Youth E-Cigarette Use and the Food and Drug Administration's Multifaceted Approach

See also Dasgupta and Fiala, p. 759, and the *AJPH* After FDA Vaping Guidance section, pp. 771–789.

Results from the National Youth Tobacco Survey (NYTS)—an annual survey conducted by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention—showed that in 2019, more than five million US middle and high school students reported current use (at least once in the past 30 days) of e-cigarettes and other electronic nicotine delivery systems (ENDS), and nearly one million students cited daily use.[1] These numbers are indicative of an epidemic of youth e-cigarette use in this country and are particularly troubling, as nicotine exposure during adolescence could harm brain development and lead to a number of long-term and long-lasting health effects, including nicotine addiction. There is also evidence that youths who use ENDS are more likely to start smoking cigarettes.[2,3]

Importantly, the NYTS data also showed that youths overwhelmingly used cartridge-based ENDS, such as JUUL,[1] as their usual brand in 2019. Additional data from the National Institute on Drug Abuse's Monitoring the Future (MTF) survey on JUUL use suggested that youths preferred mint- and fruit-flavored—including mango—much more than menthol- and tobacco-flavored products.[4]

No currently marketed e-cigarette is lawfully on the market because none has received a marketing authorization, as required by law, from the FDA. From late 2016 until recently, these products remained on the market as a result of the agency's exercise of enforcement discretion. That policy needed to change. We sought to create guidance for the industry that struck the right public health balance between preventing minors' access to e-cigarettes and avoiding the hindrance of—even temporarily—one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful ones.

So, informed by the 2019 NYTS and MTF findings, in January 2020, the FDA announced our intention to prioritize enforcement against illegally marketed ENDS products by focusing on three main groups that do not have premarket authorization:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product),
- All other ENDS products for which the manufacturer fails to take adequate measures to prevent minors' access, and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

Recognizing that the tobacco market changes rapidly, we were careful to design our policy to allow flexibility in enforcement, enabling the agency to focus our priorities where they are most needed to address increased youth use. If we see that a product is targeted to adolescents, we will not hesitate to pursue actions against the maker or sellers of that product.

Accordingly, the FDA intends to take action against any ENDS product—regardless of whether it is cartridge-based, disposable, flavored, or otherwise—if it is targeted to youths, if its marketing is likely to promote use by minors, or if the manufacturer fails to take adequate measures to prevent minors' access. For example, the FDA has taken actions against ENDS products marketed with labeling or advertising that resemble child-friendly foods and drinks, such as juice boxes and child-friendly cereal. Another area of focus is ENDS products that are marketed directly to minors by promoting that they can be easily concealed from parents, teachers, or other adults.

We will also consider whether manufacturers have implemented adequate programs and retailer penalties to ensure that retailers comply with age and sales restrictions, as well as whether the manufacturer uses—or requires retailers to use—adequate age-verification technology to prevent underage access to its Web site or underage sales through the Internet. Consideration will also be given to whether manufacturers limit or require retailers that sell their products to limit the quantity of ENDS products that a customer may purchase within a given period of time.

Although we intend to prioritize enforcement against companies that have not taken the proper precautions to restrict youths from exposure and access to tobacco products, the policy is just one of many steps that the FDA is taking to combat youths' use of ENDS products.

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For example, the FDA is addressing the youth e-cigarette epidemic with comprehensive compliance and enforcement measures. Since 2016, the FDA has conducted more than 2000 vape shop inspections, has issued more than 11 000 warning letters, and has filed more than 1900 civil money penalties to retailers—both online and in brick-and-mortar retail stores—for selling ENDS and their components to minors.

The agency is also enforcing the increased minimum age at which a young person can legally be sold tobacco products. In December 2019, the US president signed legislation raising the federal minimum age for sale of tobacco products to 21 years. "Tobacco 21" is in effect now. Research shows that the younger people are when they start to use tobacco products, the more likely they are to become addicted to nicotine. By enforcing the new federal minimum age of sale of tobacco products, the FDA can help prevent youths and young adults from accessing tobacco products and a lifetime of nicotine addiction.

We also know from past successes with the FDA's award-winning "The Real Cost" smoking prevention campaign that effective public education campaigns can produce incredible results in terms of knowledge, attitude, and behavior change. Using the success in reducing youths' cigarette use and in response to the growing rates of adolescent e-cigarette use, the FDA launched its newest full-scale effort in September 2018, "The Real Cost" Youth E-Cigarette Prevention Campaign. The campaign's messages are delivered through a variety of channels, including television, online video ads, banner ads, an interactive "The Real Cost" Web site, and social media.

Since its launch, "The Real Cost" E-Cigarette Prevention Campaign has generated significant viewership, including nearly 3.6 billion adolescent impressions in 16 months. Across social media platforms, we have engaged adolescent audiences with more than 950 000 likes, 130 000 shares, and 50 000 comments.

We will continue to expand these highly successful and innovative efforts to warn and inform youths about the dangers of all tobacco products, including e-cigarettes. Through public education, compliance and enforcement, an investment in research, and our rigorous science-based approach to regulation, we have developed a multifaceted strategy to ensure that we are doing all we can to protect youths from the harms of tobacco products. The FDA remains committed to ending the youth epidemic of e-cigarette use and preventing the next generation from facing a lifetime of addiction and other potential tobacco-related dangers. AJPH

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CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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Flavors Are a Major Driver of the Youth E-Cigarette Epidemic

See also Dasgupta and Fiala, p. 759, and the *AJPH* After FDA Vaping Guidance section, pp. 771–789.

Considerable declines in cigarette smoking have occurred among US high school students over the past two decades: smoking declined from 30% in 2000 to 6% in 2019.[1] However, e-cigarette use has increased substantially over the past decade, with current use among high school students increasing from about 1% in 2011 to nearly 28% in 2019.[1] This increase was of greater magnitude in recent years, which coincided with the growing popularity of cartridge-based e-cigarettes known as "pod mods," including those made by Juul, the market leader since 2017.[2] These newer products use nicotine salts, which allow higher levels of nicotine to be inhaled more easily and with less irritation than the free-base nicotine used in earlier e-cigarettes. Nicotine is an addictive drug that can harm adolescent brain development and prime the brain for addiction to other drugs.[3]

The increase in youth e-cigarette use has been driven by multiple factors, including advertising, high nicotine content, and the availability of flavors that appeal to youths.[3] Youths report that flavors are a primary reason they use e-cigarettes, and most youth e-cigarette users first initiate use with flavored products.[4] Among youth e-cigarette users in 2019, 70% reported using flavored varieties, making e-cigarettes the most common flavored tobacco product used among youths.[1]

Under authority from the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA), the Food and Drug Administration issued a policy in January 2020 that prioritized enforcement against certain unauthorized cartridge-based e-cigarette flavors that appeal to youths, including fruit and mint. The policy was informed by available data, including from (1) a study of high school students that found the most commonly

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