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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reported flavors used by current exclusive e-cigarette users were fruit (66%) and menthol or mint (57%),[5] and (2) a study that assessed mint and menthol separately that found that among current Juul users in 8th, 10th, and 12th grades, the self-reported use of mint-, mango-, and other fruit–flavored e-cigarettes was greater than the use of tobacco- or menthol-flavored e-cigarettes.[6] The FSPTCA does not preempt states and localities from adopting more restrictive regulations than the federal standard in some instances. Accordingly, several communities have restricted flavored e-cigarette sales, including menthol; additionally, Massachusetts and New Jersey have enacted legislation prohibiting all flavored e-cigarette sales, and beginning in late 2019, seven other states issued executive or emergency actions to temporarily prohibit flavored e-cigarette sales, some of which were overturned after legal challenges (www.tobaccofreekids.org/assets/factsheets/0398.pdf).

Evaluation of these policies is critical to ascertain their impact on youth e-cigarette use. Such studies will also be important to identify any potential unintended consequences, including transitions to other tobacco products, e-cigarette types, or flavors excluded from some policies. In addition to annual self-reported surveys of youths, subannual assessments—including retail sales data from commercial databases and self-reported data from existing or newly developed Web panels—can quickly inform policy refinements that may be warranted to best protect public health.

We are at the precipice of a critical period in the history of tobacco control. Cigarette smoking has declined, but this progress has been offset by increased youth e-cigarette use.[1] The situation has been compounded by the recent outbreak of e-cigarette, or vaping, product use–associated lung injury (EVALI), which has mostly affected young adults and is strongly linked to vitamin E acetate in tetrahydrocannabinol-containing products from informal sources.[7] Although both the EVALI and youths' use epidemics have warranted urgent public health action, efforts to address each must focus on their drivers.[7] To effectively combat the youth e-cigarette epidemic, efforts at the national, state, and local levels are critical to make flavored e-cigarettes less acceptable, accessible, and appealing to youths.[3] It is important that such efforts are part of a comprehensive approach alongside other evidence-based population-level strategies.[3] AJPH

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CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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A List of Permissible Electronic Nicotine Delivery Systems Ingredients Would Be More Effective

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

On January 2, 2020, the US Food and Drug Administration (FDA) released a final guidance document for industry that restricted the sale of some flavors of some e-cigarettes.[1] As of February 6, 2020, the FDA prohibited the sale in all retail locations, including online, of cartridge-based e-cigarettes that are flavored with anything other than menthol or tobacco. This guidance is intended to reverse the epidemic of e-cigarette use among youths by restricting access to vape products that appeal to youths. Although a well-crafted policy has the potential to make a big difference, this guidance is riddled with vague or missing definitions, and these omissions create unacceptable loopholes.

Any enforceable policy should have precisely and clearly crafted definitions and provisions to ensure ease in compliance and enforcement. This guidance fails to provide such clarity. First, the administration applies this restriction to only "cartridge-based ENDS products"—the vague definition includes products that have "cartridges or pods," which are "small, enclosed units (sealed or unsealed)" that are made to be used with e-cigarettes. This definition does not specify clearly which e-cigarettes are included and which are not, and this presents enforcement challenges. Although the FDA clarifies in the guidance that it does not intend to restrict tank systems, the definition does not clearly exempt such systems.

A second shortcoming of this guidance is that it leaves open a major loophole by omitting disposable products from the definition of cartridge-based ENDS products. Although Juul has commanded a large market share

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