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E-Cigarettes and FDA Nicotine Cap

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To the Editor

The proposal to cap nicotine concentrations in combustible cigarettes is based on sound scientific evidence that cigarettes with very low levels of nicotine will significantly reduce smoking- and tobacco-related harm. However, we believe that a proposal presented in a recent Viewpoint¹ for a federal nicotine cap on e-cigarettes is misguided and runs contrary to current evidence. The focus on e-liquid nicotine concentrations alone is problematic because these restrictions fail to consider that e-cigarettes, unlike cigarettes, offer users ways beyond nicotine concentrations to control nicotine delivery, including manipulating device power and compensatory puffing. In fact, the best evidence suggests that this proposed policy would lead to a product that is as addictive as e-cigarettes with higher nicotine concentrations, which may be more appealing to young people, and more harmful.

Earlier-generation e-cigarettes, as noted by the Viewpoint authors, ¹ often contained lower levels of nicotine (1%-2%) compared with current products. Missing from their analysis is that these low nicotine concentrations also led vapers to use devices with much higher power (ie, wattage) to improve nicotine delivery. Users of e-liquids with very low nicotine concentrations paired with relatively high-powered devices are more than capable of mimicking the nicotine delivery of cigarettes.² Another study³ demonstrated that across a range of nicotine concentrations less than 2%, e-cigarette users are able to achieve cigarette-like nicotine yield by simply manipulating device power. Of concern, increased device power is associated with increased toxicant production due to higher heating of the e-liquid. Moreover, in response to e-cigarettes with low nicotine concentrations, users self-titrate, engaging in compensatory puffing by increasing their puffing intensity to maintain nicotine delivery, which further increases their toxicant exposure.²

Emerging evidence also suggests that e-cigarettes with lower nicotine concentrations (1%) are more appealing to young people because they are more satisfying and less harsh than e-liquids with higher concentrations (5%).⁴ Internal tobacco industry documents show that to entice youths and those naive to nicotine, tobacco companies established a "graduation program" that introduced new users to "starter products" with lower nicotine concentrations

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that would not overwhelm them with nicotine, while at the same time providing nicotine-dependent users with products that contain higher nicotine concentrations to maintain dependence.

E-cigarettes need to be regulated to protect public health, but e-cigarettes are a unique product class and require a comprehensive strategy to ensure the protection of youths as well as smokers looking for a less harmful alternative to cigarettes.⁵

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