



E-CIGARETTES HAVE NOT BEEN PROVEN TO BE EFFECTIVE AT HELPING SMOKERS QUIT SMOKING

No major scientific body in the United States has concluded that e-cigarettes are an effective tobacco cessation device.

- Leading public health authorities in the U.S. have found that there is not enough evidence to recommend e-cigarettes for tobacco cessation, and no e-cigarette has received approval from the FDA to be sold as a tobacco cessation product.
 - The 2020 Surgeon General Report on Smoking Cessation, released in January 2020, concluded that “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.” The Surgeon General also cautions that because e-cigarettes are not a single product, but “a continually changing and heterogeneous group of products” that “are used in a variety of ways,” it is difficult to make broad generalizations about the efficacy of e-cigarettes for smoking cessation based upon any one study or any one product.¹
 - The U.S. Preventive Services Task Force, which makes recommendations about the effectiveness of specific preventive care services after a thorough assessment of the science, recently updated its recommendation statement on tobacco smoking cessation adults and concluded that “the current evidence is insufficient to assess the balance of benefits and harms of electronic cigarettes (e-cigarettes) for tobacco cessation in adults...The USPSTF recommends that clinicians direct patients who use tobacco to other tobacco cessation interventions with proven effectiveness and established safety.”²
 - A 2018 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded, “[o]verall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”³
 - Researchers from the CDC stated, “There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service.”⁴
 - In a court brief from 2019, the FDA stated that, “the claim that vaping helps smokers quit in meaningful numbers remains unproven.”⁵ FDA is the federal agency charged with determining what products are effective at helping smokers quit.
- In October 2020, the Cochrane Library’s Tobacco Addiction Group, based at the University of Oxford, published a review of the evidence regarding the role of e-cigarettes in quitting smoking and found that e-cigarettes can “probably” help people stop smoking for at least six months.⁶ These conclusions are inconsistent with those of other public health authorities who have comprehensively reviewed the evidence and concluded that there is inadequate evidence to conclude that e-cigarettes are effective for smoking cessation.
 - The Cochrane review relies on just four studies to reach its main conclusions regarding the effectiveness of e-cigarettes for cessation. The review itself acknowledges that the evidence remains limited, noting that their results are based on a small number of studies and that “we need more, reliable evidence to be confident about the effects of e-cigarettes, particularly the effects of newer types of e-cigarettes that have better nicotine delivery.”

- The conclusions of the review are only based on quitting at six months and do not take into account what proportion of smokers may relapse into smoking or dual use of e-cigarettes and cigarettes after the initial six months. One recent study found that six months is not a good predictor of long-term quitting success.⁷

Several studies have found that e-cigarette use is not associated with successful quitting.⁸

- A 2018 study did not find any evidence that ENDS help adult smokers quit at a higher rate than smokers who did not use these products despite ENDS users being more likely to make a quit attempt. In fact, the authors state that “findings indicate that, at the time of this study, ENDS under “real world” use and conditions may have suppressed or delayed quitting among some adult smokers.” Specifically, of the 27 percent of smokers who reported using ENDS at baseline, about 90 percent were still smoking at one year follow-up. Moreover, the study found that ENDS users quit at a lower rate than non-ENDS users regardless of frequency or duration of ENDS use, device type, quitting as reason for use, or e-liquid flavor.⁹
- Meta-analyses that examine the association between e-cigarette use and smoking cessation among adult smokers have found no association between e-cigarette use and smoking cessation. A 2016 meta-analysis of 38 studies found that the odds of quitting were less among smokers using e-cigarettes.¹⁰ A more recent meta-analysis of 55 studies also found that e-cigarette use was not significantly associated with smoking cessation. The analysis did find that daily e-cigarette use was associated with increased smoking cessation while less than daily e-cigarette use was associated with significantly less smoking cessation.¹¹
- A systematic review that examined consumer preference for various e-cigarette attributes found “inconclusive evidence” as to whether flavored e-cigarettes assisted quitting smoking,¹²
- Two studies released in 2020 that analyze data from FDA’s Population Assessment of Tobacco and Health (PATH) survey reinforce findings from earlier studies that using e-cigarettes is not more effective in helping smokers quit compared to nicotine replacement therapy (NRT) or other FDA-approved pharmacotherapies. Of concern, these studies also showed that the majority of participants who either tried or successfully used e-cigarettes to quit smoking were still using e-cigarettes at follow-up, suggesting that e-cigarettes may contribute to ongoing nicotine dependence.¹³
- While a New England Journal of Medicine study found that certain e-cigarettes may help smokers to quit cigarettes, the study’s findings and implications, especially in the U.S., are limited.¹⁴
 - **The study does not speak to the efficacy of e-cigarettes in general.** The study examined only one type of e-cigarette – a refillable, open-tank device that differs greatly from e-cigarettes like Juul that now dominate the U.S. market. E-cigarettes vary widely, including in how much nicotine they deliver, how efficiently, and for how long. Studies are needed to determine whether or not the newer, more popular products sold in the U.S. are effective in helping U.S. smokers quit.
 - **The study does not speak to the efficacy of e-cigarettes in a non-clinical setting.** Smokers in this study were enrolled in a clinical stop smoking program and received weekly face-to-face counseling support from local health care providers. The authors state that “further trials are needed to determine whether our results are generalizable outside the UK services.”
 - **The study is not generalizable to all smokers.** Study participants were smokers who were motivated to quit and sought help quitting through the U.K. National Health Service’s stop-smoking program.
- Many e-cigarette users report using both e-cigarettes and cigarettes. According to the 2019 NHIS, 36.9% of adult e-cigarette users are also current cigarette smokers (dual users).¹⁵ While little data on

what happens with dual users over time are available, analysis of PATH data found that nearly 9 out of 10 early dual users were still smoking cigarettes at follow-up.¹⁶

- E-cigarette companies may claim that adult smokers are the target audience, but that is not who is using the product. E-cigarettes have become increasingly popular among youth and young adults, while there has been no significant uptake among older adults. 3.6 million middle and high school students are current e-cigarette users¹⁷ About 25% of all e-cigarette users in the US are youth, and 44% are under age 25.¹⁸ More than half of 18-24 year-old e-cigarette users (56.0%) have never smoked cigarettes.¹⁹
- At the same time, there has no significant uptake of e-cigarettes among adults. Data from the National Health Interview Survey (NHIS) show that in 2019, 4.5% of adults currently used e-cigarettes.²⁰
- Several evidence-based treatment options are available to help adult smokers quit. There are seven FDA approved tobacco cessation medications on the market today that are proven effective, in addition to cessation counseling, which has also been identified as an effective cessation tool. No e-cigarette has been approved or even reviewed for smoking cessation purposes by the Food and Drug Administration. No e-cigarette manufacturer has ever even applied to FDA with evidence that e-cigarettes are effective at helping smokers quit.
- While we should keep an open mind about the potential for e-cigarettes as a cessation tool, we need science to back this up. And any potential that e-cigarettes may have at helping smokers quit cannot come at the expense of large scale youth use. E-cigarettes are addicting kids, putting their health at risk and threatening decades of progress in reducing youth tobacco use. As former FDA Commissioner Scott Gottlieb noted in June 2018, “If by opening a path for e-cigs to be an alternative for adult smokers, all we end up doing is hooking a new generation of kids on nicotine, we’ll have failed in our purpose. We’ll have swapped one public health tragedy for a new one.”²¹

There is no credible evidence demonstrating that flavored e-cigarettes are needed to help adult smokers quit.

- For all the discussion about flavors being necessary to help someone switch from cigarettes to e-cigarettes, there is little evidence to support it. Public health authorities in the U.S., including the CDC, have not found enough evidence to recommend e-cigarettes, including any flavored e-cigarette, for tobacco cessation.
- A systematic review that examined consumer preference for various e-cigarette attributes found “inconclusive evidence” as to whether flavored e-cigarettes assisted quitting smoking,²²
- There is no evidence that adults who say they quit using flavors would not be able to quit without the flavors. Just because some adults may like flavors, it does not mean flavors are needed to help them quit.
- On the other hand, the evidence is clear that flavors attract youth. Nearly all (97%) youth e-cigarette users have used a flavored e-cigarette in the past month, and 70 percent say they use e-cigarettes “because they come in flavors I like.”²³
- No e-cigarette manufacturer has published a single randomized controlled trial on the effectiveness of their product for cessation, let alone the efficacy of *flavored* e-cigarettes.
 - If a manufacturer has evidence that a flavored e-cigarette helps smokers quit and does not appeal to kids, then the manufacturer should submit that evidence to the FDA for review and get authorization to sell that product. Not a single manufacturer has done so.

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- ² United States Preventive Services Task Force, "Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons, Final Recommendation Statement", 2021 <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>
- ³ National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>;
- ⁴ King, BA, et al., "Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011," *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, King, BA, et al., "Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013," *Nicotine & Tobacco Research*, first published online September 19, 2014 and Fiore, MC, et al., Treating Tobacco Use and Dependence: 2008 Update, U.S. Public Health Service Clinical Practice Guideline, May 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.
- ⁵ American Academy of Pediatrics et al., v. U.S. Food & Drug Administration, et al. Government's Opposition to the Motions for Stay Pending Appeal and Consent to the motion to Expedite Review, December 31, 2019.
- ⁶ Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Hajek P. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews* 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4. Accessed 17 December 2020.
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- ⁹ Weaver, Scott R., et al., "Are electronic nicotine delivery systems helping cigarette smokers quit? Evidence from a prospective cohort study US adult smokers, 2015-2016," *PLoS One* 13(7), July 9, 2018.
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- ¹² Zare, S, et al., "A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type," *PLoS One*. 2018 Mar 15;13(3), 2018.
- ¹³ Chen, R, et al., "E-cigarette Use to Aid Long-term Smoking Cessation in the US: Prospective Evidence from the PATH Cohort Study," *American Journal of Epidemiology*, online ahead of print, doi: 10.1093/aje/kwaa161, July 27, 2020. Pierce, JP, et al., "Role of e-cigarettes and pharmacotherapy during attempts to quit cigarette smoking: The PATH Study 2013-16," *PLoS ONE* 15(9):e0237938, 2020.
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²¹ Dr. Scott Gottlieb Remarks to the American Society of Clinical Oncology (ASCO) Annual Meeting, June 2, 2018

<https://www.fda.gov/news-events/speeches-fda-officials/remarks-american-society-clinical-oncology-asco-annual-meeting-06022018>

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