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FDA Should Require Research on Impact of E-Cigarettes and Other Tobacco Products on Youth Before Authorizing Marketing of Tobacco Products and Claims of Modified Risk

Tobacco Control Experts Highlight Risks to Youth in Commentary Published in Journal of Adolescent Health

WASHINGTON, D.C. – In a new commentary published in the *Journal of Adolescent Health*, a group of leading tobacco control experts called on the U.S. Food and Drug Administration (FDA) to require tobacco companies to submit research showing the impact on youth and young adults in the United States before authorizing the marketing of any new tobacco product, including e-cigarettes, or permitting any claim that states or implies a tobacco product is less harmful than any other tobacco product.

The commentary was published as manufacturers of e-cigarettes and certain other tobacco products face a court-ordered September 9, 2020, deadline to apply to the FDA to keep their products on the market, known as the Premarket Tobacco Product Application (PMTA) process. It also comes as the FDA is considering a number of applications by tobacco companies to market certain products as "modified risk tobacco products" (MRTP).

Under the 2009 Family Smoking Prevention and Tobacco Control Act, which gave the FDA authority over tobacco products, tobacco manufacturers must obtain FDA authorization before they can introduce a new tobacco product or make a modified risk claim about a tobacco product. The law requires manufacturers to demonstrate that allowing the marketing of the product or claim would be appropriate for the protection of public health, accounting for both the impact on current tobacco users and non-users, including whether they will start using the product. The commentary notes that for the FDA to properly assess the impact of a tobacco product, the agency must require manufacturers to submit comprehensive research involving youth in the United States and provide the FDA sufficient evidence to evaluate the impact of the product as it will be marketed on America's youth.

The commentary notes that the FDA, to date, has failed to require sufficient evidence based on studies or other data to assess the impact of new tobacco products on American youth under either the premarket or modified risk application process, including in its recent review of Philip Morris International's IQOS heated tobacco product.

"Given that 90% of long-term smokers began smoking as adolescents, and the sensitivity of the adolescent brain to nicotine addiction, an assessment of the impact of a tobacco product on youth initiation and progression to established use is essential to any determination of population-wide impact for both PMTA and MRTP applications," the commentary states.

The commentary was written by tobacco control experts at Stanford University, the Campaign for Tobacco-Free Kids, Truth Initiative Schroeder Institute, and the Yale University School of Medicine.

According to the commentary, the FDA should require tobacco companies to submit studies in the U.S. evaluating the impact of their product, marketing and labeling on youth. The FDA should require the inclusion of the following critical components and data for every PMTA and MRTP application:

- Scientific evidence related to harm perceptions, product appeal and the addictive potential of the product among youth.
- A review of existing comparative studies of similar products, including research on adolescent perceptions as they relate to intentional and actual use.
- Evidence specific to youth in the United States.

Given the tobacco industry's long history of manipulating research, the commentary calls on the FDA to establish strong safeguards to ensure that the evidence submitted is objective, reliable and protected from industry influence. All studies should be conducted by third-party, independent researchers and research protocols should be approved by an independent review committee and meet minimum standards for designing, conducting and reporting results of studies. Any research conducted by or funded by the industry, in which the protocols are not reviewed by FDA and independent third parties, is unacceptable.

"As experts on youth tobacco use, we have great concern over the number of new tobacco products entering the U.S. market without authorization and oversight," the authors write. "The FDA must require manufacturers to submit empirical evidence related to the impact on youth for all PMTA and MRTP applications. It is critical that the FDA set and enforce strict protocols to ensure scientific integrity and protect youth."

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