

**COMMENT SUBMITTED IN RESPONSE TO FDA QUESTIONS ON MENTHOL POSED IN ITS  
ADVANCED NOTICE OF POTENTIAL RULEMAKING**

Docket No. FDA-2013-N-0521

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The Public Health Advocacy Institute at Northeastern University School of Law is a 501(c)(3) public health law and policy research organization with a 30-year history of examining and devising legal and regulatory approaches to tobacco control.

We have carefully reviewed both scientific reports that summarize the Agency's findings on menthol as well as the industry perspective report.<sup>1</sup> In addition, we have methodically reviewed all presentations and the thousands of pages of submissions to the Tobacco Products Scientific Advisory Committee concerning menthol as part of a larger research endeavor.<sup>2</sup>

We strongly agree with the scientific conclusions presented in the TP-SAC<sup>3</sup> report as well as the internal peer-reviewed report.<sup>4</sup> These findings clearly establish an evidence base that justifies regulatory action by the Secretary to stop the harm to public health caused by permitting mentholated cigarettes to remain on the market. To put it simply, the most acute harm appears to be that mentholated cigarettes facilitate smoking initiation by youth, frustrate quit attempts by addicted smokers, and include brands that have particularly targeted African Americans in a way that amplifies health disparities.

**Regulating Menthol Cigarettes Can be Accomplished Under Sec. 906 of FSPTCA**

Section 906(d) of the Family Smoking Prevention and Tobacco Control Act covers, "General Provisions Respecting Control of Tobacco Products." In promulgating rules under this section, three factors are to be considered:

- 1) Is the rule appropriate for the protection of public health?<sup>5</sup>
- 2) Will the rule increase the likelihood of cessation?<sup>6</sup>
- 3) Will the rule decrease the likelihood of initiation?<sup>7</sup>

All of these factors support eliminating menthol brands of cigarettes and similar products from the market.

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<sup>1</sup> Non-voting members of Tobacco Products Scientific Advisory Committee. Menthol Cigarettes: No Disproportionate Impact on Public Health (March, 2011).

<sup>2</sup> These materials are found here:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm> and here:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm>

<sup>3</sup> Tobacco Products Scientific Advisory Committee: Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. (March, 2011).

<sup>4</sup> Food and Drug Administration. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes (October, 2011).

<sup>5</sup> Family Smoking Prevention and Tobacco Control Act §906(d)(1).

<sup>6</sup> Family Smoking Prevention and Tobacco Control Act §906(d)(1)(a).

<sup>7</sup> Family Smoking Prevention and Tobacco Control Act §906(d)(1)(b).

Rules should be promulgated by the Secretary under the authority conferred by sec. 906(d) of the Family Smoking Prevention and Tobacco Control Act to prohibit cigarette manufacturers from selling or distributing cigarettes that are:

- a) Branded as a menthol product;
- b) Marketed as a successor to a previously marketed menthol product; or
- c) Otherwise likely to be perceived as a menthol product or menthol product successor in the marketplace.

The third provision, “c),” should be understood to include the presence of menthol in the product such that it might potentially taste or smell like or otherwise be perceived to be a menthol product or menthol successor product or potentially affect consumers in a manner similar to current menthol brands.

We agree with other commenters that there is no valid reason to permit the use of menthol in cigarettes in any amount. Its use, even in products that are not marketed as menthol brands, tends to reduce or mask the irritation that cigarette smoke causes to the respiratory system. Such irritation inhibits initiation and encourages cessation. Masking that irritation would tend to have the opposite effect. A sufficient record to justify taking action in this regard at a total ban under sec. 907 does not appear yet to have been established.

We suggest that once sec. 906 regulations have been promulgated to eliminate the sale and distribution of menthol cigarette brands and similar products from the market, a closer investigation of the use of menthol as an additive under sec. 907 tobacco product standards is indicated.