Center for Regulatory Effectiveness

Ms Cristi L. Stark, M.S.
Center for Tobacco Products
9200 Corporate Blvd, Rm 110H
Rockville, Maryland 20850

Dear Ms. Cristi:

I am writing with respect to the rules of governance concerning the Tobacco Products Scientific Advisory Committee (TPSAC). My observations are based upon years of participating as a member of the federal advisory process and as my former position as the Assistant Director of the White House Office of Management and Budget where I had to approve the establishment of advisory Committees.

The views expressed herein are based upon my observations of the meeting of the advisory committee held in Washington. DC in March 30, 2010.

l. TPSAC An Operating Arm of the FDA

TPSAC is hardly an advisory committee in the traditional sense of an advisory committee. Instead of opining on ad hoc issues of interest to the FDA, the TPSAC is going to "review every application regarding a claim of reduced harm". For this reason, TPSAC is an operating arm of the FDA.

2. FDA Has Prohibited any Meaningful Public Participation with TPSAC

The FDA has prohibited any meaningful public participation with TPSAC in that it restricts public input to the TPSAC to public meetings of the committee which are very infrequent. In addition, the public can testify to the TPSAC only in those instances where the public reads the Federal Register each and every day and so notifies the FDA of its intent to testify when a notice appears in the Federal Register announcing a very restrictive window when members of the public must register to make a public comment at a forthcoming TIPSAC meeting.

3. TPSAC is Dominated by the FDA.

The TPSAC is dominated by the FDA, a conclusion reached by the following actions of the FDA:

(a) The FDA announced at the aforementioned meeting that TPSAC members were forbidden to discuss issues with fellow committee members during breaks in the TPSAC meeting.

(b) The FDA prohibited any public contact with committee members.

(c) In that TPSAC members are prohibited from one-on-one discussions with fellow members, the FDA will prepare the initial draft of the committee reports in the absence of a draft prepared by members of TPSAC

4. Violation of the Obama Adminsitration Open Government Initiative

The Obama Administration has emphasized its commitment to "Open Government", Comments (2) and (3) above are completely counter to the principles of "open government". It will be difficult for the FDA to receive public support for its actions on tobacco if the public has been prohibited from participating in the decision process.

5. FDA Issuance of TPSAC Governance Rules

What is needed is for the FDA to develop rules of governance for TPSAC and release them for public comment. The governance rules should include:

(a) A well defined process which allows for public participation.

(b) Advising committee members that the work products of TPSAC can not be adopted by the FDA until which time the FDA determines that the said work product meets the requirements of the Data (Information) Quality Act.

(c) Encouraging the public to develop innovative ways to communicate with TPSAC through the use of Interactive Public Dockets, see the description at http://en.wikipedia.org/wiki/Interactive_Public_Docket

CRE is a regulatory watchdog which recently wrote an article on TPSAC and menthol, see http://www.thecre.com/wdw/2010/20100329.html

Respectfully,

Jim Tozzi
Member, Board of Advisors

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