (D.C. Cir. 2004). It added:

> Time and again the Supreme Court has emphasized that there is a "strong presumption" in favor of judicial review, [*Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667,] 672 n.3 [(1986)], and that "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review."

Ibid. (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967)). FDA has failed to provide any such "clear and convincing evidence," and thus the claims of Lorillard and Reynolds are justiciable under the APA.

To be "aggrieved" within the meaning of § 702, a party must be "arguably within the zone of interests to be protected or regulated by the statute that he says was violated." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 132 S. Ct. 2199, 2210 (2012). The Supreme Court has repeatedly

emphasized that the zone-of-interest test establishes an extremely low bar that:

> . . . is not meant to be especially demanding. . . . We do not require any indication of congressional purpose to benefit the would-be plaintiff. And we have always included the word "arguably" in the test to indicate that the benefit of any doubt goes to the plaintiff. The test forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.

Ibid. Lorillard and Reynolds comfortably satisfy the zone-of-interest test.[5]

FDA suggests that the sole purpose of the relevant conflicts statutes is to protect the *government* from nefarious, conflicted individuals who might seek to advance their own financial interests at the expense of the government's goals. The relevant statutory language belies such a limited purpose. For example, 21 U.S.C. § 379d-1 (2010) contained provisions strictly limiting the grounds upon which FDA could waive conflict-of-interest requirements and the number of exceptions it could grant each year; it also required detailed public disclosure of all waivers. *See* § 379d-1(c)(2)(B) & (C); § 379d-1(c)(3). Those provisions indicate

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[5] The zone-of-interest test is sometimes placed within the rubric of prudential standing. But as the Supreme Court recently explained, "'prudential standing is a misnomer' as applied to zone-of-interest analysis, which asks whether 'this particular class of persons ha[s] a right to sue under this substantive statute,'" not whether the plaintiffs have standing to invoke the court's jurisdiction. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1387 (2014) (quoting *Assoc. of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667, 675-76 (D.C. Cir. 2013) (Silberman, J., concurring)).

that Congress adopted the FDA conflicts statute for the benefit of the public at large, not simply for the benefit of FDA. Moreover, the Supreme Court explicitly held that Congress adopted a predecessor to 18 U.S.C. § 208 to protect the public, not government agencies. *United States v. Miss. Valley Generating Co.*, 364 U.S. 520, 563 (1961) ("[T]he primary purpose of [a predecessor of 18 U.S.C. § 208] is to protect the public from the corrupting influences that might be brought to bear upon government agents who are financially interested in the business transactions [they conduct for] the Government.").

As members of the public, Lorillard and Reynolds have as strong a claim as anyone to the benefits of government decision-making that is free from financial conflicts. It certainly cannot be said that their "interests are so marginally related to or inconsistent with the purposes implicit in [§ 208 and § 379d-1 (2010)] that it cannot reasonably be assumed that Congress intended to permit them" to sue under those statutes. *Match-E-Be-Nash-She-Wish Band*, 132 S. Ct. at 2210. Indeed, no other groups or individuals have a greater interest than tobacco companies in ensuring that the work of the TPSAC is conflict-free. Accordingly, they satisfy the undemanding zone-of-interest test.

FDA also argues that the claims are nonjusticiable because the agency's review of conflict issues "is committed to agency discretion by law," 5 U.S.C.

§ 701(a)(2), and thus is excepted from review under the APA. FDA Br. 31-38. That argument is without merit.

The § 701(a)(2) exception is "applicable in those *rare* instances where statutes are drawn in such broad terms that in a given case there is no law to apply." *Delta Air Lines, Inc. v. Export-Import Bank of United States*, 718 F.3d 974, 977 (D.C. Cir. 2013) (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)) (emphasis added). FDA's assertion that there is "no law to apply" under 18 U.S.C. § 208 and 21 U.S.C. § 379d-1 (2010) simply ignores the elaborate provisions of those two statutes. For example, § 208(a) provides a detailed definition of what constitutes a "financial interest" that disqualifies an executive branch officer or employee from participating in specified matters. Although § 208(b) authorizes government officials in certain instances to grant waivers from the § 208(a) financial conflict rules, the statute clearly spells out the circumstances under which such waivers may be granted. Section 379d-1 (2010) adopted by reference § 208(a)'s definition of "financial interest" and included detailed provisions that similarly circumscribed FDA's authority to waive financial conflicts for individuals it wished to appoint to advisory committees. *See* 21 U.S.C. § 379d-1(c)(2)(C) & (c)(3). The courts have not experienced any significant difficulty in discerning applicable legal standards when addressing conflict-of-interest claims

raised under § 208 or under related statutes governing conflict-of-interest standards governing judges, such as 28 U.S.C. § 455(a). *See, e.g., In re Kensington Int'l Ltd.*, 368 F.3d 289 (3d Cir. 2004).

While § 208 and § 379d-1 no doubt grant FDA some discretion in deciding how it will apply the conflict statutes in any given instance, the detailed provisions of those statutes belie any claim that there is no law to apply here and thus that this is one of those rare instances in which an agency is granted unreviewable discretion to decide for itself when an individual's financial conflicts bar his participation in agency proceedings.[6] *See Robbins v. Reagan*, 780 F.2d 37, 45

[6] Because the Challenged Members' financial conflicts are obvious to any reasonable observer, WLF has not drafted a separate section to argue the point. A significant portion of the Challenged Members' livelihood consists of serving as paid expert witnesses for plaintiffs in tobacco product liability litigation. Lawsuits filed by smokers of menthol-flavored cigarettes invariably contend that the inclusion of such flavoring is one of the product defects that caused them injury. Were any TPSAC member to support a conclusion that: (1) menthol cigarettes do *not* have an adverse health impact on public health in the United States; or (2) removal of menthol cigarettes from the marketplace would *not* benefit the public health of the United States, they would immediately disqualify themselves from lucrative future service as expert witnesses for plaintiffs in such lawsuits. Plaintiffs' lawyers would be unwilling to offer testimony from such individuals because their TPSAC conclusions could be used to discredit their testimony in support of the plaintiffs. *See, e.g.*, Robert C. Clifford, *Qualifying and Attacking Expert Witnesses* (James Publishing 1998). Accordingly, the Challenged Members faced a severe financial conflict of interest: they were required to support anti-menthol conclusions in the Menthol Report without regard to the record, or else abandon a substantial portion of their income.

(D.C. Cir. 1985) ("The mere fact that a statute grants broad discretion to an agency does not render the agency's decisions completely nonreviewable under the 'committed to agency discretion by law' exception unless the statutory scheme, taken together with other relevant materials, provides absolutely no guidance as to how that discretion is to be exercised.") FDA complains that permitting judicial review of its TPSAC appointment decisions would undermine effective agency operations by potentially "depriv[ing] it of the services" of some highly qualified individuals. FDA Br. 24. But as this Court explained in rejecting a similar argument against judicial review under the APA:

> The [defendant federal agency] contends that judicial review would undermine its ability to operate effectively. No doubt many agencies feel that way at times, but an agency that wants a carve-out from the APA should direct its arguments to Congress.

Delta Air Lines, 718 F.3d at 977.

III. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION BY GRANTING INJUNCTIVE RELIEF

Having found that FDA violated the APA by appointing the Challenged Members to the TPSAC, the district court did not abuse its discretion in barring FDA from using the Menthol Report and requiring FDA "to reconstitute TPSAC's membership so that it complies with the applicable ethics laws." Slip op. at 35. The district court's conclusion that its injunction was necessary in order to provide

Lorillard and Reynolds with an effective remedy was well supported by the record. In the absence of a use injunction, they will have been deprived of the very interest that the conflict statutes were designed to protect: one's interest in ensuring that federal government bodies deciding important issues are not tainted by financial conflicts of interest.

A. A Use Injunction Is Consistent with Circuit Precedent, Including *Pena*

In challenging the injunction as an abuse of discretion, FDA argues that "a use injunction prohibiting FDA from relying on the Menthol Report cannot be reconciled with this Court's reasoning in *NRDC v. Pena*, 147 F.3d 1012 (D.C. Cir. 1998)." FDA Br. 52. That argument is based on a misreading of *Pena*.

The district court in *Pena* had held that an advisory committee—formed at the behest of the U.S. Department of Energy to study scientific issues associated with "inertial confinement fusion"—had not been organized in compliance with FACA procedures. As a remedy for the FACA procedural violations, the district court issued an injunction barring use of the committee's report. This Court reversed on the grounds that the plaintiffs had failed to establish Article III standing because they had not demonstrated that their claimed injury would be redressed by the requested relief. *Id.* at 1021-22. It remanded the case to the

district court to provide the plaintiffs with an additional opportunity to establish standing. *Id.* at 1022-24.

FDA relies on *dicta* in *Pena* that discussed how the district court should proceed should it determine on remand that the FACA plaintiffs had standing. The Court stated, "If the district court concludes that the plaintiffs have standing to sue for a use injunction, that conclusion would not *mandate* a judgment in their favor." *Id.* at 1025. The Court then discussed factors that would be relevant in determining whether a use injunction is appropriate in response to FACA procedural violations. It opined that relevant factors would include: (1) whether the plaintiff unreasonably delayed in asserting its claim for relief ("the district court should be reluctant to award relief" when the plaintiff has delayed unreasonably and the delay has prejudiced the government); (2) the likelihood that a use injunction would cause wasteful expenditures; (3) whether the FACA violation had significant "deleterious effect on the committee's output and accountability and the public's participation"; and (4) whether the effects of any improper denials of opportunities for public participation can be "rendered harmless" by providing future opportunities to comment on agency decision-making. *Id.* at 1026. The Court further opined that use injunctions "should be issued only rarely" in response to FACA procedural violations because alternative remedies might sufficiently redress the plaintiffs'

injuries. *Id.* at 1025-26.

FDA has badly mischaracterized *Pena*, which addressed use violations arising in the entirely distinct context of FACA violations. To the extent that the factors cited in *Pena* are relevant here, they support a conclusion that the district court acted well within its discretion in enjoining use of the report.

With respect to the fourth factor cited above, FDA asserts that *Pena* stated that a district court should determine whether an additional opportunity to submit comments before an agency makes a final decision will render harmless "any violation" of the statute. FDA Br. 52. *Pena* said no such thing. Rather, as noted above, *Pena* opined that additional commenting opportunities might render harmless a FACA violation that resulted in "the loss of any past opportunity to participate." 147 F.3d at 1026. But the loss of a past commenting opportunity is not on par with the loss of the right to unbiased, unconflicted decision-making. Providing Lorillard and Reynolds with an opportunity to file comments urging FDA not to rely on conclusions of the Menthol Report does not "render harmless" the fact that those conclusions were issued by an advisory committee rife with financial conflicts and that the conflicts arose as a direct result of FDA's APA violations.

Other factors cited by *Pena* strongly support the use injunction issued by the

district court in this case. FDA cannot claim to have been prejudiced by delay in raising the conflict claims. Lorillard and Reynolds objected as soon as FDA announced that it planned to appoint the Challenged Members to the TPSAC, and they filed suit well before the TPSAC issued the Menthol Report. Moreover, barring use of the Menthol Report will not cause any "wasteful expenditures" because the only items that will be "wasted"—the conclusions of a federal advisory committee whose deliberations were tainted by financial conflicts—are not worth preserving.[7]

This Court has held that an injunction against use of an advisory committee's report may well be appropriate if "the unavailability of an injunction" in response to a statutory violation would effectively render the statute "a nullity." *California Forestry Assoc. v. U.S. Forest Service*, 102 F.3d 609, 614 (D.C. Cir. 1996). In the absence of any plausible suggestion from FDA regarding an alternative remedy that would provide effective relief to Lorillard and Reynolds

[7] In this respect, use bars issued in cases alleging FACA procedural violations are much different from use bars issued in cases alleging violations of the conflicts statutes (or FACA "fair balance" violations). In cases involving FACA procedural violations, the advisory committee's report often involves basic scientific research whose accuracy is not subject to serious challenge. In contrast, cases arising under the conflicts statutes often (as here) involve disputes over the conclusions to be drawn from the basic scientific research. Use bars will often be more appropriate in the latter category of cases, particularly where (as here) there is reason to doubt the impartiality of committee members.

from the financial conflict that tainted the Menthol Report, the district court acted within its discretion in issuing an injunction against use of the report.

B. The District Court's Injunction Is Particularly Appropriate in Light of FDA's Disturbing History of Catering to the Interests of the Plaintiffs' Bar

FDA's inability to recognize the obvious financial conflicts of individuals who derive substantial income as expert witnesses for plaintiffs in tobacco litigation, FDA Br. 24, is consistent with its recent history of aligning itself closely with the plaintiffs' bar, to the detriment of consumers and the regulated business community. This apparent "regulatory capture" of FDA by the litigation industry provides an additional reason for the Court to ensure that those injured by FDA's APA violations are afforded an effective remedy.

FDA's special solicitude for the plaintiffs' bar dates from at least the 1990s, when—working in close conjunction with lawyers suing tobacco companies on behalf of States—the agency ignored statutory limits on its jurisdiction and sought to regulate tobacco products as "drug delivery devices" and the nicotine contained in tobacco products as a "drug." 61 Fed. Reg. 44418 (1996). The Supreme Court struck down the regulation, concluding that FDA lacked authority to regulate tobacco products as customarily marketed. *FDA v. Brown & Williamson Tobacco*

Corp., 529 U.S. 120 (2000).[8]

In addition, FDA has assisted the plaintiffs' bar by repeatedly seeking to restrict federal preemption of state-law tort suits filed against the manufacturers of prescription drugs and medical devices. Most recently, it issued a proposed regulation that would grant generic drug manufacturers authority to make unilateral changes in their product labels. *See* "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," 78 Fed. Reg. 67985 (Nov. 13, 2013). FDA met with only one group before issuing its proposed regulation: the plaintiffs' bar. *See* Paul M. Barrett, "House GOP Demands the FDA Explain Plaintiffs'-Lawyer Lobbying," *Bloomberg Business* (July 22, 2014). The only apparent purpose of the proposed regulation is to overturn several recent Supreme Court decisions—including *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)—that expanded federal preemption of tort suits against generic drug manufacturers. The proposed rule has been warmly supported by the plaintiffs' bar

[8] Appellant Mitchell Zeller, the current Director of FDA's Center for Tobacco Products, has a history of especially close ties to the plaintiffs' bar. Indeed, a 1996 WLF investigation uncovered documents demonstrating that Zeller, while serving as an assistant to then-FDA Commissioner David Kessler, violated FDA regulations by secretly meeting in 1995 with prominent plaintiffs' attorneys to discuss their product-liability claims against medical device manufacturers. Following a complaint filed by WLF on June 13, 1996 with FDA's Office of Internal Affairs, Zeller was admonished for his violation. Zeller later played a prominent role in FDA's ultra vires efforts to regulate tobacco products.

but has been met with extreme skepticism by public health experts (who are concerned that the labeling change will generate confusion among consumers) and by the FDA bar (which views the proposed regulation as inconsistent with labeling requirements imposed by the Food, Drug, and Cosmetic Act).

Congress's concern over FDA's close relationship with the plaintiffs' bar may well have played a role in the TCA's requirement that the TPSAC undertake a menthol study. Although Congress authorized FDA to adopt "tobacco product standards" that require the elimination from tobacco products of any additive (including menthol) if FDA determines that such elimination is "appropriate for the protection of the public health," 21 U.S.C. § 387g(a)(3)(A), the TCA made clear that FDA was not to take any action with respect to menthol without first obtaining advice from independent, outside experts regarding whether menthol flavoring in tobacco products has any adverse health effects. 21 U.S.C. § 387g(e)(1). The district court's determination that the Menthol Report was tainted by financial conflicts means that FDA has not yet received the independent, unbiased report on menthol that Congress wanted it to receive before taking any action with respect to menthol. By enjoining use of the tainted Menthol Report, the district court has helped ensure that FDA may yet receive the independent, unbiased report mandated by Congress.

C. FDA Is Not Entitled to a Remand to Allow It to Argue for the First Time that Financial Conflicts Should Be Waived

Finally, FDA's assertion that the district court's injunction improperly abrogated its statutory right to waive conflicts is misguided. At no time in this litigation has FDA articulated any grounds for concluding that it could satisfy the waiver criteria set forth in § 208 and § 379d-1 (2010). If FDA really believes that the Challenged Members were crucial to successful completion of the TPSAC's work, and that the waiver provisions of the conflict statutes authorized FDA to waive Challenged Members' close financial ties to the plaintiffs' bar, it should have explained that position when the conflict of interest was first raised, and certainly no later than its opening brief on appeal. The good faith of any after-the-fact assertion of waiver is subject to question, given the obvious temptation for an agency to concoct a waiver as an alternate means of affirming a prior decision to appoint an official later determined to have a financial conflict.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court affirm the judgment of the district court.

Respectfully submitted,

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Dated: April 27, 2014

CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation (WLF). Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced CG Times type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 6,992, not including the Circuit Rule 26.1 disclosure statement, table of contents, table of authorities, glossary, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of April, 2015, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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