

Center for Regulatory Effectiveness

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November 7, 2011

via fax, e-mail, and first class mail

Hon. Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
Eisenhower Executive Office Bldg., Rm. 262
1650 Pennsylvania Ave., NW
Washington, DC 20502

Dear Administrator Sunstein,

On August 8, 2011, I sent a letter to both Lawrence R. Deyton, Director of FDA's Center for Tobacco Products, and to you (via cc), explaining how FDA's Information Quality Act (IQA) peer review plan for mentholated cigarettes did not comply with the peer review rules issued pursuant to OMB's IQA regulatory authority, and requesting that FDA/CTP take specific steps to come into compliance with the rules. A copy of that August 8, 2011 letter is attached.

The August 8 letter emphasized particularly the need for compliance with the transparency and public participation requirements of the peer review rules.

To date, I have not received any response from FDA or OIRA, and FDA has not taken any action to come into compliance with the IQA peer review rules.

The peer review rules state that OIRA, in consultation with OSTP, "shall be responsible for overseeing implementation" of the rules by the agencies.

In addition, since the IQA peer review rules were issued by OIRA, this Administration has issued a number of other relevant directives on "Transparency and Open Government" and "Scientific Integrity" that are not being complied with regarding this matter:

- On January 21, 2009, President Obama issued to the Heads of Executive Departments and Agencies a Memorandum on "Transparency and Open Government." That Memorandum emphasized the Administration's commitment to transparency with regard to Government proceedings and to public participation in Government proceedings in order to provide the Government with the benefits of the public's collective expertise and information.

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- On December 8, 2009, the Director of OMB (then Peter R. Orszag), issued a Memorandum to the Heads of Executive Departments and Agencies, titled "Open Government Directive," in further implementation of the President's January 21, 2009 instructions. The Director's Memorandum emphasized again the "three principles of transparency, participation, and collaboration," and it contained a specific section to "Improve the Quality of Government Information," which stated that "senior leaders should make certain that the information [disseminated to the public] conforms to OMB guidance on information quality [footnote omitted] and that adequate systems and processes are in place within the agencies to promote such conformity." This statement, and a subsequent statement directing appointment of a senior agency official to ensure accountability, referenced (in footnotes 3 and 4) the IQA and its guidelines.
- On March 9, 2009, President Obama issued to the Heads of Executive Departments and Agencies a Memorandum on "Scientific Integrity." The Memorandum set out a number of principles of scientific integrity, which included the following: "(c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate" The President directed the head of OSTP, in consultation with the head of OMB and other Administration officials, to develop recommendations to "guarantee" scientific integrity throughout the Executive Branch based on the principles he had specified.
- On December 17, 2010, the head of OSTP, John P. Holdren, issued a Memorandum for the Heads of Executive Departments and Agencies, titled "Scientific Integrity," to implement the President's scientific integrity instructions and principles. The Memorandum stated that "Agencies should develop public communications policies that promote and maximize, to the extent practicable, openness and transparency with ... the American people [with regard to scientific and technological matters]."

We urge OIRA and OSTP to work with FDA to ensure compliance with the IQA peer review rules as applied to the FDA/CTP peer review proceedings on mentholated tobacco by taking the actions recommended in my August 8 letter, and consistent with the above policy directives issued by the President, OMB, and OSTP.

Tobacco is a legal product; it is entitled to the same safeguards accorded to other products. To this end it is imperative that you ensure that the FDA follows the public participation and transparency requirements established by law and that the Administration takes responsibility for enforcing those requirements, which the U.S. Court of Appeals for the D.C. Circuit has held to be legally binding.

Our most significant concern is that the peer review rules require FDA to allow the public to meet with the peer review panel and provide comments to them while they are conducting the peer review. No such opportunity has been given to stakeholders in this proceeding.

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Consequently pursuant to aforementioned regulations it is imperative that the peer reviewers not complete their report until they have received the required public input.

Respectfully,

A handwritten signature in black ink, appearing to read "Jim J. Tozzi". The signature is stylized with a large, sweeping initial "J" and a distinct "T" at the end.

Jim J. Tozzi
Member, CRE Board of Advisors

Attachment (Aug. 8, 2011, letter from Jim J. Tozzi of CRE to Lawrence R. Deyton of FDA, CTP, with a cc to the Administrator of OIRA)

cc's w. attachment:

Jacob J. Lew, Director, Office of Management and Budget
John P. Holdren, Asst. to the President for Science and Technology and Director, OSTP
Lawrence R. Deyton, Director, FDA Center for Tobacco Products
Jesse Goodman, M.D. MPH, FDA Chief Scientist
Luciana Borio, M.D., Acting Director, FDA Office of Scientific Integrity