Center for Regulatory Effectiveness (CRE) assessment of the following research report:

"Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults"

by:

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August 2010

References:

a. Research Report: "Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults." American Journal of Public Health, Vol. 98, No. 9, September 2008, pp. 1685-1692, by Jennifer M. Kreslake, et al.
b. Substance Abuse & Mental Health Data Archive, website: www.oas.samhsa.gov
c. Research Report: "What do Marlboro Lights smokers know about low-tar cigarettes?" Nicotine and Tobacco Research, Volume 00, No. 0, October 2004, pp. 1-10, by K. Michael Cummings, et al.

Background

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 a special exception for menthol cigarettes. There is a need to investigate possible health hazards of smoking menthol cigarettes as well as cessation (quitting) efforts.

The Tobacco Products Scientific Advisory Committee (TPSAC) 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 CRE assessment is to consider the merits and shortfalls of the study as well as present the reader with topics for further discussion and investigation.

The report at reference (a) was identified for review and public discussion due to its stated conclusion that additives to cigarettes, such as menthol, should be federally regulated. Leading up to this conclusion, the researchers presented the following primary results:

- The tobacco industry has attracted new smokers by promoting cigarettes –
  - with lower menthol content to adolescents and young adults, and
  - with higher menthol content to long-term smokers
- Menthol cigarette sales remained stable from 2000 to 2005 in the U.S., despite a 22% decline in overall packs sold.

The researchers further concluded "[t]obacco companies manipulate the sensory characteristics of cigarettes, including menthol content, thereby facilitating smoking initiation and nicotine dependence." [p. 1685]

The report at reference (a) used three separate methods of analysis to formulate their aforementioned results and conclusions. Specifically:

- Marketing advertisement analysis (approximately 580 menthol-related tobacco industry documents were text-tagged to determine: market share trends, as well as advertising expenses - menthol vs. non-menthol brands, and industry strategies for introducing varying levels of menthol products).

- Laboratory tests (a smoking machine was used to "…analyze tar, nicotine…and menthol in smoke, as well as menthol and nicotine in the menthol cigarette rod" [p. 1686])
- "[M]enthol brand use by age and race/ethnicity from the National Survey on Drug Use and Health (using data from 2005 and 2006)." [p. 1686]

The CRE conducted a limited assessment which comprised a review of the report, internet research on "ventilated cigarettes," and publically available data from the reference (b) website.

Under the Data [Information] Quality Act, the 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 Kreslake, et al., and has identified the following merits and shortfalls. The shortfalls (issues), if valid after outside peer review, would deem it non-compliant with the DQA. CRE is requesting public comment for the material set forth herein.

Summary of Findings and Issues

Publically available data supports the transparency requirements of the Data [Information] Quality Act.

For parts of their report, the authors used data from a publically available database at reference (b). The data and associated reporting provided by the Substance Abuse & Mental Health Data Services Administration (SAMHDA) – Office of Applied Studies was assessed as meeting the DQA transparency requirements .. In particular, the website provides the public the flexibility to conduct statistical analysis on the annual data sets, from the website.

Consequently, CRE was able to check the statistical findings reported in the survey-part of the subject report.

Is there an age and race correlation with cigarette choice (menthol)?

The researchers stated "[n]ational survey data showed that significantly more adolescents and young adults than older persons smoked menthol cigarettes." [p. 1688] Using year 2006 survey data, they reported:

Current smokers (menthol or regular cigarettes in past 30 days)	
Age category	Percentage who smoked menthols
12 to 17 years old	43.8%
18 to 24 years old	35.6%
Older than 35 years old	30.6%

The above statistics were verified at http://www.icpsr.umich.edu/SAMHDA. The data set variable "CIG30MEN" (which is described as "menthol or regular cigarettes smoked most in the past 30 days.") was used as the variable of interest and the data set variable "CATAGE" (defined as age categories) was used as the filter. These statistics indicate that a higher percentage of

menthol cigarettes are being smoked by younger smokers than older-aged smokers (e.g. 43.8% vs. 30.6%)

The researchers focused on year 2006 data. The following graph ("Figure 1") shows menthol statistics, filtered by age groups, across the years 2004-2008. This graphic indicates a correlation between menthol cigarette preference and young-aged smokers.

Figure 1. Trends in Past Month Menthol Cigarette Use among Past Month Cigarette Smokers Aged 12 or Older, by Age Group: 2004 to 2008

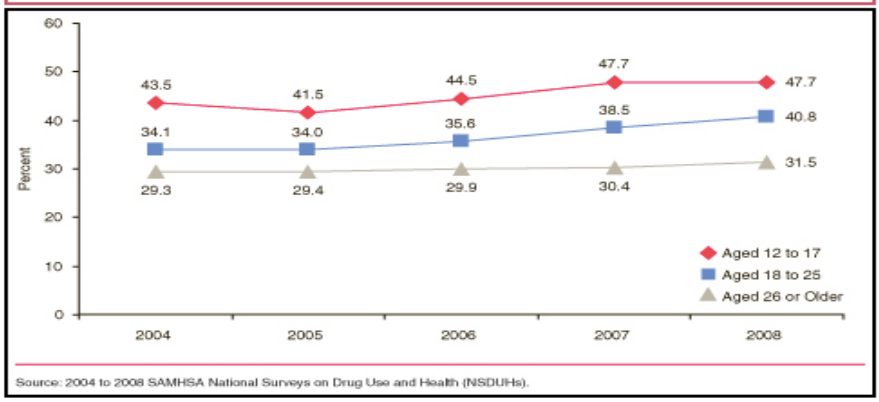

Figure 1 Table. Trends in Past Month Menthol Cigarette Use among Past Month Cigarette Smokers Aged 12 or Older, by Age Group: 2004 to 2008

Age Group	2004	2005	2006	2007	2008
Aged 12 to 17	43.5%	41.5%	44.5%	47.7%	47.7%
Aged 18 to 25	34.1%	34.0%	35.6%	38.5%	40.8%
Aged 26 or Older	29.3%	29.4%	29.9%	30.4%	31.5%

Source: 2004 to 2008 SAMHSA National Surveys on Drug Use and Health (NSDUHs).

The researchers also stated that "[r]ace was also a factor in use and brand choice. African American adolescents and young adult smokers used menthol as frequently as did older African American smokers, but they were more likely to choose a lower-menthol variety." [p. 1688]

However, the researchers did not provide the statistics and CRE was not able to identify the variables at the SAMHDA website to verify their statement. Therefore, the reader must be cautioned about the validity regarding the correlation between race and mentholated cigarettes.

The report stated that "[c]igarettes were analyzed for tar…,"but the report provided no data on tar delivery.

Researchers used a smoking machine to "…analyze tar, nicotine…and menthol in smoke, as well as menthol and nicotine in the menthol cigarette rod."

However, only nicotine and menthol analysis was presented. A completeness issue.

Is the use of a smoking machine a realistic mechanism for determining smoke and nicotine delivery from menthol ventilated cigarettes?

"Machine smoking was conducted under Federal Trade Commission, and more intensive Health Canada smoking conditions." [p. 1686] Here is a synopsis of their findings:

Figure 2. Summary of reported statistics from laboratory results.

Cigarettes ranked from least menthol content (top) to most menthol content (bottom)	Menthol in smoke (under FTC smoking conditions)	Nicotine per puff (under FTC smoke conditions)	Nicotine per cigarette (under FTC smoke conditions)	Nicotine per puff (under intense Health Canada smoking conditions)	Nicotine per cigarette (under intense Health Canada smoking con-ditions)	Menthol in the smoke (under intense Health Canada smoking conditions)	
						Total menthol	Menthol per puff
Newport	0.45 mg/ cigarette	0.16 mg/puff	1.20 mg/ cigarette	0.26 mg/puff		0.88 mg/cig	0.10 mg/puff
Marlboro Milds	0.27 mg/ cigarette	0.11 mg/puff	0.82 mg/ cigarette	0.22 mg/puff	1.91 mg/cig	0.80 mg/cig	0.09 mg/puff
Salem Black Label	0.52 mg/ cigarette					0.96 mg/cig	0.09 mg/puff
Camel Menthol	0.59 mg/ cigarette						0.12 mg/puff
Kool Milds	0.34 mg/ cigarette			0.26 mg/puff			0.14 mg/puff

The researchers stated that, "[o]verall, the smoke menthol ratings were comparable to the menthol content analysis, with Newport and Marlboro Milds consistently lowest in menthol ratings." [p. 1687] The highlighted brands (Newport, Marlboro Milds, Camel Menthol and Kool Milds) were designated as brands that target younger smokers.

CRE compiled the above table to confirm that several statistics were not provided. The lack of comparable data precludes the reader from making any meaningful comparisons or inferences.

Does the use of a smoking machine provides the opportunity for precise measurement?

There are interesting pros and cons associated with experiments that use human smoking subjects versus the smoking machines, as revealed in this excerpt from a study at reference (c):

"In the smoking machine the puff volume is constant so that with dilution the quantity of 'equivalent undiluted smoke' delivered to the Cambridge filter is reduced. Not so with the

human smoker who appears to adjust to the diluted smoke by taking a larger puff so that he still gets about the same amount of equivalent smoke…. The smoker is thus apparently defeating the purpose of dilution to give him less smoke per puff. He is certainly not performing like the standard smoking machine; and to this extent the smoking machine data appear to be erroneous and misleading. It probably always has been so for diluted smoke cigarettes, whether dilution is obtained by porous paper or holes in the filter (Wakeham, 1967)."

Hence, the smoking machine does not appear to capture the real smoking nuances. A data utility issue.