The decision by the Food and Drug Administration (FDA) allowing R.J. Reynolds Tobacco Co. to market e-cigarette products with high nicotine levels is wrong on multiple levels—but the agency’s gravest error is to frame its action as “appropriate for the protection of the public health.”

The Premarket Tobacco Product Application pathway requires applicants to provide scientific data that demonstrates a product is appropriate for the protection of public health. In the case of Vuse, the agency found that tobacco-flavored products could benefit addicted adult smokers who switch to these products by reducing their exposure to harmful chemicals due to cigarette consumption.

However, the role that e-cigarettes may play in smoking cessation strategies is unclear. To date there has not been a rigorous independent study that supports e-cigarettes as a gateway to quitting smoking. In fact, a recent study published in *JAMA Network Open* suggests that smokers who turned to e-cigarettes as a cessation device had a higher relapse rate back to smoking than those who remained tobacco-free.

As the FDA acknowledges in allowing the marketing of Reynolds’ Vuse brand, “all tobacco products are harmful and addictive.” The AMA has specifically recognized the use of e-cigarettes and vaping as an urgent public health epidemic and has called for a total ban on all e-cigarette and vaping products that do not meet FDA approval standards as cessation tools.

Data has shown that using FDA-approved cessation medicine can double a person’s chance of quitting smoking successfully. These products include over-the-counter options like skin patches, lozenges and gum, as well as prescription medicines.

We don’t yet know what the corresponding death toll from e-cigarettes is or will be, because the technology has not been around long enough to measure its long-term impact on health. A study by researchers from the FDA and Centers for Disease Control and Prevention estimated that more than 2 million U.S. middle and high school students reported using e-cigarettes in 2021, with more than eight in 10 of those youth using flavored e-cigarettes. The use of products containing nicotine in any form
among youth, including e-cigarettes, is unsafe and can cause addiction.

E-cigarettes’ growing popularity

The rapid adoption of e-cigarettes and other electronic nicotine delivery system (ENDS) devices by adolescents, teens and young adults—especially in fruit- and candy-flavored versions—has only compounded the problem. Young people are even more at risk based upon the effect nicotine has on the developing brain in the areas of impulse control, attention span and the ability to learn.

We know that brain development takes place into a person’s early 20s, and that addiction itself is a form of learning. Addiction to nicotine at an early age effectively “primes” the brain for addiction to other drugs.

Of particular concern is the continued dominance of candy- and fruit-flavored e-cigarettes among youth. To its credit, the FDA has warned 10 manufacturers of flavored disposable e-cigarettes and e-liquid products to stop selling these items because they lack the premarket authorization required for legal sale. The FDA has also issued marketing denial orders to three companies covering for more than 50,000 flavored ENDS products, which have proven highly popular with teens and young adults. Even so, the FDA has yet to rule on pending applications from more than 500 other companies.

Faster regulatory action needed

Based on prior FDA action, sales of cartridge-based e-cigarettes such as Juul—now sold only in tobacco and menthol flavors—have plummeted among youth, who have switched their preference to disposables in flavors like strawberry, watermelon and mango. The latest CDC survey indicated that 85% youths who vape opt for candy, fruit, mint and other flavors.

Our AMA believes the FDA must act much more quickly to keep flavored disposable e-cigarettes and ENDS devices out of the hands of adolescents and teens. We simply cannot afford to allow another generation of Americans to endanger their health by using e-cigarettes and other vaping devices. We will continue to support policies and regulations aimed at preventing another generation from becoming dependent on nicotine.

Our AMA has led the fight against tobacco use for more than half a century, and our fight against nicotine addiction will remain robust no matter what method is used to deliver this harmful drug. The FDA’s action regarding Vuse, and its slow pace of enforcement actions on flavored disposables, sends the wrong message that these instruments of nicotine addiction are safe when reality, science and evidence tells us otherwise.

URL: https://www.ama-assn.org/about/leadership/fda-made-wrong-choice-allowing-vuse-marketing
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