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E-cigarette regulation: a delicate balance for public health

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Abstract

To address youth vaping, a regulatory strategy is required that includes removal of flavors from all tobacco products, closing the cartridge loophole, and an e-cigarette liquid product standard that decreases palatability to naïve users. Lawmakers, public health officials, and scientists need to collaborate, utilizing evidence-based approaches, to rigorously evaluate tobacco regulation policy.

Keywords

E-cigarettes; electronic nicotine delivery systems; public health policy; tobacco regulation; tobacco regulatory science; youth

In response to the rapid increase of youth e-cigarette use, the US Food and Drug Administration (FDA) recently announced their intention to prioritize enforcement against any flavored, cartridge-based e-cigarettes (other than tobacco or menthol), and raised the age of tobacco sales to 21 [1]. These policies are a well-intentioned step towards reducing e-cigarette use among youth, who have been shown to prefer cartridge-based devices, as well as fruit and mint flavors, over other tobacco-flavored e-cigarettes [1]. While the focus on cartridge-based flavors will probably reduce the appeal of e-cigarettes among youth, its overall effect on youth vaping may not be as impactful as intended. Its focus is too narrow, neglecting to consider the rapidly changing e-cigarette market and other product elements. First, our data suggest that in response to a cartridge flavoring restriction, youth will probably switch to a different product rather than discontinue e-cigarette use. In April 2019, 5 months after JUUL Laboratories, a popular e-cigarette company in the United States, removed the sale of fruit-flavored pods to brick-and-mortar stores, we conducted a national

survey among youth ever-users of e-cigarettes (aged 13–17 years; $n = 507$; 37% current e-cigarette users) to examine if these restrictions altered use among youth ever-users of any e-cigarette product. Data were collected through Qualtrics, and youth self-selected into the study if they had ever used JUUL, vapes or e-cigarettes. Qualtrics recruited a national sample of youth and data were weighted to be nationally representative based on US Census data. Among youth who had tried JUUL (74.6% of the sample (weighted), unweighted $n = 389$), only 28% (unweighted $n = 70$) indicated that the flavor restrictions had impacted their use; of those, 46% stopped using JUUL (unweighted $n = 19$), 27% changed their purchasing behavior to either obtain pods on-line or use non-JUUL branded pods (unweighted $n = 27$) and 25% switched to a mint or tobacco flavor (unweighted $n = 19$). Youth use of mint and menthol is supported in other, more comprehensive national surveys. Recent data from Monitoring the Future, an annual national survey on tobacco, drug and alcohol use among youth, indicated that mint was the most popular flavor among high school JUUL users and the second most popular flavor among middle schoolers [2]. While mint cartridges are now impacted by the regulation, menthol—a close relative of mint—remains on the market. Data from the 2019 National Youth Tobacco Survey suggest that youth use of flavored tobacco products is not limited to e-cigarettes, much less cartridge-based e-cigarettes [3]. In fact, flavored tobacco product use is common among current tobacco-using middle and high school students, with almost half this group using flavored smokeless tobacco (48%), menthol cigarettes (47%), flavored cigars (42%) and almost a third using flavored hookah (31%) [3]. Taken together, enforcement against e-cigarette flavors without a restriction on all flavored tobacco products [2], including menthol products [4–6], may inadvertently provide flavored alternatives to e-cigarettes and potentially lead to an increase in youth use of more harmful products.

Secondly, e-liquid flavors do not appear to be the only major catalyst for the surge in youth vaping. Our data suggest that a flavor restriction may not be enough to prevent youth from experimenting with or using pod-style e-cigarettes. If tobacco were the only flavor available to youth, 46% of respondents indicated they still would have tried JUUL (unweighted $n = 163$) and 44% indicated that they would continue to use JUUL (unweighted $n = 39$). Flavored e-cigarettes have been on the market since the late 2000s, yet youth e-cigarette use declined by 29% during 2015–16, where it remained up to 2017 [7]. It was not until the proliferation of nicotine-salt-based, pod-style e-cigarette devices, of which the most well-known is JUUL, that youth e-cigarette use increased by 135% to the current re-cord high (28%) [7]. Sales of pod-style devices increased between 2017 and 2018, yet prevalence of current and daily e-cigarette use declined or remained stable in older age groups, suggesting that youth and young adults are the primary consumers [8]. Unlike ‘free-base’ nicotine e-liquids used in earlier e-cigarette models, the lower pH of nicotine salt-based e-liquids reduces the harshness of the aerosol, making it easier for ‘tobacco-naive’ users to in-hale high levels of nicotine. The tobacco industry has utilized similar methodology to alter the pH and alkalinity [9] chemistry of the smoke from different brands of cigarettes to improve user palatability and create more effective nicotine delivery. Thus, by increasing palatability (i.e. increasing protonation of the e-liquid), recent and emerging data suggest that nicotine salts allow for higher nicotine concentrations in e-liquids and leads to more intense puffing (i.e. greater average flow rate and puff volumes) and greater nicotine delivery [10]. Future

research focused on the impact of e-liquid product standards (e.g. minimum pH level) on product use experience and liability is needed to inform federal regulations to make pod-style and other emerging products less desirable for tobacco-naive and never-users. In the meantime, we would encourage tobacco regulatory scientists and researchers to work with state and local governments to identify evidence-based tobacco control policies to help curb youth use in their respective communities.

Thirdly, in the newly published enforcement document from the FDA [1], the definition of a cartridge is too narrow, leaving the door open for youth to immediately switch to disposable, all-in-one e-cigarette devices. The FDA guidance defines a cartridge as ‘any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an ENDS product’ [1]. While this definition will capture both closed-system cartridge devices such as JUUL and open-system cartridge devices such as Suorin, it explicitly excludes devices that are completely self-contained, disposable products [1]. Unfortunately, there are already several products on the market that fall into this loophole (e.g. SEA Pods, Puff Bar), which offer flavors ranging from watermelon and pineapple lemonade to banana ice, all of which use high concentrations of palatable nicotine salts. Given the rapidly changing e-cigarette market-place and emerging new tobacco products (e.g. heat-not-burn devices such as IQOS), and other cigarette products which contain flavored capsules (e.g. Camel Crush), it will be important for the FDA to include guidance for emerging products to circumvent any legislative change and other unintended consequences of more comprehensive e-cigarette flavor ban (e.g. black market products; unregulated mixing of nicotine and food flavors).

Finally, it is important that we do not lose sight of the fact that cigarette smoking remains the leading cause of preventable death in the United States [11]. Although preventing youth use of e-cigarettes remains a critical goal for public health, we cannot ignore the potential impact of e-cigarette regulation on adult smokers who have switched to vaping [12]. Concurrent efforts to regulate flavored combustible tobacco products, especially menthol cigarettes, should be considered to lower cigarette consumption among adult smokers [13,14] and prevent those who have switched to vaping from returning to conventional cigarettes [15]. In sum, to begin to effectively address youth vaping, we recommend a regulatory strategy that includes the removal of flavors, including menthol, from all tobacco and emerging products (e.g. IQOS) and closing the cartridge definition loophole in the current regulation. We also recommend rapidly conducting studies to evaluate the efficacy of an e-cigarette liquid product standard that makes the product less palatable to naive users by setting a minimum pH level to limit the proportion of nicotine in the protonated form. It is important for lawmakers, public health officials and scientists to work together, utilizing evidence-based approaches whenever possible, to rigorously evaluate tobacco regulation policy.

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