FEBRUARY 2019

POLICY IN BRIEF

American Heart Association.

New and Emerging Tobacco Products and the Nicotine Endgame:

THE ROLE OF ROBUST REGULATION AND COMPREHENSIVE TOBACCO CONTROL AND PREVENTION[1]

3 THINGS TO KNOW

1. In the 2011–2018 National Youth Tobacco Surveys show a dramatic increase in adolescent e-cigarette initiation. During 2017–2018 alone, e-cigarette use rose by 78 percent in high school students and 48 percent in middle school students.

2. The Monitoring the Future Survey releases annual results, surveying over 40,000 8th, 10th, and 12th graders. In 2018, e-cigarette use nearly doubled in high school students. This is the largest one-year increase seen for any substance in the history of the survey.

3. Noting this unprecedented spike in e-cigarette use, in December 2018, the US Surgeon General issued an advisory for parents, teachers and health professionals about the negative health consequences of e-cigarettes.

The advent of new tobacco products, such as electronic cigarettes (e-cigarettes) and the dramatic rise of their use especially in adolescents and young adults is of significant concern. E-cigarettes have now become the most popular tobacco product for youth and adolescents in the United States and are attracting youth to different avenues for nicotine addiction.

Although these products may have benefit by helping some smokers to quit or to move to a less harmful product, the long-term health effects of these products and the net public health effect associated with their use remain unclear and widely debated.

There is increasing concern that the use of newer tobacco products (e-cigarettes, e-hookah, e-cigars) may catalyze transition to the use of other tobacco products or recreational drugs, particularly in young adults. The next most popular tobacco products among youth and adolescents are cigars, cigarettes, smokeless tobacco, hookah, pipe tobacco, and bidis. The trend in newer tobacco product use is particularly concerning because it is unfolding at a time when the rates of cardiovascular disease (CVD) mortality, which have been steadily decreasing since the 1970s, have slowed down and may even be increasing in some population groups.

There is urgent need for robust Food and Drug Administration (FDA) regulation of all tobacco products to avoid the significant economic and population health consequences of continued tobacco use.

Although the AHA acknowledges that the ultimate endgame would be an end to all tobacco and nicotine addiction in the US, it supports first minimizing the use of all combustible tobacco products, while ensuring that other products do not addict the next generation of youth and adolescents.

The endgame strategy needs to be coordinated with the long-standing evidence-based tobacco control strategies that have significantly reduced tobacco use and initiation in the US including tobacco excise taxes, comprehensive clean indoor air laws, comprehensive coverage of evidence-based tobacco

Reference

[1] Bhatnagar, A., Whitsel, LP., Blaha, MJ., Huffman, MD., Krishan-Sarin, S., Maa, J., Rigotti, N., Robertson, RM., Warner, JJ. New and Emerging Tobacco Products and the Nicotine Endgame: The Role of Robust Regulation and Comprehensive Tobacco Control and Prevention: A Presidential Advisory. Circulation. 2019.

cessation therapies, eliminating the sale of tobacco in pharmacies and other health-related outlets, increasing the sales age of tobacco to 21 (i.e. Tobacco 21), implementing advertising restrictions, and de-normalizing tobacco use.

Summary of the American Heart Association's Positions on Newer Tobacco Product Regulation and the Endgame.

Issue	AHA Position
The Endgame	While the AHA acknowledges the ultimate endgame would be an end to all tobacco and nicotine addiction in the US, the association supports first ending the use of all combustible tobacco products while assuring that other products do not addict the next generation of youth and adolescents and achieving a realistic goal of getting to 5% or less tobacco use prevalence.
Vulnerable Populations	Tobacco control and prevention efforts and regulation should be targeted and tailored to vulnerable populations including youth and adolescents, those who live in rural areas, high tobacco use, racial and ethnic groups, those with mental health conditions, those with less education and low income and the LGBTQ community.
FDA Regulation of Newer Tobacco Products	
Nicotine Reduction Strategy	The AHA supports lowering nicotine concentration in all combustible tobacco products to reduce tobacco-related mortality. Research favors doing this quickly rather than a stepwise reduction over time. This will likely be most successful if nicotine is available in noncombustible forms as nicotine replacement therapy to reduce withdrawal symptoms as smokers adjust. Any nicotine reduction strategy should consider the relationship with switching and dual use. Also, FDA action should be taken to ensure that further changes are not made by industry to reduced-nicotine products to retain their appeal, such as altering other ingredients or flavors. Over the long term, subsequent research is needed to determine whether nicotine should be reduced in non-combustible products as a strategy to end all nicotine addiction in the US.
Flavorings	The removal of all characterizing flavors from all tobacco products is essential for reducing their appeal to youth. Controversy arises because, while there is no experimental evidence to support the view that flavors help adults switch from combustible to non-combustible tobacco products or to quit tobacco altogether, there are individual reports suggesting that for some adults, flavors are appealing. However, maintaining flavors to attract adult smokers increases the risk of these products becoming available for youth and young adults. Additional research is needed to determine how best to balance the need to reduce flavorings' appeal to youths with the potential that flavorings may facilitate smoking cessation among adult smokers. Recognizing that this is a difficult decision, the AHA's position at this time is that the FDA should ban the use of all characterizing flavors other than tobacco in all tobacco products. Emerging evidence also suggests that sweeteners in tobacco products may play a role in increasing appeal of the product; this evidence suggests that the FDA should also consider the inclusion of high-intensity sweeteners in their definition of "characterizing flavors." This should be accompanied by research aimed at studying the role of flavors in enhancing adult cessation and on the toxicity of flavors. This research and surveillance will be required to determine any negative effects on the efficacy of cessation, with new approaches developed to counteract these if found.
Market Review	The AHA supports restricting the marketing of JUUL and other similar e-cigarettes until their health risks to youth and adolescent users are clearly assessed and their potential benefits and harms in promoting tobacco cessation among adults is better understood. The agency should suspend Internet sales of these products until adequate mechanisms and rules for age verification are established. Also, the ban on underage sales by retailers should be effectively enforced, and the FDA should require these products to be submitted for review sooner. The FDA should reverse its 2017 decision that allows e-cigarettes that were already on the market as of August 8, 2016 to stay on the market until at least 2022 without filing applications and undergoing a public health review by the FDA.

Newer Tobacco Products and Cessation	Further research and legal analysis are needed to facilitate e-cigarettes being regulated and sold only as FDA-approved cessation products, and the Center for Drug Evaluation and Research needs to reduce existing barriers to accomplish this work. Rigorous randomized controlled trials are critical to evaluate the effectiveness of e-cigarettes as cessation devices. Significant public health questions need to be answered about the level of nicotine in non-combustible products that optimally helps dependent smokers quit all tobacco use, while developing robust regulation that protects against youth access and initiation, re-initiation by former smokers, and initiation by never smokers. The AHA encourages the Center for Drug Evaluation and Research work in close collaboration with the Center for Tobacco Products to develop e-cigarette regulation.
Cigars, cigarillos, and little cigars	These tobacco products, including "premium" cigars should continue to be subject to robust FDA regulation. Regulation for cigars, cigarillos and little cigars should restrict flavorings, sales to minors, develop product standards, graphic warnings, and limit their marketing and advertising. These products should also be included in all tobacco excise taxes.
Marketing and Advertising	The AHA supports robust FDA regulation restricting all tobacco marketing and advertising to youth and vulnerable populations, including the use of television, radio, and print ads and commercials, celebrity endorsement, movie placements, price promotions and free sampling, and branded events and non-tobacco merchandise.
Warning Labels	The AHA supports the FDA requiring immediate implementation of impactful, evidence-based, graphic warning labels on all tobacco products in the US.
Coordinating Global Efforts	The AHA supports coordinated, collaborative tobacco control and prevention efforts between dedicated global health networks, the World Health Organization, government agencies, individuals, and non-governmental organizations around a unified policy framework that minimizes the devastating impact of tobacco product use in vulnerable populations around the world. Robust regulation in the US should not increase the export of these deleterious products to other parts of the globe, especially low- and middle- income countries.
Illicit Market	The FDA and other government agencies can and should develop and strengthen enforcement efforts to minimize the effects of illicit markets.
Healthcare Providers and Screening for and Counseling on the Newer Tobacco Products	Health care providers should screen for all tobacco product use and counsel cessation. Young patients should be screened for newer tobacco use and substance abuse and counseled on the dangers of these products. A previous AHA policy statement elucidated how clinicians should advise adult patients regarding cessation.[10] Youth substance use prevention programs should target reduction of e-cigarette and cigar use. In the intersection between the health care system and public health, there is a need to develop public health messages that accurately convey the scientific data on the potential harm of newer tobacco products and differentiate the absolute from the relative harm of these products compared with combustible tobacco.
Taxation	Tobacco excise taxes should be highest for combustible products while FDA-approved modified risk products would be taxed at a lower rate, and tobacco cessation aids would not be taxed at all.
Comprehensive Smoke Free Air Laws	Smoke-free laws should explicitly include aerosolized, alternative nicotine delivery systems as well as all combustible products in comprehensive smoke free air laws to ensure there is no passive exposure to any harmful constituent byproducts nor risk of de-normalizing tobacco use. Opening up existing smoke free air laws to include e-cigarettes should be done with caution to avoid weakening existing statute.
Tobacco 21	The AHA advocates for Tobacco 21 laws that incorporate all tobacco products to minimize youth and adolescent initiation.

Access to Comprehensive Cessation Therapies	Users of newer tobacco products should be offered all comprehensive tobacco cessation therapies including counseling and pharmacotherapy. Anyone using tobacco products should have access to comprehensive cessation services with no co-pay.
Sales Restrictions in Pharmacies and Health-Related Institutions	All tobacco products, including e-cigarettes and other newer tobacco products should not be sold at pharmacies or other health-related institutions unless they are regulated as nicotine replacement therapy.