MEMORANDUM

TO: TPSAC
FROM Center for Regulatory Effectiveness
SUBJECT: Tobacco Product Constituents Subcommittee's Compliance with FACA
DATE: August 29, 2010

I. Introduction

The purpose of the memorandum is to determine whether the subcommittee of the Tobacco Products Scientific Advisory Committee (TPSAC), the Tobacco Product Constituents Subcommittee (Subcommittee), is compliant with the Federal Advisory Committee Act (FACA). The threshold issue is whether the Subcommittee is an "advisory committee" and thus governed by FACA. Accordingly, Section II below discusses whether FACA applies to the Subcommittee and whether it was properly established. Section III finds that even if the Subcommittee has been properly established under FACA, it is not operating in compliance of FACA.

II. The Subcommittee has not been properly established pursuant to FACA and FDA regulations

A. The Subcommittee is an Advisory Committee as Defined by FACA

FACA defines "advisory committee" to include "any subcommittee or other subgroup."[1] Thus, as a subcommittee, the FDA's Tobacco Product Constituents Subcommittee is governed by FACA provisions setting forth the establishment and use of advisory committees.

Importantly, the FDA's advisory committee regulations excludes "sub-groups" of advisory committees from FACA's jurisdiction on the basis that it is not a distinct advisory

[1] 5 U.S.C. Appendix § 3

committee.[2] It is very likely that the FDA has established the Subcommittee as a "sub-group" of TPSAC and thus has not established the Subcommittee pursuant to FACA.[3] However, this regulation directly contradicts the plain meaning of "advisory committee" as defined by FACA which includes "subcommittees" and "sub-groups" as distinct advisory committees.

Accordingly, although it is a subcommittee of TPSAC, the Subcommittee is an advisory committee and is thus governed by FACA.

B. The Subcommittee is not Formally Established Under FACA[4]

FACA states, "No advisory committee shall be established unless such establishment is… determined as a matter of formal record, by the head of the agency involved after consultation with the Administrator, with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law."[5]

In the present case, the Subcommittee has neither been established as a matter of formal record by the Commissioner of the FDA nor has timely notice been published in the Federal Register. Thus, the Subcommittee has not been properly established as an advisory committee as required by FACA.

Furthermore, FDA regulations require that to create an advisory committee, it must be approved by the Department and by the General Services Administration.[6] In addition, the FDA also requires, "When an advisory committee is established or renewed, the Commissioner will

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[2] 21 CFR Part 14.40(d) available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=11e8d4afbeabcb1e5ef75ba72c69179a&rgn=div6&view=text&node=21:1.0.1.1.10.3&idno=21.

[3] Notably, of the 14 members of the Subcommittee, only 1 member is a voting member of TPSAC. Thus, even a finding a finding of the Subcommittee as a "sub-group" of TPSAC would be quite tenuous. *Tobacco Product Constituents Subcommittee Roster* , available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM217973.pdf.

[4] Importantly, the Family Smoking Prevention and Tobacco Control Act has provided for the creation of the TPSAC, but has not authorized the creation of the Subcommittee or any Subcommittees. Family Smoking Prevention and Tobacco Control Act, H.R. 1256, Sec 917, 111th Cong. (2009).

[5] 5 U.S.C. Appendix § 9 (a).

[6] 21 CFR Part 14.40

issue a Federal Register notice certifying that the establishment or renewal is in the public interest and stating the structure, function, and purposes of the committee.[7] Finally, FDA regulations mandate, "A notice of establishment will be published at least 15 days before the filing of the advisory committee charter."[8]

Here, there is no public information regarding whether the Subcommittee was approved by the Department and the General Services Administration. Furthermore, the Commissioner has not issued a Federal Register notice certifying the establishment of the Subcommittee as an advisory committee.[9] The only notice in the Federal Register pertains to meeting times for the Subcommittee.[10] Thus, without proper approval by the Department and notice in the Federal Register, the Subcommittee has also not been established properly pursuant to FDA regulations.

C. The Subcommittee is meeting in violation of FACA

FACA states, "No advisory committee shall meet or take any action until an advisory committee charter has been filed" with the Administrator or the head agency to whom the committee reports.[11] In addition, FDA regulations state no advisory "committee may meet or take action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act.[12]

Here, a charter has not been prepared and filed for the Subcommittee. The charter for TPSAC is posted on the FDA TPSAC's website.[13] However, the FDA website does not provide the charter for the Subcommittee. Despite not having a charter, the Subcommittee has held meetings on June 8-9 and July 7-8, and has a meeting schedule for August 30. Therefore, meetings are being held in violation of the FDA's regulations and FACA.

III. The operation of the Subcommittee is in violation of FACA

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[7] 21 CFR Part 14.40(b).
[8] 21 CFR Part 14.40(b).
[9] Search conducted for the terms "Tobacco Product Constituents Subcommittee" on August 24, 2010 on the Federal Register website http://www.gpoaccess.gov/fr/
[10] *Id.*
[11] 5 U.S.C. Appendix § 9 (c).
[12] 21 CFR Part 14.40
[13] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/default.htm

As discussed above, the Subcommittee falls under FACA jurisdiction. Even if the Subcommittee were properly established, it is operating in violation of FACA in two regards: 1- the Subcommittee is improperly influenced by its appointing authority and 2-the Subcommittee is not fairly.

D. The Subcommittee is Inappropriately Influenced by the FDA

FACA requires that the appointing authority, the FDA in this case, establish guidelines "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."[14]

Here, the FDA has not established any guidelines to assure that the recommendations of the Subcommittee will not be inappropriately influenced by the FDA. In contrast, it seems the Subcommittee was established to achieve this very result—to be unduly influence by the FDA. The Subcommittee consists of fourteen members.[15] Three of the members of the Subcommittee are currently employed by the FDA and six members are employees of the Federal Government. Furthermore, of the fourteen members of the Subcommittee, only one member is a voting member of the parent committee, TPSAC.

Given the composition of the Subcommittee, it is quite difficult to find how any report or recommendation of the Subcommittee would not be inappropriately influenced by the FDA. The operation of the Subcommittee undermines the very independent judgment and expertise that Congress intended advisory committees to provide to executive agencies when it passed FACA.

E. The Overrepresentation of the FDA and the Federal Government Violates FACA's "Fairly Balanced" Requirement

FACA also requires, "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."[16] FDA regulations echo FACA by providing, "[committee] membership is

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[14] 5 U.S.C. Appendix § 5 (b).
[15] *Tobacco Product Constituents Subcommittee Roster* , available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM217973.pdf.
[16] 5 U.S.C. Appendix § 5 (b).

balanced fairly in terms of the points of view represented in light of the functions to be performed." Congress has not defined "fairly balanced" and the courts have been reluctant to do so as well.

Importantly, the 9th Circuit refused the opportunity to review whether the Industry Trade Advisory Committees (ITACs), established under the Trade Act, were fairly balanced.[17] The 9th Circuit held that Congress had not provided any meaningful standards for judicial review in the particular case. However, the 9th Circuit held, "we do not suggest that FACA's "fairly balanced" requirement is non-reviewable in every circumstance. It remains an open question in this circuit whether FACA's "fairly balanced" requirement presents a reviewable controversy in other circumstances." Thus, whether an advisory committee is fairly balanced may still be challenged through the courts, though the likelihood of success is uncertain.

Moreover, in the 9th Circuit case, ITACS were challenged as not being "fairly balanced" because it did not include a particular constituent, which the plaintiff argued was necessary for balanced membership. In contrast, in the present case, the Subcommittee is not "fairly balanced" because it is overrepresented by the FDA and the federal government. The overrepresentation by the FDA and the Federal government undermines the very spirit of FACA that Congress intended. By passing FACA, Congress intended to provide for advisory committee that were transparent, independent, and balanced that could provide agencies with technical expertise. FACA did not envision advisory committees that would rubberstamp agency policies, which is the very danger posed by the overrepresentation of the FDA on the Subcommittee. While Congress has provided little guidance on the metric of what constitutes fairly balanced, it is clear that the composition of the Subcommittee does not meet the fairly balanced requirement.

IV. Conclusion

In sum, as a subcommittee, the Tobacco Product Constituents Subcommittee clearly falls under the definition of an "advisory committee" governed by FACA. As an advisory committee governed by FACA, the Subcommittee has been improperly established and has been operating in violation of FACA. Your response is requested not later than October 15, 2011

[17] *Ctr. for Pub. Analysis on Trade v. Office of the United States Trade Representative*, 540 F.3d 940 (9th Cir. 2008).