HHS Public Access

Author manuscript

JAMA Pediatr. Author manuscript; available in PMC 2022 July 12.

Published in final edited form as:

JAMA Pediatr. 2021 November 01; 175(11): 1102–1104. doi:10.1001/jamapediatrics.2021.2432.

Collaborative Public Health Strategies to Combat e-Cigarette Regulation Loopholes

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The 2020 National Youth Tobacco Survey reported a decline in youth electronic cigarette (e-cigarette) use from the previous year, reversing an increasing trend. Although reported use of all e-cigarettes fell to 19.6% and 4.7% among high school and middle school students, respectively, the use of disposable e-cigarettes increased 1000% and 400% for these groups.[1] This shift may have been precipitated by the 2020 US Food and Drug Administration (FDA) policy action that exempted disposable devices from restrictions on flavored e-cigarettes. The current popularity of disposable e-cigarette brands, such as Puff Bar, suggests that e-cigarette companies were able to exploit this loophole. Although the FDA's warning letters[2] in July 2020 temporarily caused Puff Bar to cease sales, the company resumed sales and marketing in January 2021, claiming use of synthetic nicotine. This highlights the need for coordinated comprehensive action by policy makers as well as public health and medical professionals to curb youth e-cigarette use. This Viewpoint summarizes recent efforts by the FDA and state lawmakers to address the youth e-cigarette epidemic and offers a framework to further guide these efforts.

The FDA and e-Cigarette Regulations: A Game of Cat and Mouse

In 2019, e-cigarette use by US youth reached an all time high with 27.5% of high school students and 10.5% of middle school students reporting use. These rates were propelled by flavored e-cigarette products that were particularly appealing to youth.[3] e-Cigarette companies, such as JUUL, used appealing flavors like mango in their social media–based marketing strategies. Not surprisingly, JUUL became the market leader, and the majority of youths who reported using e-cigarettes named JUUL as their preferred product.[3]

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Additional Contributions: We thank Michelle Woods, MA (University of Pittsburgh), for her editorial assistance and Beth Hoffman, MPH (University of Pittsburgh), for her insightful discussions. Neither received compensation for her contributions.

Conflict of Interest Disclosures: Dr Chu reported receiving an award from the National Cancer Institute, and Dr Sidani reported receiving awards from the National Institute on Drug Abuse and the American Heart Association. No other disclosures were reported.

Prompted by the National Youth Tobacco Survey results, in April 2020 the FDA issued an enforcement policy halting "the manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes" as well as requiring manufacturers to reduce youth access.[4] In an effort to balance considerations for adult e-cigarette users, this regulatory action focused on cartridge-based products, such as JUUL, and exempted disposable devices. e-Cigarette companies quickly took advantage of this loophole. The most popular disposable brand, Puff Bar, looked nearly identical to JUUL and sold similar flavors.

In July 2020, the FDA issued warning letters[2] to 10 of these companies, including Puff Bar, instructing them to remove their products from the market, citing their introduction after the August 8, 2016, effective date of the deeming rule bringing all tobacco products under FDA authority. For several months, Puff Bar's website ceased product sales, although anecdotal evidence suggested sales continued in alternative online retailers as well as offline outlets. In January 2021, however, Puff Bar resumed website sales—including flavored products—stating that their "nicotine-based products are crafted from a patented manufacturing process, not from tobacco," while also stating their "products are not intended to diagnose, treat, cure, or prevent disease,"[5] thus potentially circumventing regulation from the FDA as either a tobacco product (regulated by the Center for Tobacco Products) or a drug (regulated by the Center for Drug Evaluation and Research). As mentioned in a recent advocacy letter to the FDA acting commissioner, this game of cat and mouse illustrates the need to use additional strategies to reduce youth e-cigarette use, especially in consideration of potential regulatory loopholes.[6]

The PSA Framework

The following framework offers a strategy for those focused on tobacco control (eg, policy makers, researchers, and clinicians) to work together to comprehensively address youth e-cigarette use. We coined the title "PSA Framework" to reflect the public health strategy of public service announcements, which have often been employed for youth substance use prevention.

P: Policy Surveillance

Individual states may already possess some enforcement authority over products containing synthetic nicotine. Some states (eg, California, Colorado) define *tobacco products* as including products derived from nicotine. Other states (eg, Alaska) do not include e-cigarettes in the definition of *tobacco products*, but they do include nicotine within their definition of e-cigarettes.[7]

A comprehensive assessment of state-level policies is needed to gain a thorough understanding of how products containing synthetic nicotine might be regulated by states. Policy makers may not be aware that these products exist or how they fit within the state's policies. Therefore, we suggest that state policy makers be queried to measure their knowledge about these products and potential policy loopholes. Tobacco prevention and control agencies, state and local health departments, and schools of medicine and public health are likely valuable partners in this regard, as are state attorneys general, who are engaged in enforcement activities against e-cigarette manufacturers and retailers.

S: Study Policy Consequences

Given the intersection between individual-level factors, social factors, and policy, it may be valuable for researchers to use systems science approaches—interdisciplinary methods that present more holistic and interactive models—in conducting research on the potential implications, both intentional and unintentional, of policies designed to curb youth e-cigarette use. Traditional statistical models are often inattentive to the interdependence and multi-level factors that affect the real-world implications of these policies. Techniques such as social network analysis could be applied to understand how peer relationships affect the consequences of policy; agent-based modeling, which inherently incorporates sociodemographic characteristics and geospatial variables, can reveal important factors in e-cigarette trends. For example, agent-based modeling can help identify potential system adaptations to specific policies, as seen in the shift in youth e-cigarette use from JUUL to disposable devices such as Puff Bar after FDA policy action.

A: Ask Youths

Youths use different terminology than adults when discussing e-cigarette products, and many do not understand the presence of nicotine in popular e-cigarette brands.[8] Thus, if youth-serving clinicians inquire only about tobacco and nicotine use without specifying e-cigarette use or even popular brand names, youths may inadvertently fail to disclose their use. This could result in a missed opportunity for clinicians to deliver educational messaging and connect them to tobacco cessation services. Research examining this discordance can aid in the development of comprehensive screening tools for clinicians. Likewise, community-partnered research with youths can lead to interventions that are more effective in reaching and resonating with young people. For example, peer health educators can use common terminology to educate other youth on both the dangers of e-cigarettes and other tobacco or nicotine use and on tobacco marketing.

Conclusions

Actions such as those by Puff Bar demonstrate that e-cigarette companies will find avenues to continue selling flavored e-cigarettes despite federal regulatory actions meant to curb youth use. The sudden uptake of disposable e-cigarettes demonstrates the success of this strategy. While the FDA continues to act at the federal level, the PSA framework can help guide additional multilevel coordinated efforts to inform the agency of apparent regulatory loopholes and their effects. This may best be achieved through a consortium of entities and individuals (eg, researchers, clinicians, organizations) interested in tobacco control, policy makers (eg, state attorneys general, lawmakers at all governmental levels), and other key stakeholders (eg, youth, parents, educators) convened and guided by a federal agency such as the Centers for Disease Control and Prevention. For example, this consortium may use the PSA framework to conduct activities such as in-depth examinations of youth use of new tobacco and nicotine products; this information can then be used to review existing policies for potential loopholes and inform policy solutions to close such loopholes.

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