



ASAM American Society of
Addiction Medicine

Public Policy Statement on E-Cigarettes

Background

Smoking combustible cigarettes (“cigarettes”) is the leading cause of preventable death and disability in the United States. More than 480,000 people die each year from smoking cigarettes, many of whom live with significant disability prior to death; it is reported that smoking cigarettes kills over time 50% of the people who use them.^{1,2} There are more than 7,000 chemicals in the smoke created by burning tobacco leaves, more than 70 of which are carcinogenic to humans.^{3,4} Cigarette smoking also has a harmful effect on the U.S. economy with the total economic cost estimated to be more than \$300 billion dollars per year in health care costs and lost productivity due to illness and death.¹

Electronic cigarettes, also referred to as e-cigarettes, vaporizers or electronic nicotine delivery systems (ENDS), are non-standardized, battery-operated devices that use a “liquid” that most commonly would contain nicotine, as well as varying compositions of flavorings, in addition to propylene glycol, vegetable glycerin as vehicle forming a vaping cloud when exhaled, and other ingredients. The liquid is heated to create an aerosol that the user inhales.⁵ The flavoring agents, propylene glycol and glycerin are generally recognized as safe for human consumption by the FDA as food additives when ingested by mouth, but their impact is not well studied or known when inhaled in vapor or mist form. It is difficult to generalize about e-cigarettes because the products and e-liquids are not standardized, and it is difficult for consumers to know what they are using because labels are often not accurate nor consistent.⁶

E-cigarette aerosol contains fewer carcinogens in lower levels than does smoke from combustible tobacco cigarettes, but they still expose users to high levels of ultrafine particles and other toxicants that may substantially increase cardiovascular and non-cancer lung disease risk.⁷ Exposure to nicotine and toxicants is dependent on the type of device and user characteristics, for example, the 4th generation e-cigarettes that are pod-based also known as “JUUL” or “JUUL-like” devices use a novel mixture of nicotine salts along with benzoic acid resulting in a smoother experience while reaching blood nicotine levels similar to those achieved after using a combustible cigarette.⁸ The overall potential for harm or benefit on public health is dependent on the effect of e-cigarette use on the later initiation of combustible cigarette use or continued e-cigarette use by youth, the potential to facilitate cessation of combustible tobacco use by adults, and the long-term harm of exclusive e-cigarette use.⁹

Youth Use

In 2019, for the sixth year in a row, e-cigarettes were the most commonly used tobacco product among youth, with 27.5% of high school students (4.1 million) and 10.5% of middle school students (1.2 million) reporting past-month use of e-cigarettes, compared to 5.8% of high school students and 2.3% of middle school students who reported past-month use of combustible cigarettes.¹⁰ While the combustible cigarette use among youth has reached historical lows the ever increasing trend in e-cigarettes use is concerning because longitudinal studies of tobacco and e-cigarette use among youth have found that the odds of subsequent cigarette smoking were quadrupled among e-cigarette users.⁷ This indicates that e-cigarette use may be perpetuating and worsening the tobacco use epidemic by attracting low-risk youth who would otherwise not initiate nicotine use with a combustible cigarette. Indeed, the 2019 National Youth Tobacco Survey found that youth perceive e-cigarettes to be less harmful than combustible cigarettes, and cite use by friends or family as well as availability of flavors such as mint, candy, fruit or chocolate as the reasons for use.¹⁰ The vast majority (68.8%) of youth e-cigarette users reported using flavored products in 2019.¹¹

Further, the 2019 Monitoring the Future Survey revealed that past-month vaping of marijuana-based products among 12th graders nearly doubled in a single year to 14% from 7.5%—the second largest one-year jump ever tracked for any substance in the history of the survey.¹² The long-term effects of vaping tetrahydrocannabinol (THC), the psychoactive ingredient in cannabis, are unknown, but vaping THC-containing e-liquids has been linked to the 2019 outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI) (see below).

Smoking Cessation

Currently, there are seven Food and Drug Administration (FDA)-approved medications for addiction involving nicotine. Among those, five are nicotine replacement therapies (NRTs), those are the nicotine gum, patch, lozenge, inhaler and nasal spray. There are also two non-nicotine pharmacological therapies approved by the FDA including the antidepressant/nicotine receptor antagonist bupropion and the nicotinic-receptor partial agonist varenicline tartrate. Varenicline and bupropion act in different ways on nicotine receptors in the brain and may help people quit by easing withdrawal symptoms and blocking the effects of nicotine if they continue smoking. Medications are used to relieve nicotine withdrawal symptoms, reduce the reward from smoking, and are twice as effective when combined with behavioral therapy.¹³

Some public health experts have promoted e-cigarettes as a harm reduction or smoking cessation tool. Public health officials in the United Kingdom (UK) have taken an unequivocal, positive stance on the use of e-cigarettes, and the National Health Service has approved retail vaping sales outlets on hospital premises.¹⁴ The U.K. has gone so far as to license specific e-cigarette devices as medicines, which has not happened in the U.S. Public Health England has encouraged smokers in the UK to switch to e-cigarettes claiming they are 95% less harmful to health than combustible cigarettes, and can be used with psycho-social smoking cessation services to help smokers quit tobacco completely.¹⁵ And a U.S. report by the National Academies of Science, Engineering and Medicine drew heavily on the British positions leading to its

encouraging conclusions about the potential benefits of e-cigarettes.⁹ However, the “95% less harmful” assertion has been viewed with skepticism, and there are several important distinctions between the U.S. and the U.K. that affect the discussion about e-cigarettes. In general, the U.K. has tighter regulation of smoking and vaping than does the U.S., including restrictions on the nicotine content in e-cigarettes. Thus, there is less nicotine in Juul pods or e-cigarette cartridges sold in the UK: Juul in the US contains up to 59mg per ml, while nicotine levels in e-cigarettes across Europe are capped at 20mg per ml by an EU directive enshrined in British law.¹⁶ Also, there are marketing restrictions in the U.K. not present in the U.S., and there are mandatory warning labels on smoking and vaping products that are not present in the U.S.

As of January 2020, research studies have suggested that e-cigarettes may actually reduce smoking cessation rates, possibly by attracting smokers who want to quit but reducing the likelihood that they quit successfully.⁷ Large epidemiologic surveys in the US from 2015 and 2016 found that the majority (~60%) of adult e-cigarette users reported “dual use” of e-cigarettes and combustible cigarettes.¹⁷ This is especially concerning because dual use has been associated with greater health risks, in particular respiratory symptoms, when compared to smoking either combustible cigarettes or e-cigarettes alone.^{18, 19}

Moreover, the 2020 Report of the Surgeon General on Smoking Cessation concluded that anti-smoking medications approved by the FDA and behavioral counseling increase the likelihood of successfully quitting smoking, particularly when used in combination, but that there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.²⁰

EVALI

The poorly understood and potentially fatal syndrome known as EVALI emerged in the summer of 2019 and started to subside around end of that year. As of January 21, 2020, there have been 2,711 cases and 60 deaths reported to the Centers for Disease Control and Prevention (CDC).²¹ Most EVALI patients (82%) reported using e-cigarette products containing THC.²² Vitamin E acetate, an adulterant to THC-containing e-cigarette products, is strongly linked to the EVALI outbreak. In the face of the alarming reports, the CDC and FDA have advised consumers to stop using THC-containing e-cigarettes.²³ Several jurisdictions have taken more extreme actions and completely banned all vaping products or flavored products.^{24, 25} The American Medical Association (AMA) has called for total ban on all e-cigarette and vaping products that do not meet FDA approval as smoking cessation tools.²⁶

Evolving US Regulatory Landscape

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which gave the FDA the immediate authority to regulate the manufacturing, marketing and sale of cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco and authorized the agency to extend its jurisdiction to all other tobacco products. In May 2016, the FDA issued a final “deeming rule” extending its authority to all tobacco products, including e-cigarettes, cigars and hookah. The rule required manufacturers of all e-cigarette products to submit pre-market tobacco product applications (PMTAs) within 24 months.²⁷

In 2017, the FDA postponed the PMTA deadline until August 2022 in a new Compliance Policy,²⁸ but it was subsequently challenged in court by public health organizations and physician groups and eventually vacated by a U.S. District Court in May 2019. The court ordered that applications for deemed tobacco products including e-cigarettes must be filed with FDA no later than May 12, 2020.²⁹ Products with timely filed applications may remain on the market for one year after the deadline while the FDA reviews their application.

Finally, in December 2019, Congress raised the federal minimum age to purchase any tobacco products including e-cigarettes to 21.³⁰ This is now federal law enforced by the FDA. In addition, the FDA issued a policy in January 2020 prioritizing enforcement action against unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol).³¹

Recommendations

Considering the rapidly changing regulatory landscape, emerging research, and continued controversy, the American Society of Addiction Medicine recommends:

1. That all substances and behaviors involved with addiction, including nicotine, be included in the medical care plan of treatment in all treatment settings.
2. That the FDA accelerate and intensify the regulation of e-cigarettes and e-fluids as tobacco products including ingredients and delivery systems to include specified nicotine concentration and standardized manufacturing techniques.
3. That the FDA's enforcement of the 21-year-old minimum age for purchase of e-cigarettes be closely monitored to ensure compliance. Advertising campaigns discouraging e-cigarette use by youth should be disseminated to complement the FDA's efforts to enforce this age requirement.
4. That taxes be applied to e-cigarettes comparable to other tobacco products. Tax revenue obtained from these sources should be earmarked for public health prevention and treatment efforts.
5. That e-cigarette flavors be prohibited unless a flavor has been demonstrated to help current tobacco users to stop smoking, will not lead non-tobacco users to start, and does not increase risk of harm from using the product.
6. That the FDA create specific rules to continuously monitor and limit marketing tactics, particularly those that target children and young people, including flavors and cartoon themes, etc.
7. That the use of e-cigarettes be prohibited in places defined by statute or regulation as tobacco-free environments.
8. That there be continued and increased research into the long-term potential for harms from the use of e-cigarettes and the component parts of their delivery system.
9. That research be expanded and accelerated on the potential for e-cigarettes, in particular for those who have not been able to quit or not interested in quitting, to be used as a potential tool in the treatment for nicotine/tobacco use and especially addiction involving nicotine, or as a component of a comprehensive harm reduction strategy.

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¹ U.S. Department of Health and Human Services. [The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General](#). Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 [accessed 2017 Oct 26].

² Doll R, Peto R, Wheatley K, Gray R, Sutherland I. Mortality in relation to smoking: 40 years observations on male British doctors. *British Medical Journal* 1994; 309:901-911.

³ U.S. Department of Health and Human Services (USDHHS). *A Report of the Surgeon General: How Tobacco Smoke Causes Disease: What It Means to You* (Consumer Booklet). Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2010

⁴ U.S. Department of Health and Human Services (USDHHS). *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2010.

⁵ U.S. Food and Drug Administration. Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS). January 3, 2020. Available at: <https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends> Accessed January 29, 2020

⁶ Raymond BH, Collette-Merrill K, Harrison RG, Jarvis S, Rasmussen RJ. The Nicotine Content of a Sample of E-cigarette Liquid Manufactured in the United States. *J Addict Med*. 2018 Mar/Apr;12(2):127-131

⁷ Glantz SA and Bareham DW. E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications. *Annu Rev Public Health*. 2018 April 01; 39: 215–235. doi:10.1146/annurev-publhealth-040617-013757

⁸ Yingst JM, Hrabovsky S, Hobkirk A, et al. Nicotine absorption profile among regular users of a Pod-Based electronic nicotine delivery system. *JAMA Netw Open* 2019;2:e1915494

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- ⁹ National Academies of Sciences, Engineering, and Medicine 2018. Public Health Consequences of E-Cigarettes. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24952>.
- ¹⁰ Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019. *MMWR Surveill Summ* 2019;68(No. SS-12):1–22. DOI: <http://dx.doi.org/10.15585/mmwr.ss6812a1>
- ¹¹ Wang TW, Gentzke AS, Creamer MR, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019. *MMWR Surveill Summ* 2019;68(No. SS-12):1–22. DOI: <http://dx.doi.org/10.15585/mmwr.ss6812a1>
- ¹² NIDA. Vaping of marijuana on the rise among teens. National Institute on Drug Abuse website. <https://www.drugabuse.gov/news-events/news-releases/2019/12/vaping-marijuana-rise-among-teens>. December 18, 2019. Accessed February 3, 2020.
- ¹³ National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services. Cigarettes and Other Tobacco Products, 2017 [accessed 2017 Nov 7].
- ¹⁴ Vape shops open in two UK hospitals to help smokers kick the habit. *The Guardian*. July 10, 2019. Available at: <https://www.theguardian.com/society/2019/jul/10/vape-shops-hospital-smokers-kick-habit-west-midlands>
- ¹⁵ E-cigarettes: an evidence update, A report commissioned by Public Health England, Authors: McNeill A, Brose LS, Calder R, Hitchman SC Hajek P, McRobbie H (Chapters 9 and 10)
- ¹⁶ Boseley S. The great vape debate: are e-cigarettes saving smokers or creating new addicts? *The Guardian*. February 18, 2020. Available at: <https://www.theguardian.com/society/2020/feb/18/the-great-vape-debate-are-e-cigarettes-saving-smokers-or-creating-new-addicts>
- ¹⁷ *QuickStats*: Cigarette Smoking Status Among Current Adult E-cigarette Users, by Age Group — National Health Interview Survey, United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65:1177. DOI: <http://dx.doi.org/10.15585/mmwr.mm6542a7>; Mirbolouk, M, et al., Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016. *Annals of Internal Medicine*, published online August 28, 2018.
- ¹⁸ Hedman L et al. Association of Electronic Cigarette Use With Smoking Habits, Demographic Factors, and Respiratory Symptoms. *JAMA Network Open*. 2018;1(3):e180789. 2018
- ¹⁹ Dinkeloo, E. et Al. Vaping, Smoking, and the Physical Fitness of Active Young Men. *Am J Prev Med* 2020;58(1):e31–e37
- ²⁰ U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.
- ²¹ Centers for Disease Control and Prevention (CDC). Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products. January 28, 2020. Available at: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information Accessed January 30, 2020.
- ²² Krishnasamy VP, Hallowell BD, Ko JY, et al. Update: Characteristics of a Nationwide Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury — United States, August 2019–January 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:90–94. DOI: <http://dx.doi.org/10.15585/mmwr.mm6903e2>
- ²³ Food and Drug Administration. Statement on consumer warning to stop using THC vaping products amid ongoing investigation into lung illnesses. October 4, 2019. Available at: <https://www.fda.gov/news-events/press-announcements/statement-consumer-warning-stop-using-thc-vaping-products-amid-ongoing-investigation-lung-illnesses>
- ²⁴ Corum, J. Vaping Illness Tracker: 2,602 Cases and 59 Deaths. *The New York Times*. January 13, 2020. Available at: <https://www.nytimes.com/interactive/2020/health/vaping-illness-tracker-evali.html> Accessed January 31, 2020.
- ²⁵ Du Y, Liu B, Xu G, et al. Association of Electronic Cigarette Regulations With Electronic Cigarette Use Among Adults in the United States. *JAMA Netw Open*. 2020;3(1):e1920255. doi:10.1001/jamanetworkopen.2019.20255
- ²⁶ American Medical Association. AMA calls for total ban on all vaping products not approved by FDA. November 19, 2019. Available at: <https://www.ama-assn.org/press-center/press-releases/ama-calls-total-ban-all-vaping-products-not-approved-fda>
- ²⁷ Food and Drug Administration. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. May 10, 2016. Available at: <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>

²⁸ Food and Drug Administration. FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. FDA News Release. July 27, 2017. Available at: <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>

²⁹ Norman E. "Ned" Sharpless, MD. FDA Regulation of Electronic Nicotine Delivery Systems and Investigation of Vaping Illnesses. Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. September 25, 2019. Available at: <https://www.fda.gov/news-events/congressional-testimony/fda-regulation-electronic-nicotine-delivery-systems-and-investigation-vaping-illnesses-09252019>

³⁰ Food and Drug Administration. Selling Tobacco Products in Retail Stores. December 20, 2019. Available at: <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores>

³¹ Office of Medical Products and Tobacco, Center for Tobacco Products, Food and Drug Administration. Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization. Guidance for Industry. Docket FDA-2019-D-0661. January 2020. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>