

## Center for Regulatory Effectiveness

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July 13, 2010

The Honorable Margaret Ann Hamburg, M.D.  
Commissioner  
US Food and Drug Administration  
Room 2217  
White Oak Building 1  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

### **RE: Transparency and Integrity of the TPSAC**

Dear Dr. Hamburg:

I am writing with respect to your duty, as Commissioner of the Food and Drug Administration (“FDA”), to ensure that the advice provided to the agency by advisory committees is independent and not influenced by agency staff.

On this point I note that one of the duties of agency chiefs under the General Services Administration’s rule implementing the Federal Advisory Committee Act (“FACA”) is to ensure that committee recommendations are not unduly influenced by the agency. Specifically, 41 CFR 102-3.105 states,

*The head of each agency that establishes or utilizes one or more advisory committees must: ...*

*(g) Develop procedures to assure that the advice or recommendations of advisory committees **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**; [Emphasis added]*

As a former member of a federal advisory committee, I recognize that a committee’s advice must independent of agency views if is to have value.

With respect to the Tobacco Products Scientific Advisory Committee (“TPSAC”), the concern is that FDA staff will develop a draft report for the committee. Even though the TPSAC would have the ability to edit and change the draft, FDA providing the committee with a draft report would unquestionably: 1) bias the committee’s advice; 2) undermine public confidence in the integrity of the final document; and 3) violate FACA regulations and the FDA’s commitment to transparency.

The concern that FDA will be preparing a draft report for the committee is heightened by the *de facto* ex parte rules imposed on the committee which instruct them not to discuss meeting topics with each other or anyone else during breaks. Unless the committee members are able to communicate with each other on substantive matters while out of formal session, it will be impossible for them to prepare a report.

**Requested Action to Preserve TPSAC Independence**

The FDA should publicly announce that they will not develop or provide to the TPSAC any draft reports or other documents other than publicly disclosed reference materials.

I reiterate that the above action is essential if the TPSAC is to fulfil congressional intent and if FDA is to adhere to its own standards and the law.

Sincerely,

/s/

Jim Tozzi  
Member, Board of Advisors