ORAL ARGUMENT NOT YET SCHEDULED
No. 14-5226

United States Court of Appeals
for the District of Columbia Circuit

Lorillard, Inc., *et al.*

Plaintiffs-Appellees,

v.

United States Food and Drug Administration, *et al.*

Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH GROUPS IN SUPPORT OF DEFENDANTS-APPELLANTS

Of Counsel:
Mark Greenwold
Dennis Henigan
Campaign for Tobacco-Free Kids
1400 Eye Street, NW
Washington, DC 20005

Carlos T. Angulo (D.C. Bar No. 466257)
Andrew N. Goldfarb (D.C. Bar No. 455751)
ZUCKERMAN SPAEDER LLP
1800 M Street, NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800; Fax: (202) 822-8106
cangulo@zuckerman.com
agoldfarb@zuckerman.com

Justin M. Gundlach (D.C. Bar No. 1005306)
Hope M. Babcock (D.C. Bar No. 14639)
Institute for Public Representation
Georgetown University Law Center
600 New Jersey Ave. NW, Suite 312
Washington, D.C. 20001
Tel: (202) 662-9535
justin.gundlach@law.georgetown.edu
babcock@law.georgetown.edu

Counsel for *Amici Curiae*

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT PURSUANT TO FEDERAL RULES OF APPELLATE PROCEDURE 26.1 AND 29(C) AND D.C. CIRCUIT LOCAL RULE 26.1

Amici curiae[1] are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(C)(5)

Counsel for *amici curiae* hereby states that:

- no counsel for any party to this litigation authored this brief in whole or in part;
- no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submission of this brief; and
- no person, other than the *amici curiae*, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

[1] The *amici* include the following organizations: the American Academy of Otolaryngology-Head and Neck Surgery; the American Academy of Pediatrics; the American Association for Respiratory Care; the American Cancer Society Cancer Action Network; the American College of Cardiology; the American Heart Association; the American Legacy Foundation; the American Lung Association; the American Medical Association; the American Thoracic Society; the Campaign for Tobacco-Free Kids; the General Board of Church and Society of the United Methodist Church; the National African American Tobacco Prevention Network; the National Association of City and County Health Officials; the National Latino Alliance for Health Equity; the Partnership for Prevention; the Society for Research on Nicotine and Tobacco; and the Tobacco Control Legal Consortium.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(A) AND D.C. CIRCUIT LOCAL RULE 29(B)

All parties to this litigation have consented to the participation of *amici curiae* in this matter and to the filing of this brief.

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

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CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

The parties in this case and the ruling under review are set forth in the opening brief of the appellants.

GLOSSARY

FDA	U.S. Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDCA	Federal Food, Drug and Cosmetic Act
JA	Joint Appendix
TCA	Family Smoking Prevention and Tobacco Control Act of 2009
TPSAC	Tobacco Products Scientific Advisory Committee

STATUTES AND REGULATIONS

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

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici include the following organizations: the American Academy of Otolaryngology-Head and Neck Surgery; the American Academy of Pediatrics; the American Association for Respiratory Care; the American Cancer Society Cancer Action Network; the American College of Cardiology; the American Heart Association; the American Legacy Foundation; the American Lung Association; the American Medical Association; the American Thoracic Society; the Campaign for Tobacco-Free Kids; the General Board of Church and Society of the United Methodist Church; the National African American Tobacco Prevention Network; the National Association of City and County Health Officials; the National Latino Alliance for Health Equity; the Partnership for Prevention; the Society for Research on Nicotine and Tobacco; and the Tobacco Control Legal Consortium.

Each of the *amici* is a non-profit organization that is committed to advancing the public health. Each has worked for decades to protect the public from the devastating harms caused by use of tobacco products, which are the leading cause of preventable death in America, claiming over 480,000 lives every year.[2] Many of the *amici* include among their membership academics and other experts who serve on federal scientific advisory committees.

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[2] *See* Dep't of Health and Human Services, *The Health Consequences of Smoking-50 Years of Progress: A Report of the Surgeon General*, at 659 (2014), *available at* http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.

Amici have a strong interest in ensuring that the membership of the Food and Drug Administration's Tobacco Products Scientific Advisory Committee is consistent with the goals and intent of Congress when it established this advisory committee as part of the Family Smoking Prevention and Tobacco Control Act of 2009. *Amici* also have a strong interest in ensuring that federal courts in general give appropriate deference to federal agency determinations relating to actual or potential conflicts of interest on federal advisory committees, given the extensive experience these agencies possess in the management of these issues. Finally, *amici* have a strong interest in ensuring that the federal conflict of interest rules are interpreted so as to not discourage participation in federal advisory committees by the experts who are the most qualified persons to join those committees, and from whose insights federal agencies stand to benefit the most.

SUMMARY OF ARGUMENT

The district court erred in holding that Drs. Jack Henningfield, Neal Benowitz, and Jonathan Samet (the "Experts") should be disqualified altogether from the Food and Drug Administration's Tobacco Products Scientific Advisory Committee (the "TPSAC") because of conflicts of interest. This Court should uphold FDA's carefully considered determination that the Experts were not precluded from participation on the TPSAC.

The district court's disqualification of the Experts—three of the world's foremost authorities on nicotine addiction (Drs. Henningfield and Benowitz) and the health consequences of tobacco use (Dr. Samet)[3]—and its invalidation of the TPSAC's report on menthol cigarettes rested on the court's analysis of the general conflict of interest provisions governing federal employees, found in 18 U.S.C. § 208 and related regulations. Contrary to well-established principles of statutory interpretation, the court's analysis failed to consider the effect of the specific, later-enacted conflicts provisions of the Family Smoking Prevention and Tobacco Control Act of 2009 (the "TCA")[4] that are applicable specifically to the TPSAC, or of the overall policy priorities that Congress stated explicitly in the TCA, on the general conflicts provisions on which it relied. The TCA was premised on Congress's findings that tobacco products are "addictive" and "inherently dangerous" and that the "actions of the tobacco industry" have caused a "public health crisis" in the United States. Congress declared one of the law's main purposes to be "promot[ion of] cessation to reduce disease risk and the social costs associated with tobacco-related diseases."

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[3] The Experts' credentials in the relevant areas are set forth in detail in Judge Kessler's opinion in *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006). *See* 449 F. Supp.2d at 352-53 (Dr. Henningfield); *id.* at 577 (Dr. Benowitz); and *id.* at 705 (Dr. Samet).

[4] Pub. L. No. 111-31, 123 Stat. 1776 (2009). The TCA amended, and has been codified mainly as part of, the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*

Congress's findings and the TCA's overall pro-cessation purpose rested in large part on the groundbreaking scientific research performed by the Experts, and on consensus public health reports in which the Experts played leading roles. The TPSAC was structured by Congress to reflect and advance the TCA policy priorities, and the conflicts provisions applicable to the TPSAC were intended to be consistent with those aims, focusing on limiting *tobacco industry* involvement in the TPSAC. In other words, Congress clearly intended that the TPSAC's voting members would include the top non-industry experts on tobacco control and smoking cessation—such as the Experts disqualified by the district court.

However, the district court's decision deprived FDA of critical expertise on the very scientific issues that are at the heart of the TCA. This result cannot be what Congress intended when it enacted the TCA and established the TPSAC. Contrary to the district court's conclusion, the Experts' participation in outside activities consistent with the TCA's statutory purposes, and consistent with the specific conflicts provisions of that statute, was not grounds to disqualify them from serving in any capacity on the TPSAC.

Given the TCA's TPSAC language and overall policy direction, it is not surprising that FDA reasonably concluded, after careful analysis of the relevant TCA and non-TCA conflicts provisions, that the Experts should not be disqualified from serving on the TPSAC altogether (although FDA did determine that one of

the Experts would be recused from one specific issue before the TPSAC). FDA's thorough and nuanced analysis should be reinstated under the well-established principle that under the APA, the role of a reviewing court is to determine whether an agency's decision was a reasonable one, not, as the district court did here, to substitute its own judgment for the agency's.

A deferential approach is particularly necessary in the context of FDA conflict of interest determinations for its scientific advisory committee members. Federal agencies in general, and FDA in particular, routinely wrestle with the application of conflict of interest rules, balancing the benefits of receiving the best possible expert advice to guide their decisions against the threat of undue influence. This is an area where agencies' experience and expertise outweighs the courts'. In this case, the district court's untethered speculation about the potential conflict between the Experts' TPSAC involvement and their non-TPSAC activities should not be allowed to override FDA's conclusion, after careful determination, that the Experts could serve on the TPSAC. Indeed, this conclusion would have been correct even under a proper application of the general conflicts provisions of 18 U.S.C. § 208 alone.

Finally, the district court's decision has serious implications that go beyond the TPSAC, generally threatening federal agencies' ability to attract to their scientific advisory committees the very expertise that is most needed by

governmental decision makers. The fact that the most attractive candidates for federal advisory committee members are involved in related activities within their areas of expertise is not surprising, given that these experts, by definition, are in the greatest demand in their fields. The district court's speculative findings of conflicts of interest in this case would, if applied generally, make it more difficult for federal agencies to engage the most qualified scientific experts, and would discourage the most qualified experts from serving on outside panels that are integral to sound, scientifically supported federal agency decision making.

ARGUMENT

I. The District Court Failed To Apply the General Conflicts Language in 18 U.S.C. § 208 in Light of the TCA's Specific Language and Overall Purposes, Both of Which Support the Experts' Membership on the TPSAC.

An analysis of the Experts' conflicts cannot be divorced from either the specific statutory language relating to TPSAC conflicts, or the overarching purposes and policy orientation of the TCA. But the district court did just that, disqualifying the Experts based entirely on a misapplication of the general conflict of interest provisions relating to special government employees, found in 18 U.S.C. § 208, without any effort to apply these provisions in light of the later-enacted, TPSAC-specific conflicts provisions in the TCA or with that law's overall purposes and intent. Both the specific TCA provisions and the law's overall purpose support the Experts' membership on the TPSAC. The district court's

approach violated well-established principles of statutory construction and compels that this Court reverse the district court's disqualification of the Experts.

A. Longstanding Principles of Statutory Construction Require Courts To Interpret Earlier, More General Statutory Provisions in Light of Later, More Specific Statutory Provisions.

A court interpreting a statutory provision must consider that provision in relation to later-enacted, more specific statutory language on the same subject. "[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citing *United States v. Estate of Romani*, 523 U.S. 517, 530-31 (1998), and *United States v. Fausto*, 484 U.S. 439, 453 (1988)). This is true even where the later statute does not amend, but merely exists side-by-side with, the earlier statute. *See, e.g.*, *Estate of Romani*, 523 U.S. at 530-31 ("[A] specific policy embodied in a later federal statute should control our construction of the [earlier] statute, even though it ha[s] not been expressly amended."). When a court considers two related statutes, it is engaged in the "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' *in combination* . . . ." *Fausto*, 484 U.S. at 453 (emphasis added). This task "necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *Id.*

In this case, the district court made no attempt to interpret the *earlier-enacted, general* conflict of interest provisions in 18 U.S.C. § 208 in light of the *later-enacted, more specific* TPSAC/TCA conflict of interest provision, which in turn implements the general policy purposes and intent of Congress in the TCA. The district court ignored the "necessary assumption" that the scope of the earlier general provisions would be affected by the later, more specific provisions, which indisputably speak "more specifically to the topic at hand." *See id.*; *Brown & Williamson*, 529 U.S. at 133 (citations omitted). Indeed, the district court, once it concluded that the specific, later-enacted TPSAC provisions did not require the Experts' disqualification, merely moved on to a review of the earlier-enacted general provisions as though the TPSAC provisions specifically and the TCA in general did not exist.[5]

This approach was in error. The specific TPSAC conflict of interest provisions and the overall anti-smoking, pro-cessation purpose of the TCA support

[5] In justifying its focus on the general conflicts provisions, the district court explained that "notwithstanding how narrowly Congress drafted this specific conflicts provision, other general conflicts laws apply to FDA's composition of the Committee, and failure to adequately consider potential conflicts arising from the opposite end of the spectrum . . . would amount to 'failure to consider an important aspect of the problem.'" *Lorillard, Inc. v. FDA*, No. 11-440 (RJL), 2014 WL 3585883, at *11 (D.D.C. July 21, 2014) (citing *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Yet by failing to interpret the earlier general statutory provisions in light of Congress's clear intent as expressed in the later, more specific provision, the district court failed to consider an *even more* important aspect of the problem.

the Experts' inclusion on the TPSAC, notwithstanding their work on smoking cessation products and their expert testimony, and the district court should have interpreted the general conflict provisions consistent with the later congressional language and purposes.

B. The Findings and Overall Purpose of the TCA Reflect a National Consensus that Smoking Is Harmful and that Cessation Is the "Only Known Safe Alternative" to Tobacco Use.

The TCA represents Congress's recognition of a "consensus . . . within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." TCA § 2(2) (findings).

The TCA's extensive findings emphasize "the Federal Government's substantial interest in . . . preventing the life-threatening health consequences associated with tobacco use" and the "public health goals" of the TCA. *Id.* § 2(30)-(31). Congress also found that the use of tobacco by children "is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," and that the tobacco industry has successfully directed its advertising, marketing, and promotion "to attract young persons to use tobacco products." *Id.* § 2(1) and (15); *see also id.* § 2(47) and (48) (summarizing findings in *Philip Morris*, *supra* n. 3, about tobacco industry targeting and marketing to youth). Congress further found that "[n]icotine is an addictive drug" and noted the

conclusions in *Philip Morris USA* that the major U.S. tobacco companies engineered their cigarettes "to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction . . . ." *Id.* § 2(3) and (49).

Based on these and other findings, Congress concluded that it was "in the public interest . . . to adopt legislation to address the public health crisis created by actions of the tobacco industry." *Id.* § 2(29). Regarding smoking cessation, Congress found that cessation is "the *only* known safe alternative to smoking" (*id.* § 2(34)) (emphasis added) and stated explicitly that one of the purposes of the TCA is "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." *Id.* § 3(9).

In short, Congress clearly set out the TCA's anti-smoking, pro-cessation objective, emphasizing the negative health effects of tobacco products, the importance of promoting cessation, and the corrupting influence of the tobacco industry on the public health.

C. Congress Structured the TPSAC Consistent with the Purposes of the TCA.

Congress structured the TPSAC to provide FDA with input from leading non-industry scientists in furtherance of the TCA's stated policies and purposes, and with a specific concern about the effects of the tobacco industry on these policies and purposes. Accordingly, Congress established the TPSAC as a 12-

member committee, seven members of which must be "physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty." 21 U.S.C. § 387q(b)(1)(A)(i). Congress affirmatively curtailed the influence of the tobacco industry on the TPSAC in two ways. First, it made the three members of the TPSAC representing tobacco industry interests nonvoting "consultants" to the TPSAC. *Id.* § 387q(b)(1)(B). Second, Congress defined what a conflict of interest means *for the TPSAC*:

> Conflicts of Interest. -- No members of the committee, other than [the tobacco industry representatives] shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.

Id. § 387q(b)(1)(C). With these two provisions, Congress made clear that it intended to prevent people with tobacco industry financial ties from serving as voting members of the TPSAC because of their potential corrupting threat. Importantly, however, Section 917 of the TCA (codified at 21 U.S.C. § 387(q)) makes equally clear, through the absence of other limits to TPSAC membership, that Congress did *not* intend to preclude from such membership altogether scientists involved in outside activities that align completely with the pro-cessation

and anti-tobacco use policy objectives of the TCA—including the activities that the district court found to disqualify the Experts.

Indeed, by definition, the policy premises of the TCA and the particular role of the TPSAC contemplate that FDA will identify, and benefit from, the service on the TPSAC of persons exactly like the Experts, notwithstanding their outside activities. Not only are the Experts eminently qualified to address the issues facing FDA and the TPSAC, but many of the findings and objectives in the TCA derive in no small part from scientific research performed by the Experts. Each Expert has served on numerous governmental panels convened to evaluate the scientific evidence relating to tobacco use and nicotine addiction, and has held leadership roles on such panels. The reports produced by these panels cite heavily to the scientific research the Experts have conducted in their respective fields. As but one example, the TCA finding that "[n]icotine is an addictive drug" rests on the 1988 Report of the United States Surgeon General titled, "The Health Consequences of Smoking: Nicotine Addiction." Drs. Benowitz and Henningfield were two of the four scientific editors of that consensus document, and each authored, in whole or part, chapters of the report. *See* Dep't of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General* (1988), *available at* http://profiles.nlm.nih.gov/NN/B/B/Z/D/.

It would be ironic in the extreme, and contrary to Congress's intent when it passed the TCA, if the individuals whose research contributed to the scientific foundation of that statute were disqualified from membership on the FDA advisory committee charged with assisting the agency in implementing the statute.

D. Congress Knows How To Apply the General Conflicts Provisions When It Chooses To, and Treated the TPSAC Differently for a Reason.

Congress's extensive findings explaining the purposes of the TCA, coupled with its express provision in the TCA regarding what constitutes a disqualifying conflict of interest for TPSAC members, "altered . . . the implications" of the scope of the general conflicts provisions in 18 U.S.C. § 208 as those provisions apply to the TPSAC. *See Fausto*, 484 U.S. at 453. Congress's enactment of Section 917 should have caused the district court to read the earlier, more general provisions in light of the specific approach to conflicts in the later statute and to uphold the Experts' membership on the TPSAC.

There are real differences between the TPSAC and other FDA advisory committees that justify why Congress took the specific approach to conflicts that it took in the TCA for the TPSAC. Unlike most FDA advisory committees, which review data in order to make recommendations to FDA about particular products seeking marketing approval, the TPSAC has been charged by Congress to address broad public health issues and to advance specific congressional legislative priorities—*i.e.*, reducing the harm from tobacco products and promoting cessation

as a critical public health goal. As FDA noted in one of its memoranda addressing the conflicts issues related to the Experts in connection with the menthol report, "the TPSAC meetings regarding menthol are unusual because [Congress's charge in the TCA] to explore the public health implications of menthol is very broad. FDA advisory committees are often asked to evaluate the quality and sufficiency of the data supporting the potential approval or licensing of a product. Under these circumstances, conflict of interest screening is more focused and it is easier to clearly identify the direct and predictable effects on financial interests." JA 221.

The unusually broad mandate given FDA and the TPSAC by Congress, and the difficulty of easily identifying conflicts in that setting (unlike the usual FDA advisory committee setting), compels a broad, inclusive approach to the TPSAC's membership that ensures that FDA would have the most expert scientific minds at its disposal. The district court ignored this context and how it should affect interpretation of the general conflicts provisions.

Had Congress simply chosen to have the earlier, general provisions apply without consideration for the later, specific provisions, it knew how to do so. *Cf. INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotation marks and citations

omitted). Indeed, shortly before passage of the TCA, in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007), Congress amended the FDCA to address conflict of interest issues for FDA advisory committees overall, adding a new Section 712 to the FDCA concerning the type, timing, and publication of financial interest disclosures for FDA advisory committee members. Throughout that section, Congress expressly incorporated the general ethics standards of 18 U.S.C. § 208. *See*, *e.g.*, 21 U.S.C. §§ 379d-1(a)(2), (c)(1), & (c)(2). By contrast, when it enacted the TCA, Congress adopted specific conflicts provisions for TPSAC members that fit better with the TCA's overall emphasis and policy objectives. Thus, Section 917 must be read to "alter" the 18 U.S.C. § 208 standards as applied to the TPSAC, and the district court's failure to attempt to read the two statutory provisions to "'make sense' in combination," *Fausto*, 484 U.S. at 453, led it to err in this case.

II. The District Court Also Erred in Not Deferring to FDA's Careful, Comprehensive Analysis of the Experts' Interests.

FDA's own analysis of the Experts' conflict issues carefully reviewed both the TCA and general conflicts provisions and, as discussed above, fully recognized the TPSAC's broad mandate from Congress and the particular challenges of identifying conflicts in that context. FDA's conclusion that the Experts were not disqualified altogether from TPSAC membership, but that Dr. Henningfield was recused from one particular aspect of the Committee's work, was eminently

reasonable and indeed correct. The district court's failure to uphold FDA's decision was error.

A. In General, Under the APA Courts Should Not Substitute Their Own Opinions for Agency Determinations.

The district court's casual dismissal of FDA's decision and rationale amounted to nothing more than a substitution of the court's opinion for FDA's own careful analysis. That is not a court's job under the APA. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (holding that under the APA, "[t]he reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry."); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 ("The scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency.").

Instead, the district court was required to affirm FDA's decision "if a rational basis for the agency's decision exists." *Bolden v. Blue Cross & Blue Shield Ass'n*, 848 F.2d 201, 205 (D.C. Cir. 1988). Here, FDA's decisional memos in the Administrative Record confirm that FDA took a thorough and careful approach to the Experts' conflicts of interests, including the exact interests the district court held disqualifying, and ultimately reached a reasoned conclusion. JA 217-27; JA 228-33. It was error for the district court to substitute its judgment for FDA's, for the reasons discussed below.

B. Federal Agencies Routinely Wrestle with Conflicts Issues in Connection with Advisory Committees and Have Far Greater Expertise In This Area Than the Courts.

In the real world, the notion that a federal advisory committee can be "interest free"—embraced by the district court in this case [6] —is largely illusory. Advisory committees like the TPSAC are established to furnish the federal government with the most current expert advice, ideas, and diverse opinions. 5 U.S.C. app. 2 § 2(a); 21 U.S.C. § 379d-1(b)(3). Yet relevant scientific expertise is a finite resource, and the qualities that make the science advisors attractive to government agencies also often make them equally appealing to the entities with business before those same agencies.[7]

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[6] *See Lorillard*, 2014 WL 3585883, at *15 ("The only way the agency can correct its error of law in evaluating the credentials of future members of the TPSAC is for this Court to remand the case to the agency for the appointment of a newly-constituted, *interest free*, TPSAC panel of authorities consistent with the applicable ethics laws.") (emphasis added).

[7] *See, e.g.*, Katherine A. McComas, Leah Simone Tuite, & Linda Ann Sherman, *Conflicted scientists: the "shared pool" dilemma of scientific advisory committees*, 14 Pub. Understanding of Sci. 285, 286 (2005); Alison McCook, *Conflicts of interest at Federal Agencies*, The Scientist, July 24, 2006, *available at* http://www.the-scientist.com/?articles.view/articleNo/24174/title/Conflicts-of-interest-at-Federal-agencies/; Nyssa Ackerley, John Eyraud, & Marisa Mazzotta, E. Research Grp., Measuring Conflict of Interest and Expertise on FDA Advisory Committees 1-3 (2007), *available at* http://www.fda.gov/oc/Advisory/ERGCOIreport.pdf; Elizabeth R. Glodé, *Advising Under the Influence?: Conflicts of Interest Among FDA Advisory Committee Members*, 57 Food & Drug L.J. 293, 301 (2002).

Indeed, in 2008 the Government Accountability Office observed that "FDA staff and former FDA advisory committee members generally agreed that individuals with the expertise FDA sought for its advisory committees were the same leading experts industry sought to conduct research." U.S. Gov't Accountability Office, GAO-08-640, *FDA Advisory Committees: Process for Recruiting Members and Evaluating Potential Conflicts of Interest* 6 (2008)). A 2006 FDA-commissioned study concluded that FDA's ability to create conflict-free advisory panels was "speculative." Nyssa Ackerley, et al., *supra*, at iii (2007).

Given the inherent tension between an agency's desire to utilize the most accomplished outside experts, and the likelihood that those experts will have outside interests related to the matters under consideration, the solution is rarely to simply disqualify experts altogether from advisory committee membership—and certainly not where, as here, the committee's mandate relates broadly to the public health. *See* JA 221. Rather, Congress directs and authorizes federal agencies to *manage* membership of their advisory committees. In some instances, as in relation to tobacco industry representation on the TPSAC itself, Congress provides guidance to an agency about specific types of conflicts it must police when creating or filling an advisory committee.[8] In other instances, Congress

[8] *See also* 49 U.S.C. § 60115(b)(4)(D) (establishing the Technical Pipeline and Technical Hazardous Liquid Pipeline Safety Standards Committees and prohibiting a "significant financial interest in the pipeline, petroleum, and natural gas industry"

incorporates the generally applicable conflict-of-interest laws, directing agencies to handle potential conflicts within the parameters established by the Federal Advisory Committee Act ("FACA"), 5 U.S.C. app. 2 § 8.[9] But even in the TPSAC context, as discussed above, Congress chose to make tobacco industry representatives non-voting members of the TPSAC, not to bar them altogether. And, as discussed above, if Congress does want to exempt certain experts from advisory committee membership altogether, it certainly knows how to do so. In general, the task of managing conflicts issues is left by Congress to the agencies themselves, which recognize that the mere existence of outside interests "does not imply that a person will act in a biased manner" such that he or she cannot participate on the advisory committee *at all*,[10] and that a more nuanced approach is required.

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in five individuals on each committee); 30 U.S.C. § 812(a)(3) (establishing Mine Safety and Health Research Advisory Committee and prohibiting appointment of a majority of members with "economic interests in the coal or other mining industr[ies]. . . .").

[9] FACA directs each agency head and designated Advisory Committee Management Officer to establish administrative guidelines and exercise management controls. *Id.*

[10] Nyssa Ackerley, et al., *supra*, at 1-1 (2007) (citation omitted); *see also* Katherine McComas, et al., *supra*, at 289 ("[T]he mere presence of a conflict of interest does not mean that an individual or party has acted or will act inappropriately or misuse their authority, but it does indicate that the conditions exist for bias to occur."). *See also* 21 U.S.C. § 379d-1(c)(1)(A)-(B)("[T]he Secretary shall disclose . . . the type, nature and magnitude of the financial interests of the advisory committee

Indeed, federal agencies manage conflicts issues frequently and effectively. "An average of 1,000 advisory committees with more than 60,000 members advise the President and the Executive Branch . . . ." U.S. Gen. Serv. Admin., *The Federal Advisory Committee Act (FACA) Brochure*, http://www.gsa.gov/portal/content/101010 (last visited Mar. 23, 2015). Identifying and handling potential conflicts are regular features of agency management of these committees.

C. FDA In Particular Has Extensive Experience Handling Conflicts Issues.

FDA is a "sophisticated and experienced consumer of expert advice" that deals with the issues of identifying and then managing conflicts as a matter of course. Erika Lietzan, *Advisory Committees at FDA: The Hinchey Amendment and "Conflict of Interest" Waivers*, 39 J. Health L. 415, 446-47 (2006) (noting FDA's decades of experience with outside consultants, standing advisory committees, and application of federal conflicts laws to those committees). A 2006 study found that in 161 of 221 FDA meetings (73 percent), at least one committee member had disclosed a financial conflict of interest. *See* Peter Lurie, et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 J. Am. Med. Ass'n 1921, 1921 (2006). A 2009 study FDA commissioned to extend Lurie's 2006 analysis found a similar level of

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member . . . [and] the reasons of the Secretary for such determination or certification [that the expert may participate under 18 U.S.C. § 208], including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.").

conflicts of interest. *See* Nyssa Ackerley, et al., *Financial Conflict-of-Interest Disclosure and Voting Patterns at FDA Advisory Committee Meetings*, at 4-2, E. Research Grp. (2009) ("Financial conflicts-of-interest were disclosed by at least one standing or temporary advisory committee member at 76 percent of product meetings (2001 through 2008).") *available at* http://www.fda.glv/downloads/AdvisoryCommittees/AboutAdvisoryCommittees/UCM165328.pdf. As of 2015, FDA convened 33 agency "technical and scientific review groups." *See* 21 U.S.C. § 394(1); *Committees & Meeting Materials*, FDA, *available at* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ (last updated Feb. 18, 2015).

One commentator, after examining the "elaborate forms, procedures, and logarithms that guide [FDA's] decisionmaking," concluded FDA is "well aware of, and capable of taking into account, the extent to which each panel member's views may be affected by personal interests." Lietzan at 438, 446. Other studies confirm that conclusion. *See* Elizabeth Glodé, *supra*, at 321-22 ("Overall, FDA has done an admirable job of establishing conflict of interest safeguards and of making its procedures as transparent as possible to committee members and to the public.").

FDA's handling of the advisory committee that produced the menthol report provides an illustrative example of such conflict management. An FDA selection committee evaluated nearly 100 nominees before selecting the 12 committee

members, who underwent conflict of interest screenings prior to their appointment to TPSAC. *Lorillard*, 2014 WL 3585883, at *13. Further screenings occurred on a meeting-by-meeting basis, a process that resulted in Dr. Henningfield being recused from meetings about dissolvable tobacco products to avoid appearance or financial conflicts arising from his ownership interest in a tobacco cessation product development company. *Id.*

D. Courts Should, and Do, Defer to Agency Conflicts Determinations Because They Fall within the Agency's Area of Expertise.

Given agencies' general experience in the area of conflicts, and the need for balancing of numerous policy and scientific issues within the agency's particular expertise as part of any specific conflicts determination, courts should be, and routinely are, "highly deferential" to agency decisions about how to constitute advisory committees. *See Cargill, Inc. v. United States*, 173 F.3d 323, 335 n.24, 342 (5th Cir. 1999) (citing approvingly *Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419, 424 (D.C. Cir. 1989) (Edwards, J., concurring in part and dissenting in part) (noting that "the difficulty of determining what precisely constitutes a 'fair balance' may incline courts to be deferential in reviewing the composition of advisory committees.")). In this complex area, in which agencies have extensive experience and a strong track record, it is inappropriate for a court to apply its own "common sense" approach to

overturn an agency decision, as occurred in this case. *See Lorillard*, 2014 WL 3588553, at *12.

The dangers of not according agencies deference in this area are immediately apparent from a review of the district court's decision in this case. The district court provided neither a logical nor a factual basis for its conclusion that FDA's conflicts analysis was "flawed . . . and not worthy of deference." *Id.* In fact, it is clear that the district court's analysis of the general conflict provisions 18 U.S.C. § 208 was incorrect, even in the absence of the provisions of the TCA.

First, the district court offered no evidence—just the Plaintiffs' speculation—to support what it termed a "common sense" conclusion that *if* FDA were to ban menthol cigarettes and that ban would "likely" result in higher sales of smoking cessation products, *then* the makers of such products would demand more consulting services from Drs. Henningfield and Benowitz. *Id*. Even using the district court's assumption that a ban on menthol would cause an increase in demand for smoking cessation products—an assumption FDA examined and rejected as too speculative to restrict participation on the TPSAC, JA 223-26—it simply does not follow that there would be a consequent increase in demand for the Experts' consulting services. For example, the district court did not explain why a smoking cessation product manufacturer would rely on consultants to respond to an increase in product demand (as opposed to, for example, using in-

house scientists), or why the demand for the services of these particular Experts would grow. The *Lorillard* plaintiffs' speculative cause-and-effect hypothesis, without any evidence, was a wholly insufficient basis for the district court's decision.

Second, the fact that the Experts have given expert testimony and may do so in the future should not have disqualified them from service on the TPSAC. The expertise that qualifies an individual to inform a judicial decision maker can be equally relevant to inform a regulatory agency. In either case, the expert's conclusions are only as strong as the factual record adduced to support them. Here, FDA made a reasonable judgment that it should not be disqualifying for the Experts to have previously formed opinions on a scientific question relevant to the TPSAC's work, regardless of whether such opinions were articulated as an expert witness in court and regardless of whether the expert might express those opinions in future court proceedings. The district court's decision to the contrary would deprive the TPSAC of the expertise of precisely those who have studied the issues sufficiently to have formed opinions, including those whom courts have found to be qualified (and credible) experts in judicial proceedings.

III. The District Court's Conflicts Determination Will Discourage Participation of Qualified Experts in Scientific Advisory Committees Generally.

The district court's decision has negative implications not just for the TPSAC, but for agency policymaking more broadly. As discussed above, the most highly qualified scientists are often sought out for their expertise by both the public and private sectors, Congress entrusts agencies to manage potential conflicts when they appoint committee members, and agencies perform this task consistently and well. The decision below threatens to deter the most qualified scientists from serving on federal advisory committee, with adverse repercussions for public policy.

Participation on expert advisory committees, and the process leading up to appointment to such committees, entails costs as well as benefits for the experts involved. The GAO reported in 2008 that several features of the FDA's committee recruiting process deter experts from participating, including public exposure of financial holdings and professional engagements, and the possibility of negative media attention. U.S. Gov't Accountability Office, *supra*, at 30.

Upholding the decision below, which involved not only the disqualification of the Experts from the TPSAC's future work, but also the invalidation of work already completed by the TPSAC, would further deter experts from considering service on advisory committees. Experts would be discouraged by the heightened

possibility of a lawsuit that overrides an agency's vetting and nullifies a committee's recommendations, by the potentially wasted years of work in the event of an after-the-fact adverse decision by a court, and by the prospect that even a failed lawsuit may spawn accusations of unethical conduct. Encouraging such challenges by litigious industry interests would necessarily impose on potential committee participants uncertainty and risks of protracted litigation, public attention, and embarrassment.[11]

By adding these costs and uncertainties to committee participation, the decision below can be expected to shrink the pool of candidates willing to seek or accept membership. If scientists lose confidence that agencies will be permitted to manage conflicts in a way that allows experts to balance public service on advisory committees with their other pursuits, experts are likely to choose only one path. And evidence suggests they will opt for the latter. *See* Elizabeth Glodé, *supra*, at 319 ("Because many top experts work in academic settings, they are expected to bring in grants, contracts and other funding–often from industry . . . . [M]ost experts would be unwilling to put their careers in jeopardy for a temporary term as an FDA committee member . . . .").

[11] *See, e.g.*, David Kesmodel & Jared A. Favole, *FDA Tobacco Panel Includes Members With Quit-Smoking Ties*, WALL ST. J., Mar. 1, 2010 7:23 p.m. ET, *available at* http://www.wsj.com/articles/SB10001424052748704358004575096023131826574; Duff Wilson, *Advisory Panel Urges F.D.A. to Re-examine Menthol in Cigarettes*, N.Y. TIMES, Mar. 18, 2011, *available at* http://www.nytimes.com/2011/03/19/business/19tobacco.html?_r=0.

Reducing the number of qualified experts available to serve will also reduce the quality of decision making by agencies on behalf of the public. The President's Commission in Federal Ethics Law Reform stated that using recusal to eliminate any conflict would be an "'unworkable remedy' because it would deprive the committee of the conflicted individual's expertise." President's Comm'n on Fed. Ethics Law Reform, *To Serve with Honor: Report and Recommendations to the President* 30 (1989). The danger of "overzealous" recusal is real: by pressing a committee to rely on unconflicted but less qualified experts, "the FDA risked basing a decision on advice and recommendations from people who . . . were unqualified to weigh in on that subject." Katherine McComas, *supra*, at 297. The decision below nonetheless pushes in this direction, and upholding it risks "the public los[ing] when 'experts' can't give their expertise because of perceived 'conflicts.'" *Id*.

Ironically, the lower court's decision achieves a result contrary to what Congress intended when it enacted mechanisms to restrict tobacco industry influence over the TPSAC. The decision allows the tobacco industry to influence TPSAC and its recommendations through *ex post* litigation. This Court should correct the district court's error.

CONCLUSION

For the foregoing reasons, this Court should reverse the decision below.

Respectfully submitted,

/s/ Carlos T. Angulo
Carlos T. Angulo (D.C. Bar No. 466257)
Andrew N. Goldfarb (D.C. Bar No. 455751)
ZUCKERMAN SPAEDER LLP
1800 M Street, NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Facsimile: (202) 822-8106
cangulo@zuckerman.com
agoldfarb@zuckerman.com

Justin M. Gundlach (D.C. Bar No. 1005306)
Hope M. Babcock (D.C. Bar No. 14639)
Institute for Public Representation
Georgetown University Law Center
600 New Jersey Ave. NW, Suite 312
Washington, D.C. 20001
Tel: (202) 662-9535
justin.gundlach@law.georgetown.edu
babcock@law.georgetown.edu

Counsel for *Amici Curiae*

Of Counsel:

Mark Greenwold
Dennis Henigan
Campaign for Tobacco-Free Kids
1400 Eye Street, NW
Washington, DC 20005

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 6,492 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ Carlos T. Angulo
Carlos T. Angulo

CERTIFICATE OF SERVICE

Pursuant to D.C. Circuit Local Rule 25(c), I hereby certify that on this 26th day of March, 2015, I electronically filed the foregoing **BRIEF OF *AMICI CURIAE* PUBLIC HEALTH GROUPS IN SUPPORT OF DEFENDANTS-APPELLANTS** with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Carolos T. Angulo
Carlos T. Angulo