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.	)	

MEMORANDUM ORDER
(July 31, 2012) [Dkt. ##18, 37]

Plaintiffs Lorillard, Inc., Lorillard Tobacco Company, and R.J. Reynolds Tobacco Company (collectively, "plaintiffs") filed their second amended complaint against the United States Food and Drug Administration ("FDA"); the United States Department of Health and Human Services ("DHHS"); Kathleen Sebelius, the Secretary of DHHS; Margaret Hamburg, the Commissioner of Food and Drugs; and Lawrence Deyton, the Director of the Center for Tobacco Products (collectively, "defendants") on July 5, 2011, seeking declaratory and injunctive relief.[1] Second Amended Complaint ("2d Am. Compl.") [Dkt. #33] ¶¶ 1, 4, 7. Plaintiffs assert five causes of action, challenging the composition of the Tobacco Products Scientific Advisory Committee ("TPSAC" or the

[1] Plaintiffs filed their original complaint on February 25, 2011 [Dkt. #1] and filed their first amended complaint on March 21, 2011 [Dkt. #12].

"committee")[2] and the committee's alleged lack of compliance with the Federal Advisory Committee Act ("FACA").[3] 2d Am. Compl. ¶¶ 129-84. Plaintiffs allege that: (1) defendants' appointment of three voting committee members and two nonvoting Constituent Subcommittee members (together, the "conflicted members") with 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, was "arbitrary, capricious, an abuse of discretion, and otherwise not in compliance with law" under the Administration Procedure Act ("APA"), 5 U.S.C. § 706(2)(A), 2d Am. Compl. ¶¶ 129-40 (Counts I & II); (2) defendants' appointment of 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), was "arbitrary, capricious, an abuse of discretion, and otherwise not in compliance with law" under the APA, 2d Am. Compl. ¶¶ 141-49 (Count III); (3) members of the committee held a private meeting on March 17, 2011, violating FACA because the meeting was not open to the public and timely notice of the meeting was not previously published, 2d Am. Compl. ¶¶ 150-57 (Count IV); and (4) defendants, in violation of FACA, failed to disclose various

[2] Of the nine voting committee members, seven must be "scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty"; one must be "an officer or employee of" a local, state, or the federal government; and one must be "a representative of the general public." 21 U.S.C. § 387q(b)(1)(A)(i)-(iii). The three nonvoting committee members, who serve as "consultants" to the voting members, *id.* § 387q(b)(1)(B), must represent "the interests of the tobacco manufacturing industry[,] . . . the small business tobacco manufacturing industry, . . . [and] the tobacco growers," *id.* § 387q(b)(1)(A)(iv)-(vi).

[3] Section 14 of FACA, 5 U.S.C. app. 2 § 14, which addresses the termination and renewal of advisory committees, does not apply to the TPSAC. 21 U.S.C. § 387q(d)(3).

documents that were created by TPSAC and its subcommittee and related to the Menthol Report, the committee's report on the use of menthol in cigarettes, 2d Am. Compl. ¶¶ 158-84 (Count V).

Defendants filed a Motion to Dismiss counts I through IV on April 29, 2011 [Dkt. #18], and a Motion to Dismiss Plaintiffs' Fifth Cause of Action on September 8, 2011 [Dkt. #37]. Defendants move to dismiss Counts I, II, and III pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction, and to dismiss Counts IV and V for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Specifically, as to Counts I through III, defendants argue that: (1) plaintiffs lack standing to challenge the conflict of interest rules and FACA's fair balance standard because plaintiffs' "alleged injuries are entirely speculative," not "fairly traceable," and "unlikely to be redressed by the relief they seek," Am. Mem. in Supp. of Defs.' Mot. to Dismiss ("Mot. to Dismiss") [Dkt. #22] at 20-29; (2) plaintiffs challenge defendants' enforcement of the conflicts of interest rules and, because enforcement is within the FDA's discretion, it is not subject to judicial review, *id.* at 3, 29-33 (citing 5 U.S.C. § 701(a)(2)); and (3) TPSAC complies with FACA's fair balance standard because the committee meets the Tobacco Control Act's composition requirements and any review of the viewpoint-based objections is non-justiciable, *id.* at 4, 33-38. Defendants maintain that the March 17, 2011 meeting was not subject to FACA's public meeting requirement and, in any event, plaintiffs failed to exhaust their administrative remedies; thus, Count IV should be dismissed. *Id.* at 4, 38-42. Finally, defendants argue that Count V should be dismissed for failure to state a claim because FACA's disclosure requirements do not apply to the

subcommittees that drafted the requested documents. Defs.' Mem. in Supp. of Defs.' Mot. to Dismiss Pls.' Fifth Cause of Action ("Mot. to Dismiss 5th COA") [Dkt. #37] at 11-21. Upon consideration of the pleadings, the parties' oral arguments, relevant law, and the entire record herein, the defendants' motions are DENIED.

First, drawing all inferences at the pleading stage in favor of plaintiffs, I find that plaintiffs have satisfied the standing requirements.[4] Plaintiffs allege that they have been injured by the disclosure of confidential information to the conflicted members, who can, and have, used the information to "consult and testify for parties adverse to Plaintiffs," Pls.' Opp'n to Defs.' Mot. to Dismiss ("Pls.' Opp'n") [Dkt. #27] at 6; 2d Am. Compl. ¶¶ 119-20; by the conflicted members' ability to shape TPSAC reports to support their work as expert witnesses, Pls.' Opp'n at 6; 2d Am. Compl. ¶¶ 85, 90, 121-23; and by

[4] To survive a motion to dismiss, a complaint must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). However, the complaint is construed liberally in plaintiff's favor, and the court must grant plaintiff the benefit of all reasonable inferences that can be derived from the facts alleged. *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994). But, "the court need not accept inferences drawn by plaintiff[] if such inferences are unsupported by the facts set out in the complaint." *Id.* When facing a Rule 12(b)(1) motion to dismiss, plaintiff bears the burden of demonstrating that jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008). A "defect of standing is a defect in subject matter jurisdiction." *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). The constitutional standing requirement, derived from Article III's case or controversy limitation, *Allen v. Wright*, 468 U.S. 737, 750 (1984), requires a plaintiff to demonstrate that (1) it has "suffered an injury in fact" that is "concrete and particularized and [] actual or imminent"; (2) the injury is fairly traceable to the defendant's conduct; and (3) "the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (citations and internal quotation marks omitted). For standing purposes, an increased risk of injury constitutes an injury-in-fact where there is a substantially increased risk of harm and a substantial probability of sustaining the threatened injury. *Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1295 (D.C. Cir. 2007).

Lorillard's "loss of $2 billion in shareholder value," Pls.' Opp'n at 15. Plaintiffs additionally allege that their procedural right to "fair decisionmaking," Pls.' Opp'n at 10 n.8, was violated when the FDA was advised by a committee "tainted by conflicts of interest," *id.* at 9-10; and that this violation caused the "distinct risk" of economic loss, Pls.' Opp'n at 8, 10-17 (quoting *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996) (en banc)); *see, e.g.*, 2d Am. Compl. ¶¶ 9-12, 26-27, 117-18. Plaintiffs have sufficiently pled injury in fact. Furthermore, the facts alleged sufficiently establish that the alleged injuries are fairly traceable to the defendants' conduct and can be redressed by the requested relief. *See* Pls.' Opp'n at 18-20, 23-25.

Next, plaintiffs' conflicts of interest challenges are, indeed, subject to judicial review under the APA. *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 792 (D.C. Cir. 2004) (noting the "strong presumption" in favor of judicial review where a plaintiff was injured by agency action). Plaintiffs are not requesting this Court to direct the FDA "to take penal or remedial action against" the conflicted members for their alleged conflicts of interest. Pls.' Opp'n at 26, 28; 5 C.F.R. § 2635.106(c) (providing for agency remedies against an individual who violates the ethics rules). Rather, 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 at 26. Any review of these actions by the Court would, of course, be highly deferential. *AT&T Corp. v. FCC*, 86 F.3d 242, 247 (D.C. Cir. 1996).

Similarly, I find plaintiffs' fair balance and special interest challenges to be justiciable. Our Circuit Court has addressed the merits of such challenges under FACA

on two different occasions. *See Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419 (D.C. Cir. 1989) (per curiam) (Friedman, J., concurring in judgment) (Edwards, J., concurring in part and dissenting in part); *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Private Sector Survey on Cost Control*, 711 F.2d 1071 (D.C. Cir. 1983). Although some of my colleagues have since found similar challenges to be non-justiciable under *Heckler v. Chaney*, 470 U.S. 821 (1985), *see, e.g.*, *Fertilizer Inst. v. EPA*, 938 F. Supp. 52 (D.D.C. 1996); *Pub. Citizen v. Dep't of Health & Human Servs.*, 795 F. Supp. 1212 (D.D.C. 1992), I find that, in these circumstances, judicial review is available. When evaluating the fairly balanced standard, a court must determine whether the committee's members "represent a fair balance of viewpoints given the functions to be performed." *Microbiological*, 886 F.2d at 423; 5 U.S.C. app. 2 § 5(b)(2). Although the TPSAC was created to provide advice and recommendations related to the regulation of tobacco products, 21 U.S.C. § 387q, the Tobacco Control Act specifically mandated the committee to address the use of menthol and impact of dissolvable tobacco products on public health, 21 U.S.C. §§ 387g(e)(1), 387g(f)(1). Because of the limited number of viewpoints on these issues, the scientific—as opposed to political—nature of those viewpoints, and the distinct responsibilities of the committee, I believe I have sufficient standards against which I can evaluate the agency's discretion. *Heckler*, 470 U.S. at 830.

Finally, based on the facts currently in the record, I find that the Menthol Report Subcommittee and its writing groups[5] are advisory committees under FACA because they "were organized, managed, and funded by FDA, consisted only of TPSAC members, and performed" a major task of the committee: drafting the Menthol Report. Pls.' Supplemental Mem. in Opp'n to Defs.' Mots. to Dismiss [Dkt. #42] at 3; 2d Am. Compl. ¶¶ 151-56; *see* Pls.' Opp'n to Defs.' Mot. to Dismiss 5th COA [Dkt. #38] at 4-30. Thus, because the subcommittee and its writing groups were "established or utilized" by the FDA "in the interest of obtaining advice or recommendations," 5 U.S.C. app. 2 § 3(2) ("The term 'advisory committee' means any committee . . . or any subcommittee or other subgroup thereof . . . established by statute or . . . established or utilized by one or more agencies, in the interest of obtaining advice or recommendations . . . ."), Counts IV[6] and V survive defendants' motions to dismiss. Additionally, at this stage of the proceeding, I find that plaintiffs have sufficiently demonstrated that exhaustion of their administrative remedies as to Count IV would have been futile and should be excused. Pls.' Opp'n at 41-45.

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[5] The nonvoting committee members did not participate in the writing groups because the groups reviewed confidential information that the nonvoting members were not authorized to review. Mot. to Dismiss 5th COA at 6. The nonvoting committee members, "however, did participate in all full Subcommittee and full TPSAC discussions of the Menthol Report." *Id.*

[6] The March 17, 2011 meeting was attended by several voting TPSAC members and the Designated Federal Officer, who discussed the Menthol Report. 2d Am. Compl. ¶¶ 151-56. Accepting these allegations as true, the meeting should have complied with FACA's *open meeting requirements*, 5 U.S.C. app. 2 § 10(a)(1).

Accordingly, for the reasons set forth above, it is hereby

ORDERED that defendants' Motion to Dismiss [Dkt. #18] is **DENIED**; and it is further

ORDERED that defendants' Motion to Dismiss Plaintiffs' Fifth Cause of Action [Dkt. #37] is **DENIED**.

SO ORDERED.

RICHARD J. LEON
United States District Judge