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## **“Are Menthol Cigarettes a Starter Product for Youth?”**

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### References:

- a. Study: “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.
- b. 2002 National Youth Tobacco Survey Data and Codebook, Centers for Disease Control
- c. 2000 National Youth Tobacco Survey Data and Codebook, Centers for Disease Control

### Background

The harmful effect of cigarette smoking on our nations’ youth is an important issue. On June 22, 1999, 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 Nation’s Centers for Disease Control sponsors the conduct of a predominantly biennial National Youth Tobacco Survey, to study the cigarette smoking trends in middle school and high school aged students. These publically available surveys include data regarding menthol cigarette use as well as cessation efforts.

The reference Study was identified for review and public discussion due to its focus on the effects of menthol smoking on children. The study used 2000 and 2002 data from the National Youth Tobacco Survey (NYTS) to assess the relationship between menthol use and nicotine dependence. Middle School and High School students comprised the NYTS data set. The researchers 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

The researchers suggested that menthol cigarettes are a starter product that may be associated with smoking uptake by youth.

The CRE conducted an assessment which comprised of a review of the: reference study, 2000 and 2002 National Youth Tobacco Survey data and Codebook, and internet research (including comparison of various state level studies such as the Iowa, Hawaii and Connecticut Youth Tobacco Surveys, years 2008, 2007 and 2003, respectively). Since the NYTS is a biennial national survey, the assessment approach considers the NYTS as the “population” and more focused (regional) surveys, such as the Connecticut and Iowa studies as “samples” from which to generally compare and contrast.

The Tobacco Products Scientific Advisory Committee provisioned under the bill is to submit a recommendation on menthol cigarettes to the United States Secretary of Health and Human Services no later than March 23, 2012. The intent of this assessment is to consider the merits

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and shortfalls of the study as well as present the reader with topics for further discussion and investigation.

### Summary

Is there really an increase in menthol cigarette smoking among our youth?

As a part of its review as to whether or not menthol cigarette smokers have a higher nicotine dependence, the FDA is analyzing the study by *Hersey et al.* and its attendant review of the Connecticut Youth Tobacco Study (which used 2002 state data) which concluded that “[m]ore than 1 in 2 middle school current smokers smoke menthol cigarettes.” The 2007 Hawaii Youth Tobacco Survey reported an increase of menthol smoking among middle school students, from 61.5% in 2000 to 70.3% in 2007.

Under the Data [Information] Quality Act FDA is prohibited from using any information from a third-party, such as TPSAC, unless it meets the requirements of the DQA. CRE has reviewed the study by *Hersey et al.* And has identified the following shortcomings, which if stand after outside peer review, would deem it non-compliant with the DQA. CRE is requesting public comment for the material set forth herein.

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

The most important aspect of the reference report is the lack of a clear and consistent definition for the menthol smokers group. On page 405 of the study, the menthol group appears to be defined as smokers who smoke Kool and Newport brands. However, Table 1 includes other categories. While the “true” size of menthol smokers may not be attainable, an over-inflated size will inaccurately impact the researchers’ two primary claims.

2. *Are the survey responses consistent?*

The researchers’ first claim, illustrated by the bar chart at Figure 2, page 408, is suspect since the authors counted brand and/or menthol status. Specifically, a student could select a non-menthol brand, but then respond positively to smoking menthol cigarettes. A young student (particularly Middle School students) may not be sufficiently knowledgeable about menthol cigarettes. Using a more comprehensive brand selection list would contribute towards reducing subjectivity and response errors.

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 ( $\beta$ ) co-efficient values associated with the variable (M, L, T, A, X) values and the error ( $\epsilon$ ) 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.

### *4. Should future survey questions be changed to improve communication with our youth?*

It is difficult for the study to present a comprehensive correlation between menthol smoking and high nicotine dependence based on pre-dated national survey questions (and unchanged over the years). More recent youth tobacco surveys, at the state level (i.e. Hawaii and Iowa), indeed indicate a increase over the years, of menthol cigarette smoking by middle school and high school students. For example, a 2008 Iowa study indicated 44% and 138% increases among middle school students and high school students, respectively, over an eight year period (2000-2008). In response to changing metrics, state level surveys and subsequent studies are being tailored to analyze the effectiveness (or lack thereof) of preventative programs.

## Discussion/Detailed Technical Issues

Menthol Group Size (page 405). The study includes a very detailed Table 1 (page 405), providing a roll-up of the numbers that were considered for the menthol smokers group. However, the roll-up includes 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.” The addition of this subjective sub-group can lead to artificially increasing the group size. The Menthol Group should be defined, such as the reported Kool- and Newport-brands. Alternatively the researchers should have only computed the percentage of reported “menthol smokers” ( $1661/4288 = 38.7\%$ ).

Analysis Comparing Menthol and Non-menthol Smokers (page 406). The authors state that they “...used the Nicotine Dependence Scale for Adolescents (Nonnemaker et al., 2004). [A] scale that consisted of six items that asked respondents how soon they smoked after they woke up and whether they experienced cravings for cigarettes (Table 2).” However, the authors do not show the results from the model. The reader should also be aware that these six questions are standard questions contained in the NYTS (i.e. the researchers did not “add” or conduct an additional survey). So, this analysis can be independently verified since the raw data responses are publically available.

Results (pages 406-407). Statements made regarding the increased use of menthol cigarettes and the bar charts at Figure 1, appear to be incorrect. 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

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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).

Logistic Regression Models (pp. 408-409). The study does not adequately lay-out the complete models (values for coefficients and variables are missing). Typical statistical analysis includes a first-step of developing simple correlation plots (an x-variable (the explanatory variable) and a y-variable (the response variable)). An initial study of correlation contributes towards identifying the explanatory variable(s) that could be incorporated into a more complex regression model.