

# Center for Regulatory Effectiveness

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September 14, 2011

Lawrence R. Deyton, MSPH, MD  
Director, Center for Tobacco Products  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

## RE: FDA Review of the TPSAC Report

Dear Dr. Deyton:

We reviewed a recent World Trade Organization (WTO) Panel Report resulting from a complaint by Indonesia regarding a provision in the Family Smoking Prevention Tobacco Control Act that bans clove cigarettes. I read the report with interest, particularly the section in which the United States Government (USG) informs the WTO panel that menthol cigarettes are not banned “because of issues including the potential impact on the health care system and the potential development of a black market and smuggling of menthol cigarettes”<sup>1</sup> and cites the following FDA determinations in support of the USG position:

*The United States refers the Panel to the following FDA conclusions:*

*"The sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous. First, there could be significant health risks to many of these individuals. Second, it is possible that our health care system would be overwhelmed by treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Third, the agency also believes that, given the strength of the addiction and the resulting difficulty of quitting tobacco use, a black market and smuggling would develop to supply smokers with these products. It also seems likely that any black market products would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives." [Emphasis added]<sup>2</sup>*

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<sup>1</sup> World Trade Organization, “United States – Measures Affecting the Production and Sale of Clove Cigarettes: Report of the Panel,” WT/DS406/R, 2 September 2011, p. 88.

<sup>2</sup> *Id* at Footnote 522.

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FDA/CTP is charged with reviewing the TPSAC report, *Menthol Cigarettes and the Public Health: Review of the Scientific Evidence and Recommendations* and issuing a report thereon.

Since the FDA has concluded that: 1) a black market would develop in response to a ban; and 2) black market cigarettes would be considerably more dangerous than legal products, we expect that your report on the review of the TPSAC report will be fully consistent with FDA's conclusions stated above.

Should the agency choose to deviate from the position it announced to the WTO it is incumbent on the agency to:

1. Publish for notice-and-comment any revised conclusions related to contraband and menthol; and
2. Disclose the data that resulted in the agency changing its position on the issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Tozzi". The signature is written in a cursive style with a large initial "J" and "T".

Jim Tozzi

Member, Board of Advisors