products to be maximally addictive, and more.[2] Without regulation or product review, the irresponsible actors had an upper hand in the marketplace.

The FDA's January 2020 guidance has to be viewed in light of this history. The FDA has now belatedly responded to the flavored e-cigarettes that have flooded the market and contributed to the surge in youths' e-cigarette use, but the FDA's guidance is no substitute for premarket review. Among other missed opportunities, the guidance does not address flavored cigars and only applies to a too-narrow subset of the e-cigarette market. But the missed opportunity that stands as a microcosm of FDA tobacco regulation is the exemption for menthol-flavored e-cigarettes.

In 2009, Congress exempted menthol from the Tobacco Control Act's rule restricting flavored cigarettes, instead instructing the FDA to review the science and determine whether menthol cigarettes should be prohibited as well. Since that time, the agency has seemingly gone out of its way to avoid regulating menthol. The agency commissioned reviews from its advisory committee, its own scientists, and external peer reviewers, with all groups concluding that removing menthol from cigarettes would benefit public health.[2] The FDA has also requested additional information on menthol from the public twice. But after all of this research—and despite numerous commitments from FDA commissioners—the agency has yet to even propose removing menthol from cigarettes or any other tobacco product. Not only that, but the FDA continues to authorize new menthol tobacco products for sale, including combustible products.

In the January 2020 guidance, the FDA insists that menthol should be exempted because people who currently use menthol cigarettes "may be looking for an alternative product to seek to transition completely away from combusted products."[3(p23)] Whether menthol e-cigarettes actually make it easier for current menthol smokers to quit is still unknown,[4] but regardless, a better way to reduce cigarette use would be for the agency to remove menthol from combustible products, rather than exempt it again in noncombustible ones. The FDA's past missteps should not be the excuse preventing further progress. (The FDA also tries to establish that youths are not attracted to menthol e-cigarettes, a conclusion not supported by the evidence.[5])

Premarket review was intended to allow the FDA to proactively protect the public from new products that pose population health risks. But with the January 2020 guidance, the FDA is still stuck looking backward. AJPH

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The authors jointly conceptualized, drafted, and edited the comment.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

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Shortcomings of the Food and Drug Administration Guidance Addressed by Congress 2020 HR 2339

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

The Food and Drug Administration (FDA) took an important step toward curbing youth access to flavored vaping products by outlining clear enforcement priorities in guidance released in January 2020. A close review of the guidance reveals, however, that it is lacking. If the FDA is unwilling or unable to address significant gaps in its approach to regulating vaping products, it is incumbent on federal and state legislators to step in to protect our children.

Data from the 2019 survey E-Cigarette Use Among Louisiana Youth reveal deeply troubling patterns that require decisive and immediate action.[1] Before flavored vaping products became widely available and marketed toward youths, my home state of Louisiana saw trends of declining tobacco use among youths.[2] This trend was promising in a state that has long ranked among the highest in the nation on rates of tobacco use and tobacco-related disease. Unfortunately, more recent surveys on youths' use of e-cigarettes show a reversal of those hopeful trends: 31.6% of high school students report e-cigarette use in the last 30 days in 2019, up from 12.3% in 2017. Research shows that vaping is a gateway to cigarettes and more traditional tobacco products.[3] Additionally, exposure to nicotine negatively affects cognitive function in adolescents.[4]

The regulatory gaps left unaddressed by the FDA guidance are clearly outlined in comments submitted to the FDA by a bipartisan group of 26 attorneys general in February. The FDA guidance does not apply to menthol vaping products and does not apply to refillable or sealed disposable vaping products, the latter of which are

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becoming increasingly popular among youths.[5,6] The guidance also refers to vaping as a means of transitioning off traditional tobacco products, overlooking the fact that vaping products are not recognized as effective methods of tobacco cessation and therefore the FDA has not given any of them premarket authorization for that purpose.

Many of the shortcomings of the FDA guidance have been addressed by legislation passed by the US House of Representatives. HR 2339, the Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020, bans flavored vaping products regardless of the type of electronic delivery system and outlaws menthol-flavored vaping and tobacco products, including menthol cigarettes.[7] The bill also imposes a tax on the nicotine in e-cigarettes and establishes a demonstration grant program to develop strategies for smoking cessation in medically underserved communities. However, in the Republican-controlled US Senate, this legislation and similar legislation introduced by Senator Sherrod Brown (D, OH) faces an uphill battle.

When crafting critical policy solutions, policymakers should carefully consider unintended consequences. Penalties and enforcement should be focused on sellers of illegal vaping products, rather than users of such products. Laws and regulations should evolve as new products emerge. Evidence-based tobacco cessation solutions should be ubiquitous and available without cost sharing or other restrictions.

Lawmakers should know from their experience with the tobacco industry that the companies that manufacture and sell vaping products cannot be trusted to self-regulate or to stop targeting these products to youths. Lawmakers at all levels of government have a critical role to play in protecting the next generation from the dangers of nicotine addiction and tobacco use. Tobacco use continues to be the leading cause of preventable death worldwide. Skyrocketing youth vaping rates, if left unchecked, could not only undo critical gains from decades of efforts to curb tobacco use but worsen the rates of smoking from previous baselines. These gaps must be addressed in additional FDA guidance or targeted legislation. AJPH

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CONFLICTS OF INTEREST

R. E. Gee reports no relationships or financial interest with any entity that would pose a conflict of interest with the subject matter of this comment.

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Restricting Flavors in ENDS Could Have Repercussions Beyond Youths' Use

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

In January of this year, the Food and Drug Administration (FDA) issued a guidance ("Guidance") prioritizing removal from the market of flavored, cartridge-based electronic nicotine delivery systems (ENDS), as well as products that the agency deems to target underage youths. The FDA reasoned that this Guidance was a necessary response to youths' use of ENDS and a 2019 outbreak of vaping-related lung disease (EVALI), although the latter was confirmed to be associated with products containing THC (tetrahydrocannabinol, the principal psychoactive constituent of cannabis). This approach appears to be a stark departure from former FDA commissioner Scott Gottlieb's 2017 views that ENDS were a helpful step down the risk continuum.

Smart tobacco harm reduction regulation should be comprehensive with respect to the nicotine products it addresses and should aim to move consumers down the risk continuum toward use of reduced risk products. Bans decelerate harm reduction and renormalize cigarette use. Worryingly, a number of countries have already veered down the path of prohibition. Existing regulatory actions include the following: ENDS flavor restrictions in the United States, a ban on snus in the European Union (although the FDA has recognizing this product as less risky than cigarettes), and complete bans on noncombustible nicotine products in several Asian and South American countries.

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