



**Campaign for Tobacco-Free Kids Perspective on AJPH article:
“Balancing Considerations of the Risks and Benefits of E-Cigarettes”**

An article on e-cigarettes published in the September edition of the *American Journal of Public Health* (AJPH), “Balancing Considerations of the Risks and Benefits of E-Cigarettes”¹ calls for “policies and interventions that both reduce youth vaping and increase adult smoking cessation,” goals we and many others strongly share, but then goes on to challenge the evidence cited by those concerned about the impact of e-cigarettes on youth and to present a one-sided view about the impact of e-cigarettes on adult tobacco use.

By taking this approach, the article misses an opportunity to present a balanced view of the evidence and articulate a set of policies for the regulation of these products that might have helped bring those who assess the science differently closer together to work towards solutions that will both reduce youth vaping and help more smokers quit.

The article portrays the debate as if those who have raised concerns about e-cigarettes are less committed to reducing the death toll from the use of any tobacco product and less committed to helping those who face the greatest risk, cigarette smokers. Nothing could be further from the truth. Virtually everyone, except tobacco and e-cigarette companies, is supportive of policies, programs and/or products that will accelerate the progress in reducing tobacco use among adults as well as youth and the number of people who die from tobacco caused disease. Virtually everyone also agrees that the debate should carefully balance the risks and benefits of new policies and new products on both adults and youth based upon the totality of the scientific evidence and the impact of these policies and products on the population as a whole when used in the real world.

Unfortunately, the AJPH article does not present a comprehensive framework for regulation or a balanced view of the science. It omits important data and gives undue credibility predominantly to those studies that support its point of view while criticizing those that reach different conclusions. It side-steps the difference in the evidence when these products are used in conjunction with a supervised therapeutic intervention from when they are sold as a commercial product subject to little or no regulation.

Overall, as discussed in detail below, the article understates the severity of youth e-cigarette use and resulting nicotine addiction and overstates the evidence to date about the overall impact of e-cigarettes on adult cigarette smokers. It does not address the real world evidence regarding whether or under what circumstances e-cigarettes are effective at helping smokers quit, especially on a population basis and when sold as a consumer product and not as part of a therapeutic intervention. It also ignores how the e-cigarette market has been transformed since the introduction of Juul, and how these newer products greatly increased the risk of youth addiction

because of their appeal to youth and because they deliver massive, unprecedented levels of nicotine.

The article also ignores the highly salient fact that the benefits and risks of e-cigarettes vary from country to country, as the recent WHO Global Tobacco Control Report² notes, because of factors the AJPB article does not address including (1) the ability and political will of governments to implement regulations that increase the likelihood that the benefits will be attained and the risks minimized, and (2) the role and behavior of the companies that market e-cigarettes. It is not sufficient to look just at the product; it is necessary to look at the full context in which it is marketed. Even a product that is safer than a cigarette can have a negative impact on population health if it is not properly regulated.

Generalizations without regard to the different regulatory frameworks in different countries is a serious omission. The United States poses a special problem. In countries like the United Kingdom and elsewhere, there are far stronger regulations to restrict tobacco marketing than in the U.S., where tobacco companies routinely challenge any government marketing restriction on First Amendment grounds. The U.S. experience also demonstrates how the e-cigarette companies will market their products when not constrained by effective government regulation. In addition, the United Kingdom and other countries have set maximum nicotine levels for e-cigarettes so the level of nicotine allowed in e-cigarettes elsewhere is far lower than the amount of nicotine in e-cigarettes sold in the United States. The AJPB article addresses the youth problem by stating that e-cigarette companies should not market to youth and that e-cigarettes should only be sold in vape shops, but the experience with both cigarettes and e-cigarettes demonstrates in the US that neither a broad general prohibition against marketing to youth, nor youth access restrictions have ever been effective. The companies always find a way to target youth while denying that they are doing so.

There is another important factor that is not discussed in the AJPB article. The debate would be different if e-cigarette manufacturers had sought to have their products approved for therapeutic purposes by the FDA Center for Drug Evaluation and Research (CDER), or by comparable government authorities outside the United States and delivered under medical supervision as tobacco cessation products, but they chose not to do so. If they had done so, scientific review would have required proof as to the impact of specific flavors and specific doses of nicotine on both youth and adults seeking to quit smoking cigarettes. Distribution would have been regulated as a therapeutic intervention and/or under medical supervision in ways that prevent youth use and ensure that adult smokers would be informed about the proper use of the products. Instead, the e-cigarette industry chose to avoid that process and to maximize their profits by making these products widely available as consumer products. Therefore, it is not a surprise that they are not perceived as tobacco cessation devices and are not being used properly to assist smokers. The equivalent would be if the makers of nicotine replacement therapy (NRT) or varenicline now chose to avoid the drug review process by instead applying for approval as a new tobacco product for

recreational use through the FDA's Center for Tobacco Products (CTP), making their products widely available for sale in retail outlets without dose or flavor restrictions or labels describing how they should be used.

The Center for Tobacco Products is not a substitute for the Center for Drug Evaluation and Research and selling e-cigarettes as consumer products does not produce the same result as when they are marketed as part of a therapeutic intervention. It is, therefore, necessary to separate the studies that examine the impact of these products when used as part of a clinical intervention from their impact when sold as consumer products not under the supervision of medical professionals.

The article also gives e-cigarette companies a free pass on their marketing tactics and their opposition to the type of responsible regulation that might have altered this debate from the beginning. Imagine how different the discussion would be today if e-cigarette makers had developed the science to support the claim that their products help smokers quit smoking or if they did not market aggressively to a new generation of non-addicted youth, or if they had supported FDA regulation of e-cigarettes as a tobacco product instead of fighting regulation at every step. Company behavior does impact outcome, especially in the absence of effective government regulation.

It is also important to correct the article's mischaracterization of concerns that have been raised about e-cigarettes. These concerns do not pit youth versus adults or reflect a lack of commitment to doing more to help smokers quit. The reality is that the irresponsible behavior of the e-cigarette companies and the failure of governments in the United States and elsewhere to effectively regulate e-cigarettes have resulted in a far greater risk to youth than was necessary and, at the same time, have not served adult smokers well because e-cigarette companies have failed to conduct or publish the research needed to determine which, if any, e-cigarettes are effective at helping smokers quit smoking.

Understating the Problem of Youth E-Cigarette Use and Nicotine Addiction

It is troubling that the article mentions only in passing the huge increase in youth e-cigarette use that occurred from 2017 to 2019 – an increase that led the U.S. Surgeon General and the FDA to declare e-cigarette use a public health “epidemic.” The facts are clear: From 2017 to 2019, e-cigarette use among U.S. high school students more than doubled, from 11.7% to 27.5%, an increase of over 3 million youth using e-cigarettes in just two years, according to the National Youth Tobacco Survey (NYTS).³ The [Monitoring the Future](#) survey found that the increase in youth vaping of nicotine from 2017 to 2018 was, by far, the single largest one-year increase in any drug use recorded in the 45-year history of the survey.⁴ Remarkably, the AJPB article omits these startling statistics. While youth e-cigarette use declined in 2021, over 2 million middle and high school students still use e-cigarettes.⁵

The article further downplays the severity of the youth e-cigarette problem by claiming “the evidence does not suggest it is addicting very large numbers.” Data from the NYTS, never presented in the AJPB article, indicates otherwise. The NYTS shows that the percentage of high school e-cigarette users who report frequent (use on 20 of the past 30 days) or daily use – a strong indicator of addiction – has increased steadily, from 15.5% in 2014 to 38.9% in 2020.⁶ The proportion of youth who use e-cigarettes frequently remains high. In 2021 (data released after the article came out), 43.6% of high school e-cigarette users reported frequent use.⁷ These are large numbers that should not be ignored.

In downplaying the magnitude of the youth problem, the article is out of step with the conclusions of reports of two U.S. Surgeon Generals, as well as the conclusions of two directors of the U.S. Centers for Disease Control and Prevention, several U.S. FDA commissioners, and every major U.S. public health organization, all of which receives little attention in the AJPB article.

Adding to the concern is the growing evidence that youth who use e-cigarettes are at greater risk of trying cigarettes and becoming smokers – evidence which the article dismisses. In doing so, the article is once again out of step with virtually every major public health authority. The U.S. Surgeon General has concluded that e-cigarette use is “strongly associated” with the use of other tobacco products among youth and young adults, including conventional cigarettes.⁸ Studies also document that many of the youth who use these products were previously non-smokers and were at low risk of smoking.⁹ The National Academies of Sciences, Engineering and Medicine (NASEM) concluded that “There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults”.¹⁰ More recent research bolsters this finding: there are now at least 10 studies that reach the same conclusion.¹¹ Most recently, the 2021 WHO Global Tobacco Control Report reached the same conclusion.¹²

The skyrocketing rate of youth e-cigarette use was driven by the introduction and heavy marketing of Juul and other high-nicotine, flavored e-cigarettes that were introduced after Juul became popular. While there was legitimate concern about youth e-cigarette use before Juul’s introduction, Juul fundamentally changed the e-cigarette marketplace, triggering dramatic growth in youth use and in the percentage of youth e-cigarette users who become frequent and likely addicted users. Juul itself has stated that each of its 5% nicotine cartridges (pods) contains as much nicotine as a pack of cigarettes, and researchers have reported that Juul sparked a [“nicotine arms race.”](#)¹³ Yet, the AJPB article completely ignores the role of Juul and other high-nicotine products that have changed the marketplace in the US and driven youth use since their introduction, with a profound impact on the relative risks and benefits of e-cigarettes.

Overstating the Evidence About the Impact of E-Cigarettes on Adult Tobacco Use, Including the Evidence on Whether E-Cigarettes Help Smokers Quit

The AJPB article also overstates the evidence regarding the effectiveness of e-cigarettes in helping smokers quit, especially on a population level. [Every major U.S. public health authority](#) that has

comprehensively reviewed the scientific evidence has reached the same conclusion: To date, there is limited and inadequate evidence to conclude that e-cigarettes are effective for smoking cessation. The World Health Organization reached the same conclusion in a July 2021 report. Here's what U.S. health authorities have said:

- [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: “the evidence on the use of e-cigarettes for tobacco smoking cessation in adults, including pregnant persons, is insufficient, and the balance of benefits and harms cannot be determined.”¹⁴ (January 2021)
- [The 2020 Surgeon General Report on Smoking Cessation](#): “there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.”¹⁵ (January 2020)
- The FDA in a 2019 court brief: “the claim that vaping helps smokers quit in meaningful numbers remains unproven.”¹⁶
- The CDC and the National Academies of Sciences, Engineering, and Medicine have reached similar conclusions.¹⁷

The evidence is even weaker that *flavored* e-cigarettes are effective at helping smokers quit. For all the discussion about flavors being necessary to help smokers switch from cigarettes to e-cigarettes, there is little evidence to support it. None of the major studies have documented the role of flavored e-cigarettes in reducing smoking. While there is no evidence that e-cigarette flavors help adults quit cigarette smoking, there is ample evidence that flavors appeal to and promote e-cigarette use among youth. The population data do not support the conclusion that the use of flavors is either necessary for, or even correlates with, greater reductions in adult tobacco use. Indeed, before the introduction of Juul, tobacco was the most popular e-cigarette flavor in the United States.¹⁸

We recognize that there have been studies that indicate that as part of a clinical program with smokers, e-cigarettes have been found to be more effective for getting smokers to quit smoking cigarettes than NRT,¹⁹ and that there are studies that found that daily e-cigarette use has been associated with increased quitting smoking cigarettes (although with a high percentage still using e-cigarettes).²⁰ At the same time, other studies have found that e-cigarette use is not associated with increased rates of quitting cigarette smoking.²¹ In contrast to those studies that examined the impact of e-cigarettes when provided as part of a therapeutic intervention under medical supervision, the evidence indicates that [adult smokers who use e-cigarettes as consumer tobacco products are no more likely to stop smoking cigarettes](#) than adult smokers who do not use e-cigarettes.

In considering the population impact of the current regulatory environment, it is important to note that the evidence also indicates that when distributed in retail outlets with no controls and no instruction, the impact of e-cigarette use on smokers may discourage quitting. Studies have shown that non-daily e-cigarette use and dual use of e-cigarettes and cigarettes have been found to

reduce a smoker's chances of cessation compared to not using e-cigarettes at all.²² This is of concern since a significant percentage of e-cigarette users do not use e-cigarettes daily and a significant percentage are dual users. Given the number of non-daily users and the number of smokers who are dual users, the finding that non-daily e-cigarette use reduces the likelihood of quitting means that there is a chance that, when used without direction or guidance, the net population impact could well be harmful, even apart from any increase in tobacco product initiation.

The article also does not acknowledge that, following the introduction of Juul and other flavored, high-nicotine e-cigarettes, the market changed. As the ITC Four Country study published in 2020 showed, the rapid rise in youth use of Juul was not accompanied by an increase in adult use of Juul or similar products.²³ So it should not be a surprise that there was a dramatic rise in e-cigarette sales and youth e-cigarette use, but little change in adult e-cigarette use or the adult smoking rate – precisely the opposite of what you would expect if these products were helping smokers quit. With no concurrent significant change in annual adult smoking rates, the “harm reduction” opportunity these products purport to provide has yet to be realized in any meaningful way on a population basis.

The numbers since Juul and similar products became popular are troubling. Between 2015 and 2019, adult smoking rates moved from only 15.1% to 14%;²⁴ and high school cigarette smoking held steady at about 8% between 2016 and 2018 before falling in 2019.²⁵ Declines in youth smoking slowed between 2015 and 2018, after Juul was introduced and surged in popularity.

It is also concerning that among adults in the United States, e-cigarette use is greatest among young adults, many of whom have not previously smoked cigarettes. Data from the CDC's National Health Interview Survey show that in 2019, 4.5% of all adults currently used e-cigarettes, compared to 3% of 45-64 year olds, 9.3% of 18-24 year olds currently used e-cigarettes.²⁶ Further, more than half of these 18-24 year-old e-cigarette users (56%) had never smoked cigarettes, the highest percentage among the age groups.²⁷ There is simply no reason for people who have never used tobacco products to be using e-cigarettes and exposing themselves to such massive levels of nicotine and other health risks.

The Health Harms of E-Cigarettes are Still Unknown

We have much more to learn about e-cigarettes. As the AJPB article noted, there are no data on long-term health effects of e-cigarettes, and determining the short-term health effects is difficult. According to the Surgeon General, the CDC, and NASEM, e-cigarettes deliver fewer toxins than combustible cigarettes, but that doesn't mean that they are safe or without risk. In a 2020 report, the Surgeon General found that “the long-term health effects of using these products remain unknown, and short-term risks are only slowly coming into focus.”

We do know that nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development and has been linked to a variety of adverse health outcomes for the developing fetus.²⁸ In addition, while e-cigarette aerosol contains fewer of most of the chemicals and toxins compared to cigarette smoke, it still contains numerous harmful and potentially harmful chemicals and more research is needed about the impact of inhaling these chemicals deeply into the lungs.²⁹

E-cigarettes have been found to increase heart rate and blood pressure, and initial research indicates that the aerosol can damage DNA and the respiratory system.³⁰ Most recently, the WHO Global Tobacco Control Report³¹ detailed the emerging evidence of the harmful effects of e-cigarettes, including studies suggesting that e-cigarettes have negative effects on aspects of cardiovascular and respiratory health, and the effects among smokers who engage in dual use or who delay overall quitting.

Recent changes to e-cigarette devices can also impact their potential health impacts: the devices are now more powerful, create more aerosol, and expose users to more toxicants. The proliferation of e-liquids with nicotine salts allow users to inhale significantly higher levels of nicotine.³²

While the evidence to date indicates that e-cigarettes expose users to fewer harmful chemicals than traditional cigarettes, the evidence of the harms of these products continues to emerge and the growing body of evidence indicates that they are certainly not safe, especially for kids and others who do not currently use tobacco products.³³

Conclusion

In the United States, the experience of an unregulated marketplace has hurt both youth and smokers. The issue is what regulations are needed to protect youth and to require e-cigarette makers to produce high quality science about whether, how and to what extent any of their products help smokers quit.

We couldn't agree more that we need policies and interventions that reduce youth vaping **and** increase adult smoking cessation – and we are committed to supporting policies that do just that.

Campaign for Tobacco-Free Kids, September 2021

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² WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. <https://www.who.int/publications/i/item/9789240032095>

³ Wang, TW, et al., "E-Cigarette Use Among Middle and High School Students – United States, 2020," *MMWR* ePub, September 9, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

⁴ University of Michigan, *Monitoring the Future Study*, 2018. <http://monitoringthefuture.org/data/18data/18drtbl3.pdf>.

⁵ Park-Lee, E, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021," *MMWR*, 70(39): 1387-1389, October 1, 2021, <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf>

⁶ Wang, TW, et al., “E-cigarette Use Among Middle and High School Students – United States, 2020,” *MMWR*, Volume 69, September 9, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>

⁷ Park-Lee, E, et al., “E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021,” *MMWR*, 70(39): 1387-1389, October 1, 2021, <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf>

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⁸ Barrington-Trimis, JL, et al., “E-Cigarettes and Future Cigarette Use,” *Pediatrics*, 138(1), published online July 2016. Wills, TA, et al., “E-cigarette use is differentially related to smoking onset among lower risk adolescents,” *Tobacco Control*, published online August 19, 2016.

⁹ Barrington-Trimis, JL, et al., “E-Cigarettes and Future Cigarette Use,” *Pediatrics*, 138(1), published online July 2016. Wills, TA, et al., “E-cigarette use is differentially related to smoking onset among lower risk adolescents,” *Tobacco Control*, published online August 19, 2016. Berry, KM, et al., “Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths,” *JAMA Network Open*, 2(2), published online February 1, 2019. Owotomo, et al., “Smoking Intention and Progression from E-Cigarette Use to Cigarette Smoking,” *Pediatrics*. 2020;146(6);

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¹² WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. <https://www.who.int/publications/i/item/9789240032095>

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¹⁶ 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.

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²² The most recent study by McDermott, MS., et al, "The Effectiveness of using e-cigarettes for quitting smoking compared to other cessation methods among adults in the United Kingdom,". *Addiction*, 09 March 2021 highlighted its finding that daily e-cigarette users in the study increased their likelihood of abstinence for 30 days, but did not highlight the fact that it decreased the odds of cessation among non-daily users and that most of the e-cigarette users in the study were non-daily users. On dual use, see: Coleman, B., et al., "Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015)," *Tobacco Control*, published online April 25, 2018.

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³¹ WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. <https://www.who.int/publications/i/item/9789240032095>

³² Eissenberg, T., et al., "Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes," *AJPH*, published online January 8, 2020, <https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305424>.

³³ HHS, *E-Cigarette Use Among Youth and Young Adults. 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, 2016.