Including E-Cigarettes in the FDA Rule Limiting Nicotine

The Biden administration, in conjunction with the US Food and Drug Administration (FDA), recently announced plans to cap the nicotine concentration in combustible cigarettes. In decoupling cigarettes from the addictive compound nicotine, this rule could end more than a century of illness and death from traditional cigarettes. But that proposal leaves out youths: only 2% of US high school students smoke, yet 14% of them use e-cigarettes. For the following reasons, the FDA should consider capping nicotine levels in e-cigarettes as well.

From Cigarettes to E-Cigarettes

The proposed nicotine limit is an overdue response to the 100-year lesson that cigarettes are gravely hazardous to public health. Historically in vogue in the early 1900s, viewed as healthy, and even promoted by physicians, cigarettes would not see coalescing opposition until the late 1950s, culminating in the US surgeon general’s 1964 report that made national headlines. Even then, the tobacco industry continued to defeat regulation into the 1990s, when a large wave of lawsuits hurt tobacco sales and led to the 1996 Master Settlement Agreement between 46 states and the major tobacco companies. In part due to the difficulty in regulating tobacco companies, tobacco use became—and remains—the leading cause of death in the US. The FDA’s plan to limit nicotine content in cigarettes could produce historic public health gains.

Cigarettes are not the only tobacco product impacting public health: e-cigarettes, which rose to prominence in the last decade, spawned a new generation of combustible cigarettes. In decoupling cigarettes from the addictive compound nicotine, this rule could end more than a century of illness and death from traditional cigarettes. But that proposal leaves out youths: only 2% of US high school students smoke, yet 14% of them use e-cigarettes. For the following reasons, the FDA should consider capping nicotine levels in e-cigarettes as well.

Failing to include e-cigarettes [in the proposed nicotine cap] runs the risk of reversing decades of public health progress against tobacco.

E-cigarette advocates often point to the UK as a model for public health-driven e-cigarette use. The UK (as well as the European Union) imposes a nicotine limit of 20 mg/mL on e-cigarette products (a concentration of approximately 2%). The US is an outlier for permitting much higher nicotine concentrations in e-cigarettes.

Perhaps the biggest concern with limiting nicotine in e-cigarettes would be causing e-cigarette users to switch to combustible cigarettes. But because a more expansive rule could cap nicotine levels in both products, the FDA has a unique opportunity to benefit youths and adults. Importantly, nicotine replacement therapy and the drugs bupropion and varenicline are FDA approved for tobacco cessation and would remain available. Pharmacotherapy coupled with behavioral therapy remains the gold standard for helping adults quit smoking, receiving an “A” grade from the US Preventive Services Task Force, compared with an “I” (insufficient evidence) for e-cigarettes.

E-cigarettes also carry significant long-term risks. To generate aerosol, e-cigarettes reach a range of higher temperatures that can trigger chemical reactions within the device. In contrast, nicotine replacement therapy delivers nicotine into the body without exposure to other harmful chemicals found in e-cigarettes.

Cigarette companies pushed their products into the US consciousness in part by portraying them as benign, even healthful. It took a century to build the political will to establish a regulatory apparatus that would address cigarettes and obtain some control over tobacco company practices. According to industry and some researchers in the harm reduction community, e-cigarettes carry medical and public health promise. But the practices of...
e-cigarette companies suggest that they are following in the footsteps of cigarette companies. In a recent example, Altria Group Inc (the rebranded parent company of Philip Morris USA) acquired vaping company NJOY Holdings Inc in March 2023 for $2.75 billion.

**The FDA’s Authorities and Legal Concerns**

The Family Smoking Prevention and Tobacco Control Act of 2009 granted the FDA the power to create “tobacco product standards,” including provisions about “nicotine yields” or “respecting the construction, components, ingredients, [and] additives” of tobacco products. These authorities give the FDA clear authority to limit nicotine in tobacco products. Given that the tobacco industry has been quick to sue the FDA’s Center for Tobacco Products throughout its history, FDA must be prepared for innovative legal arguments.

The FDA has already authorized a handful of e-cigarette devices, finding that the products were “appropriate for the protection of public health.” Tobacco companies might assert that a nicotine limit is inconsistent with those prior authorizations. The FDA could counter by noting that e-cigarettes were authorized to displace more addictive traditional cigarettes, but with a nicotine limit for cigarettes in place, e-cigarettes with higher levels of nicotine would no longer be “appropriate for the protection of public health.”

More worrisome, the Supreme Court’s “major questions doctrine” gained elevated status in *West Virginia v EPA* (2022). This judicially created rule allows courts to scrutinize actions deemed “major” in their economic or political significance. Because limiting nicotine content in cigarettes and e-cigarettes to nonaddictive levels might meet this threshold, Congress must have been “clear” in giving the FDA this power. Although the FDA can create standards for nicotine yields and ingredients and additives, a court might consider a standard that substantially lowers nicotine content to be de facto ban. Indeed, the law prohibits the FDA from reducing nicotine levels in tobacco products to zero. But the FDA is permitted to cut nicotine levels to nonzero quantities; and this authority applies equally to cigarettes and e-cigarettes.

The Biden administration must move fast—both because of the urgency of tobacco addiction and the possibility that a change in administration could derail the substantial effort the FDA has put into this proposal. Any rulemaking must be approved by the US Department of Health and Human Services, the Office of Management and Budget, and the White House. A larger proposal would be more legally complex, and the FDA might understandably want to take a smaller bite out of US tobacco use for the moment by focusing exclusively on cigarettes. On the other hand, because rulemaking is a lengthy and intensive process, it would be more efficient in the long term to include e-cigarettes as part of the current process.

**Ending the Tobacco Epidemic**

Although cigarettes were once the main product of concern for youths, tobacco companies have pivoted to e-cigarettes. If the FDA caps nicotine in e-cigarettes, tobacco companies might shift again—to chewing tobacco, snuff, roll-your-own tobacco, cigars, candies, or some other product. Given this possibility, the FDA should at some point consider limiting nicotine in all nonmedical tobacco products to try to end the tobacco epidemic.

In proposing a nicotine cap, the FDA’s stated goal is to “reduce youth use, addiction, and death.” But the proposal ignores the most popular youth tobacco product today: e-cigarettes. Failing to include e-cigarettes runs the risk of reversing decades of public health progress against tobacco.

**REFERENCES**