UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LORILLARD, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 11-cv-00440 (RJL)
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

MEMORANDUM OF AMICI CURIAE PUBLIC CITIZEN, INC., THE AMERICAN ACADEMY OF PEDIATRICS, THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, THE AMERICAN HEART ASSOCIATION, THE AMERICAN CANCER SOCIETY, THE AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, THE AMERICAN LUNG ASSOCIATION, THE AMERICAN MEDICAL ASSOCIATION, THE AMERICAN SOCIETY OF PREVENTIVE ONCOLOGY, THE AMERICAN THORACIC SOCIETY, THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH, THE CAMPAIGN FOR TOBACCO FREE KIDS, THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST, AND THE ONCOLOGY NURSING SOCIETY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

Amici curiae are organizations concerned both about public health issues and about the scientific integrity of advice that agencies receive on such issues through advisory committees subject to the Federal Advisory Committees Act (FACA), including the Tobacco Products Scientific Advisory Committee at issue in this case. The plaintiffs seek to invalidate the appointment to that Committee of expert scientists who undisputedly possess the exact qualifications specified by the governing statute for membership on the Committee, in part on the ground that those scientists have conducted research and expressed views on scientific issues related to those that the Committee is charged to address. The plaintiffs purport to base their claim on FACA's requirement that the membership of advisory committees be "fairly balanced."

5 U.S.C. App. § 5(b)(2). But the fair balance requirement does not disqualify an otherwise qualified expert from serving on an advisory committee whose membership requires scientific expertise merely because affected industries disagree with the expert's scientific views, nor does it empower courts to find a committee to be unlawfully constituted because it does not include those who disagree with the scientific opinions and conclusions of the committee's members.

Accepting the plaintiffs' position that the fair balance requirement is violated whenever committee members have views on scientific matters that are not counterbalanced by opposing views would threaten the utility of advisory committees in a number of ways. It would deprive agencies of advice from the very experts most qualified to give it: those who have actual knowledge and research experience concerning the subjects to be addressed by the committee. It would deter qualified scientists from accepting appointment to advisory committees out of concern that their very expertise would become a matter of distracting controversy and litigation. It would encourage politicization of scientific matters as interested parties sought to exclude scientists whose views were inconvenient to them, or, alternatively, attempted to use the requirement of fair balance to force agencies to appoint advisory committee members whom the agencies would not otherwise have chosen based on their credentials, merely because they disagreed with the scientific views of other committee members. And it would force courts to assume a role to which they are singularly ill-suited: assessing the merits of opposing scientific views to determine which ones are sufficiently subject to legitimate debate to require that all opposing views be represented on an advisory committee.

FACA cannot be read to permit, let alone require, such an attempt to set up the judiciary as judge of the merits of scientific views held by members of advisory committees. Plaintiffs' effort to set aside the appointment of members of the Tobacco Products Scientific Advisory

Committee on the ground that certain members have conducted research and developed and expressed views on technical subjects related to those that the Committee is tasked to address (and that contrary views are not represented), should be dismissed under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim on which relief may be granted.[1]

INTEREST OF AMICI CURIAE

The amici curiae joining this memorandum are described in detail in the accompanying motion for leave to file the memorandum. All are organizations with a longstanding interest in sound public health policies, and in ensuring that such policies are formulated on the basis of the best available scientific knowledge and expertise. Federal advisory committees with members chosen on the basis of their scientific credentials play an important role in bringing science to bear on federal public health policies. Amici fully support the activities of federal advisory committees and the aims of FACA, including a proper construction of FACA's requirement that advisory committees be fairly balanced. But amici are gravely concerned that the concept of fair balance underlying the plaintiffs' complaint in this case—under which a committee appointed in full compliance with statutory requirements aimed at achieving a fair balance of affected interests may nonetheless be found to lack a fair balance because members of affected industries object to the scientific opinions of some of its members—runs counter to the aims of FACA and would embroil the courts in politically based attacks on scientific integrity and independence. Amici therefore submit this memorandum in support of the defendants' motion to dismiss the complaint.

[1] Some of the amici curiae joining this memorandum disagree with the government's position that FACA claims are nonjusticiable and that persons claiming a lack of fair balance in a committee whose activities affect their interests lack standing. Other amici curiae take no position on those issues. This memorandum argues only that the defendants' motion should be granted under Rule 12(b)(6).

ARGUMENT

I. Inclusion of Expert Members with Scientifically Based Views on Relevant Matters on the Tobacco Products Scientific Advisory Committee Conforms with FACA's Fair Balance Requirement.

A. The Committee Reflects the Balance Required by Its Authorizing Statute.

Section 5 of FACA states that any legislation establishing a federal advisory committee shall "require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." 5 U.S.C. App. § 5(b)(2). Consistent with this general admonition, the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Act"), in establishing the Tobacco Products Scientific Advisory Committee to advise the Food and Drug Administration (FDA) on scientific and medical issues relating to the agency's responsibilities under the Tobacco Act, expressly defines the points of view to be represented on the Committee, to enable that Committee to fulfill its function of providing the desired technical advice:

> The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—
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> (i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;
>
> (ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;
>
> (iii) 1 individual as a representative of the general public;
>
> (iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;
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> (v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based

on areas of expertise relevant to the topics being considered by the Advisory Committee; and

(vi) 1 individual as a representative of the interests of the tobacco growers.

21 U.S.C. § 387q(b)(1)(A).

The Tobacco Act further provides that the three tobacco industry representatives shall be non-voting members of the Committee, that no members other than the industry representatives may receive any compensation from the tobacco industry, and that no full-time FDA employee may be appointed to the Committee (other than as a non-voting, ex officio member). *Id.* §§ 387q(b)(1)(B), (b)(1)(C) & (b)(2).

The plaintiffs' complaint does not allege that those provisions, which define the viewpoints to be represented on the Committee and categorically exclude persons who represent or are compensated by the tobacco industry (but not other industries) from voting membership, violate FACA's directive that advisory committees be fairly balanced in light of the functions they are to perform.[2] Nor do the plaintiffs allege that the members of the Committee (including those whose membership they challenge) fail to meet the relevant requirements of the Tobacco Act—namely that they "are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products," and that they "are 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), (b)(1)(A)(i).

[2] Such a claim would, in any event, be untenable, because one Congress cannot limit the ability of a later Congress to pass legislation through the process set forth in Article I of the Constitution, and thus a later-passed act of Congress cannot be held unlawful because it fails to comport with a requirement purportedly set forth in earlier legislation. *Cf. Lockhart v. United States*, 546 U.S. 142, 147-48 (2005) (Scalia, J, concurring).

B. Scientific Advisory Committees Are Intended to Comprise Members with Scientific Opinions, and the Presence of Such Members Is Consistent with FACA's Fair Balance Requirement.

Unable to claim any violation of the Tobacco Act's criteria for membership on the Committee, the plaintiffs instead argue that the Committee violates FACA's fair balance provision because—even though the members satisfy the Tobacco Act provisions that implement that requirement—certain members allegedly have conducted research and taken positions on matters within their fields of scientific expertise with which the plaintiffs disagree, and there are allegedly no members of the committee who have taken contrary positions on those subjects. These allegations, even if true, fail to state a legally cognizable claim that the Committee violates FACA's fair balance requirement. Indeed, accepting the conception of fair balance that underlies the plaintiffs' complaint would profoundly distort FACA, impair the functioning of advisory committees, and improperly place the courts in the role of inquisitors into the views of advisory committee members on scientific matters far outside the courts' expertise.

Federal advisory committees serve an important function by providing government agencies with access to expert advice as to scientific, technical, and (in some instances) policy matters from persons outside of government. There are nearly 1,000 federal advisory committees serving a broad range of agencies, including the FDA, the Environmental Protection Agency, the National Institutes on Occupational Safety and Health, the Energy Department, the Department of Interior, and NASA. As the GAO has stated:

> Approximately 950 federal advisory committees with about 62,000 members play an important role in shaping public policy by advising policymakers on a wide array of important and challenging issues. For example, advisory committees provide advice in the form of peer reviews of scientific research that may be used to support health, environmental, and safety regulations; recommendations about specific policy decisions; identification of long-range issues facing the nation; and evaluations of grant proposals, among other functions. Federal advisory committees have been established to work in broad areas of public policy, such as national security, the economy, the environment, and public health. Illustrative of

> the range of issues addressed by federal advisory committees are the current committees that advise agencies on matters related to AIDS research, food safety, hazardous waste cleanup, trade policy, and homeland security.

GAO, *Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance* 4 (2004).

Among this large array of advisory committees, a little more than 200 are categorized as "scientific and technical committees." *Id.* at 64. Other advisory committees address nonscientific matters, matters of national policy, regulatory negotiation, and review of grant applications. *Id.* at 64-65. In addition to the Tobacco Products Scientific Advisory Committee at issue here, advisory committees with a scientific and technical focus include more than 30 other FDA advisory committees that advise key agency components on such matters as whether to approve (or withdraw approval of) regulated drugs, medical devices, and biologic agents, *see* GAO, *FDA Advisory Committees: Process for Recruiting Members and Evaluating Potential Conflicts of Interest* 9 (2008); the EPA's Scientific Advisory Board Panels, which review scientific studies and provide advice on methodological and other technical issues related to the agency's mission of protecting the environment and public health, *see* GAO, *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance* 3 (2001); and committees that advise other federal agencies on such matters as food safety, protection of human research subjects, prevention of childhood lead poisoning, toxicological study methods, genomics, climate change, effects of radiation, DNA sequencing, earthquake hazards, and space exploration. *See* GAO, *Federal Advisory Committees*, *supra* at 67-92.

For members of such a committee, possessing information and expert views on matters within the purview of the committee is not a disqualifying factor or an indicium of a lack of fair balance. To the contrary, it is critical to the very purpose of the committee. The FDA, for example, "convenes scientific advisory committees to provide independent expertise and

technical assistance to help the agency make decisions about the development and evaluation of products regulated by FDA." GAO, *FDA Advisory Committees, supra*, at 1. Committee members "are chosen for their expertise and skills and are expected to provide advice on the basis of their own best judgment." *Id.* at 12. As a result, "[m]ost [FDA] advisory committee members are expert scientists and esteemed clinicians." Eastern Research Group, *Measuring Conflict of Interest and Expertise on Federal Advisory Committees* 1-3 (2007), *available at* http://www.fda.gov/oc/advisory/ergcoireport.pdf. Such experts are likely to have developed views on a variety of subjects based on their professional experience, including their own independent research and their review of data compiled by other researchers. As a legal matter, neither the fact that experts have acquired information and reached conclusions in the course of their work, nor the possibility that other scientists not on the committee might reach different conclusions upon review of the same data renders a scientific advisory committee not "fairly balanced."

C. The Courts Have Construed FACA's Fair Balance Requirement to Refer to Appropriate Representation of Entities Affected by Policy Recommendations Where Congress Has Not Otherwise Specified the Membership of Committees, Not to a Balancing of Opinions Held by Committee Members Chosen on the Basis of Scientific Expertise.

FACA's fair balance requirement is aimed at ensuring that advisory committees that consider matters of policy with effects on various private and public interests provide at least some degree of representation to the affected groups. As the D.C. Circuit has put it, FACA's "legislative history makes clear, [that] the 'fairly balanced' requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee." *National Anti-Hunger Coalition v. Executive Comm. of the President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983); *accord Public Citizen v. National Advisory Comm. on Microbiological Criteria for*

Foods, 886 F.2d 419, 423 (D.C. Cir. 1989) (opinion of Friedman, J.); *id.* at 433 (opinion of Edwards, J.). In other words, the "fairly balanced" requirement applies principally to the selection of committee members chosen as representatives of groups affected by governmental policy, not members who are selected for their technical or scientific expertise.[3] When Congress implements FACA's fair balance requirement by enacting legislation that specifically provides what interests must receive fair representation on a committee, the statutory requirement has been satisfied.

No court, to our knowledge, has extended the fair balance requirement so far as to use it to assess the scientific opinions of committee members chosen on the basis of technical expertise in an effort to determine whether the presence of members with those opinions (or the absence of members with opposing opinions) rendered the committee unfairly imbalanced. Indeed, while a panel of the D.C. Circuit in the *Committee on Microbiological Criteria* case split sharply over how to apply the fair balance requirement (and even about whether a committee's compliance with the fair balance standard is a justiciable issue), even the judge who would have applied the standard most rigorously agreed that as long as relevant interest groups were fairly represented on a committee, the statute did not allow for review of whether particular views on issues were represented. *See* 886 F.2d at 436 n.5 (opinion of Edwards, J.).[4]

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[3] Some federal advisory committees that address mostly matters of policy consist primarily of members chosen as representatives of particular interests. Others, typically committees involving both technical and policy matters, include members selected as representatives of, for example, industry and consumer interests as well as members selected on the basis of expertise, who are not expected to represent any particular interest group. *See* GAO, *Legal Principles Applicable to Selection of Federal Advisory Committee Members* 2 (2004).

[4] Judge Silberman, concurring in the judgment in *Committee on Microbiological Criteria*, took the view (contrary to the positions of Judges Friedman and Edwards) that fair balance claims should not be justiciable because of the absence of judicially enforceable standards to govern such claims. One need not agree with Judge Silberman (and the defendants here) that fair

(*footnote continued*)

This case involves a committee established to evaluate scientific evidence and to provide expert advice. And in this case, the balance of representation of group viewpoints is specified by the Tobacco Act itself: Three members are to represent the tobacco industry (as non-voting participants in the Committee); one is to represent the general public; one is to represent governmental entities; and seven are to come from the scientific and medical communities and represent different medical disciplines and specialties. 21 U.S.C. § 387q(b)(1)(A). The statute further defines and circumscribes the representation of the tobacco industry by providing that the public, governmental, and scientific/medical Committee members may not receive any compensation from the tobacco industry in any form. *Id.* § 398q(b)(1)(C). In sum, the Tobacco Act provides expressly for the precise degree to which various relevant interests are to be represented on the Committee, and, as noted above, the plaintiffs neither allege that the Committee fails to comport with those statutory requirements nor challenge the requirements themselves as unfair or otherwise invalid. Plaintiffs' attempt to carry the "fairly balanced" requirement beyond the issue of whether relevant interest groups are represented as required by the statute and into the realm of the scientific opinions legitimately held by members of the Committee has no basis in FACA.

Moreover, with respect to the first issue considered by the Committee—the public health effects of permitting menthol to be added to cigarettes—the three tobacco industry representatives participated vigorously in the discussions of the Committee and were given an opportunity equal to that of all other committee members to question all witnesses who appeared

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balance claims are never justiciable to recognize that Judge Silberman's forceful argument against judicial attempts to determine what particular opinions and conclusions merit inclusion on a committee, *see* 882 F.2d at 426-27, strongly counsels against reading the statute to require a balance of specific scientific opinions.

before the Committee, to critique the evidence presented to the Committee, and to present evidence and arguments. Unlike the voting members of the Committee, they are not bound by ex parte requirements and have thus provided the industry with the unique ability to have a continuing dialogue directly with members of the Committee and to ensure that industry views are presented not only by witnesses presenting testimony, but by members of the Committee itself. The report prepared by the industry representatives—with the assistance of numerous industry employees and consultants—has been submitted to the FDA together with the report of the Committee's voting members. *See The Industry Menthol Report*, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf. The FDA will evaluate both reports, together with all other evidence submitted to it, in the notice and comment rulemaking required before it promulgates any rule. The procedures followed in this case fully comport with the spirit and the letter of FACA, and hardly reflect an imbalance in the interests represented in the Committee's proceedings.

II. Reading FACA to Require Balancing of Scientific Opinions Held by Expert Committee Members Would Impair the Integrity of Advisory Committees and Would Be Judicially Unmanageable.

Adopting the contrary reading of FACA's fair balance requirement on which the plaintiffs' claim rests would have a number of negative consequences. To begin with, it would threaten the efficacy of scientific and technical advisory committees by potentially depriving them of the very expertise that they are supposed to be able to offer to the agencies they assist. The Tobacco Products Scientific Advisory Committee, for example, exists to provide the FDA with advice from scientists and physicians "who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products" and who practice in relevant fields including "oncology,

pulmonology, cardiology, toxicology, pharmacology, [and] addiction." 21 U.S.C. §§ 387q(b)(1)(A) & (A)(i). Experts who genuinely possess those qualifications can be expected to have conducted research and to have reached conclusions, based on their experience and their study of relevant data, on matters relevant to the Committee's activities. Holding that a Committee member's possession of views on subjects within his or her field of expertise renders the Committee unfairly imbalanced would force the agency either to exclude such experts from the Committee, thus depriving itself of the benefit of scientific advice from those most qualified to provide it, or to seek out members it would not otherwise have deemed to merit inclusion on the Committee based on qualifications alone, merely because they have an opposing opinion on some specific matter. In either case, the quality of the advisory committee and of its assistance to the agency would suffer.

Opening up an expert's research and conclusions on scientific matters to judicial inquiry aimed at determining whether they are somehow unfair or imbalanced would also deter qualified members from accepting appointment to scientific advisory committees. Already the FDA, like other agencies, "face[s] barriers to recruiting qualified advisory committee candidates." GAO, *FDA Advisory Committees*, *supra*, at 6. These barriers include the amount of time and effort involved, the relatively small remuneration members receive for their work, the necessity that members provide detailed, public financial disclosures, "and the negative publicity surrounding some advisory committee meetings." *Id.* Interpreting FACA in a way that would encourage deep-pocketed industries to bring lawsuits challenging the participation of particular committee members based upon the industries' disagreement with the scientific work they have performed would only heighten the disincentives to membership. Members faced with the possibility that they will be targeted in litigation precisely because of the expertise that qualifies them for

membership may well conclude that participation in the work of an advisory committee is not worth the heartache, expenditure of time, and possible damage to reputation that goes along with being dragged into litigation. And if the best-qualified experts (who, particularly in the area of smoking and health, are the most likely to be targeted by the industry) decline to participate, the usefulness of the advisory committee to the agency will be materially impaired.

Plaintiffs also appear to allege that the Committee lacks a fair balance because some members have given expert testimony in litigation involving the tobacco companies, and that those members should therefore be excluded from the Committee. Plaintiffs' attack misconceives the nature of expert testimony and confuses science-based testimony with advocacy. Scientific expert testimony is admissible only when a court makes its own determination that the testimony will be helpful to the trier of fact and that it possesses the degree of scientific validity necessary to make it relevant and reliable in relation to the issues of fact to be determined. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591-95 (1993). Expert witnesses are not advocates, nor does offering expert testimony reflect bias or closed-mindedness. On the contrary, the admission of such testimony reflects a judicial determination that it is grounded in scientific methodology. *See id.*

That the expert testimony offered by some members of the Committee may conflict with positions taken by members of the industry in some cases does not mean that those Committee members are unable to evaluate scientific evidence dispassionately or that the conclusions they reach will uniformly be contrary to positions taken by the industry. Moreover, conclusions that they have reached on the basis of scientific evidence may validly be the basis for both expert testimony and for the work they perform in their role as members of the Committee. Prior consideration of scientific evidence by a committee member, whether as an expert witness or in

some other capacity, is not evidence of bias and does not connote unwillingness to continue to examine the evidence and re-evaluate conclusions warranted by the evidence. Plaintiffs' plea that the Committee should nonetheless be found to be unfairly imbalanced because it includes scientists who have appeared as expert witnesses would unnecessarily deprive the government of the service of scientists best able to provide advice. Indeed, it would be surprising if a collection of the scientists most qualified to serve on a committee addressing issues relating to the health effects of tobacco products did *not* include at least some who have testified frequently in tobacco-related litigation.

More broadly, the plaintiffs' conception of FACA's fair balance requirement is an assault on scientific integrity and independence that threatens to contribute to the improper politicization of scientific issues. The tobacco companies' position that the evidence-based scientific opinions of members of the Committee must be "balanced" by opposing opinions reflects the misconception that science is a matter of partisanship and ideology rather than a process of arriving at conclusions based on evidence developed and tested through the scientific method. Scientific integrity is maintained not by political debate in which different "sides" are represented, but by the scientific process itself, including "(1) repeatability of observations and replication of results, (2) open communication and the sharing of data, (3) objective interpretation of the evidence, and (4) peer review." Katherine L. Gross & Gary G. Mittelbach, *What Maintains the Integrity of Science: An Essay for Nonscientists*, 58 Emory L.J. 341, 342 (2008). There is nothing improper or unbalanced about a scientist, such as those who are members of the Committee at issue here, reaching a conclusion on a matter within his or her field of expertise based on the application of that method. "If one has views for or against something based on the data, that is called an intellectual process of trying to grapple with the issue, not

bias." Sidney Wolfe, Director, Public Citizen Health Research Group, *quoted in* Steve Usdin, *FDA Reviewing Intellectual Bias*, BioCentury, Apr. 20, 2009. Moreover, plaintiffs' argument wrongly assumes that opinions expressed by scientific experts are immutable and not subject to change in the light of evidence.

Scientific integrity and independence have come under assault through efforts to politicize matters of scientific inquiry. Some critics have asserted that appointments to federal advisory committees have in some cases apparently been tainted by political considerations, to the consternation of scientists who object to "the injection of politics into science." Robert Steinbrook, *Science, Politics, and Federal Advisory Committees*, 350 New Eng. J. Med. 1454 (2004). Accepting the tobacco companies' view of FACA's fair balance requirement would only heighten the problem: It would *require* the injection of politics into science by forcing agencies either to forgo appointment to committees of experts whose views on scientific matters are inconvenient to affected industries, or to seek out "balance" by recruiting additional members solely because they espouse views favored by industry, regardless of their scientific legitimacy. And it would enlist the courts as enforcers of this newly minted requirement.

The courts are profoundly unsuited to assuming such an enforcement role. Unlike the scientists who make up advisory committees, judges generally lack technical expertise relevant to determining whether an expert's view of a particular matter reflects a scientifically valid assessment of the evidence, and whether an opposing view would be sufficiently plausible or supportable to necessitate its representation on a committee to achieve fair balance. Indeed, even for the experts themselves, it may be "difficult to draw the line between unacceptable bias and strongly held views based on a lifetime of research or personal experience." Usdin, *FDA Reviewing Intellectual Bias*, *supra*. A court would thus be wholly at sea in attempting to

determine whether the prevalence of a particular view of a scientific matter among members of an advisory committee reflected an unfair imbalance, or whether it indicated only that an opposing view was unlikely to be held by qualified experts.

To put the matter more concretely, how would a court go about deciding whether, for example, an advisory committee addressing issues related to global warming was unfairly imbalanced if it included scientific experts who had expressed the view that evidence supported the conclusion that human-caused global warming is in progress but did not include those who had expressed the opposite view—or if the former outnumbered the latter? If such a committee reflected unfairness or imbalance, would the same be true of an advisory committee addressing science education that included evolutionists but not creationists? Should a NASA advisory committee on space exploration include members who believe that the moon landings were an elaborate hoax? And what if the issue is not a binary one, but one where there are multiple possible views (even if the evidence most scientists would accept points strongly toward only one of them)?[5] Should all such views have adherents on a committee? And if so, how can that be achieved on a committee of finite size—especially one that, like the Tobacco Products Science Advisory Committee, has its size limited by congressional command in the statute authorizing it?

These considerations strongly underscore the wisdom of confining FACA's fair balance requirement within the bounds already established by precedents of this Circuit, which provide no support for expanding the concept to require balance of the scientific opinions held by expert members of a committee. Absent such expansion, the plaintiffs' claims that the Committee is unfairly imbalanced because some of its members have opinions with which the companies

[5] *Cf. Comm. on Microbiological Criteria*, 886 F.2d at 426-27 (opinion of Silberman, J.) ("[G]iven the possible range of points of view on virtually any subject, an effort to reduce points of view to a few categories—as if they were political parties—is quite artificial and arbitrary.").

disagree fails to state a cognizable claim that FACA has been violated. That claim must accordingly be dismissed under Rule 12(b)(6).

III. Plaintiffs' Claims That Committee Members Have Interests Requiring Their Disqualification from Particular Matters Considered by the Committee Must Also Be Dismissed.

Beyond the claim that the Committee violated FACA's "fairly balanced" requirement, the plaintiffs' complaint alleges that Committee members have interests that, under 16 U.S.C. § 208 and 21 U.S.C. § 379d-1(c), require their disqualification from "particular matters" addressed by the Committee. These allegations rest primarily on certain members' activities as expert witnesses and their employment as consultants by pharmaceutical companies. The claimed violations relate not to the propriety of the appointment of these members to the Committee, but to whether their involvement in specific matters addressed by the Committee is lawful. The APA, however, authorizes review of "final agency action." 5 U.S.C. § 704. Although the appointment of the Committee would appear to be final agency action subject to review under the APA (as reflected by the D.C. Circuit majority's review of the merits of an APA-based challenge to the makeup of a FACA committee in *Committee on Microbiological Criteria*, 886 F.2d 419), the propriety of the Committee's actions with respect to any "particular matter" (including the participation of individual Committee members in those actions) would not become potentially subject to review until the agency (that is, the FDA) took some final action with respect to that matter. The plaintiffs allege no such final, reviewable agency action as to any particular matter in which they contend any Committee member's participation was unlawful.

Moreover, as noted in the government's Motion to Dismiss, FDA procedures for advisory committee meetings provide for a thorough review of potential conflicts of interest on a meeting-by-meeting basis. If a member of the Committee has a conflict or the appearance of a conflict

with respect to a given subject, that member will be recused with respect to that issue.[6] These procedures provide ample protection from conflicts of interests while at the same time permitting the best qualified scientists to participate as advisory committee members. Plaintiffs' assertion that claimed conflicts should form the basis for excluding members from the Committee altogether, rather than having conflicts addressed on a matter-by-matter basis, is unfounded.

Finally, the complaint fails, as a matter of law, to make allegations that state a claim of a violation of the conflict-of-interest provisions on which the plaintiffs purport to rely. The connection between any matter that has come before the Committee and any financial benefit to a Committee member is entirely speculative and remote. Plaintiffs' allegations state no logical connection between any Committee action and financial gain for committee members resulting from their retention as expert witnesses in tobacco-related litigation or as consultants for pharmaceutical companies: Nothing beyond conjecture suggests that anything the Committee might do (or that the FDA might do upon recommendation of the Committee) would make such retention more likely or more remunerative. Similarly, to the extent pharmaceutical companies might be considered employers or prospective employers of certain committee members for purposes of 18 U.S.C. § 208, the possible indirect effects on their interests of matters before the Committee do not require recusal, particularly in light of 5 C.F.R. § 2640.203(g). That regulation, promulgated by the Office of Government Ethics, provides that "[a] special Government employee serving on an advisory committee within the meaning of the Federal Advisory Committee Act (5 U.S.C. app.) may participate in any particular matter of general applicability where the disqualifying financial interest arises from his non-Federal employment

[6] For example, Committee member Dr. Jack Henningfield recused himself from the meeting of the Tobacco Product Constituents Subcommittee held on July 7-8, 2010, but remains a member of the full Committee.

or non-Federal prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class." An example following this provision specifically cites employment by a "pharmaceutical company" as the type of employment that does not bar an advisory committee member from participating in a matter that affects the interests of pharmaceutical companies as a group. *Id*. (Example 1). Thus, the complaint's own allegations place their claim of conflict of interest outside of the applicable recusal requirement.[7]

In short, with respect to their recusal claims, the plaintiffs have alleged neither a reviewable final agency action nor a violation of the applicable statutory requirements. Those claims, like the claim that Committee members' scientific views violate FACA's "fairly balanced" requirement, must therefore be dismissed under Rule 12(b)(6). In deciding this motion, the Court need not determine whether APA review of regulatory actions can ever be premised on a violation of statutory recusal requirements, as the facts at bar do not suffice to present such a claim for review.

CONCLUSION

For the foregoing reasons, the Court should grant the defendants' motion to dismiss the complaint for failure to state a claim upon which relief may be granted.

[7] The complaint also suggests that one Committee member's ownership interest in a patent on a smoking cessation drug gives rise to a prohibited conflict, but the relationship between potential Committee action (or any resulting FDA regulatory action) and the sales of any particular cessation drug is far too indirect and speculative to disqualify that member.

Respectfully submitted,

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