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Letter

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The Debate About Nicotine Addiction and the Role of Medicinal Products: Commentary on Zeller

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Nicotine addiction has been at the core of much debate related to alternative nicotine delivery systems such as electronic cigarettes or "vaping" devices. Some tobacco control researchers and advocates emphasize the need for strong policies that would protect future and current generations from new products that lead to nicotine addiction or serve as a gateway to cigarette smoking.[1] Others emphasize the different risks for disease associated with different tobacco and nicotine products and argue policies must prioritize reducing disease risk even if that requires allowing for new products that may have high addiction potential.[2]

The Food and Drug Administration has proposed a nicotine regulation strategy designed to achieve the goal of substantially reducing tobacco-related death and disease based on the continuum of risk concept. The proposal emphasizes a rapid decline in the use of the most toxic products (combusted tobacco) by reducing their addictiveness through nicotine reduction. Reducing nicotine by 90% or more decreases the reinforcing effects of cigarettes among daily smokers,[3] youth,[4] young adults,[5] smokers with co-morbid disorders,[6] and intermittent smokers.[7] However, a standard to reduce the addictiveness of a product that is used by approximately 40 million Americans requires the availability and accessibility of alternative less harmful but also satisfying products for adults that need or want to use nicotine. While some smokers may be satisfied by relatively low addiction potential products as an alternative to reduced nicotine cigarettes, others may seek products with similar addiction liability as currently marketed cigarettes. If the FDA Center for Tobacco Products (CTP) allows for high addiction liability substitutes, then the concern over the potential of perpetuating nicotine addiction is raised; however, advocates for this approach would argue that the lives saved by facilitating this switch would outweigh the risk of continued use of nicotine or some uptake among youth. If CTP greatly limits the addiction potential of alternatives, demand for illicit cigarettes and/or more toxic alternatives could persist even if regulation minimizes concerns about the loss of control over nicotine use in some legal products. Striking the right balance is critical.

A potential compromise is to allow nicotine products with high appeal and addiction liability similar to cigarettes to be approved as medicinal products which may limit the appeal among youth and require a different approach to marketing. Adults who are highly addicted to nicotine or find it difficult to function without it could use this type of product and, over time, these individuals may or may not choose to try to stop using nicotine altogether. Whether this is the right approach is unclear, but it highlights the potential role for the FDA Center for Drug Evaluation Research and the need to operate under a different framework for drug approval that primarily targets smoking cessation rather than nicotine dependence. As described in the Zeller article,[8] efforts towards building a consensus on the role of nicotine addiction in our society as well as within the FDA will be critical for determining the best pathway to realize the greatest benefit to public health.

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Declaration of Interests

None declared.

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