

Center for Regulatory Effectiveness

May 17, 2010

Dr. James C. Hersey
RTI International
1615 M. Street
Washington, DC 20036

SUBJECT: “*Are menthol cigarettes a starter product for youth?*” Nicotine & Tobacco Research Volume 8, No. 3 (June 2006), pp. 403-413, by James C. Hersey, et al.

Dear Dr. Hersey,

I am writing on behalf of the Center for Regulatory Effectiveness (CRE) to solicit your response to questions we have regarding your menthol cigarette study.

You may be aware that on June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act, which gives the Food and Drug Administration the power to further regulate the tobacco industry. One element of the law imposes new warnings and labels on tobacco packaging, with the goal of discouraging minors and young adults from smoking. The bill bans flavored cigarettes, including cloves, cinnamon, candy, and fruit flavors, with an exception for menthol cigarettes. The CRE is keenly interested in ensuring policy makers and the general public is provided with accurate and transparent data from pertinent studies such as yours.

Your study was based on the 2000 and 2002 National Youth Tobacco Survey (NYTS) data and made two primary claims:

- menthol cigarette use was significantly more common among newer, younger smokers;
- menthol smokers had higher nicotine dependence than non-menthol smokers

In an effort to gain a better understanding of your conclusions, the CRE conducted an assessment which included an analysis of the 2000 and 2002 NYTS data and Codebook, at the CDC website. Provided directly below are some of our primary findings which indicate the need for a better understanding of how your team computed their results as well as the supporting data.

1. Is there a clear, unambiguous definition of menthol smoker category?

There appears to be a lack of clear and consistent definition for the menthol smokers group. On page 405 of the study, the researchers “...defined menthol smokers as youth who reported that they smoked menthol cigarettes.” However, the notes associated with Table 1 define Menthol smokers as including sub-groups described as “Possible menthol brand” and “Brand not described,” which comprise 16.2% and 2.3%, respectively, of the total 36.9% of menthol smokers group. A review of the 2002 NYTS Code Book reveals that there was no category described as “Possible menthol brand.” These two sub-groups should not be included within the

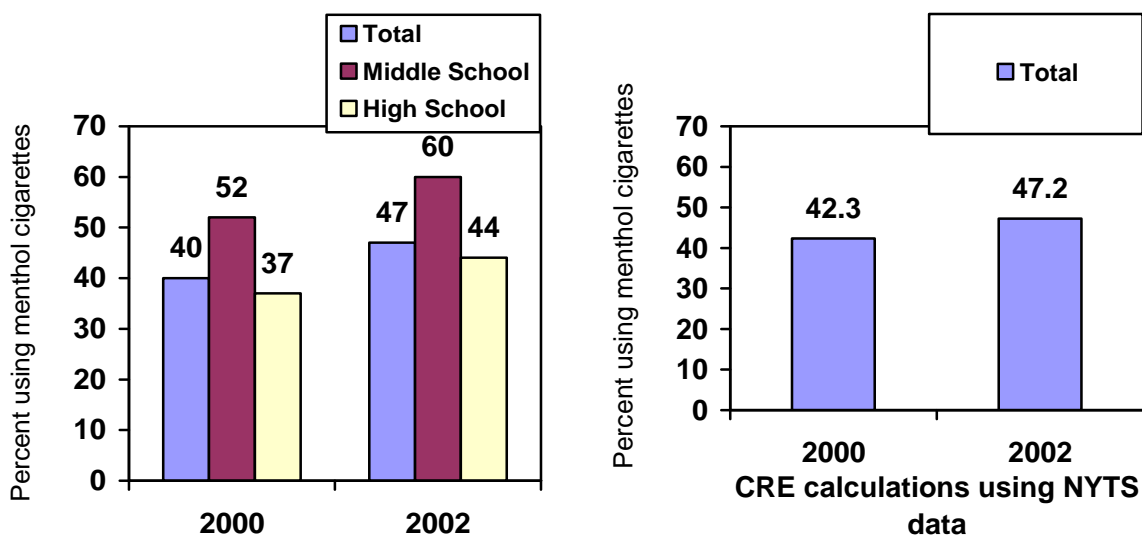
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Menthol smokers group, or the researchers should provide a better explanation for how these sub-categories were created.

While the “true” size of menthol smokers may not be attainable, an over-inflated size will inaccurately impact the researchers’ two primary claims.

2. *Is there really a significant increase in menthol cigarette smoking among our youth?*

Results (pages 406-407). Statements made regarding the increased use of menthol cigarettes and the bar charts at Figure 1, appear to be inconsistent. The authors state that “...between 2000 and 2002, the percentage of smokers who regularly used menthol cigarettes increased significantly...from 40% to 47.4% - an increase of 18.5%.” Taken at face value, this only represents a 7.4% increase. Figure 1 was further studied: the 2002 and 2000 NYTS Code Books and data were reviewed to verify the “Total” percentages of menthol smokers. For the year 2002, 1,661 students responded positive to smoking menthol cigarettes while 1,866 students responded negative to smoking menthol cigarettes. The year 2002 “Total” percentage in Figure 1 was therefore confirmed, $1,661/3527 = 47.2\%$. However, for the year 2000, 2,701 students responded positive to smoking menthol cigarettes while 3,674 students responded negative to smoking menthol cigarettes. Therefore, the year 2000 “Total” percentage in Figure 1 was found to be $2,701/6,375 = 42.3\%$. This resulted in an increase of menthol cigarette use of only 4.9% (from 42.3% to 47.2%) between the years 2000 and 2002 (as opposed to the stated 18.5% and illustrated 7.4% in the study).



3. *Are the researcher’s models transparent?*

The researchers’ second claim lacks the supporting analysis. Specifically, the authors provide the formulas for the logistic regression models that were used to conclude the relation between menthol smokers and nicotine dependence. However, the data in Table 3 of the study does not show the composition of the model (i.e. the beta (β) co-efficient values associated with the variable (M, L, T, A, X) values and the error (ϵ) amount was not provided). These missing components of the model make it impossible for the reader to verify or validate the model (i.e. the error amount alone can be used by modelers to compensate for unexplained

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behavior/factors). The relationship between menthol smoking and nicotine dependence is a primary claim for the study. Therefore, models should be transparent, complete and well illustrated.

Thank you in advance for responding to our assessment of your team's study. The CRE would be grateful if you would send this letter to your colleagues for consolidated comments. I would be happy to clarify any questions you might have regarding our findings. Please contact us at (202) 265-2383.

Sincerely,

/s/

Jim J. Tozzi
Member, CRE Board of Advisors

Cc:

Ms. Shu Wen Ng

Mr. James Nonnemaker

Mr. Paul D. Mowery

Ms. My-Charllins Vilsaint

Ms. M. Lyndon Haviland

1601 Connecticut Ave, NW.
Washington, DC 20009