



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

March 25, 2010

Denise Keane
Executive Vice President
and General Counsel
Altria Group, Inc.
6601 W. Broad Street
Richmond, VA 23230

Dear Ms. Keane:

The Food and Drug Administration has received your letter dated March 22, 2010, enumerating your concerns and objections to four members appointed to the Tobacco Products Scientific Advisory Committee (TPSAC). You requested, among other things, that FDA retract certain appointments. Your request is denied.

The agency conducted a careful process selecting the members of the Committee. This process led to the selection of superbly qualified members who are highly respected leaders in their respective disciplines. For reference, the list of the committee members, identifying their respective qualifications and resumes can be found at FDA Center for Tobacco Products webpage (under the link to Roster of the Tobacco Products Scientific Advisory Committee).

Detailed financial information from all potential advisory committee appointees was reviewed with care to identify conflicts of interest. Each member was found to satisfy the conflict of interest provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). In accordance with federal statutes, regulations, and FDA procedures, FDA has further screened, and will continue to screen, committee members for potential conflicts of interest arising from particular matters to be considered by the TPSAC.

Following the approval of the charter of TPSAC in August 2009, FDA published a request for nominations for TPSAC membership in the *Federal Register* on August 26, 2009. The request remained open until October 13, 2009, and the agency received more than 100 nominations. The selection review committee was chaired by the Assistant Secretary for Health of the Department of Health and Human Services.

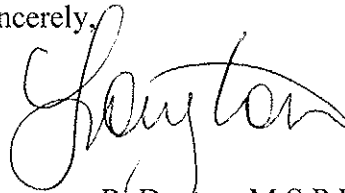
All prospective voting members were required to assure the agency that they had not received any salary, grants, payment or support from the tobacco industry in the preceding 18 months. Prospective members also submitted confidential financial disclosure reports. FDA reviewed each member's expertise and financial interests to reduce the likelihood that conflicts of interest would arise from participating in particular committee meetings.

Before each committee meeting, participants are required to submit additional confidential financial information addressing, to the best of their knowledge, any potential conflicts of interest in relation to that meeting. In accordance with relevant statutory and regulatory provisions and agency guidance, committee members are rigorously screened for conflicts of interest based upon the financial information provided, including non-tobacco-product interests that might be affected by the committee's work. Members are recused where appropriate from committee deliberations that could affect such interests.

FDA advisory committee regulations, 21 *Code of Federal Regulations* (CFR) 14.80(f), permit the agency to remove a committee member from membership if he or she demonstrates bias that interferes with the ability to render objective advice. A stated opinion on a scientific matter does not necessarily mean that a member would have a closed mind on a particular issue, and, by definition, experts have views on their particular areas of expertise.

FDA has followed existing law and procedure 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. The mere fact of having testified about tobacco-related topics, the tobacco industry or having commented on the practices of the tobacco industry is not, as a matter of law or policy, a sufficient basis for deciding that a member of the committee is disqualified. For all the reasons stated, your request to replace certain members of the advisory committee is denied.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence R. Deyton". The signature is fluid and cursive, with a large initial "L" and "D".

Lawrence R. Deyton, M.S.P.H., M.D.
Center for Tobacco Products