

Center for Regulatory Effectiveness

Suite 500

1601 Connecticut Avenue, N.W.

Washington, DC, 20009

Tel: (202) 265-2383 Fax: (202) 939-6969

secretary1@mbsdc.com www.TheCRE.com

February 15, 2011

Jonathan M. Samet, M.D., M.S.
Chair
Tobacco Products Scientific Advisory Committee
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: February 15 Data Submission: Failure to Discuss the Health Effects of a Menthol Ban-- A Statutory Violation

Dear Dr. Samet:

In accord with your statement at the TPSAC meeting on February 12, CRE is submitting the following information to TPSAC.

The Center for Regulatory Effectiveness (CRE) has participated in the TPSAC process and appreciates the openness and transparency with which you have conducted the proceedings. Based on the outline of the report chapters from menthol subcommittee discussed at the February 11th meeting, however, we are concerned that the TPSAC appears to be on the verge of violating its statutory mandate. Specifically, there is no indication that the report will discuss the **contraband-related health effects** from a menthol ban.

The law creating the TPSAC unambiguously directed the committee to:

consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects 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. (Public Law 111-31, §907(b)(2)) [Emphasis added]

Although the issue of contraband was discussed in the report outline, it lacks the required discussion of the health effects associated with contraband. Peer reviewed literature discussing contraband-specific

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health effect issues was extensively discussed in our contraband paper¹ which was submitted to the TPSAC via FDA and in my presentation to the Committee on January 10th.

The Committee's discretion in conducting itself and developing its report does not extend to refusing to address any of the statutorily-required topics of its report.

Accordingly, to further assist the committee in addressing the issue of the health effects of contraband cigarettes, the attached white paper provides information specific to contraband health issues.

The literature cited in the attachment makes abundantly clear that contraband cigarettes pose significant public health threats over and above those from legal tobacco products.

In that the Committee's work must adhere to the Data Quality Act standards set by the Office of Management and Budget and FDA in order for the agency to be able to rely on it, the attached paper consists of excerpts from the peer reviewed literature concerning contraband cigarettes and health, not CRE's analysis of the material. Citations are provided for all of materials.

Consequently it is imperative that TPSAC fulfill its statutory directive to address the effects of contraband cigarettes on the health of adolescent and adult smokers. We would like you to affirm our understanding of this requirement not later than February 28.

Respectfully,

/s/

Jim J. Tozzi
Member, CRE Advisory Board

Attachment, Health Effects of Contraband Cigarettes

cc: Lawrence R. Deyton, MSPH, MD

¹ <http://www.thecre.com/tpsac/wp-content/uploads/2011/01/AnInquiryIntoContrabandCigarettes.pdf>.