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Commentary

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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Response to the article written by Rita Rubin, "Controversial FDA Decision Authorizes Menthol-Flavored E-Cigarettes Despite Risks" JAMA. 2024 Aug 7. doi: 10.1001/jama.2024.14243. Online ahead of print.

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The medical news story [1] regarding "Controversial FDA Decision Authorizes Menthol-Flavored E-Cigarettes Despite Risks" does not take into consideration the scientific evidence and facts.

FDA-authorized less harmful products will play an important role in reducing the harm from smoking. To authorize a new tobacco product, the FDA must determine whether the marketing of the product is appropriate for the protection of public health (APPH). In its assessment of the science, the FDA considers whether the benefit of adult switching outweighs the risk of youth initiation. And the FDA did just that in the decision to authorize the NJOY ACE products.

Regarding youth initiation, we agree that no youth should ever start using *any* tobacco products. Although youth use of combustible cigarettes is at a historical low, the risk of youth initiation to e-cigarettes is real. According to the National Youth Survey (NYTS), the prevalence of e-cigarette use has declined since the peak of 20.0% among middle and high school students reporting past 30-day use of e-cigarettes in 2019 [2], down to 7.7% in 2023 [3]. While these declines in use prevalence are encouraging, more must be done.

In fact, aggressive steps to remove illicit flavored disposable e-cigarettes from the market are needed. Evidence from NYTS clearly proves that these products pose the greatest risk to youth use. The 2023 NYTS data show that among youth who currently use e-cigarettes, illicit disposable products are the leading brands cited as "usual brand" by respondents [3]. Further, manufacturers of these products market them with youth-appealing flavors, e.g., Rainbow Candy [4] with obvious disregard for the regulatory system and impact on public health. These products escape oversight regarding the ingredients they use, marketing, and

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labeling – completely evading scientific review. The FDA must act — quickly and decisively — to reign in these manufacturers who are blatantly flaunting the regulatory process.

The concern about the likelihood of youth initiation, while valid, should not jeopardize the availability of less harmful options for adults who smoke combustible cigarettes. The FDA must have adult switching to less harmful products at the forefront of its APPH analysis. Despite the overwhelming scientific evidence that cigarettes are the most harmful tobacco product [5], 28 million adults in the U.S. still continue to smoke [6]. They cannot be forgotten.

E-cigarettes, while not risk-free, are far less harmful, and the science is compelling [7][8]. Many in public health, including the FDA, have acknowledged the harm reduction opportunity of e-cigarettes. For example, Dr. Brian King, Director of FDA's Center for Tobacco Products (CTP), has stated that, "If an adult smoker were to transition completely from a cigarette to an e-cigarette, that would be a benefit to their health." [9] A publication authored by the past 15 presidents of the Society of Research on Nicotine and Tobacco mentions that "[V]aping can benefit public health, given the substantial evidence supporting the potential of vaping to reduce smoking's toll." [10]. The NASEM review in 2018 drew similar conclusions [7]. The scientific evidence is adequate to demonstrate the harm reduction potential of e-cigarettes. And while this may be true at the category level, manufacturers must present the evidence for the specific e-cigarette in their applications and allow the FDA to determine whether the product is APPH.

The article is judgmental of the FDA's decision to authorize the Menthol NJOY ACE products, perhaps due to a lack of understanding of the robust and substantial evidence included in our applications. The converging lines of evidence included in the applications clearly demonstrate that the NJOY ACE products are APPH. We provided studies demonstrating that most of the harmful and potentially harmful constituents (HPHCs) present in cigarette smoke are either below detection limits or substantially reduced in NJOY ACE products. Moreover, we also included real-world evidence demonstrating that biomarkers of exposure to select HPHCs are substantially reduced among adults who switch to NJOY ACE products. The toxicological assessment of NJOY ACE products has demonstrated that the ingredients in the products, as well as extractable and leachable constituents, were below levels that would pose a significant toxicological concern. The aerosol from the products was substantially less cytotoxic, mutagenic, and genotoxic compared to cigarette smoke.

Importantly, NJOY's applications clearly demonstrated significant and substantial complete switching, under real-world conditions, for the NJOY ACE products, balanced against extremely low youth use. As a matter of fact, data from NYTS demonstrate that among middle and high school e-cigarette users, reports of NJOY products' use have been consistently and substantially low in the U.S. for the past three years (2021-2023). The FDA conducted a rigorous review of the totality of this evidence when deciding to authorize the Menthol and Tobacco NJOY ACE products.

The article questions the merit of the FDA's decision to authorize the Menthol NJOY ACE products. As cited in the article, the recent study by Dr. Meza clearly showed that flavored e-cigarettes were significantly associated with an increased likelihood of smoking cessation, while exclusive use of unflavored or tobacco-flavored e-cigarettes was not. Our application corroborated these findings. In the

Technical Project Lead (TPL) review published by the FDA [11], the epidemiological review concluded that, “[T] he applicant’s NJOY User Study presents reliable and robust data indicating that NJOY ACE POD Menthol 5% ENDS are associated with significantly higher rates of complete switching than tobacco-flavored NJOY ACE ENDS.” Accordingly, the TPL summarized that, “[T] he applicant submitted robust and reliable data that demonstrate added benefit of using Menthol-flavored compared to Classic Tobacco flavored (not subject to this PMTA review) NJOY ACE in achieving past 30-day smoking cessation – a showing required to outweigh the risks associated with flavored ENDS among youth. Thus, as TPL, I conclude that these PMTAs contain sufficient evidence demonstrating that the menthol-flavored new products have the potential to benefit adults who smoke CC [combustible cigarettes], who switch completely or significantly reduce their CC use, that outweighs the risk to youth.”

Before casting doubts on the FDA’s decision, the science must be objectively reviewed to draw inferences based on the strength of evidence and not based on ideologies and assumptions. The FDA should be commended, not criticized, for this science- and evidence-based decision. We believe in transparently sharing our science, including actively communicating research findings at scientific conferences and publishing in peer-reviewed journals. In the meantime, we welcome questions and encourage readers to contact us to better understand the science.

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Declarations

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