

TPSAC News

Tobacco Products Scientific Advisory Committee (TPSAC) News

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Group Contends FDA Tobacco Subcommittee Violates Advisory Panel Law

Days before an FDA advisory panel on tobacco meets, a government watchdog is targeting a sub-group of the board, saying it has not been improperly established and is inherently substantially influenced by FDA, with a source close to the issue encouraging FDA and the White House's Office of Management and Budget to act or the agency could face litigation. Next week, FDA will hold a hearing of the Tobacco Products Scientific Advisory Committee (TPSAC) to assess different constituents, or many of the elements in cigarettes and smoke. The panel is set to hear from the Tobacco Product Constituents Subcommittee, a group which the Center for Regulatory Effectiveness says has been inappropriately established and violates the Federal Advisory Committee Act (FACA), according to a letter sent to FDA Thursday (Aug. 26).

The organization is calling on FDA to remedy the violations. "Hopefully, FDA will address these issues administratively so as not to necessitate other corrective actions," the group wrote to FDA in an email accompanying the letter.

But a source close to the group said OMB has the statutory authority to determine and require compliance with FACA and that eventual litigation is a possibility if FDA or the government does not act.

"Litigation is most certainly one such corrective action, but OMB has the statutory authority to get involved," the source said.

The group says FDA has not officially released a notice to establish that subcommittee, which has also not received approval from the General Services Administration. Even organizations that are considered "sub-groups" of a larger advisory committee still require adequate notification and approval, a CRE source says.

"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," the letter obtained by *FDA Week* states.

The group also contends that the subcommittee is unduly influenced by FDA. The subcommittee has only one member that is also on the larger TPSAC, with some of the committee members employed by FDA or other agencies. This high level of government representation hampers the panel's independence and legitimacy, the CRE contends.

"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 letter states. "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."

FDA received jurisdiction over tobacco products last year, when President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act.

FDA did not respond to a request for comment as of press time. — *Ben Moscovitch*

FDA Week

Inside Washington Publishers

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