The FDA Must Continue to Regulate E-Cigarettes To Protect Children

Population Health Sciences

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Editor's note: This blog post, originally appearing on the Health Affairs blog, comes shortly after the Food and Drug Administration (FDA) announced new efforts to reduce tobacco-related suffering, while also rolling back enforcement of its "deeming regulation" over e-cigarettes and cigars. PolicyLab researcher Dr. Brian Jenssen banded together with his colleagues in the American Academy of Pediatrics (AAP) Section on Tobacco Control to respond. Formed in July 2012, the section includes pediatricians who face the daily challenges of addressing tobacco issues with patients, families and the community. In this blog post, Dr. Jenssen and his colleagues provide an overview of how e-cigarettes can lead youths to traditional tobacco products and discuss the ways the FDA can help children, adolescents and families live tobacco-free lives.

Last year, after nearly a decade of inaction, the Food and Drug Administration (FDA) made significant advancements in the regulation of e-cigarettes. Through its "deeming regulation," the agency required manufacturers provide information for the assessment of public health risks of new tobacco products, defined as products introduced to the market after February 15, 2007 (referred to as the "grandfather date"). However, on July 28, 2017, the FDA announced that the office would delay the enforcement of the deeming regulation and move back the grandfather date to August 8, 2016, which would prohibit the FDA from exercising its appropriate authority over e-cigarettes currently on the market.

The FDA's e-cigarette deeming regulation was an important step to help the agency catch up with dramatic shifts in the marketplace, putting into place rules that protect children, including a ban on sales to minors, and giving adults information they need to make informed decisions by reigning in false and unverified health claims. Instead, the changes announced last month to delay enforcement would harm child, adolescent, and public health, and adversely affect the FDA's charge to protect consumers and minimize risk associated with these previously unregulated and harmful tobacco products.

As practicing pediatricians and tobacco control researchers, we are uniquely positioned to advocate for the health of children and their families, helping protect them from the harms of tobacco and empowering them to live tobacco-free lives. One out of every five deaths in the United States is related to tobacco, and tobacco causes 480,000 preventable deaths and $300 billion in costs annually. Tobacco use and addiction almost always start in childhood or adolescence, making it a critical pediatric concern.

E-cigarettes are the most commonly used tobacco product among youth. The 2016 Surgeon General's report on e-cigarette use among youth and young adults concluded that e-cigarettes are unsafe for children and adolescents. Further, strong and consistent evidence finds that children and adolescents who use e-cigarettes are significantly more likely to go on to use traditional cigarettes – a product that kills half its long-term users. E-cigarette manufacturers regularly target children with enticing candy and fruit flavors and use targeted

marketing strategies that have been previously successful with traditional cigarettes to attract youth to these products. To prevent children, adolescents, and young adults from transitioning from e-cigarettes to traditional cigarettes and minimize the potential public health harm from e-cigarette use, the FDA cannot be delayed any further in regulating the production and marketing of these products.

E-Cigarettes Pose a Unique Threat to Young People

E-cigarette use among youth has risen rapidly since their introduction to the U.S. in 2007, surpassing conventional cigarettes in 2014, with 11.3 percent of high school and 4.3 percent of middle school students reporting use in 2016. Although these percentages represent a decline compared to 2015, nonetheless more than 2 million middle and high school students used e-cigarettes in 2016. These devices typically deliver nicotine, flavorings, and other additives (including those unknown and/or unadvertised to the user) via an inhaled aerosol. There is wide variability in terminology, product design, and engineering of these products, with alternative names including e-cigs, electronic cigars, electronic hookah, e-hookah, personal vaporizers, vape pens, vaping devices, mods, and tank systems.

Nicotine, regardless of the form in which it's delivered, is highly addictive and harms the health of infants, adolescents, and young adults, as summarized in the recent U.S. Surgeon General report. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain. It also poses a threat to the unborn, as it crosses the placenta and has known effects on fetal and infant development. Therefore, nicotine delivered by e-cigarettes during pregnancy can result in multiple adverse consequences, including altered brain development and sudden infant death syndrome.

Producers and Sellers of E-cigarettes Target Children and Adolescents

Although e-cigarette advertisers often claim the secondhand aerosol is "harmless water vapor," these claims are false: known harmful toxicants and carcinogens have been found in e-cigarette emissions. Non-users can be harmed by the secondhand and thirdhand aerosol (residual nicotine and other chemicals left on surfaces), which have been shown to contain known toxicants, including carcinogens, formaldehyde, metal particles and nicotine.

E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults. The increased use of and exposure to e-cigarettes among youth, combined with dramatic increases in marketing, have serious potential to undermine successful efforts to deglamorize, restrict, and decrease the use of tobacco products. The unique flavors offered in e-cigarette solution, the majority of which are confectionary in nature and appealing to children, have been shown to encourage youth experimentation, regular use, and addiction in both traditional and e-cigarettes.

Studies of U.S. youth who use e-cigarettes identify remarkably consistent findings: adolescents and young adults who use e-cigarettes compared to those that do not are at higher risk of transitioning to traditional cigarettes. This is based on evidence from seven separate, well-designed, long-term follow-up studies, summarized and analyzed in a recent meta-analysis. Additionally, adolescents who use e-cigarettes appear to have fewer social and behavioral risk factors than conventional cigarette users, meaning that adolescents previously at low-risk for using cigarettes could find themselves drawn to traditional tobacco products through their e-cigarette use. These findings raise significant concern that e-cigarettes have the potential to addict a new generation to nicotine and tobacco, slowing or reversing the decline in adolescent cigarette smoking that has occurred over the past 20 years.

Potential Benefits to Current Tobacco Users Unsupported by Scientific Evidence

Finally, health claims that e-cigarettes are effective smoking cessation aids are not currently supported by scientific evidence. Further, studies in real world clinical settings of smokers interested in quitting find that e-cigarette users have lower rates of successful quitting compared to never e-cigarette users. E-cigarettes are neither FDA-approved nor have they been shown to be effective or safe for helping smokers quit. Several FDA-approved smoking cessation medications are already available. New treatment methods for tobacco addiction are needed and welcome. Public health recommendations and evidence-based guidelines must be based upon scientific inquiry and discovery, transparent data collection, and unbiased data interpretation and analysis. As practicing physicians, we need well-designed studies on safety and efficacy, in particular, health-related outcomes, prior to recommending e-cigarettes as another tool to help tobacco users quit. Given the current state of the science, smokers interested in quitting should seek and be referred to evidence-based, safe, and effective treatments, including nicotine replacement therapy (NRT), behavioral counseling, and additional pharmacotherapy.

Action Based on Current Evidence

The FDA's deeming regulation on e-cigarettes closed a significant regulatory gap, following the scientific evidence and appropriately extending their authority over these previously unregulated products. Delaying compliance with this 2016 regulation will have dangerous consequences and hamper the ability of FDA to carry out its mandate to protect the public's health.

A booming industry emerged during a 10-year period without regulation, intentionally targeting children, harming youth health, and making claims minimizing harms and purporting benefits unsupported by scientific evidence. In that short time, e-cigarettes have become the leading tobacco product used by youth, threatening to addict a new generation of children and adolescents to a lifetime of tobacco use. More scientific inquiry into the role, if any, of these products in helping adult smokers quit is needed. Regardless, there are clear, scientifically sound steps needed for e-cigarette regulation to protect the health of our children. Action should not be delayed any further. The e-cigarette 2016 deeming regulations should be enforced as written.

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