Peer Review

Review of: "FDA Decision to Authorize NJOY ACE Menthol Was Based on a Rigorous Review of the Science to Determine That the Benefits Outweigh the Risk"

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In the commentary titled, "FDA Decision to Authorize NJOY ACE Menthol Was Based on a Rigorous Review of the Science to Determine That the Benefits Outweigh the Risks", Dr. Mohamadi Sarkar provides a rebuttal to a medical news story published in JAMA which highlights the case of the US Food and Drug Administration's (FDA) decision to authorize the marketing of menthol-flavored electronic (e-) cigarettes (1). While the majority of the commentary was focused on attributing e-cigarettes and the marketing of menthol flavoring as an approach for combustible cigarette users to switch to a less harmful product rather than prioritizing youth and young adults initiating the use of tobacco products, a few important issues that were highlighted in the JAMA news article were not elaborated upon:

- 1. Menthol has a cooling effect that helps nicotine and other contaminants get into the lungs compared to other flavorings, which then initiates respiratory irritation and has been demonstrated to also be harmful to cardiovascular health (2,3). Therefore, the reasons for complimenting the authorization of a flavoring that has been shown to cause physiological harm were not addressed.
- 2. Youth and the public in general will switch to purchasing vaping products that are not restricted or banned. Therefore, authorizing the marketing of menthol may not only be targeting combustible cigarette users to switch to e-cigarettes, but may also increase sales among youth

- and young adult e-cigarette users rather than driving them towards quitting. This shift in sales was seen with the federal ban of flavored cartridges in 2020 (4).
- 3. There is a historical tie of tobacco companies using menthol flavoring to target Black smokers, and authorizing menthol may continue to target and draw new vapers within the Black community. This politicized issue and the targeting of minority groups among which there is a disproportionately high use of mentholated tobacco products was not addressed.

While the author of the commentary credits the FDA's decision to be based on the science the agency was provided with, research already exists that shows e-cigarettes, and particularly mentholated e-cigarettes, to be associated with harm to public health. Additionally, an important note to consider is that having individuals who are addicted to combustible cigarette use transition to then becoming addicted to e-cigarettes should not be a standard of care. Ultimately, nicotine is the culprit, and in a market where the nicotine content in e-cigarettes continues to be comparably higher than in previous cartridge-based contents (and without the option of weaning nicotine content to 0%) and also combustible cigarette contents, regulations that encourage quitting of nicotine-based products altogether may be a better strategy.

References:

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Declarations

Potential competing interests: No potential competing interests to declare.