UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LORILLARD, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Case No. 11-440 (RJL)**
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
	)	
	)	
Defendants.	)	

FILED
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Courts for the District of Columbia

MEMORANDUM OPINION
July 21, 2014 [## 65, 67]

This suit challenges the composition of the Tobacco Products Scientific Advisory Committee ("TPSAC" or "Committee"), a federal advisory committee established in 2010 by the U.S. Food and Drug Administration ("FDA") to provide advice and recommendations on scientific issues relating to tobacco products. The suit also challenges the process by which that committee drafted a 2011 report on the use of menthol in cigarettes ("Menthol Report").[1] Plaintiffs Lorillard, Inc., Lorillard Tobacco Company, and R.J. Reynolds Tobacco Company (collectively, "plaintiffs") initiated this action in February 2011 against the FDA; the U.S. Department of Health and Human Services ("DHHS"); Kathleen Sebelius, the Secretary of DHHS;[2] Margaret Hamburg, the

[1] The full title of the Menthol Report is: "Menthol Cigarettes and the Public Health: Review of the Scientific Evidence and Recommendations" (July 21, 2011). AR 19433-684.

[2] On June 9, 2014, Sylvia Burwell succeeded Kathleen Sebelius as the new Secretary of DHHS. For the purposes of this opinion, however, the Court will refer to Secretary Sebelius as the Secretary.

Commissioner of Food and Drugs; and Lawrence Deyton, the Director of the FDA's Center for Tobacco Products (collectively, "defendants") and filed their third amended complaint on April 25, 2013, seeking declaratory and injunctive relief.[3] Third Amended Complaint ("3d Am. Compl.") [Dkt. # 63] ¶¶ 1, 4, 7.

Plaintiffs assert five causes of action alleging lack of compliance with ethics laws and the Federal Advisory Committee Act ("FACA"), 5 U.S.C. app. 2 §§ 1-16, all in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.* 3d Am. Compl. ¶¶ 129-84. With regard to the Committee's composition, plaintiffs allege that defendants' appointment of three voting committee members—Drs. Neal Benowitz, Jack Henningfield,[4] and Jonathan Samet (together, the "Challenged Members"[5])—was "arbitrary, capricious, an abuse of discretion, and otherwise not in compliance with law" under the APA, 5 U.S.C. § 706(2)(A), because these three members had alleged financial conflicts of interest or the appearance of conflicts of interest, in violation of 18 U.S.C. §§ 202(a), 208; 21 U.S.C. § 379d-1; and 5 C.F.R. pts. 2635, 2640. 3d Am. Compl. ¶¶ 129-40 (Counts One and Two). Further, plaintiffs allege that defendants violated the

[3] Plaintiffs filed their original Complaint on February 25, 2011 [Dkt. # 1], their First Amended Complaint on March 21, 2011 [Dkt. # 12], and their Second Amended Complaint on July 5, 2011 [Dkt. # 33].

[4] Drs. Benowitz and Henningfield no longer serve on the TPSAC. *See* Defs.' Mot. for Summ. J. and Mem. of P. & A. in Supp. [Dkt. # 65] at 7 n.3. Plaintiffs continue to challenge their appointments, however, because their alleged conflicts of interest affect the Menthol Report. *See* Pls.' Supplemental Mem. in Opp'n to Defs.' Mots. to Dismiss [Dkt. # 42] at 8 n.13.

[5] Plaintiffs also alleged conflict of interest claims against Drs. Burns and Farone, two non-voting members of the Constituent Subcommittee, *see* 3d Am. Compl. ¶¶ 131, 133, 137, 139, 147, but plaintiffs no longer pursue those claims. *See* Pls.' Mot. for Summ. J. [Dkt. # 67] and Unredacted Mem. in Supp. of Pls.' Mot. for Summ. J. and in Opp'n to Defs.' Mot. for Summ. J. ("Pls.' Mem. & Opp'n") [Dkt. # 69] at 3 n.3.

APA by appointing a committee lacking "fair[] balance[] in terms of the points of view represented" and exhibiting "special interest" influence, in violation of FACA, 5 U.S.C. app. 2 §§ 5(b)(2)-(3), (c). 3d Am. Compl. ¶¶ 141-49 (Count Three).

Next, with regard to the TPSAC's deliberative process, plaintiffs allege that: members of the Committee held a private meeting on March 17, 2011, in violation of FACA, because the meeting was not open to the public and timely notice of the meeting was not previously published, 3d Am. Compl. ¶¶ 150-57 (Count Four); and defendants, in violation of FACA, failed to disclose various documents that were created by the TPSAC and its subcommittee and related to the Menthol Report. 3d Am. Compl. ¶¶ 158-84 (Count Five). As a remedy for these alleged violations of ethics laws and FACA under the APA, plaintiffs seek, *inter alia*, an order enjoining the FDA to reconstitute the TPSAC's membership so that it complies with applicable ethics laws and FACA, and an injunction barring defendants from using the allegedly "tainted" Menthol Report. 3d Am. Compl. at 84-91; *see also* Pls.' Unredacted Reply Mem. ("Pls.' Reply") [Dkt. # 77] at 23-24.

Before the Court are the parties' cross-motions for summary judgment.[6] Upon consideration of the pleadings, relevant law, and entire record therein, the Court concludes, first, that the FDA erred in determining that the three Challenged Members of the TPSAC did not have financial and appearance conflicts of interest, and second, that

[6] *See* Defs.' Mot. for Summ. J. and Mem. of P. & A. in Supp. ("Defs.' Mem.") [Dkt. # 65]; Pls.' Mot. for Summ. J. [Dkt. # 67] and Unredacted Mem. in Supp. of Pls.' Mot. for Summ. J. and in Opp'n to Defs.' Mot. for Summ. J. ("Pls.' Mem. & Opp'n") [Dkt. # 69]; *see also* Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. and in Reply to Pls.' Opp'n ("Defs.' Opp'n & Reply") [Dkt. # 72]; Pls.' Unredacted Reply Mem. ("Pls.' Reply") [Dkt. # 77].

therefore the FDA's appointment of those members was arbitrary and capricious, in violation of the APA, and fatally tainted the composition of the TPSAC and its work product, including the Menthol Report. Accordingly, plaintiffs' motion is GRANTED, in part, on Counts One and Two, and defendants' motion is DENIED.[7]

BACKGROUND

I. Legal Background

a. The Tobacco Control Act and the TPSAC's Role

Until recently, the FDA lacked authority to regulate tobacco products. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (holding that FDA lacked authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") to regulate tobacco products as customarily marketed). In 2009, however, Congress passed the Family

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[7] Because I find that the three Challenged Members' financial and appearance conflicts of interest, alone, are sufficient to taint the composition of the TPSAC, I need not reach the somewhat thornier "fair balance" and "special interest" claims under FACA (Count Three). *Compare Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419, 426-31 (D.C. Cir. 1989) (Silberman, J., concurring in the judgment) (finding FACA claim non-justiciable under the APA because FACA's statutory language—"fairly balanced in terms of the points of view represented and the functions to be performed," 5 U.S.C. app. 2 § 5(b)(2), and "inappropriately influenced . . . by any special interest," *id.* § 5(b)(3)—provided no "meaningful standard against which to judge the agency's exercise of discretion," *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)), *with id.* at 420-26 (Friedman, J., concurring in the judgment) (finding FACA claim justiciable but concluding that how to achieve "fair balance" lies within discretion of official who appoints advisory committee, and finding no abuse of discretion in case at bar), *and id.* at 431-38 (Edwards, J., concurring in part and dissenting in part) (finding FACA claim justiciable and that plaintiffs had made out their claim of a FACA violation in their complaint, and recommending remand for review on the merits). Further, because I find that the appointment of the three Challenged Members tainted the composition of the TPSAC from the outset and requires remand to the agency, I also find it unnecessary to reach plaintiffs' additional claims regarding the process by which the TPSAC operated (Counts Four and Five), which followed later in time. *See State of Nebraska Dep't of Health & Human Servs. v. Dep't of Health & Human Servs.*, 435 F.3d 326, 331 (D.C. Cir. 2006) (If the Court "determines that [the] agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards." (citation omitted)).

Smoking Prevention and Tobacco Control Act ("TCA" or "Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), which authorized the FDA "to regulate tobacco products under the [FDCA] . . . by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." *Id.* § 3(1) (Purpose). In part of that Act, Congress established the TPSAC, a twelve-member advisory committee, to "provide advice, information, and recommendations to the Secretary [of DHHS]" relating to the regulation of tobacco. 21 U.S.C. § 387q(c).[8]

The TCA authorizes the Secretary of DHHS to refer certain matters to the TPSAC. For instance, the FDA "may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the [TPSAC] for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment." 21 U.S.C. § 387g(d)(5)(A). Or the agency may refer an application to produce and distribute a "new tobacco product" to the Committee for a report and recommendation. 21 U.S.C. § 387j(b)(2).

But the TCA also affirmatively *requires* the Secretary to refer certain matters to the TPSAC. As relevant here, Congress chose to set two specific priorities for the Committee to address upon its formation, mandating, first, that "[i]mmediately upon the establishment of the [TPSAC] . . . the Secretary shall refer to the Committee for report

[8] Specifically, the TCA specifies that TPSAC "shall provide advice, information, and recommendations to the Secretary-- (1) as provided in this subchapter; (2) on the effects of the alteration of the nicotine yields from tobacco products; (3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and (4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary." 21 U.S.C. § 387q(c).

and recommendation . . . the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities." 21 U.S.C. § 387g(e)(1). Second, Congress also *directed* that "[t]he Secretary shall refer to the [TPSAC] for report and recommendation . . . the issue of the nature and impact of the use of dissolvable tobacco products [("DTPs")] on the public health, including such use among children." 21 U.S.C. § 387g(f)(1). The TCA further *required* that the TPSAC submit its report on menthol within one year of its establishment and its report on DTPs within two years thereof. 21 U.S.C. §§ 387g(e)(2), (f)(2). In providing such advice, the TPSAC is obligated to address the considerations the Secretary evaluates when issuing tobacco product standards, 21 U.S.C. §§ 387g(e)(1), (f)(1) (referring back to subsection (a)(3)(B)(i)), but the Act does *not* require the Secretary to defer to TPSAC's advice or recommendations, 21 U.S.C. §§ 387g(e)(3), (f)(3).

b. Laws Governing the TPSAC's Composition

Advisory committees that advise executive branch officials and agencies, such as the TPSAC, are governed by FACA, 5 U.S.C. app. 2 §§ 1-16. *See* Final Rule, Advisory Committee; Tobacco Products Scientific Advisory Committee; Establishment, 74 Fed. Reg. 43,042, 43,042 (Aug. 26, 2009) (acknowledging TPSAC is "governed by . . . the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees"). Congress passed FACA in 1972 "to ensure that new advisory committees be established only when essential and that their number be minimized; that they be terminated when they have outlived their usefulness; that their creation,

operation, and duration be subject to uniform standards and procedures; that Congress and the public remain apprised of their existence, activities, and cost; and that their work be exclusively advisory in nature." *Public Citizen v. Dep't of Justice*, 491 U.S. 440, 446 (1989) (citing 5 U.S.C. app. 2 § 2(b)). While Congress recognized that advisory committees "are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government," 5 U.S.C. app. 2 § 2(a), "Congress also feared the proliferation of costly committees, which were often dominated by representatives of industry and other special interests seeking to advance their own agendas," *Cummock v. Gore*, 180 F.3d 282, 284 (D.C. Cir. 1999). Accordingly, "FACA's principal purpose was to enhance the public accountability of advisory committees established by the Executive Branch and to reduce wasteful expenditures on them." *Public Citizen*, 491 U.S. at 459.

To achieve these purposes, FACA mandates, among other things, restrictions on the membership of advisory committees. As relevant here, FACA requires that any subsequent legislation establishing (or authorizing the establishment of) an 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. 2 § 5(b)(2). And any such legislation "shall" also "contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's

independent judgment." 5 U.S.C. app. 2 § 5(b)(3).[9]

The TCA is an example of such subsequent legislation establishing an advisory committee. That Act sets forth specific criteria for appointing the twelve members of the TPSAC, including the expertise required:

> 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;
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> (ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;
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> (iii) 1 individual as a representative of the general public;
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> (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). Further, the TCA provides that the nine members described in clauses (i)-(iii) will serve as voting members of the TPSAC, whereas the three tobacco

[9] Further, "[t]o the extent they are applicable, the guidelines set out in subsetion (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee." 5 U.S.C. app. 2 § 5(c).

industry representative members described in clauses (iv)-(vi) may not vote and "shall serve as consultants" to the voting members. 21 U.S.C. § 387q(b)(1)(B).

Notably, the provision barring tobacco industry representative members from voting is not the only way in which the TCA addresses FACA's requirement that advisory committee legislation must "contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced . . . by any special interest, but will instead be the result of the advisory committee's independent judgment." 5 U.S.C. app. 2 § 5(b)(3). The Act also includes a specific "conflicts of interest" provision governing the membership of the TPSAC:

> No members of the committee, other than [the three 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.

21 U.S.C. § 387q(b)(1)(C).

In addition to this TPSAC-specific conflicts provision, however, general conflict of interest laws and regulations apply to the voting members of the Committee, who are considered "special government employees" ("SGE"). *See* 21 C.F.R. § 14.80(b)(1)(ii) (voting members of technical advisory committees are "subject to the conflict of interest laws and regulations" as SGEs); 18 U.S.C. § 202(a) (defining SGE); *see also* AR 32 (TPSAC Charter). Specifically, the voting members must comply with the laws and regulations prohibiting financial and appearance conflicts of interest set forth in 18 U.S.C. § 208, 21 U.S.C. § 379d-1(c), and 5 C.F.R. §§ 2635.401-402, 2635.501-502; 2640.103. Absent certain exceptions, it is unlawful for an SGE to "participate[]

personally and substantially . . . through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise," in any "particular matter" in which he has a "financial interest." 18 U.S.C. § 208(a).[10] Regulations promulgated by the Office of Government Ethics ("OGE") pursuant to 18 U.S.C. § 208(d)(2) further interpret this general prohibition on financial conflicts of interest. *See* 5 C.F.R. §§ 2635.401-402, 2640.103. Specifically, 5 C.F.R. § 2635.402 ("Disqualifying financial interests") provides:

> (a) Statutory prohibition. An employee is prohibited by criminal statute, 18 U.S.C. 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to his knowledge, he or any person whose interests are imputed to him under this statute has a financial interest, if the particular matter will have a direct and predictable effect on that interest.
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> (b) Definitions. For purposes of this section, the following definitions shall apply:
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> > (1) Direct and predictable effect.
> >
> > > (i) A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy does not have a direct effect within the meaning of this subpart.
> >
> > > (ii) A particular matter will have a predictable effect if there

[10] Another statute, 21 U.S.C. § 379d-1(c), provides that members of FDA advisory committees are subject to parallel prohibitions to those in 18 U.S.C. § 208.

> is a real, as opposed to a speculative possibility that the matter will affect the financial interest. It is not necessary, however, that the magnitude of the gain or loss be known, and the dollar amount of the gain or loss is immaterial.

5 C.F.R. § 2635.402(a)-(b); *see also* 5 C.F.R. § 2640.103(a) (mirroring language of § 2635.402(a) and stating "[t]he restrictions of 18 U.S.C. 208 are described more fully in 5 CFR 2635.401 and 2635.402").

Finally, in addition to explicating financial conflicts of interest, the OGE regulations also address "appearance" conflicts of interest. *See* 5 C.F.R. § 2635.501-502. An appearance conflict exists "[w]here an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household . . . and where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter." 5 C.F.R. 2635.502(a).[11]

II. Factual Background

a. Selecting and Screening the TPSAC Members

The FDA issued the Charter for the TPSAC on August 7, 2009, *see* AR 30-33, and then began seeking nominations for voting and non-voting members by publishing notices in the Federal Register. *See* 74 Fed. Reg. 43,147 (Aug. 26, 2009) (voting); 74

[11] Despite § 2653.502(a)'s reference to "financial interest," a financial conflict is not necessary for an appearance conflict to exist because § 2653.502(a)(2) covers "circumstances other than those specifically described in the section." Further, although the plain language of § 2653.502(a) indicates that the recusal analysis should be initiated by an employee, agencies are in fact obligated to address such conflicts. *See* Memorandum to Designated Agency Ethics Officials regarding Guidance on Waivers Under 18 U.S.C. § 208(b), Authorizations Under 5 C.F.R. § 2653.502(d), and Waivers of Requirements Under Agency Supplemental Regulations, OGE, Legal Advisory DO-10-005, at 4 n.4 (Apr. 22, 2010); Pls.' Mem. & Opp'n at 61 n.60.

Fed. Reg. 43,140 (Aug. 26, 2009) (non-voting). The FDA formed a selection committee, *see* AR 6192-93, and evaluated nearly 100 nominees in a process chaired by the Assistant Secretary for Health and Human Services, *see* AR 81-87; Defs.' Am. Mem. in Supp. of Defs.' Mot. to Dismiss [Dkt. #22] at 11.

In identifying the original TPSAC members and alternates, the selection committee focused on the expertise and experience those members would bring to the topics to be addressed by the TPSAC. *See* AR 90-93; AR 2 (DHHS memo regarding establishment of TPSAC); AR 30 (Charter describing TPSAC's duties). According to the FDA, the voting members were selected in an effort "to recruit the best scientific experts and to ensure that TPSAC has a balanced composition of expertise to handle the complex tobacco-related issues that will come before it." AR 6141-42.

The FDA announced the initial nine voting members of the TPSAC on March 1, 2010.[12] In accordance with the TCA's membership criteria, the selected voting members included seven qualified health care professionals practicing in various relevant specialties, one non-FDA government representative, and one public representative. And these nine members included the three Challenged Members central to this litigation: (1) Dr. Neal L. Benowitz, the Chief of the Division of Clinical Pharmacology at the University of California, San Francisco, with expertise in nicotine, substance abuse, clinical pharmacology, and toxicology; (2) Dr. Jack Henningfield, Vice President of Research and Health Policy at Pinney Associates, with expertise in addiction medicine,

[12] *See* FDA News Release (Mar. 1, 2010), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm202394.htm.

pharmacology, and health policy; and (3) Dr. Jonathan M. Samet, the Chair of the Department of Preventive Medicine at Keck School of Medicine, with expertise in internal medicine, pulmonology, epidemiology, tobacco control, and public health, who serves as Chair of the committee. AR 89. The FDA also appointed three-nonvoting members to represent the tobacco industry. AR 112.

Before appointing the TPSAC members, the FDA conducted initial screenings to address potential conflicts of interest. *See* 74 Fed. Reg. 43,147, 43,148 (Aug. 26, 2009) (Notice, Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee) ("FDA will ask the potential candidates to provide detailed information concerning matters related to financial holdings, employment, and research grants and/or contracts.").[13] The FDA required all prospective voting members "to assure the agency that they had not received any salary, grants, payment or support from the tobacco industry in the preceding 18 months," and the agency then "reviewed each prospective member's expertise and financial interests to reduce the likelihood that conflicts of interests would arise from participating in particular committee meetings." AR 6192-93.

In accordance with 21 U.S.C. § 379d-1(c), the FDA also conducted conflict of interest screenings for TPSAC members before particular committee meetings that would address particular matters. *See* AR 3937-4307; AR 4308-4510 (screenings of Benowitz); AR 4511-4615 (screenings of Samet); AR 4616-6027 (screenings of Henningfield).

[13] *See also* Advisory Committees: Applying for Membership, http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ApplyingforMembership/default.htm.

Specifically, in accordance with procedures set out in *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflicts of Interest and Eligibility for Participation in FDA Advisory Committees* (Aug. 5, 2008),[14] before each meeting the FDA developed a list of products, companies, or entities that could be affected by the particular matter that was the subject of the Committee meeting. AR 6445. The FDA then screened the Committee members for interests in those products, companies, or entities and evaluated whether work on the "particular matter" would have a "direct and predictable effect" on the individual's financial interests. *See id.* (citing 5 C.F.R. § 2640.103(a)).

Immediately following the FDA's appointment of TPSAC's members in March 2010, and thereafter, various tobacco manufacturers, including plaintiffs, objected to the agency that certain members were conflicted and biased based on their ongoing work as expert witnesses in tobacco litigation, or their consulting work in connection with smoking cessation products. 3d Am. Compl. ¶¶ 35-50 (detailing objections submitted to FDA and FDA's responses). The agency rejected these objections. *Id.* In addition, the FDA's meeting-by-meeting approvals of the members repeatedly found no conflicts.[15]

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[14] *See* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf.

[15] The meeting-by-meeting approvals are at: AR 3937-49 (Mar. 30-31, 2010, TPSAC meeting), AR 4025-50 (July 15-16, 2010, TPSAC meeting), AR 4067-89 (Aug. 30, 2010, TPSAC meeting), AR 4125-45 (Oct. 7-8, 2010, TPSAC meeting), AR 4146-67 (Nov. 18, 2010, TPSAC meeting), AR 4168-82 (Jan. 10-11, 2011, TPSAC meeting), AR 4183-203 (Feb. 10, 2011, TPSAC meeting), AR 4219-36 (Mar. 2, 2011, TPSAC meeting), AR 4237-55 (Mar. 17-18, 2011, TPSAC meeting), AR 4256-75 (July 21-22, 2011, TPSAC meeting), AR 4276-84, 4297-98 (Jan. 18-20, 2012, TPSAC meeting), AR 4299-4307 (Mar. 1-2, 2012, TPSAC meeting). The FDA repeatedly found that Drs. Benowitz and Henningfield had no conflict as to the Menthol Report on the ground that they did not testify about menthol. *See* Pls.' Reply at 17 n.29. On the other

b. Facts Regarding Challenged Members' Alleged Conflicts of Interest

The facts regarding the Challenged Members' alleged conflicts of interest are relatively straightforward and uncontested. Plaintiffs contend that these individuals' employment as consultants to the pharmaceutical industry regarding nicotine replacement therapy ("NRT") products and other smoking-cessation products, as well as their service as paid expert witnesses in litigation against tobacco product manufacturers, created both financial conflicts of interest and appearance conflicts of interest. *See* 3d Am. Compl. ¶¶ 51, 76; *id.* ¶¶ 56-69 (detailing Challenged Members' alleged conflicts).

i. Dr. Benowitz

Since the 1980s, Dr. Benowitz has consulted for numerous pharmaceutical companies about the design of their NRT and other smoking-cessation drugs. AR 6163, 25488-91, 25499-500, 25508-09; *see also* AR 6130-31, 6377-78, 6411. He consulted for affiliates of Pfizer, Inc. ("Pfizer") & GlaxoSmithKline plc ("GSK") as to such products, even while serving on the TPSAC. AR 4257-58, 4423, 4448, 25499-500, 6163-64, 25508-09.[16] He also has received grant support from them. AR 6164 & n.38. In 2010, Dr. Benowitz co-authored a study, funded by Pfizer, of a Pfizer smoking-cessation drug. AR 6164.

Dr. Benowitz has also served as a paid expert witness for lawyers suing tobacco-product manufacturers. AR 6164-65, 25469-79, 25485-500, 25503-09; *see also* AR

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hand, the FDA did find that Dr. Henningfield had a conflict of interest due to his ownership interest in a company developing an NRT drug and recused him from the July 21 and 22, 2011, TPSAC meetings regarding DTPs. AR 4293, 5344.

[16] Pfizer, Inc. is a manufacturer of NRTs and other smoking-cessation drugs. AR 4289. GSK also markets NRT drugs. AR 25501, 27521.

6130. In that role, he has testified about the effect of menthol cigarettes on the public health. *See* AR 6164, 25474-75, 25486-87, 25496; *see also* AR 6131. He testified as a paid expert witness while serving on the TPSAC, AR 4402-03, and, as of June 30, 2010, he was designated to testify in 585 pending tobacco cases, AR 6164.

ii. Dr. Henningfield

Before and while serving on the TPSAC, Dr. Henningfield consulted for GSK and other drug companies as to NRT and other smoking-cessation drugs. AR 27065-66, 6377-78, 6411-12. He also had an ownership interest in a company that was developing a patented NRT product. AR 4293, 6134-35, 6169.

Dr. Henningfield has testified as an expert for GSK, AR 3693, and for lawyers suing tobacco-product manufacturers, AR 6169, 25639-70; *see also* AR 6134-35. In that role—before, during, and since serving on the TPSAC—he has testified about the effect of menthol cigarettes on the public health. *See* AR 6415 & nn.6-10, 6429-30, 26847-48, 26859. As of June 30, 2010, he was designated to testify in 350 pending tobacco cases. AR 6169.

iii. Dr. Samet

Dr. Samet received grant support from GSK at least six times, including in 2010. AR 6170 & n.64; *see also* AR 6136 & nn.37-38, 6378, 6412. He also led the Institute for Global Tobacco Control, funded by GSK and Pfizer. Until 2009, he had received regular honoraria from Pfizer for his service on the Pfizer Global Tobacco Advisory Board. AR 6170, 25673-74. But he was not consulting for GSK or Pfizer when FDA appointed him to the TPSAC or while serving on it.

Dr. Samet has also testified for lawyers suing tobacco-product manufacturers. AR 6170, 25673-78; *see also* AR 6135-36. As of June 30, 2010, he was designated to testify in two pending tobacco cases. AR 6170.

c. Activities of the TPSAC

Upon its formation, the TPSAC devoted its first meetings to the impact of menthol in cigarettes on the public health, as directed by the TCA. Defs.' Mem. at 9-15; AR 6453-7482 (Mar. 30-31, 2010, TPSAC meeting); AR 8749-10056 (July 15-16, 2010, TPSAC meeting). After holding numerous public meetings and considering an array of materials and submissions, the TPSAC discussed and adopted a complete version of the Menthol Report at its March 18, 2011, meeting. The TPSAC then held a follow-up meeting on July 21, 2011, at which it considered proposed revisions, and then voted to adopt the final Menthol Report and submitted it to the FDA. AR 19433-684 (Menthol Report). In its Conclusions and Recommendations (Chapter 8), the Report concluded that "[m]enthol cigarettes have an adverse impact on public health in the United States" and "[t]here are no public health benefits of menthol compared to non-menthol cigarettes." AR 19655. The Report further recommended that "[r]emoval of menthol cigarettes from the marketplace would benefit the public health in the United States," AR 19660, but it offered no recommendations about FDA's regulatory options. Further, while the Report found that there is insufficient evidence to support a conclusion that menthol cigarettes are more harmful than non-menthol cigarettes, AR 19633-38, it nonetheless did conclude that there is sufficient evidence that, among certain groups and among the general population, menthol cigarettes make it more likely that individuals

will start smoking and less likely that they will quit, increasing overall smoking rates. *Id.*[17]

III. Procedural Background

Plaintiffs initiated this action on February 25, 2011. *See* Compl. [Dkt. # 1]. After plaintiffs amended their complaint for the first time, *see* First Am. Compl. [Dkt. # 12], defendants filed a Motion to Dismiss (regarding Counts One through Four) [Dkt. # 18] on April 29, 2011. After plaintiffs once again amended their complaint to add a fifth cause of action, *see* Second Am. Compl. [Dkt. # 33], defendants filed an additional Motion to Dismiss regarding Count Five [Dkt. # 37] on September 8, 2011. This Court heard oral argument on the two motions on February 14, 2012, and after receiving supplemental memoranda from the parties [Dkts. ## 42, 43], I denied defendants' motions to dismiss. *See* Mem. Order (July 31, 2012) ("2012 Order") [Dkt. # 44]. I concluded that: (1) plaintiffs had standing; (2) their conflicts of interest challenges (Counts One and Two) were justiciable; (3) their FACA "fair balance" and "special interest" challenges (Count 3) were justiciable; and (4) concerning Counts Four and Five, the Menthol Report Subcommittee and its writing groups were advisory committees under FACA. *Id.* at 4-7. Thereafter, plaintiffs again amended their complaint on April 25, 2013, *see* 3d Am. Compl., and the parties briefed cross motions for summary judgment, the last of which was filed on September 23, 2013. *See supra* note 6.

[17] With respect to DTPs, the TPSAC considered their effect on the public health at its July 21-22, 2011, January 18-20, 2012, and March 1, 2012 meetings, AR 19685-21983, and on March 1, 2012, the Committee submitted to the FDA an eight-page summary report of its advice and recommendations regarding DTPs, AR 23495-502.

STANDARD OF REVIEW

I. Summary Judgment

Summary judgment is appropriate when the record evidence demonstrates that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The burden is on the moving party to demonstrate an "absence of a genuine issue of material fact" in dispute. *Celotex*, 477 U.S. at 323. In a case involving judicial review of final agency action under the APA, however, "the Court's role is limited to reviewing the administrative record." *Air Transp. Ass'n of Am. v. Nat'l Mediation Bd.*, 719 F. Supp. 2d 26, 32 (D.D.C. 2010) (citations omitted). "[T]he function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to made the decision it did." *Select Specialty Hosp.–Bloomington, Inc. v. Sebelius*, 893 F. Supp. 2d 1, 2 (D.D.C. 2012) (citations and internal quotation marks omitted).

II. Administrative Procedure Act

The APA "establishes a cause of action for those 'suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action.'" *Koretoff v. Vilsack*, 614 F.3d 532, 536 (D.C. Cir. 2010) (quoting 5 U.S.C. § 702). Under the APA, a court must set aside agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard of review is "highly deferential and presumes the validity of agency action." *Neighborhood Assistance Corp. of Am. v. CFPB*, 907 F. Supp. 2d 112, 125 (D.D.C. 2012) (citing *AT&T*

Corp. v. FCC, 220 F.3d 607, 616 (D.C. Cir. 2000)) (internal quotation marks omitted)). But while a court may not "substitute its judgment for that of the agency," *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), it will set aside agency action as arbitrary and capricious if the agency committed a "clear error of judgment," such as when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

ANALYSIS

Plaintiffs challenge final agency action under the APA: the FDA's appointment of the Challenged Members to the TPSAC and its March 1, 2010, announcement of the TPSAC roster, as well as the FDA's subsequent meeting-by-meeting screenings of those members for conflicts of interest as to menthol and DTPs. In assessing plaintiffs' conflict of interest claims, I will proceed in two steps.[18] First, I must address whether plaintiffs'

[18] At the motion to dismiss stage, I concluded that plaintiffs had alleged sufficient facts to satisfy the standing requirements. *See* 2012 Order at 4-5. On summary judgment, defendants again contest plaintiffs' standing to challenge the composition of the TPSAC. *See* Defs.' Mem. at 18-19; Defs.' Opp'n & Reply at 2-10. And, once again, I have concluded that plaintiffs have standing because, of the four types of injury they allege—(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 plaintiff Lorillard, Inc. due to the composition of the TPSAC, *see* Pls.' Mem. & Opp'n at 12; 3d Am. Compl. ¶¶ 112-124—the first, second, and fourth types have occurred, and the third type, a procedural injury, is substantially probable and not merely speculative. *See* Pls.' Mem. & Opp'n at 12-17 (articulating factual basis of plaintiffs' standing); *id.* at 43-45; Pls.' Reply at 11-

claims are subject to judicial review. I conclude that they are, just as I did at the motion to dismiss stage of this litigation. Next, I must determine whether the Challenged Members did, in fact, have financial and/or appearance conflicts of interest under relevant laws. Accordingly, I have to review and evaluate the conclusions the FDA reached when performing its conflict screenings. For the following reasons, I have concluded that both types of conflicts did exist, and the FDA's determinations showed a "clear error of judgment" and were thus arbitrary and capricious in violation of the APA.

I. Justiciability

In order to address whether judicial review is available for the FDA's conflicts determinations, it is first important to properly characterize what this case is about. In their motion to dismiss, defendants characterized plaintiffs' complaint as "challeng[ing] how the government enforces conflict of interest laws," Defs.' Am. Mem. in Supp. of Defs.' Mot. to Dismiss at 29, which, in turn, led them to argue that such enforcement decisions are "committed to agency discretion by law," 5 U.S.C. § 701(a)(2). *See* Defs.' Am. Mem. in Supp. of Defs.' Mot. to Dismiss at 29-33 (relying on, *inter alia*, *Heckler v. Chaney*, 470 U.S. 821 (1985)). Defendants briefly renew that "committed to agency discretion by law" argument in their motion for summary judgment. *See* Defs.' Mem. at 25-26. But I rejected that argument before, *see* 2012 Order at 5, and I reject it again now because it relies on a fundamental mischaracterization of plaintiffs' legal challenge. Plaintiffs do *not* seek to compel government enforcement of conflict of interest laws

15. Moreover, plaintiffs have shown traceability and redressability. *See* Pls.' Mem. & Opp'n at 43-45; Pls.' Reply at 11-15.

against third parties. *See* Pls.' Opp'n to Defs.' Mot. to Dismiss [Dkt. #27] at 26-28. Rather, plaintiffs seek judicial review of whether the FDA, itself, "in creating and maintaining an advisory committee tainted by conflicts of interest," acted arbitrarily and capriciously in violation of the APA. *See id.* at 26. Accordingly, judicial review is available.

Undaunted, defendants have repackaged their argument for unreviewability, emphasizing now in their summary judgment motion that plaintiffs' *appearance* conflict of interest claim (Count Two) is unreviewable for another reason—it is precluded by regulation. *See* Defs.' Mem. at 26. Defendants point to 5 C.F.R. pt. 2635 ("Standards of Ethical Conduct for Employees of the Executive Branch")—the only set of regulations that addresses appearance conflicts of interest—which includes a provision entitled "Disciplinary and corrective action," providing, in relevant part:

> A violation of this part or of supplemental agency regulations, as such, does not create any right or benefit, substantive or procedural, enforceable at law by any person against the United States, its agencies, its officers or employees, or any other person. . . .

5 C.F.R. § 2635.106(c). Defendants argue that the express language of this regulation bars plaintiffs from challenging whether the FDA complied with Part 2635, either through a private right of action or under the APA. *See* Defs.' Mem. at 26. In support, they rely on a case from our Circuit Court which found that similar language in an Executive Order ("E.O.") precluded private parties from bringing an APA action to challenge whether the agency complied with the E.O. *See Air Transp. Ass'n v. FAA*, 169 F.3d 1, 8-9 (D.C. Cir. 1999); *accord Defenders of Wildlife v. Jackson*, 791 F. Supp. 2d

96, 120-21 (D.D.C. 2011). I disagree.

Put simply, I am not persuaded either that the provision's text overcomes the "strong presumption" in favor of reviewability of agency action under the APA, *see PDK Labs. Inc. v. DEA*, 362 F.3d 786, 792 (D.C. Cir. 2004), or that the cited Circuit precedent is controlling here. First, § 2635.106(c) is not itself a judicial review provision, unlike the provision of the E.O. at issue in *Air Transportation Association*, which is titled "Judicial Review." *See* E.O. 12893, 59 Fed. Reg. 4233, 4235 (Jan. 31, 1994); *PDK Labs. Inc.*, 362 F.3d at 792-93. Second, unlike the language of the provision of the E.O. at issue in *Air Transportation Association*—which provides, "*This order is intended only to improve the internal management of the executive branch* and does not create any right or benefit, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person, " E.O. 12893 (emphasis added)—there is no such limiting language of intent in § 2635.106(c) *See Air Transp. Ass'n.*, 169 F.3d at 8; *see also Meyer v. Bush*, 981 F.2d 1288, 1296 n.8 (D.C. Cir. 1993). Accordingly, as I found at the motion to dismiss stage, I again find that plaintiffs' conflicts of interest claims are indeed subject to judicial review under the APA.

II. The Merits

On the merits, plaintiffs contend that the Challenged Members had financial and appearance conflicts of interest because they (1) consulted for manufacturers of NRT drugs and other smoking-cessation drugs that would benefit from a ban or restriction on menthol cigarettes and/or DTPs, and (2) testified in lawsuits against tobacco product manufacturers. *See* Pls.' Mem. & Opp'n at 1; 3d Am. Compl. ¶¶ 51-69, 76-77, 129-140.

As a result of these alleged conflicts, plaintiffs seek judicial review of the FDA's "creati[on] and maint[enance of] an advisory committee tainted by conflicts of interest." Pls.' Opp'n to Defs.' Mot. to Dismiss at 26. As I noted in my ruling on defendant's motion to dismiss, "[a]ny review of these actions by the Court would, of course, be highly deferential." 2012 Order at 5. But such deference is not boundless. Having reviewed the record in its entirety, I conclude that applicable ethics laws do *not* permit the FDA to do what it did here and compose a committee including a number of members with financial and appearance conflicts of interest.

As an initial matter, it is important to note that plaintiffs do not allege any direct violations of the TCA's specific conflicts of interest provision applicable to members of the TPSAC. *See* 21 U.S.C. § 387q(b)(1)(C). That is because this provision only contemplates conflicts arising from one perspective: it bars voting members from receiving any remuneration from tobacco industry businesses. *Id.* But 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—i.e. entities with interests adverse to tobacco companies—would amount to "fail[ure] to consider an important aspect of the problem," *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43. And to the extent the FDA did consider these potential conflicts, I must review its determinations for any "clear error of judgment," such as if the agency "offered an explanation for its decision that runs counter to the evidence before the agency," *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43.

a. Financial Conflicts of Interest

In Count One of their complaint, plaintiffs allege that the three Challenged Members have financial interests that create conflicts in violation of 18 U.S.C. §§ 202(a) and 208, 21 U.S.C. § 379d-1, and 5 C.F.R. Parts 2635 and 2640. These laws prohibit government employees from working on "particular matters" in which they have a financial interest. In plaintiffs' view, therefore, the FDA's appointment of the Challenged Members to the TPSAC was arbitrary and capricious in violation of the APA, 5 U.S.C. § 706(2)(A). *See* 3d Am. Compl. ¶¶ 130, 132. Plaintiffs also contend that the meeting-by-meeting screening and approval of these members by the FDA as to menthol and DTPs violated these ethics laws, and thus the APA. Pls.' Reply at 17. For the following reasons, I agree.

As a preliminary matter, defendants argue that plaintiffs' challenge to the *appointment* of individual TPSAC members should fail as a matter of law because the FDA's act of appointing is not a "particular matter" within the purview of applicable conflict of interest laws. *See* Defs.' Mem. at 27 (suggesting that the issuance of a report by TPSAC may be a "particular matter," but the appointment of a member to TPSAC is not).[19] But defendants miss the point here by once again misconstruing plaintiffs'

[19] The applicable regulation defines "particular matter" as follows:

> The term "particular matter" includes only matters that involve deliberation, decision, or action that is focused upon the interests of specific persons, or a discrete and identifiable class of persons. . . . It does not, however, cover consideration or adoption of broad policy options directed to the interests of a large and diverse group of persons.

5 C.F.R. § 2640.103(a)(1).

complaint. Plaintiffs' legal claim is that the FDA's appointment of members with financial conflicts of interest (as to a "particular matter") was arbitrary and capricious in violation of the APA. Therefore it is irrelevant whether the appointment *itself* is a "particular matter" because that definitional phrase is part of determining whether a conflict of interest exists, not whether an APA violation has occurred. *See* Pls.' Mem. & Opp'n at 46.

Defendants nonetheless proceed to argue that if it is irrelevant whether or not the appointment itself is a "particular matter," then this Court could only review the appointment under the APA if the challenged TPSAC member "had a foreseeable conflict as to *every* future particular matter TPSAC was to address." Defs.' Opp'n & Reply at 24. Not so. The legislation establishing the TPSAC specifically mandated not just that the Committee would address menthol and DTPs, but that it would do so within its first and second years of existence, respectively. *See* 21 U.S.C. § 387g(e), (f). Accordingly, if any prospective members already had a conflict as to either or both of those particular two issues—which defendants do not dispute are, in fact, "particular matters"—then the *very act of appointment itself* implicates those two particular matters because the TPSAC was certain to address them. Put differently, screening potential members for appointment to the TPSAC was functionally no different from screening them before particular meetings to address menthol and DTPs.

Turning to the merits, plaintiffs contend that the Challenged Members had financial conflicts of interest because they: (1) consulted for manufacturers of NRT drugs and other smoking-cessation drugs that would benefit from a ban or restriction on

menthol cigarettes and/or DTPs; and (2) testified in lawsuits against tobacco product manufacturers, before, during, and after serving on the TPSAC. *See* Pls.' Mem. & Opp'n at 18-20. An SGE, such as a TPSAC member, "is prohibited . . . from participating personally and substantially in an official capacity in any particular matter in which, to his knowledge, he . . . has a financial interest, if the particular matter will have a direct and predictable effect on that interest." 5 C.F.R. § 2635.402; *see also* § 2640.103. Plaintiffs argue that the Challenged Members' participation in the TPSAC's consideration of menthol and DTPs had a "direct and predictable effect" on their financial interests in consulting and expert testimony work. Under the circumstances of this case, I agree.

i. Consulting Work

As described above, Drs. Benowitz and Henningfield consulted for manufacturers of NRT drugs and other smoking-cessation drugs, and Dr. Samet had the prospect of future fees from them. *See supra* 15-17 (Factual Background). Defendants contend that the FDA "conducted extensive screenings" of each TPSAC member (and, where appropriate, recused members). *See* Defs.' Mem. at 28; AR 4022, 4062, 4089, 4275. In particular, defendants argue that the FDA considered the specific possibility of conflicts stemming from consulting work, determined that no such conflicts existed, and this Court should defer to the agency's determination. For the following reasons, however, I disagree and find the agency's "explanation for its decision . . . runs counter to the evidence before the agency," *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43, and therefore its conflicts determinations were arbitrary and capricious.

First, as regards menthol, the FDA solicited advice from the DHHS Designated Agency Ethics Official, who concluded that the TPSAC's advice on menthol would have no "direct and predictable effect" on the financial interests of drug companies that manufacture smoking-cessation drugs. AR 4121. Further, the memorandum concluded that even "an outright ban on menthol cigarettes[] cannot be determined to result in an increased demand for tobacco cessation products." *Id.* Accordingly, in the agency's view, TPSAC members who performed consulting work for such drug companies had no financial conflict of interest. Please!

This conclusion defies common sense. A ban or sales restriction on menthol cigarettes would have a "direct and predictable effect" on the Challenged Members' financial interests because it would likely increase the sales of such smoking-cessation drugs by *some* amount, which would in turn lead the manufacturers of such drugs to demand further consulting services from the challenged members. *See* Pls.' Mem. & Opp'n at 51. Indeed, the TPSAC's own Menthol Report suggests that removing menthol cigarettes from the market would lead a substantial number of menthol smokers to try to quit, which would increase demand for cessation services, including smoking-cessation drugs. *See* AR 19660-62; Pls.' Mem. & Opp'n at 51-52. Suffice it to say, the causal connection between any recommendation by the TPSAC on menthol and the effect on the Challenged Members' financial interests in consulting fees from manufacturers of smoking-cessation drugs is sufficiently "close," and that effect (of whatever magnitude)[20]

[20] The magnitude of any potential financial gain or loss is immaterial. *See* 5 C.F.R. 2635.402(b)(1)(ii).

is sufficiently "real" and not merely "speculative," to render the FDA's conflicts analysis flawed on this front and not worthy of deference. Put simply, if a Challenged Member stands to profit from the sale of products that help people quit smoking, then he faces a conflict in his duty to render impartial advice regarding the regulation of menthol cigarettes, which comprise a substantial share of the cigarette marketplace.[21]

Next, as regards DTPs, defendants similarly argue that the FDA adequately screened the Challenged Members with regard to financial interests in consulting work related to smoking cessation products. *See* Defs.' Mem. at 29. In this case, the FDA actually did find that one of the Challenged Members, Dr. Henningfield, had a conflict of interest due to his ownership interest in a company developing an NRT drug and recused him from the July 21 and 22, 2011, TPSAC meetings regarding DTPs. AR 4293, 5344. But the FDA also concluded that the other Challenged Members, Drs. Benowitz and Samet, did *not* have conflicts of interest for two reasons: (1) past consulting work did not create a conflict because a current TPSAC meeting would not have a "direct and predictable effect" on their financial interests, AR 6445, 4291-92, and (2) even ongoing relationships with pharmaceutical companies are "not per se disqualifying interests," AR 6445, AR 4285-96; *see also* Defs.' Mem. at 29. While the agency correctly concluded that past work, alone, cannot create a financial conflict in light of the applicable regulation's forward-looking language, *see* 5 C.F.R. § 2640.103(a)(3)(ii) (defining "predictable effect" as "a real, as opposed to speculative, possibility that the matter *will*

[21] *See* AR 19476 (Menthol Report) ("menthol smokers as a group account for between 28 percent and 34 percent of all U.S. cigarette smokers, depending on the data used").

affect the financial interest" (emphasis added))—and therefore Dr. Samet was not conflicted—I find the agency's conclusions show a "clear error of judgment" with regard to Dr. Benowitz and his ongoing consulting work.[22] How so?

The FDA erred in concluding that current, ongoing financial relationships with smoking-cessation drug manufacturers did not constitute a conflict. Since manufacturers of such smoking-cessation drugs compete with manufacturers of DTPs, *see* Pls.' Mem. & Opp'n at 24-25, and since Dr. Benowitz stood to profit from the sale of NRT drugs, he faced a conflict with regard to providing advice in the TPSAC's report on DTPs. *See* Pls.' Mem. & Opp'n at 54. Indeed, the regulations' own illustrative examples support this conclusion. As a specific example of a "disqualifying financial interest," Part 2640 includes the following scenario:

> Example 3: A special Government employee serving on an advisory committee studying the safety and effectiveness of a new arthritis drug is a practicing physician with a specialty in treating arthritis. The drug being studied by the committee would be a low cost *alternative* to current treatments for arthritis. If the drug is ultimately approved, the physician will be able to prescribe the less expensive drug. The physician does not own stock in, or hold any position, or have *any business relationship* with the company developing the drug. Moreover, there is no indication that the availability of a less expensive treatment for arthritis will increase the volume and profitability of the doctor's private practice. Accordingly, the physician has no disqualifying financial interest in the actions of the advisory committee.

5 C.F.R. § 2640.103(b) (emphasis added). It is plain in this example that if the SGE physician *did* currently have "any business relationship" with the company developing the drug, he would have a conflict. And that is very nearly the situation in the instant

[22] Dr. Samet did not have any current, ongoing business relationships with smoking-cessation drug manufacturers while serving on the TPSAC. *See supra* 16-17.

case: the TPSAC was charged with studying the public health impact of a drug (i.e. DTPs), and Dr. Benowitz had an ongoing business relationship (i.e. consulting work) with companies developing "alternative" or competing drugs (i.e. smoking-cessation drugs). Accordingly, I find that the FDA's conclusion with regard to Dr. Benowitz was a "clear error of judgment."

ii. Expert Litigation Testimony

Next, turning to the Challenged Members' previous work as paid expert witnesses in litigation against tobacco manufacturers, the FDA again concluded that such activity did not constitute a financial conflict of interest. Despite plaintiffs' protests, the FDA concluded that Drs. Benowitz's and Samet's testimony did not pose a conflict regarding the TPSAC's work on DTPs, AR 6446, 4291, 4293; Defs.' Mem. at 30, and that Dr. Henningfield's testimony did not pose a conflict regarding menthol, AR 6427. In reaching these conclusions, the FDA analyzed the issue by posing the following test for a financial conflict: "where there is an expert witness relationship [the test for a financial conflict] is whether the particular matter discussed at the [TPSAC] meeting will have a direct and predictable effect on that expert witness contract—specifically on the individual's ability to continue earning fees as an expert witness or consultant *in a given case*." AR 4287 (FDA Memorandum) (emphasis added); *see also* AR 6446. By confining the focus to the context of a given case, however, the FDA disregarded both common sense and the factual information they had about these voting members.

As outlined in the Factual Background above, the Challenged Members not only testified in the past, but at the time of their appointment were slated to testify in pending

cases. In particular, Drs. Benowitz and Henningfield and were designated to testify in *hundreds* of pending tobacco cases and had testified about menthol in the past. *See supra* 15-16. Those two Challenged Members thus had *ongoing* relationships with lawyers or firms extending into the future, regarding multiple cases in which they could be expected to give the same or similar testimony, which related to menthol. *See* Pls.' Mem. & Opp'n at 48-49. Accordingly, Drs. Benowitz and Henningfield had a conflict because they had a financial incentive to ensure that the Menthol Report did not include recommendations or statements that would undermine that future testimony. *See* Pls.' Mem. & Opp'n at 50.

Of course, the ethics laws cannot be applied so broadly as to disqualify from membership in an advisory committee every scientist who has *ever* testified as an expert witness. But where, as here, the two Challenged Members repeatedly testified against tobacco manufacturers, to similar opinions (which concerned menthol), and were committed to do so in the future, there is a conflict of interest because they have a financial incentive in protecting their opinions. The TPSAC's conclusions about menthol would undoubtedly have a "direct and predictable effect" on their ability to continue earning fees as expert witnesses. Pls.' Mem. & Opp'n at 50. Accordingly, I find that the FDA acted arbitrarily and capriciously in concluding that the Drs. Benowitz's and Henningfield's commitments to testify in the future did not constitute financial conflicts of interest.

b. Appearance Conflicts of Interest

For similar reasons, I also conclude that all three Challenged Members' consulting

and expert testimony activities created appearance conflicts of interest. Unlike the financial conflicts plaintiffs raised to the FDA, the agency failed to even address these appearance conflicts and respond to plaintiffs' objection letters, *see* Pls.' Mem. & Opp'n at 20 n.30, and therefore acted arbitrarily and capriciously by "entirely fail[ing] to consider an important aspect of the problem." *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43.

An appearance conflict exists "[w]here an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household . . . and where the employee determines that the circumstances would cause a *reasonable person* with knowledge of the relevant facts to *question his impartiality in the matter* . . ." 5 C.F.R. 2635.502(a) (emphasis added).[23] Plaintiffs contend that the Challenged Members had "staked out [their] opinions," "already made up [their] mind[s]," and "had a firm position" regarding menthol and DTPs, which, in addition to their financial conflicts of interests, created appearance conflicts of interest. *See* Pls.' Mem. & Opp'n at 21-22; Pls.' Reply at 19. But I need not delve into whether the Challenged Members' litigation testimony (or consulting work) evinced firm opinions or a "closed mind" on the subjects of menthol and DTPs, because I find that their financial conflicts resulting from the combination of their expert testimony and consulting sufficed, in themselves, to create appearance conflicts. Indeed, the very fact that these apparent financial conflicts of interest led numerous observers and media

[23] As discussed above, notwithstanding the language of § 2653.502(a), a financial conflict is not necessary for an appearance conflict to exist, and agencies are obligated to address such conflicts even absent initiation by an employee. *See supra* note 11.

outlets to publicly question the impartiality of the TPSAC members is strong evidence that appearance conflicts existed. *See* Pls.' Mem. & Opp'n at 22, 22-23 n.32 (citing *Boston Globe* editoral, *Wall Street Journal* column, *Washington Examiner* column, objections raised by three organizations, and other commentators discussing the composition of the TPSAC and the financial ties of its members to drug companies).

Moreover, whereas the plain language of the general conflict of interest regulations precludes viewing past business relationships as technically "financial conflicts," *see supra* 29-30, past relationships can nevertheless constitute appearance conflicts because they bear directly on a member's impartiality. Indeed, it is telling that the specific tobacco conflicts provision contained in the TCA has a retrospective focus, expressly disqualifying members who received "any salary, grants, or other payment or support" from any tobacco company in the 18-month period *prior to serving* on the TPSAC. 21 U.S.C. § 387q(b)(1)(C). If Congress deemed that past remuneration from tobacco companies constituted a conflict of interest, it stands to reason that past remuneration from direct *competitors* of those companies, such as manufacturers of smoking-cessation drugs, would also constitute a conflict of interest.

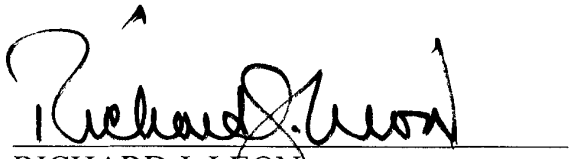
III. Remedy

In picking the TPSAC, Congress specifically recognized that in order for the Committee's work product to be credible and reliable, it had to be perceived by both the public and the interested industries as being free of bias—in either direction. In short, conflicts of interest—whether actual or perceived—undermine the public's confidence in the agency's decision-making process and render its final product suspect, at best. Here,

the presence of conflicted members on the Committee irrevocably tainted its very composition and its work product. In turn, the Committee's findings and recommendations, including reports such as the Menthol Report, are, at a minimum, suspect, and, at worst, untrustworthy.[24] 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.

CONCLUSION

Thus, for the foregoing reasons, the Court GRANTS, in part, plaintiffs' Motion for Summary Judgment [Dkt. # 67] and DENIES defendants' Motion for Summary Judgment [Dkt. # 65]. Accordingly, I will enter an order that (1) enjoins the FDA to reconstitute TPSAC's membership so that it complies with the applicable ethics laws, and (2) bars defendants from using the Menthol Report.



RICHARD J. LEON
United States District Judge

[24] I am mindful that our Circuit Court—in the context of a FACA violation—has cautioned that a use injunction on an advisory committee's report "should be awarded only rarely," in part due to concerns about the waste of resources expended in preparing that report. *See NRDC v. Pena*, 147 F.3d 1012, 1025-27 (D.C. Cir. 1998). But where, as here, a report such as the Menthol Report is prepared by an advisory committee that has multiple members with clear conflicts of interest, giving reason to question the impartiality of its conclusions and recommendations, it is not a "waste" to reject it.