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Mitch Zeller, J.D.
Director, Center for Tobacco Products
Document Control Center, Room 020J
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Re: Docket No: FDA-2013-N-0521, Regulation of Menthol In Cigarettes & Smoked Tobacco Products

This letter is on behalf of the Board of Directors for the Society for Research on Nicotine and Tobacco (SRNT), in response to the invitation for public comment on menthol in cigarettes from the U.S. Food and Drug Administration (FDA), July 23rd, 2013. SRNT is the largest scientific organization dedicated to interdisciplinary nicotine and tobacco research from molecular to societal levels, with an international membership, many of whom have contributed to the scientific evidence on the effects of menthol added to cigarettes.

SRNT recognizes that a thorough review of the scientific evidence on the effects of menthol was produced by FDA's Tobacco Products Scientific Advisory Committee (TPSAC) and that on July 21, 2011 TPSAC voted to approve its final report and recommendations, which concluded, *"removal of menthol cigarettes from the marketplace would benefit public health in the United States."*

In addition, SRNT recognizes that FDA also subsequently produced an independent "Preliminary Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes," based on weighing the collective body of evidence for the impact of the use of menthol in cigarettes on public health. That report concluded that:

"Consistent patterns have emerged as a result of FDA's evaluation of the scientific evidence relevant to the impact of menthol tobacco products on public health. While there is little evidence to suggest that menthol cigarettes are more or less toxic or contribute to more disease risk to the user than nonmenthol cigarettes, adequate data suggest that menthol use is likely associated with increased smoking initiation by youth and young adults. Further, the data indicate that menthol in cigarettes is likely associated with greater addiction. Menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking. These findings, combined with the evidence indicating that menthol's cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes." (FDA, July 23, 2013)

The SRNT Board considers that the reviews of the evidence conducted by TPSAC and by FDA summarized above were thorough, balanced and that their conclusions are based on the best science available. We also note that since the publication of these reports, the more recent evidence

that has been published has continued to be broadly consistent with the conclusions of these reports (e.g. Faseru et al, 2013; Reitzel et al, 2013; Rojewski et al, 2013; D'Silva et al, 2012; Nonnemaker et al, 2013; Giovino et al, 2013).

Given the consistent conclusions from the TPSAC review, FDA's own independent review and of subsequent studies published on menthol in peer-reviewed scientific journals over the past year, the SRNT Board makes the following recommendations:

1. FDA should establish a tobacco product standard addressing menthol concentrations in all tobacco products intended to be smoked (i.e. all combusted tobacco products, cigars and tobacco rolling paper, and other menthol products intended for use to flavor tobacco).
2. The new menthol standard should entirely prohibit the sale of a smoked tobacco product containing any detectable menthol, or any other additive known to produce a menthol-like (cooling or anesthetic) sensory effect.
3. The new menthol standard should be fully implemented within 12 months from the initial announcement.
4. The new menthol standard should be combined with a public education campaign designed to educate the public about the new menthol standard, and to promote smoking cessation services for menthol smokers who want to quit smoking.
5. The effects of the new menthol standard should be thoroughly evaluated using the best evaluation and research methods available, including surveillance for switching to non-combustible products and electronic cigarettes if the new menthol standard is not implemented for all tobacco products.

We thank you for your consideration of these comments and recommendations and we would be honored to assist you in any way possible in formulating effect new standards for menthol in tobacco products.

Sincerely,

A handwritten signature in cursive script that reads "Anne Joseph".

Anne Joseph, M.D., M.P.H.
President, SRNT

On behalf of the Board of Directors of the Society for Research on Nicotine and Tobacco.

References

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