

ACTION NEEDED: E-CIGARETTES

Truth Initiative® is dedicated to achieving a culture where all youth and young adults reject tobacco. As we actively pursue our vision of a future where tobacco is a thing of the past, we recognize three important factors:

1. Combustible tobacco products are responsible for the overwhelming majority of death and disease caused by tobacco.
2. Some smokers may be unable or unwilling to quit using nicotine and would benefit by completely switching to a much lower harm nicotine delivery mechanism (including potentially a well-regulated e-cigarette).
3. The introduction of unregulated and highly addictive nicotine products into the market creates a risk of youth and young adults who might not have smoked becoming addicted to nicotine, which is concerning when the most dangerous form of tobacco — cigarettes — is easily available, affordable, appealing and aggressively marketed.

With those factors in mind, we endorse the important public health strategy of **harm minimization**, in addition to already proven tools such as taxation, clean indoor air, access to quitting interventions and public education. We know that not starting tobacco use in the first place, or quitting as soon as possible for those who have started, is the best way to protect health. However, for those who cannot or will not quit tobacco use, completely switching to the exclusive use of regulated, least-harmful, noncombustible products will substantially reduce, though not eliminate, the health harms from tobacco.

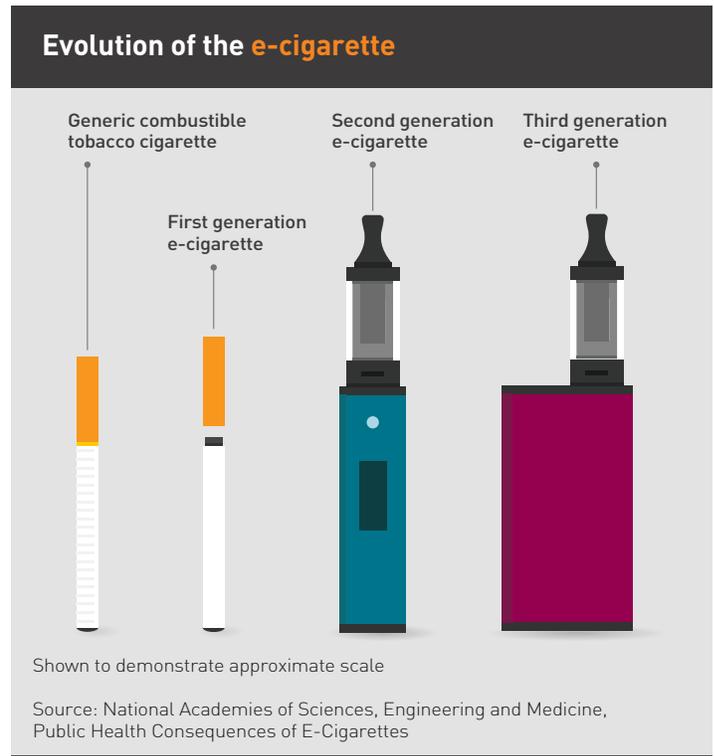


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Based on our review of [the current state of e-cigarette knowledge and the regulatory environment](#), we offer the following conclusions on and policy recommendations for e-cigarettes.

E-cigarettes are far less toxic than cigarettes, but they are not harmless. While studies show that e-cigarettes deliver significantly lower levels of many toxins than cigarettes, e-cigarettes still deliver and emit some toxic substances that are potentially harmful to users and to those around them, including children and pregnant women. This issue is complicated, because the e-cigarette category covers a large variety of products that significantly vary in the delivery of nicotine and toxins. Furthermore, because of the relatively recent entry of e-cigarettes into the market, we simply do not know the long-term health effects of frequent long-term inhalation of these products.

While regulated e-cigarettes may be beneficial to smokers who completely switch from combustible tobacco, e-cigarettes still pose health risks and nonsmokers should never use them. Most importantly, youth should not use e-cigarettes. As e-cigarettes evolve to deliver nicotine in increasingly similar ways to cigarettes, the potential for nicotine addiction increases, particularly for youth, who are more susceptible to nicotine addiction. We also know that e-cigarette use is a strong predictor of

future combustible tobacco use. Finally, we are mindful of evidence that nicotine may alter brain chemistry in ways that make adolescent brains more susceptible to addiction not just to nicotine, but also to other addictive drugs.

More research is needed to understand how e-cigarettes might help smokers completely switch from combustible tobacco products. Those who use combustible products and cannot quit need to switch completely and as quickly as possible to a Food and Drug Administration-reviewed, reduced harm product to attain maximum health benefits, because smoking even a few cigarettes a day presents significant health harms. Currently, most adults who use e-cigarettes continue to smoke combustible cigarettes. If this pattern holds, it will substantially limit potential positive health impacts from e-cigarettes.

Furthermore, any public health benefit from e-cigarettes will not be fully realized in an unregulated environment. The FDA must regulate and carefully review these products to ensure that they meet the public health standard established by the Tobacco Control Act. Only then will consumers, health care providers and public health officials be able to reliably evaluate and identify products that are of the highest quality and are most likely to help smokers completely switch from cigarettes.

We note that there is substantial consumer confusion around the potential harms of e-cigarettes. Only 36 percent of adult smokers recognize that e-cigarettes are less harmful than cigarettes. While we believe a significant portion of this confusion is driven by the lack of pre-market regulatory review, meaningful product standards and perverse incentives that make it much easier to sell e-cigarettes as recreational devices than as tools for quitting or completely switching from smoking, these misperceptions serve as an opportunity to educate adult smokers who cannot or will not quit smoking.

Finally, the FDA must pursue an agency-wide approach to regulate all nicotine products, including

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e-cigarettes. Regulated e-cigarettes are not a silver bullet for solving the tobacco epidemic. We know from recent modeling by the National Academies of Science, Engineering, and Medicine that, all other policies being equal, adding e-cigarettes to the market may yield some benefit, but will likely save fewer than 2 percent of lives that otherwise would have been lost to smoking over a 50-year period. This pales in comparison to the lives saved by evidence-based policies, such as tax increases on tobacco products, clean indoor air laws and public education. We must do better, and the FDA has a large role to play in ensuring that all nicotine products are regulated.

Specifically, we support e-cigarette policies that contribute to reducing death and disease from tobacco, including:

- > **The FDA must expeditiously undertake premarket review for e-cigarettes.** E-cigarettes vary widely in quality, toxicity and nicotine delivery, causing confusion for consumers trying to switch from cigarettes to a less harmful product. Regulation would ensure the effectiveness of e-cigarettes as devices that may help facilitate complete switching from cigarettes for adult smokers, and would be a barrier for products designed to attract youth users.
- > **The FDA must issue manufacturing requirements that ensure all e-cigarettes:**
 - >> Deliver nicotine as indicated on product packaging
 - >> Minimize the presence of hazardous constituents
 - >> Are manufactured consistently to high quality standards
- > **The FDA must issue product standards eliminating flavors from all tobacco products.** A narrow exception may apply to harm minimization products that have been demonstrated to help smokers completely switch from combustible tobacco. The



manufacturer must also show that the product is not marketed to attract youth, and that claim must be verified with careful post-marketing surveillance of actual use patterns.

- > **The FDA must use its full authority to restrict e-cigarette marketing so that it does not target or appeal to youth.** Currently, not all the same marketing restrictions that apply to cigarettes apply to e-cigarette marketing. The FDA should impose marketing restrictions such as:
 - >> Prohibiting self-service access to products (i.e., keeping products behind the counter)
 - >> Prohibiting name brand sponsorship of sports and cultural events
 - >> Prohibiting free gifts with purchase, other than tobacco products (no branded t-shirts, hats, etc.)
- > **The FDA should prohibit internet and other non-face-to-face sales of all tobacco products, including e-cigarettes.**
- > **State and local jurisdictions should limit sales of all tobacco products, including e-cigarette products and their components, to those aged 21 and older.**
- > **State and local jurisdictions should require e-cigarette use to be subject to clean indoor air laws and requirements.**

> **Federal, state and local tax-writing authorities should set taxes on e-cigarettes and all tobacco products.**

Those taxes should be proportional to the harms of each type of tobacco product to discourage use of the most harmful products. Regardless of level of harm, all taxes should be set high enough to discourage youth use. Above that, combustible tobacco products should be taxed at the highest level, and the least harmful, well-regulated and FDA-reviewed noncombustible tobacco products should be taxed at lower levels.



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