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"

Ian Fearon[1]

1 whatIF? Consulting

Potential competing interests: I act as a paid consultant to tobacco and nicotine product manufacturers, and contract research organisations, in areas related to scientific product assessment and regulatory submissions. I am a scientific advisory board member with Qnovia Inc, a platform pharmaceutical company developing an electronic inhaled prescription NRT for smokers trying to quit smoking. I am also a Non-Executive Director with Advanced Inhalation Rituals Ltd, a manufacturer of traditional and electronic waterpipe products.

This review article, written in response to an article in the Journal of the American Medical Association (JAMA) questioning the FDA's decision to issue a Marketing Granted Order (MGO) for 4 menthol-flavoured NJOY e-cigarettes, provides a succinct summary of the FDA's rigorous scientific review process and the scientific data underpinning the MGO. The article is clearly written and outlines additional reasoning as to why that MGO was issued, taking into account the opposing interests of youth use and helping adult smokers move away from deadly cigarettes. I agree with the underlying premise of the article, that decisions on making potentially life-saving products such as e-cigarettes available as a harm reduction tool for adult smokers must be scientifically based and take into account the health interests of both adult smokers and youth. As stated, the FDA's decision was clearly made in such a manner.

I have 2 suggestions for how the article could be improved:

1. The article states that NYTS data show a low prevalence of use among middle and high school students of NJOY products. It would be useful to add numbers (percentages) to this statement.
2. I agree that the FDA should be commended for the way that their review was conducted, by assessing the potential of a product to help more smokers stop smoking while ensuring that youth use risks are minimised. The article could further suggest that such a science-based approach to regulatory decision making, assessing all potential impacts of the marketing of a flavoured e-cigarette, could act as a model for other regulators globally.