Center for Regulatory Effectiveness

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via fax (301-796-8540), email and mail

Ralph S. Tyler
Chief Counsel
Food and Drug Administration
U.S. Dept. of Health and Human Services
10903 New Hampshire Ave.
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Silver Spring, MD 20993

Dear Mr. Tyler:

I am writing to express my concern that the Tobacco Products Scientific Advisory Board ("TPSAC"), which has been charged by Congress with providing a report to FDA on the public health effects of menthol cigarettes, apparently does not intend to comply with the Congressional mandate that its report examine the potential health effects that would arise from creating a contraband market for menthol cigarettes if FDA were to decide to ban or otherwise regulate menthol cigarettes. Such disregard of the Congressional mandate would surely give rise to legal challenges based on a significant procedural defect in the rulemaking process

My concern is based on having attended the TPSAC meeting on February 10 and the TPSAC Menthol Report Subcommittee meeting on February 11. At the February 10 meeting there was no discussion of the issue, and the materials given to the Committee did not recognize the need to consider the potential public health effects of contraband marketing.[1] At the February 11 meeting there was some discussion of the contraband issue in connection with discussion of draft Chapter 7 of the Committee's upcoming report to the agency; however, all the discussion was about potential economic impacts of marketing of contraband menthol cigarettes (*e.g*, lost tax revenues, pricing) and not about the potential public health impacts of contraband marketing of menthol cigarettes. Moreover, the draft title to Chapter 7 is "Public Health Impact

[1] The "Charge to TPSAC" set out in draft Chapter 1 of the Committee report to the agency, which was given to TPSAC on February 10, but not discussed, did not include any mention of the contraband issue, and the paragraph following statement of the "charge" stated that "If a standard were to be implemented in regard to menthol, under section 907(b), the Secretary needs to consider additional matters, including ... any countervailing effects on the health of adolescent and adult users and non-tobacco users. Such effects could include the creation of a significant demand for contraband." http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM242560.pdf (emphasis added). As discussed below, the Congressional "charge" to TPSAC requires that TPSAC report to the Secretary on the contraband issue so that the Secretary can decide whether to implement a standard in regard to menthol, not that the Secretary consider that issue without the benefit of a TPSAC analysis. The "charge" must reflect the Congressional mandate for TPSAC to report on the potential health effects associated with the contraband issue, as explained below. Apparently TPSAC needs the assistance of FDA legal counsel in understanding this statutory requirement.

of Menthol Cigarettes,"[2] which does not indicate any consideration of public health impacts resulting from a contraband market. CRE had previously made detailed written and verbal presentations to TPSAC on the adverse public health implications of a contraband market for menthol cigarettes.[3]

The Congressional mandate for TPSAC to report to FDA on the potential public health impacts from creation of a contraband market for menthol cigarettes is plain and explicit. Section 907(e)(1) of the statute[4] requires the Secretary to refer to TPSAC the issue of the public health impacts of menthol cigarettes, and states that "[i]n its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections [907](a)(3)(B)(i) and (b)." Subsection 907(b)(2) states as a consideration that must be addressed "the countervailing effect of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, 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]

I recommend, and request, that you clarify for TPSAC its legal responsibility to address in its report to FDA the likely public health impacts that could arise from a contraband market for menthol cigarettes as a result of a ban on menthol cigarettes. Especially in view of the apparently non-compliant materials already posted on the TPSAC website, I believe this legal clarification should be made public at the next TPSAC meeting on March 2, 2011.

Respectfully,

Jim J. Tozzi
CRE Board of Advisors

cc: Jonathan M. Samet, M.D., M.S., TPSAC Chair
Caryn Cohen, M.S., TPSAC Designated Federal Official
Lawrence R. Deyton, MSPH, MD, Director, FDA Center for Tobacco Products

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[2] See http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm242181.htm.

[3] http://www.thecre.com/tpsac/?p=950 and https://collaboration.fda.gov/p55646656/. For example, government data indicate that contraband cigarettes often contain much higher levels of lead, cadmium, tar, nicotine, and carbon monoxide. Other parties, including a representative of the Canadian convenience store industry, related to TPSAC at its January 10 meeting Canada's real-world experience with the creation of a huge contraband market when cigarettes were regulated there. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm.

[4] Pub. L. No. 111-31, June 22, 2009, 123 Stat. 1776, 21 U.S.C. § 301, note.

[5] At the January 10 TPSAC meeting, a representative of the National Association of Attorneys General explained the many ways in which a menthol tobacco standard could be circumvented by creation of a market of non-cigarette "other" tobacco products to satisfy demand for menthol.