Center for Regulatory Effectiveness

1601 Connecticut Ave, NW – Suite 500
Washington, DC 20009
Tel: (202) 265-2383 Fax: (202) 939-6969
www.TheCRE.com

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Sent via e-mail, fax (240-276-3904), and mail

Lawrence R. Deyton, MSPH, MD
Director, Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850
lawrence.deyton@fda.hhs.gov

Re: Non-Compliance of FDA's Peer Review Plan for Mentholated Cigarettes with the Requirements of OMB's DQA Peer Review Rules

Dear Dr. Deyton:

FDA and CTP have posted on the FDA peer review agenda a peer review Plan for a draft agency assessment of various stated aspects of potential public health impacts of mentholated cigarettes.[1] The peer review agenda and Plan are obviously posted so as to be in ostensible compliance with the OMB peer review rules.[2]

Legally Binding Character of the Peer Review Requirements

At the outset, we note that the degree of non-compliance discussed below suggests that the agency does not regard the OMB peer review rules to be legally binding. The rules are clearly legally binding, however. Although the rules are titled as a "Bulletin," the title given them by the agency does not have any legal effect. The criteria for determining whether rules are legally binding were spelled out long ago by the U.S. Supreme Court in *Chrysler v. Brown*, 441 U.S. 281, 316-17 (1979), and have been consistently followed by the Circuits since then. A rule is a legally binding "legislative" rule if it affects rights of outside parties, was promulgated through

[1] The peer review agenda is posted at http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm. The peer review Plan is at http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM254051.pdf.

[2] 70 Fed. Reg. 2664 (Jan. 14, 2005).

Federal Register notice-and-comment procedures, cites the legislative authority for their promulgation, and is written in mandatory language.[3]

The OMB peer review "Bulletin" meets all of those criteria. It affects the rights of outside parties in specifying requirements regarding public participation and in addressing a subject that is integral to agency rulemaking with the potential to affect other rights. It went through notice-and-comment procedures in the *Federal Register*. It specifically cites the legislative authority for its promulgation, which is the Information Quality Act ("IQA", also known as the Data Quality Act or "DQA"). At 2666. And the IQA does indeed contain such authority in 44 U.S.C. § 3516 (under the heading of "Rules and regulations"), and the Office of Law Revision Counsel placed the text of the IQA under § 3516. Last year, the U.S. Circuit Court for the District of Columbia held, in *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010), that another set of government-wide IQA "guidelines" promulgated by OMB under authority of the IQA were legally binding.[4] Lastly, the peer review rules are clearly written in mandatory language. Both the preamble and the substantive portion of the rules refer to the "requirements" of the Bulletin numerous times, specify actions that the agencies "shall" take, and make clear when the agency has complete discretion, limited discretion, or no discretion. In fact, the section of the *Federal Register* notice immediately following the section giving the IQA as the legal authority for promulgation is titled "The Requirements of This Bulletin." *Id.*

FDA apparently intends to consider using its peer-reviewed assessment as the basis for regulatory action. If it does, the "certification" requirement of the peer review rules will come into operation. The certification requirement states:

> *VII. Certification in the Administrative Record*
>
> If an agency relies on influential scientific information or a highly influential scientific assessment subject to this Bulletin to support a regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines. Relevant materials shall be placed in the administrative record.

At 2677 1st col.

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[3] Whether a rule is a legally binding legislative rule, and therefore subject to judicial review, is a matter for the courts to decide. The disclaimer of a right to judicial review at the end of the peer review Bulletin has no legal significance. An agency cannot exempt itself or other agencies from judicial review. Procedural requirements similar to those in the peer review rules are contained in the Federal Advisory Committee Act and its regulations, and the FACA requirements have always been found to be subject to judicial review.

[4] In holding that the OMB IQA guidelines were binding, the Circuit Court cited *United States v. Mead*, 533 U.S. 218, at 226-27. At those particular pages in *Mead*, the Supreme Court stated: "We hold that administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." (Emphasis added)

Agency Non-Compliance Indicated in its Published Peer Review Plan

The IQA peer review rules differentiate between "influential scientific information" and "highly influential scientific assessments," and agencies are required to indicate in each peer review plan which category the review is likely to apply. The FDA Plan for the peer review of its assessment of the impacts of mentholated cigarettes "tentatively" designates the review as a review of a "Highly Influential Scientific Assessment" (a "HISA"). Under the criteria in the peer review rules, it clearly must be considered a HISA. See p. 2675 3d col.

The requirements for HISAs are supplementary to those for influential scientific information, which have less rigorous requirements.

The planned peer review and the published Plan for mentholated cigarettes is non-compliant with the OMB rules in at least the following respects. Compliance with the first item below could disclose additional deficiencies.

1. Public Comments on Peer Review Plans. As part of their disclosure of peer review plans, agencies "shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans. Agencies shall consider public comments on peer review plans." We are not aware of any steps taken by the agency to inform the public of how it can comment on its peer review plan. At 2677 1st col.

2. Public Participation in HISA Peer Reviews. The current FDA peer review plan states that the only opportunity for public comment will be one for written comments during a 30-day period after the Final Peer Review Report is published in the *Federal Register*. This is contrary to the public participation requirements for HISAs. The OMB rules state: "Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public." At 2676 2d col. (emphasis added). In the absence of any explanation by the agency as to why such public participation is not "feasible and appropriate" (which it clearly seems to be) this requirement controls. Under established case law, a phrase such as "whenever feasible and appropriate" provides ample "law to apply" if a judicial review of the peer review process were to become necessary.

3. Presentation of Public Comments to Peer Reviewers: The agency peer review plan states that public comments will not be provided to the peer reviewers. This also is a violation of the OMB rules on public participation during HISAs, which state: "When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues." Again, the agency has not explained why this would not be "practical," and that phrase, coupled with the mandatory language "shall," would provide ample basis for judicial review.

4. Panel Review vs. Letter Review: The preamble to the peer review rules expresses a preference for panel reviews when the review involves more than one discipline, as this one does (at 2668 2d col.); nevertheless panel review is not specifically stated as an absolute requirement

as are some other facets of the process. However, the requirements for public participation clearly imply the necessity for panel review. A public meeting cannot be reconciled with letter reviews, and public presentations at such a meeting also cannot be reconciled. In order to fulfill the "whenever feasible" public participation requirements for peer review of a HISA, the review will necessarily have to be a panel review.

5. Identification of an Outside Organization to Select Reviewers: The mentholated cigarettes peer review plan states that the reviewers will be selected by a "Designated Outside Organization," but the organization is not identified. The OMB peer review rules require that the peer review plan state whether the peer reviewers are going to be selected by the agency or "by a designated outside organization." At 2676-77. This is arguably ambiguous with regard to whether the organization must be identified. However, the immediately subsequent requirement that the agency establish a mechanism for allowing the public to comment on the adequacy of the plan implies a high degree of transparency with regard to the specifics of the plan. The public cannot comment on the "designated outside organization" if it does not know what organization it is. It could be a highly biased organization or it could be one viewed as eminent and unbiased.

6. Failure of the Plan to Include Review of FDA's Assessment of the Potential for Contraband: The Family Smoking Prevention and Tobacco Control Act required TPSAC to assess, and the Secretary to consider, "countervailing effects" of a tobacco product standard "such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand."[5] However, TPSAC did not meet this requirement, and instead stated in its final report only that the Secretary would have to consider the matter[6] and characterized industry analyses and assertions rather than conducting its own analysis. TPSAC stated that it did not have the necessary expertise to carry out the Congressional mandate and essentially punted the issue to FDA. The TPSAC final report stated in conclusion on this issue:

> TPSAC acknowledges that the potential for contraband menthol cigarettes exists, should FDA choose to implement a ban or take some other policy action that restricts availability of menthol cigarettes. Consistent with the requirements of the Act, TPSAC recommends that FDA consult with appropriate experts and carry out relevant analyses depending on the actions taken in response to this report from TPSAC. At present, TPSAC is not constituted to carry out such analyses, and lacking knowledge of FDA's intent on receipt of this report, it concluded that FDA would need to assess the potential for contraband menthol cigarettes as required by the Act.[7]

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[5] Sections 907(e)(1) and 907(b)(2). And see also slide no. 3 by Carolyn Husten of FDA presented at the March 30, 2010 TPSAC public meeting.

[6] TPSAC final report at p. 2. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf.

[7] At the next-to-last page of the final report, which does not have numbered pages throughout, in the section titled "Potential Menthol Black Market." The TPSAC report does not mention the Congressional mandate that it assess the potential for contraband demand; rather, it refers only to the section of the Act

Despite the above, the agency's peer review plan is silent on the need to examine this issue and how the peer reviewers will include the expertise needed. There is no doubt that the issue is covered as part of the FDA's "highly influential scientific assessment" that must addressed by the peer reviewers,[8] and it cannot be ignored, as it currently is in the peer review plan.

Required Peer Review Process Elements Not Specifically Required to be Described in the Peer Review Plan

There are a number of requirements in the OMB peer review rules that are not stated to be required to be covered by the agency's posted peer review plan. However, the requirements that the public be provided with a means to comment on the peer review plan, and that the agency will consider those comments, implies a high degree of disclosure in HISA plans, even if not specifically required. This point is supported by President Obama's "Transparency and Open Government" directive to agencies.[9] The directive begins by stating: "My Administration is committed to creating an unprecedented level of openness in government." It then goes on to state that "Executive departments and agencies should also solicit public feedback to identify information of greatest use to the public" and that they "should offer Americans increased opportunities to participate in policy-making and to provide their Government with the benefits of their collective expertise and information."

7. The Mandate for the Reviewers to Comply with the IQA: The OMB rules state: "Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information quality." 70 Fed. Reg. 2664, 2675. This requirement is also discussed in the preamble at 2671-72, which states that "the charge should make clear that the reviewers are not to provide advice

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requiring the Secretary to consider the matter. The report's statement that its referral of the issue to FDA without any independent TPSAC analysis is "[c]onsistent with the requirements of the Act" is inaccurate, and disingenuous given the many public comments presented to TPSAC on its Congressional mandate to assess that issue under the Act.

[8] "Science" might usually be thought of as covering only subjects such as toxicology, medicine, biology, physics, and chemistry, but it also clear includes "such disciplines as the behavioral and social sciences." At 2667 This would include subjects such as economics, sociology, and criminology that would be involved in the assessment of the potential for contraband, or a "black market." Other federal agencies operating under the IQA peer review rules have routinely considered economic analyses, for example, to be "scientific assessments." See, *e.g.*, with regard to economic analyses as scientific assessments subject to the IQA peer review rules: http://www.ers.usda.gov/AboutERS/peerreview.htm (USDA Economic Research Service), http://www.epa.gov/climatechange/economics/economywidepeerreview.html (EPA), http://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=81729 (EPA), http://cfpub.epa.gov/si/si_public_pr_agenda.cfm (EPA Office of Water agenda items), http://www.dol.gov/asp/peer-review/ (OSHA agenda items 2 and 3).

[9] Memorandum to the Head of Executive Departments and Agencies, titled "Transparency and Open Government," dated January 21, 2009, 74 Fed. Reg. 4685 (Jan. 26, 2009).

on the policy (*e.g.*, the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis)." At 2669 1st col.

8. The Charge to the Reviewers: The rules require that the agency present a charge for the review to the peer reviewers, and that it contain the admonitions regarding information quality and refraining from injecting policy/precautionary views into the review deliberations referenced above. As also noted above, the plan describing the review is deficient in not covering the contraband issue. Presumably, therefore, the charge would be similarly deficient. In the interests of transparency, public participation, and obtaining a thorough and legally-compliant peer review, the agency charge should be disclosed to the public either in the posted peer review plan or prior to a public meeting. In fact, the preamble to the OMB rules recommends that the charge be given to prospective peer reviewers before they are selected. At 2668 3d col.

9. The Specific Peer Reviewers and Their Areas of Expertise: As with the charge, transparency and public participation require that the public be informed of the identity of the peer reviewers and their areas of expertise so that it is clear that the assemblage of expertise will be fully sufficient to respond to the charge.

10. Independence and Balance among the Peer Reviewers: The OMB rules contain requirements regarding expertise, balance, conflicts of interest, and independence. At 2675. Again, although the rules do not specifically require disclosure of peer reviewers in the peer review plan, there should be a public meeting, and in advance of that meeting the agency should disclose the identities of the peer reviewers so that the public will have an opportunity to review and comment on matters of expertise, balance, conflicts of interest, and independence. Also, as noted previously, we believe the agency is required to disclose in the plan the organization that is selecting the peer reviewers.

Summary of Actions that the FDA/CTP Must or Should Take

1. The agency must inform the public of how it can comment on the peer review plan and must consider any public comments.

2. Unless the agency specifically determines that it is not feasible and appropriate to do so, it must revise the peer review plan to state that it will make the agency's draft assessment that will be peer reviewed available to the public prior to or during the peer review and sponsor a public meeting at which interested members of the public will have an opportunity to present oral comments to the peer reviewers.

3. Unless the agency specifically determines that it is not practical, it must revise its peer review plan to state that it will provide public comments on significant scientific issues to the peer reviewers during the peer review.

4. The peer review plan must be revised to state that peer review will be conducted on a panel basis rather than an individual/letter review basis in order to allow for a public meeting and oral presentations.

5. The agency must identify the outside organization that will select the peer reviewers (or which already has).

6. The peer review plan, and the charge to the peer reviewers, must be revised to include assessment of the potential for a "black market" in contraband menthol cigarettes and the potential impacts of such a development. The peer reviewers must include expertise pertinent to this issue, such as expertise in economics and criminology

7. The agency must inform the peer reviewers of the requirements and standards of the IQA and its guidelines/rules and inform them in the charge of the need to refrain from injecting policy/precautionary bias into their deliberations and conclusions.

8. The agency should disclose the charge to the public for comment and ensure that it contains the IQA information required by the OMB rules. The charge must also cover the contraband issue.

9. The agency should inform the public of the identity of the peer reviewers and their areas of expertise. This is necessary in order to allow the public to comment on item 10, below.

10. The agency must ensure that the selection of peer reviewers meets the requirements of the OMB rules for expertise, balance, lack of conflicts of interest, and independence.

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Please feel free to contact me if you have any questions regarding this letter. I would appreciate a response from the agency indicating what it will do in response to the letter. I can be reached via the contact information on the letterhead or at tozzi@thecre.com.

The peer review Plan indicates the peer review is to begin in July 2011 and last approximately 3.5 months. We do not know whether in fact it has begun or when it will begin, but that stated timeframe necessitates a prompt response to this letter.

We are providing a copy of this letter to OMB because the OMB rules state that it will be responsible for overseeing implementation of the rules.[10]

Sincerely,

/s/

Jim J. Tozzi
Member, CRE Board of Advisors

cc: Administrator, OMB Office of Information and Regulatory Affairs

[10] At 2677.