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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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This commentary presents a clear and well-articulated defense of the regulatory decision to authorize menthol-flavored NJOY ACE electronic nicotine delivery systems, emphasizing harm reduction principles and the U.S. Food and Drug Administration's appropriate-for-the-protection-of-public-health (APPH) framework. The manuscript's primary strength lies in its structured presentation of regulatory rationale supported by epidemiological trends, toxicological comparisons between combustible cigarettes and e-cigarettes, and references to real-world switching data among adult smokers. The author effectively highlights the declining prevalence of youth e-cigarette use and underscores the public health argument that less harmful nicotine delivery alternatives may contribute to reducing smoking-related morbidity and mortality. The inclusion of multiple scientific and regulatory sources, including national surveillance data and toxicological assessments, enhances the credibility of the commentary and provides readers with insight into the complexity of tobacco harm reduction policy decisions.

However, several limitations reduce the overall balance and analytical depth of the article. As a commentary largely centered on defending a regulatory outcome, the manuscript presents limited critical engagement with counterarguments or conflicting evidence regarding flavored e-cigarette products and youth initiation risks. The discussion relies heavily on manufacturer-generated or regulatory review data without extensive evaluation of independent longitudinal or population-level studies that have reported mixed public health outcomes associated with flavored vaping products. Additionally, the argument that declining youth prevalence sufficiently offsets potential initiation risks

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could benefit from deeper discussion of evolving product marketing strategies, behavioral substitution patterns, and long-term nicotine dependence trajectories. The commentary would also be strengthened by a more transparent discussion of potential industry influence, regulatory uncertainty, and the heterogeneity of harm reduction effectiveness across different demographic populations. Finally, while the manuscript references harm reduction benefits, it does not sufficiently address ongoing uncertainties regarding long-term safety outcomes of menthol-flavored vaping products.

Overall, the article contributes a relevant perspective to ongoing regulatory and public health debates surrounding e-cigarette authorization and tobacco harm reduction policy. While the commentary effectively summarizes regulatory justification and supporting evidence, incorporation of a more balanced appraisal of emerging risks, independent research findings, and long-term population health considerations would improve scholarly rigor and enhance the manuscript's contribution to evidence-informed public health discourse.

Declarations

Potential competing interests: No potential competing interests to declare.