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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Potential competing interests: No potential competing interests to declare.

In light of the manuscript's response to Rita Rubin's article, "Controversial FDA Decision Authorizes Menthol-Flavored E-Cigarettes Despite Risks" (JAMA, 2024), it is clear that the author aims to counter concerns raised about the potential risks of menthol-flavored e-cigarettes. Rubin's critique highlights the FDA's controversial decision, questioning the long-term safety and public health implications of e-cigarettes, particularly due to their appeal to younger demographics. Sarkar's work, however, seems to focus heavily on harm reduction and the reduction of harmful and potentially harmful constituents (HPHCs) in NJOY ACE products, positioning itself as a defense of e-cigarettes' role in reducing tobacco-related harm. Despite this, I found it challenging to fully evaluate the manuscript's claims due to the lack of readily available data. The author cited studies claiming that most HPHCs are either below detection limits or significantly reduced in NJOY ACE products and real-world evidence demonstrating reduced biomarkers of exposure among adults who switch to NJOY ACE. However, without having access to these studies for independent evaluation, it is difficult to critically assess the validity and comprehensiveness of their findings. This limitation hinders my ability to make an informed judgment about the safety profile of NJOY ACE products. Furthermore, the reliance on industry-sponsored data raises concerns about potential bias, and the lack of long-term studies on the health effects of these products remains a significant gap in the literature. A more transparent and accessible presentation of the data, alongside an acknowledgment of the uncertainties and limitations, would strengthen the manuscript's credibility.