Introduction to Tobacco Law and Regulation: The Public Health Standard

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Poll: Who's in the Audience?

My Background

- Local public health practitioner
- FDA tobacco regulatory science fellow
- Academia
- Public health attorney

FDA staff

Industry

Law firm

Academia

Public health

Other

The Goal of FDA Tobacco Regulation

Promote and protect public health

Tobacco Control Act: To protect the public health

CTP mission: To protect Americans from tobacco-related disease and death

FDA mission: To protect the public health and to reduce tobacco use by minors

HHS mission: To enhance the health and well-being of all Americans

The U.S. Tobacco Toll

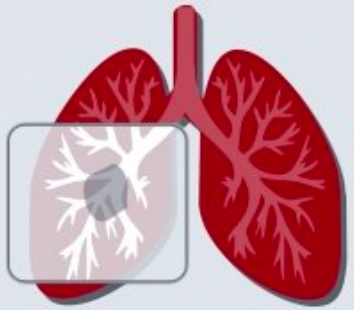
480,000 DEATHS

People who die each year from their own cigarette smoking or exposure to secondhand smoke.	approx. 480,000+
Kids under 18 alive today who will ultimately die from smoking (unless smoking rates decline)	5.6 million
People in the U.S. who currently suffer from smoking-caused illness	16 million+

CAMPAIGN for TOBACCO-FREE Kids®

ANNUAL HEALTH CARE COSTS

$226.7 BILLION



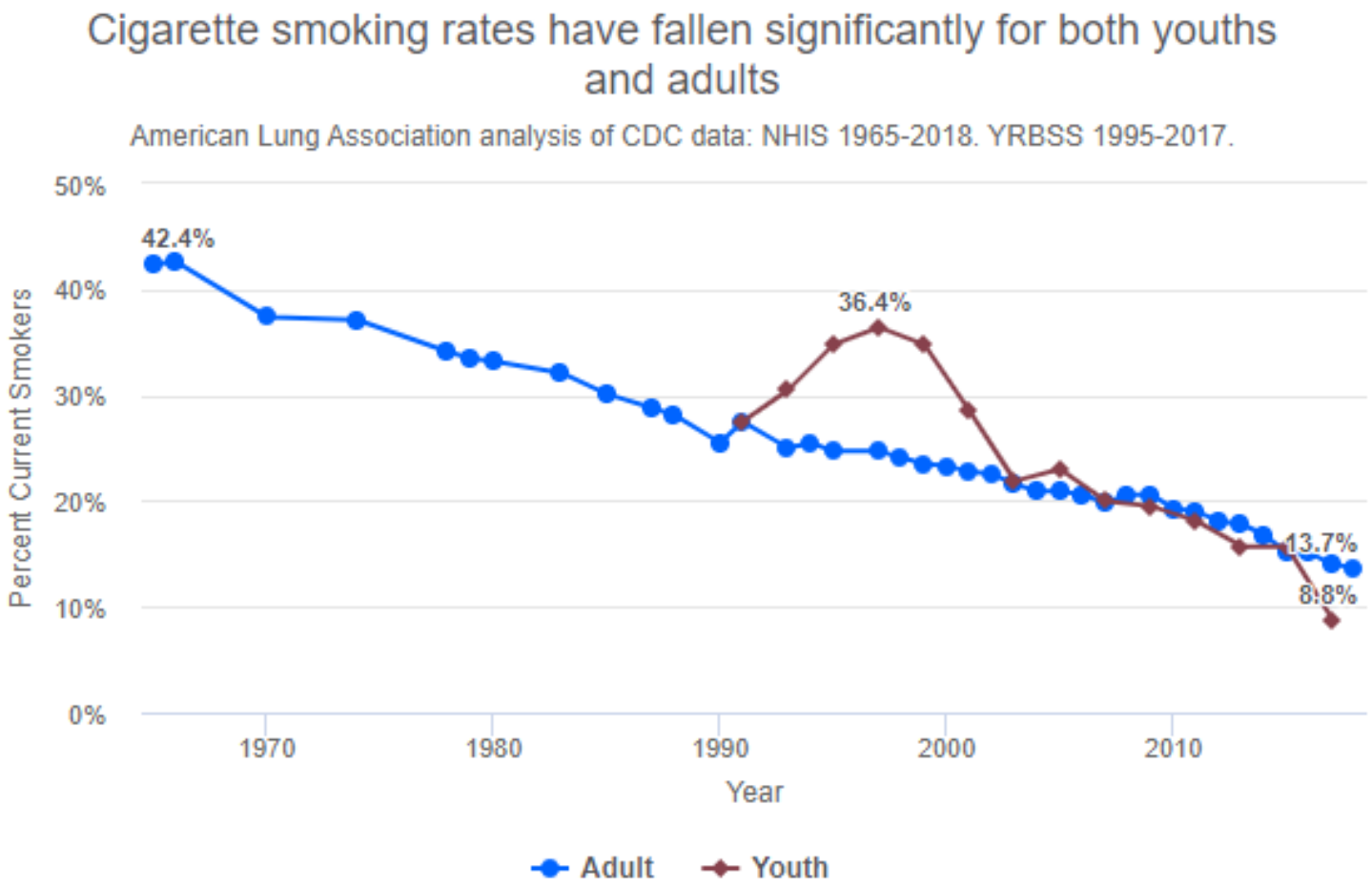
ANNUAL HEALTH CARE EXPENDITURES SOLELY FROM SECONDHAND SMOKE EXPOSURE: $6.99 BILLION

PRODUCTIVITY LOSSES CAUSED BY SMOKING EACH YEAR: $181 BILLION

ANNUAL TOBACCO INDUSTRY MARKETING
$8.4 BILLION

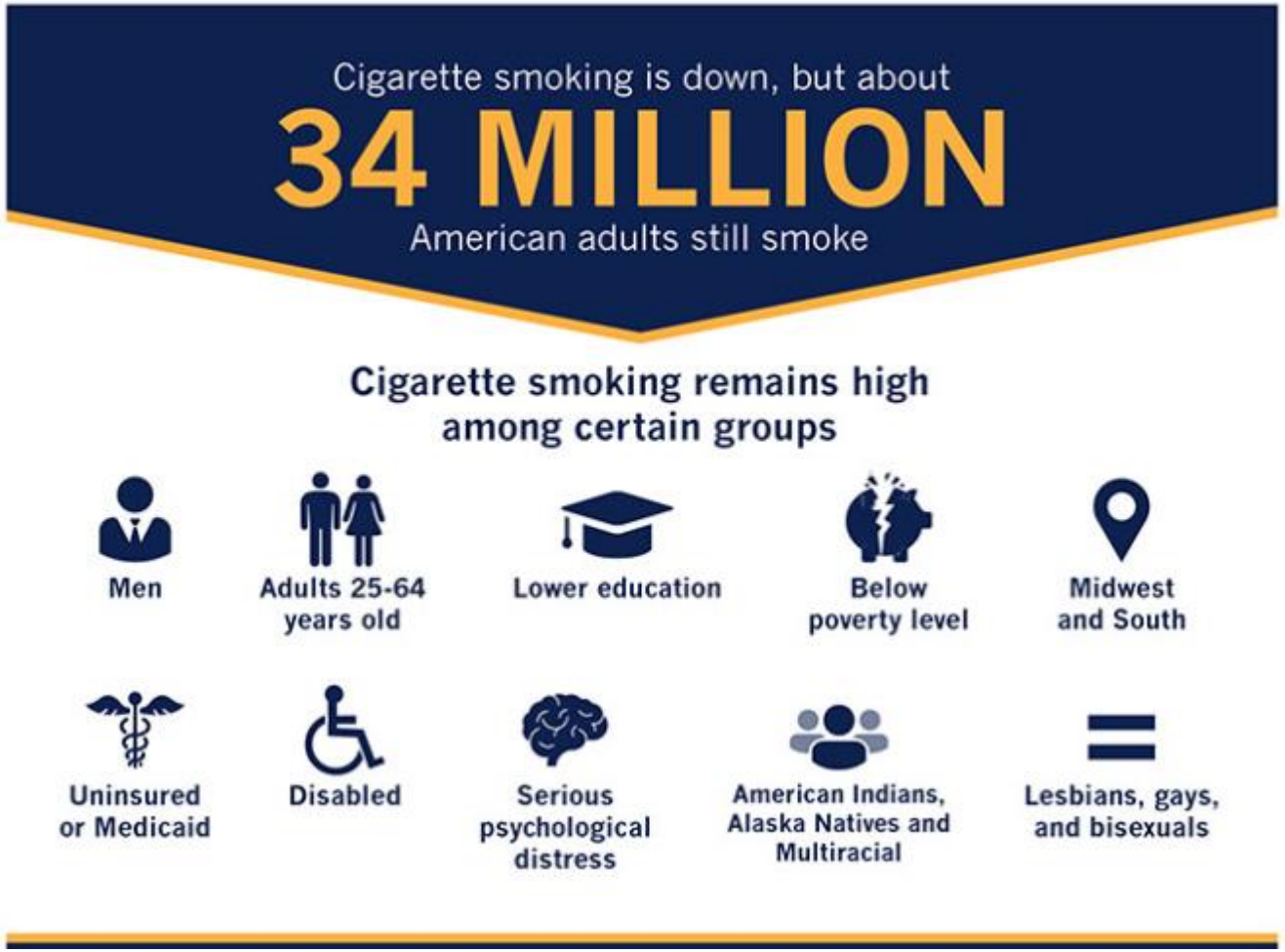
$23.0 MILLION
EACH DAY

Tobacco Use Trends



https://www.lung.org/research/trends-in-lung-disease/tobacco-trends-brief/overall-tobacco-trends

https://www.cdc.gov/tobacco/infographics/adult/index.htm



networking for HEALTH EQUITY

Impact of Menthol on Tobacco Disparity Populations

According to the Centers for Disease and Control and Prevention (CDC), many populations that experience tobacco disparities also use menthol at higher rates than the national average.[1] Tobacco use causes cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease (COPD), an additional health burden these communities can ill afford.

Populations that experience tobacco disparities are youth as well as adult African Americans, Latinxs, Asian Americans, Native Hawaiians and Pacific Islanders, Native Americans/Alaska Natives, LGBTQ people, people from non-urban areas, people with lower socio-economic status, as well as those with behavioral health conditions (mental health/addiction).

Access to menthol in cigarettes, e-cigarettes, and other tobacco products continues to disproportionately result in harm to these populations. Studies show use of menthol tobacco products facilitates smoking initiation among youth and is correlated with reduced cessation rates. Research shows a menthol ban can increase cessation rates; conversely, when menthol is exempted from flavor bans, tobacco users simply shift to menthol products.

To help end tobacco disparities and minimize tobacco-related addiction, access to all tobacco flavorings should be eliminated. Allowing access to menthol actively hurts populations already experiencing tobacco disparities and sets the stage to perpetuate these inequities for another generation.

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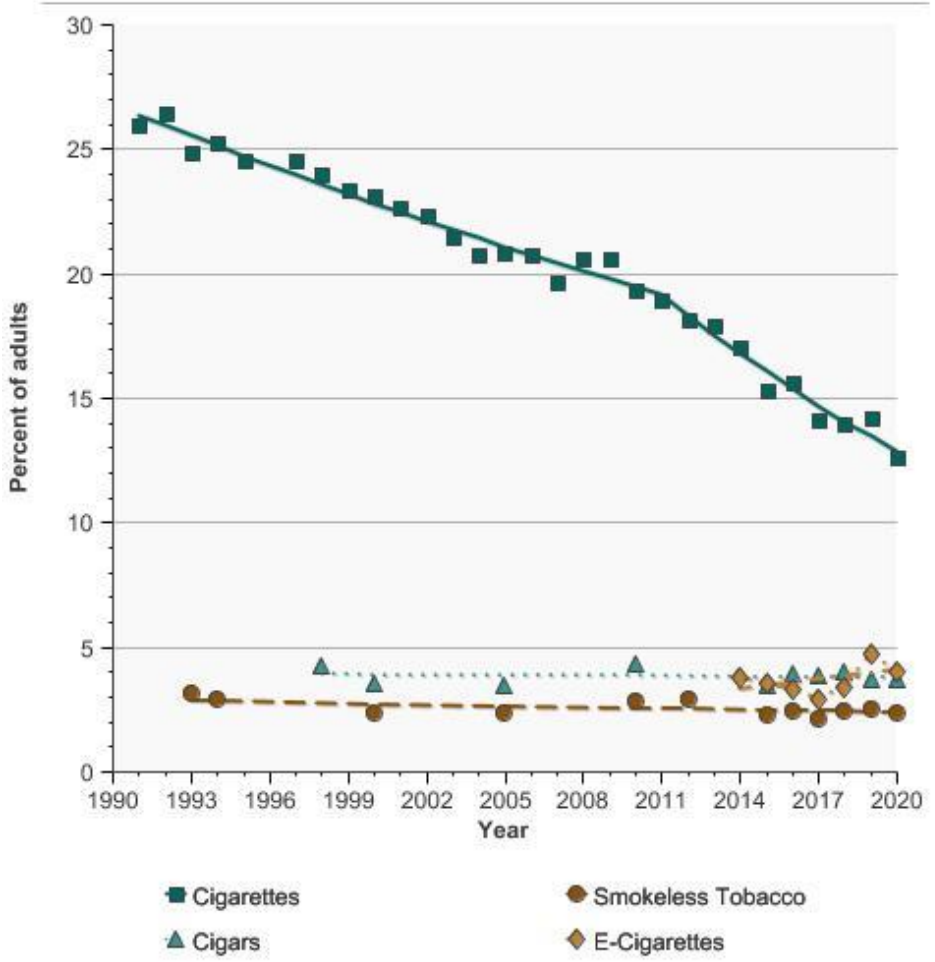
National African American Tobacco Prevention Network
National LGBT Cancer Network
SelfMade Health Network
Asian Pacific Partners for Empowerment, Advocacy, and Leadership
National Alliance for Hispanic Health
Geographic Health Equity Alliance (CADCA)
National Behavioral Health Network for Tobacco and Cancer Control
National Native Network (Keep It Sacred)

https://cancer-network.org/resources/impact-of-menthol-on-disparate-populations/

Campaign for Tobacco-Free Kids®

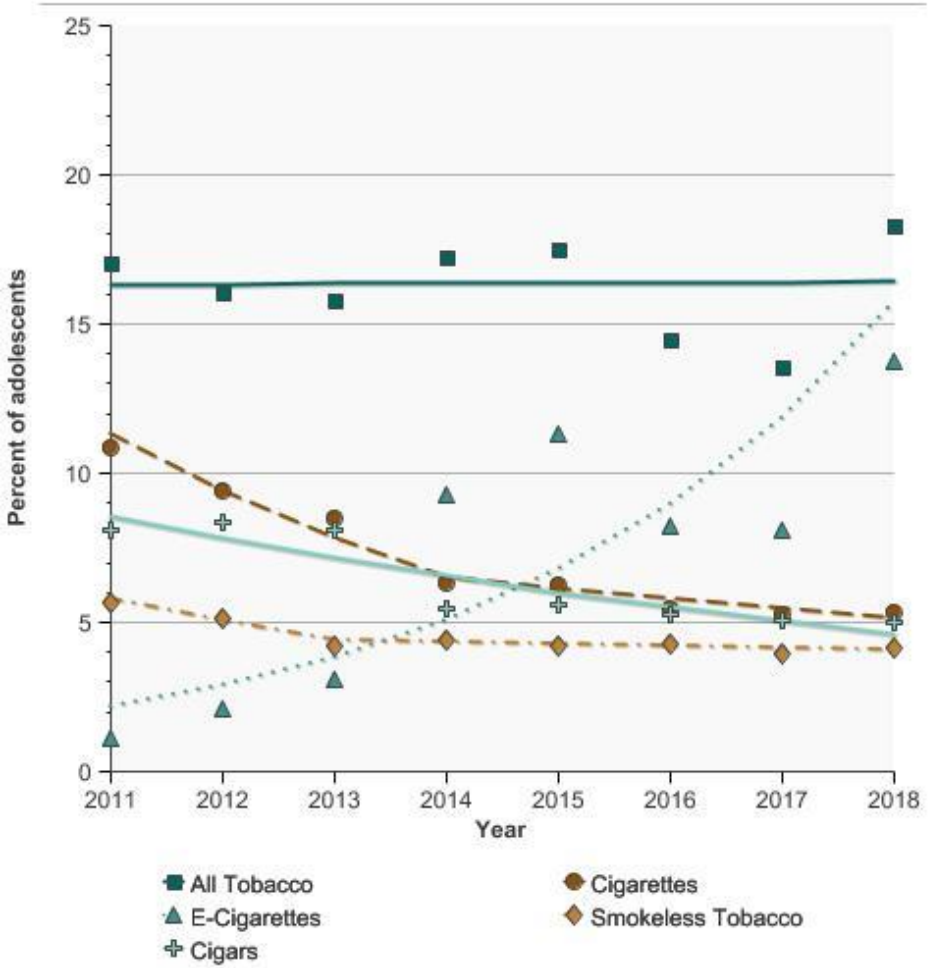
Percentage of adults aged 18 years and older who were current tobacco product users by type of tobacco product used, 1991-2020



Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Health Interview Survey.
Data are age-adjusted to the 2000 US standard population using age groups: 18-24, 25-34, 35-44, 45-64, 65+.

https://progressreport.cancer.gov/prevention/adult_smoking

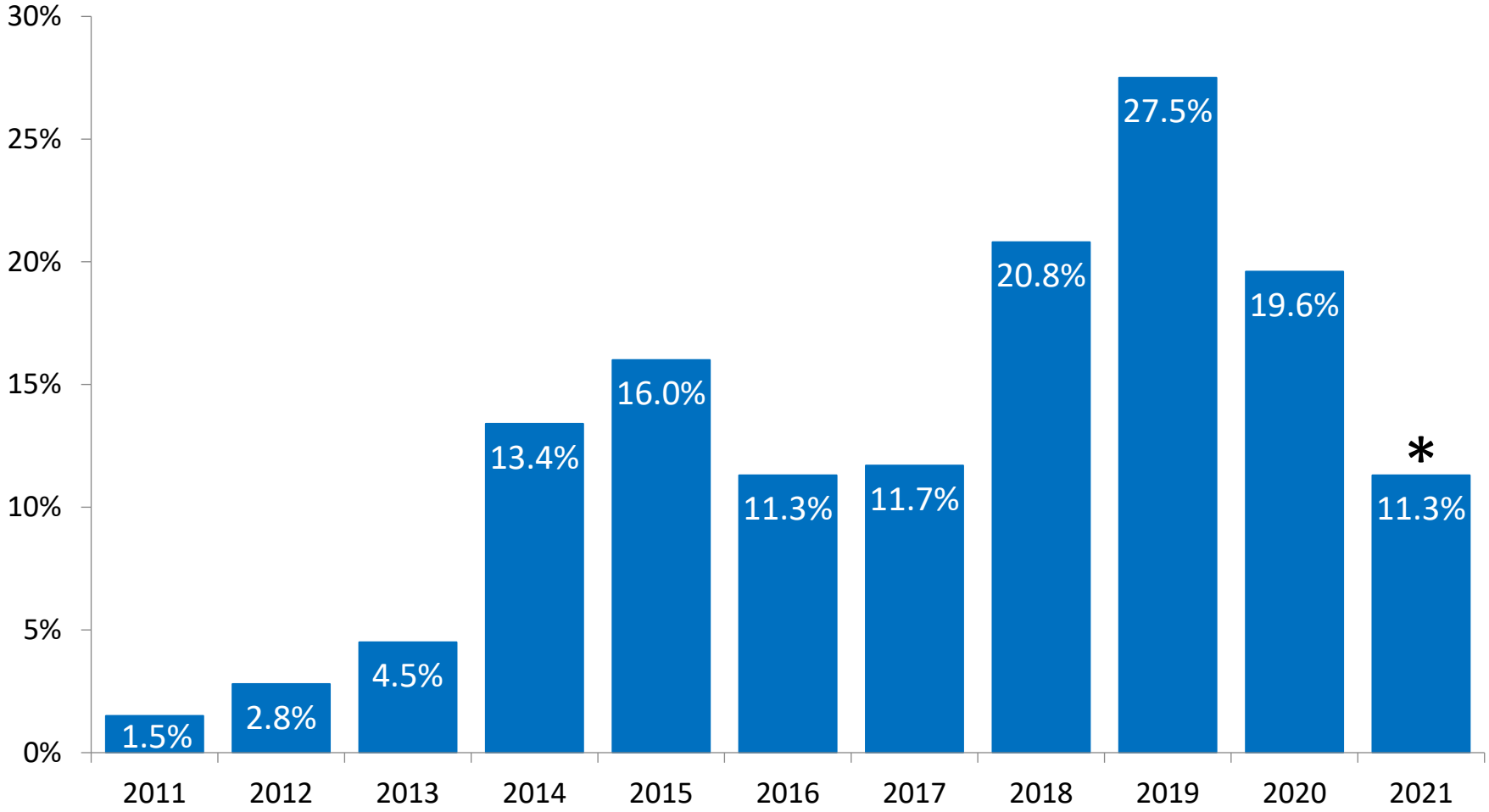
Percentage of adolescents in grades 6 to 12 who were current tobacco product users by type of tobacco product, 2011-2018



Source: Centers for Disease Control and Prevention. National Youth Tobacco Survey.
Data are not age-adjusted.
Survey participants are classified as currently using a tobacco product if they reported use of the product within 30 days prior to the survey. The 'All Tobacco' group includes the following tobacco products: cigarettes, e-cigarettes, cigars, smokeless tobacco - including chewing tobacco, snuff, dip-hookah, pipe tobacco, bidis, dissolvable tobacco, or snus.

https://progressreport.cancer.gov/prevention/youth_smoking

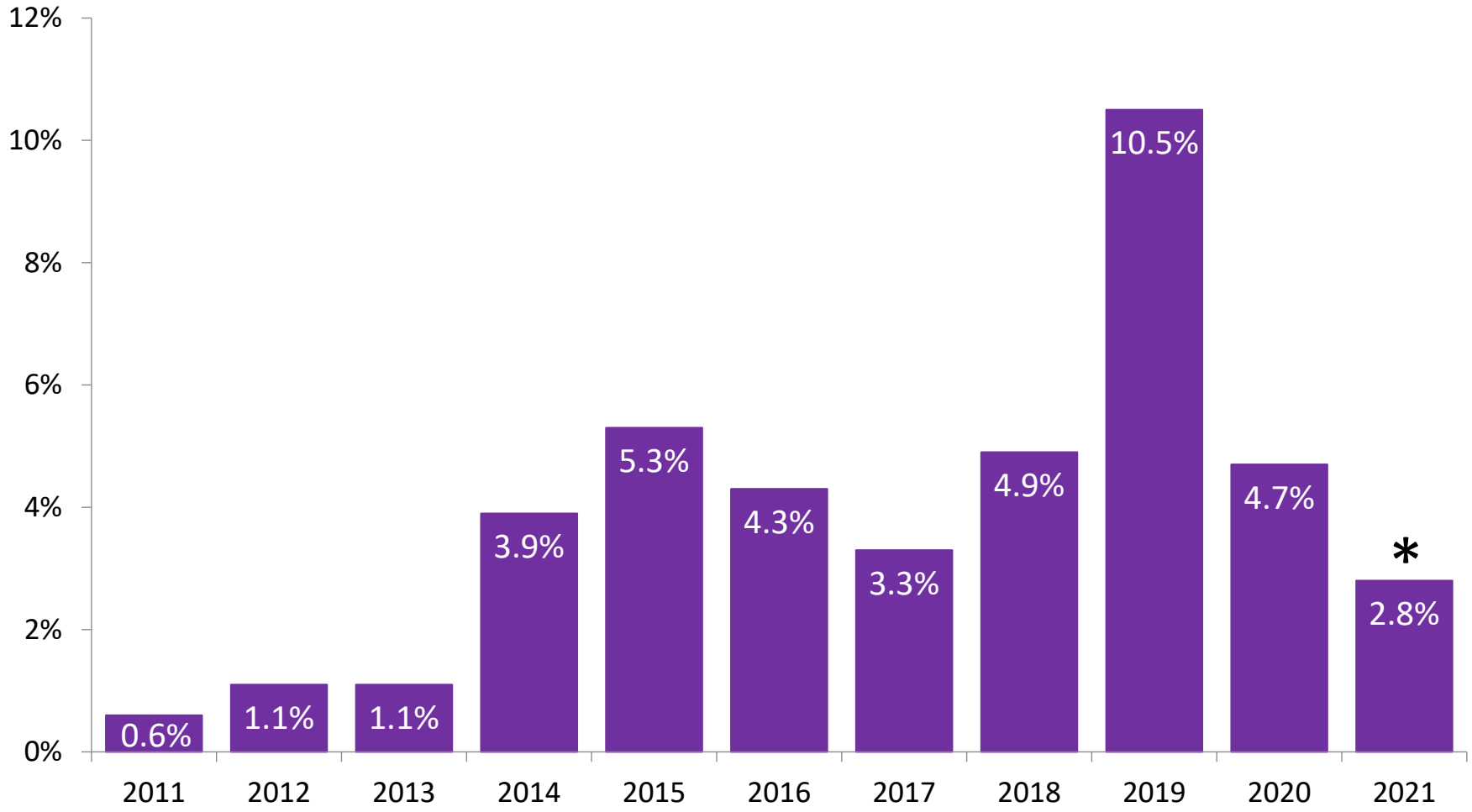
High School E-Cig Use 2011-2021 (past 30-day use)



*2021 data is not comparable to previous years due to a methodology change

Source: CDC, National Youth Tobacco Survey (NYTS)

Middle School E-Cig Use 2011-2021 (past 30-day use)

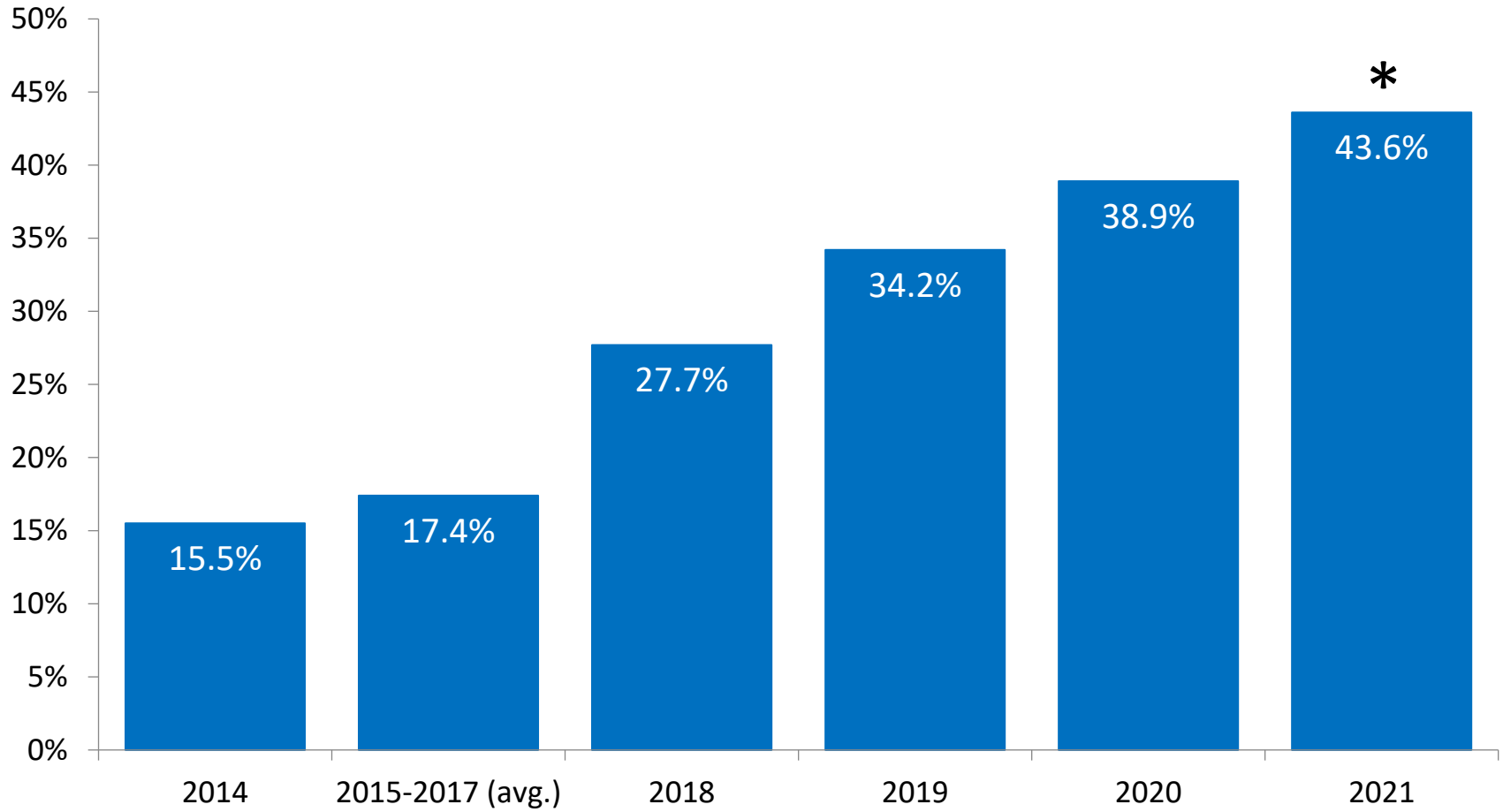


*2021 data is not comparable to previous years due to a methodology change

Source: CDC, National Youth Tobacco Survey (NYTS)

Frequent E-Cig Use Among HS E-Cig Users 2014-2021

(20+ days/month)

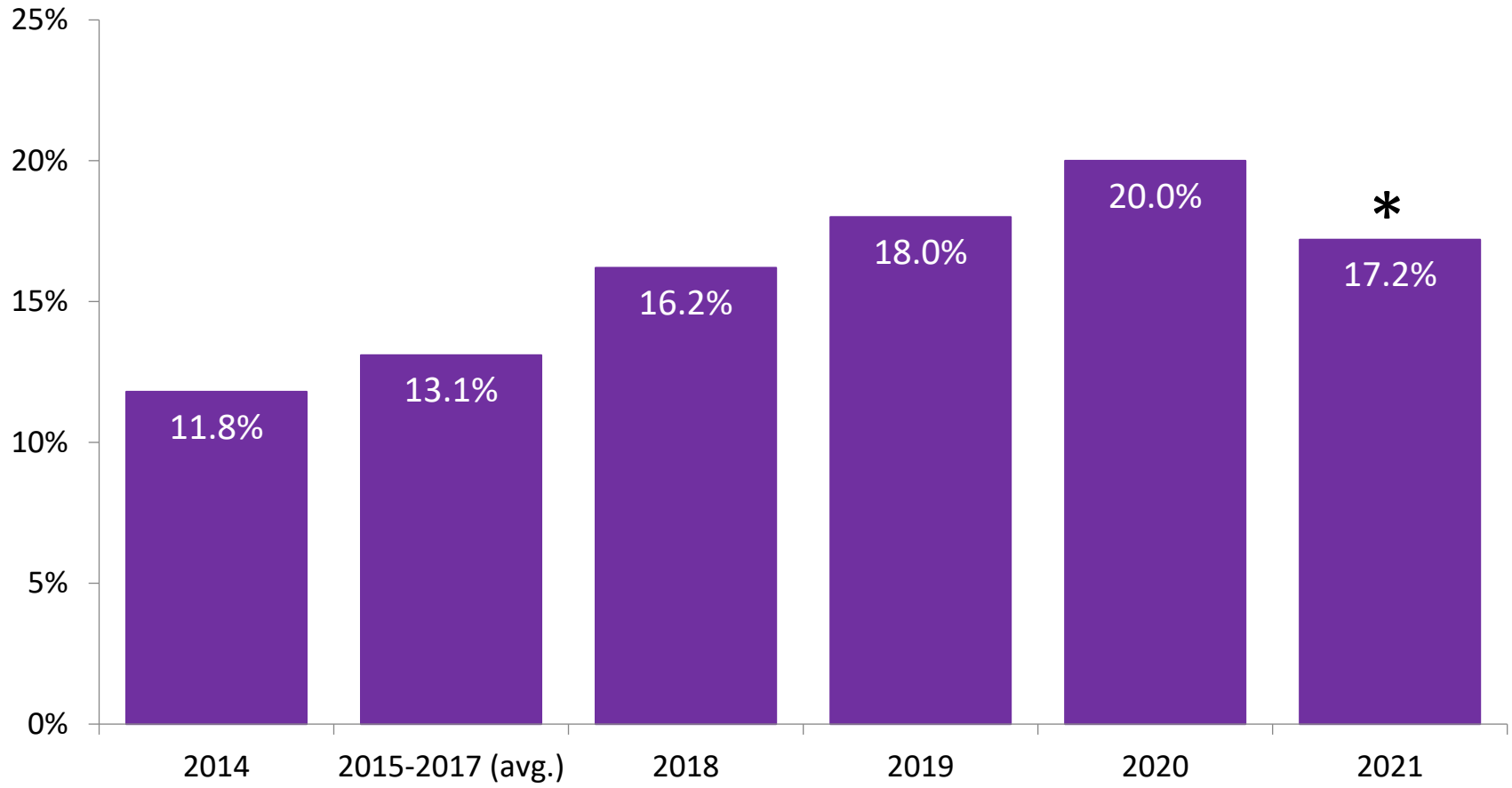


*2021 data is not comparable to previous years due to a methodology change

Source: CDC, National Youth Tobacco Survey (NYTS)

Frequent E-Cig Use Among MS E-Cig Users 2014-2021

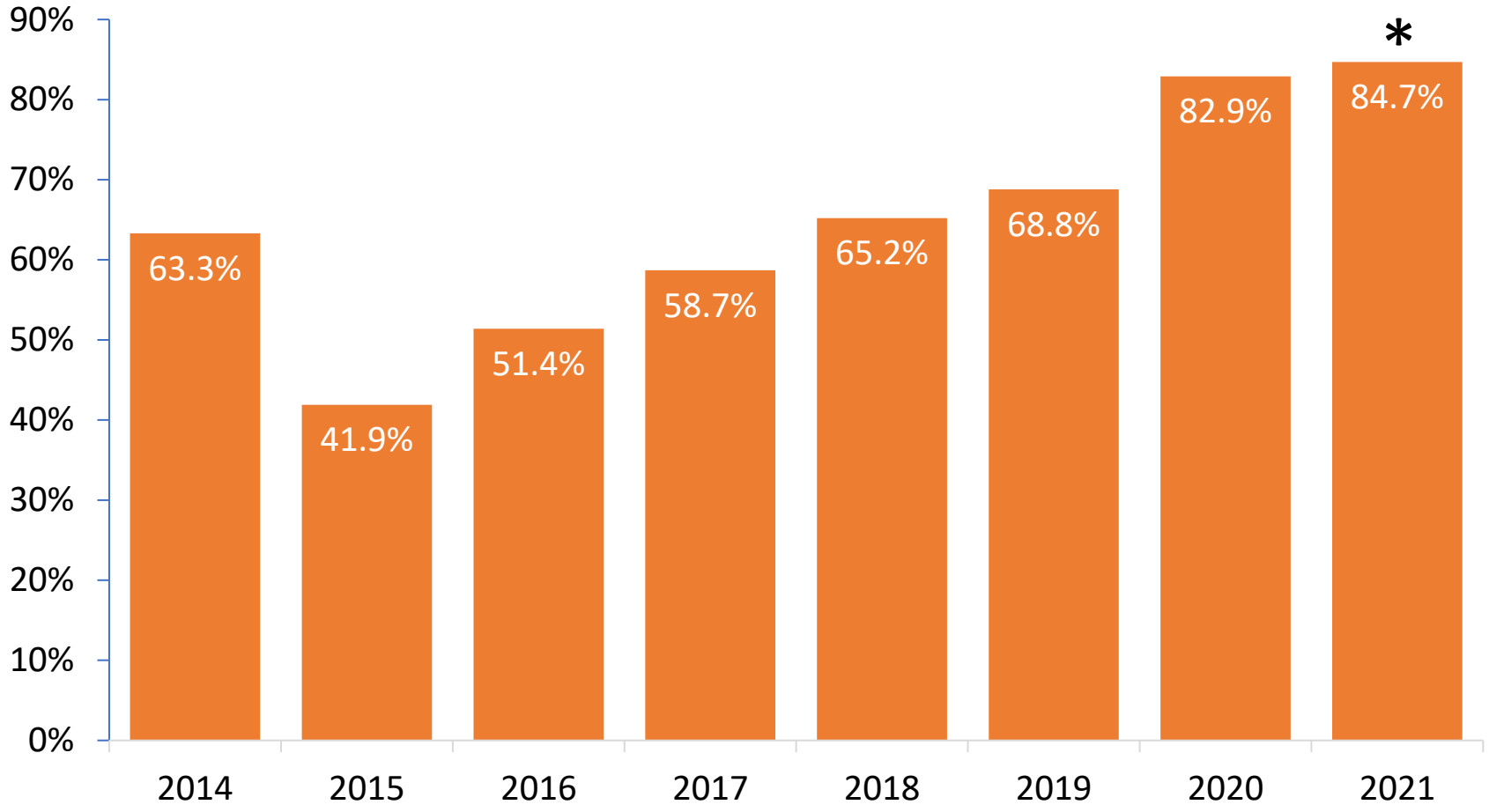
(20+ days/month)



*2021 data is not comparable to previous years due to a methodology change

Source: CDC, National Youth Tobacco Survey (NYTS)

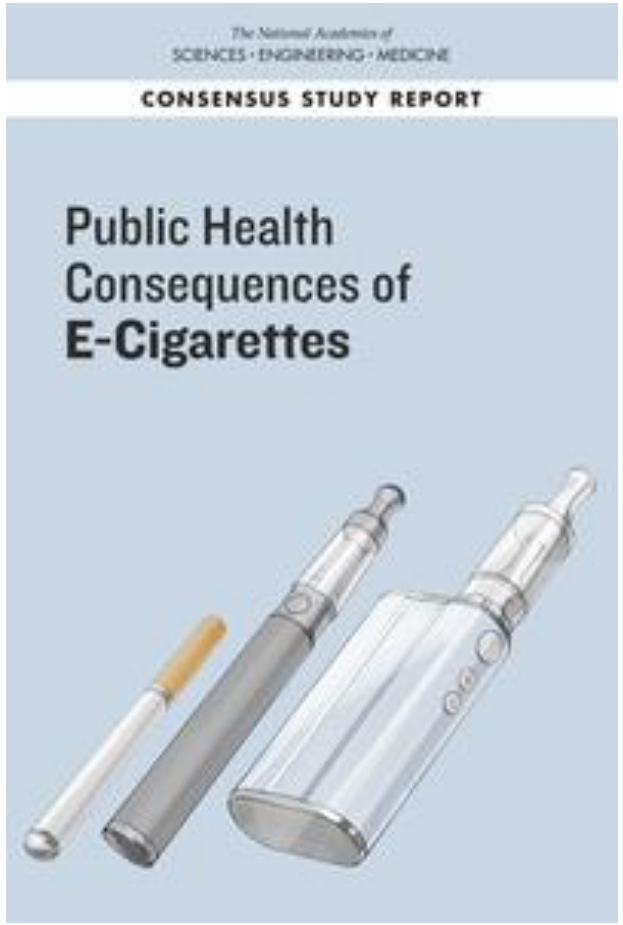
MS and HS E-Cig Users Who Use Flavored Products 2014-2021



*2021 data is not comparable to previous years due to a methodology change

Source: CDC, National Youth Tobacco Survey (NYTS)

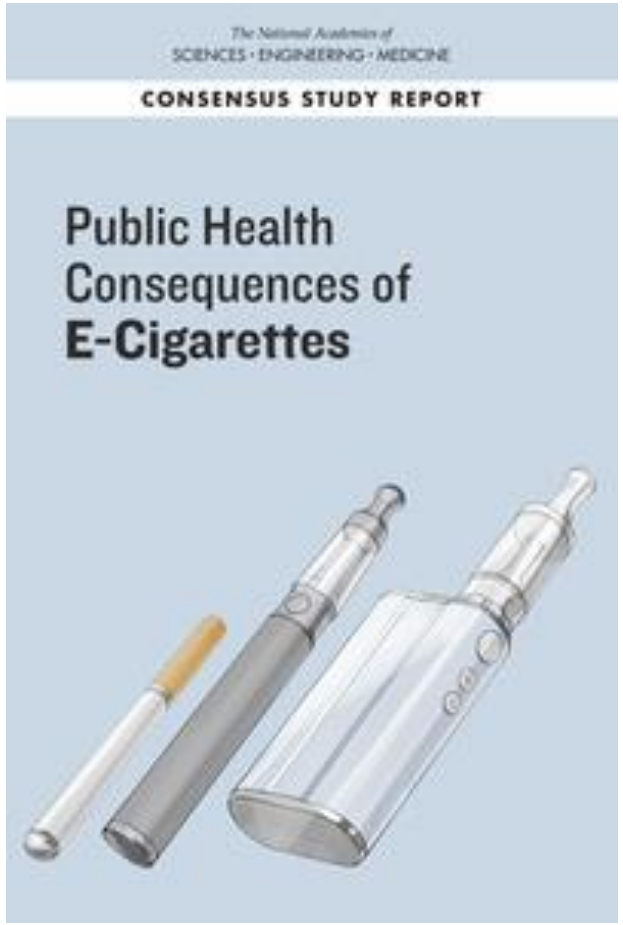
Young E-Cig Users are More Likely to Smoke



*Conclusion 16-1. There is **substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.*

- Hair EC, Barton AA, et. al. Association between e-cigarette use and future combustible cigarette use: Evidence from a prospective cohort of youth and young adults, 2017-2019. *Addictive Behaviors*. January 2021; https://doi.org/10.1016/j.addbeh.2020.106593
- Primack BA, Shensa A, Sidani JE, et al. Initiation of Traditional Cigarette Smoking after Electronic Cigarette Use Among Tobacco-Naive US Young Adults. The American Journal of Medicine. 2018;131(4):443.e441-443.e449
- Berry KM, Fetterman JL, Benjamin EJ, et al. Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths. *JAMA Netw Open.* Published online February 1, 2019; 2(2):e187794.
- Soneji S, Barrington-Trimis JL, Wills TA, et al. Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis. *JAMA Pediatrics* 2017;171(8):788–797.
- Leventhal AM, Strong DR, Kirkpatrick MG, et al. Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. JAMA. 2015;314(7):700–707.
- Loukas A, Marti CN, Cooper M, Pasch KE, Perry CL. Exclusive e-cigarette use predicts cigarette initiation among college students. Addict Behav. 2018;76:343–347
- Bold KW, Kong G, Carmenga DR, et al. Trajectories of e-cigarette and conventional cigarette use among youth. Pediatrics. 2017;141(1):e20171832.
- Doran N, Brikmanis K, Petersen A, et al. Does e-cigarette use predict cigarette escalation? A longitudinal study of young adult non-daily smokers. Prev Med. 2017;100:279–284.
- Dunbar M, Davis J, Rodriguez A, et al. Disentagling within- and between-person effects of shared risk factors on e-cigarette and cigarette use trajectories from late adolescence to young adulthood. Nicotine & Tobacco Research 2018; 1-9.

Insufficient Evidence to Recommend E-Cigs for Cessation



*Conclusion 17-1. Overall, there is **limited evidence** that e-cigarettes may be effective aids to promoting smoking cessation.*

- HHS, Office of the Surgeon General, "Smoking Cessation: A Report of the Surgeon General," 2020 https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf
- 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
- 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.
- 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
- 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

While some studies suggest that if used under certain conditions, some types of e-cigarettes may help smokers successfully quit, real-world use of e-cigarettes doesn't often match those conditions.

The Public Health Standard

- Deliberate departure from FDA's "safe and effective" standard for drugs and devices
  - *FDA v. Brown & Williamson*, 529 U.S. 120 (2000)
  - *Sottera, Inc. v. FDA*, 627 F. 3d 891 (D.C. Cir. 2010)
- Tobacco Control Act – "Appropriate for the protection of the public health" (APPH)
  - Risks and benefits to the population as a whole
  - Increased or decreased likelihood that:
    - Existing users of tobacco products will stop using such products
    - Those who do not use tobacco products will start using such products
  - Flexibility intended by Congress

When the Standard is Applied

- Section 906(d) restrictions on sale and distribution of tobacco products, including access, advertising, and promotion restrictions

- Section 907 tobacco product standards

- Section 910 premarket tobacco product applications (PMTAs)
  - (c)(2)(A): FDA "shall deny [a PMTA where] there is a lack of a showing that permitting [the product] to be marketed would be [APPH]."
  - 86 Fed. Reg. 55,300: Whether the product is likely to have a net benefit on population health, which includes youth, young adults, and other vulnerable populations

The Standard Applied: PMTAs

21 C.F.R. § 1114.7 – Required content and format

- (d)(5) – Proposed sale, distribution, advertising, or promotion restrictions
- (f)(2) – Description of marketing plans
- (h)(3) and (4) – Summary of health risk investigations and concluding discussion describing how the PMTA constitutes valid scientific evidence that establishes permitting marketing of the product is APPH
- (k) – Health risk investigations
  - Health risks to users and nonusers and comparative risks to other tobacco products
  - Impact of the product and its label, labeling, and advertising on likelihoods of tobacco use behaviors, perceptions of the product, and use intentions of users and nonusers
  - Impact of human factors on product risk
- (l) – The effect on the population as a whole

The Standard Applied: IQOS PMTAs

- FDA issued Marketing Granted Orders (MGOs) in April 2019
- Technical Project Lead (TPL) Review
  - The social science review concludes that based on the information submitted by the applicant, we have concerns with respect to: the **lack of information about youth under age 18**, as well as the **lack of a discussion of submitted data's applicability to youth** and the **lack of presentation of the data in stratified categories that would allow us to make inferences about youth, the potential for initiation among young adult never smokers**, **and the potential for dual use among current smokers with only a one cigarette per day decrease in use frequency**. Philip Morris Products S.A.'s premarket tobacco product applications do not contain sufficient information to address these concerns from a Social Science perspective.
  - As TPL, I do not agree with these social science conclusions. I agree there are limited data regarding use and possible uptake of IQOS in youth. However, I disagree that there is no data. **I agree there are concerns about dual-use**. There is evidence that U.S. cigarette smokers are interested in IQOS, but limited data for use of IQOS to achieve CC smoking cessation. The company states they intend to market IQOS "for adult smokers who wish to completely switch." The limited data available indicates that a dual-use period is common during the switching period, but those who switch 'quickly and completely' were more likely to successfully remain off conventional cigarettes. The studies conducted by the applicant have not demonstrated reduction in long-term disease risk; however, the **reduced exposures combined with the other available information, lead me to conclude IQOS is appropriate for protection of public health, even if there is some dual-use among smokers as they potentially transition to the product**.

The Standard Applied: Flavored* E-Cig PMTAs

*Flavors other than tobacco and menthol

Sample Decision Memo (Marketing Denial Order (MDO))/TPL Review

- Given the known and substantial risk of flavored ENDS with respect to youth appeal, uptake, and use, applicants would need reliable and robust evidence of a potential benefit to adult smokers that could justify that risk. Accordingly, in order to show that a flavored e-cig is APPH, the applicant must show that the benefit to adults switching from or reducing cigarettes outweighs the risk to youth.
- To effectively demonstrate this benefit in terms of product use behavior, only the strongest types of evidence will be sufficiently reliable and robust —most likely product specific evidence from a randomized controlled trial (RCT) or longitudinal cohort study, although other types of evidence could be adequate, and will be evaluated on a case-by-case basis.
- Moreover, tobacco-flavored e-cigs may offer the same type of public health benefit as flavored e-cigs, i.e., increased switching and/or significant reduction in smoking, but do not pose the same degree of risk of youth uptake. Therefore, to demonstrate the potential benefit to current users, FDA has reviewed these applications for any acceptably strong evidence that the flavored products have an added benefit relative to that of tobacco-flavored e-cigs in facilitating smokers completely switching away from or significantly reducing their smoking.

The Standard Applied: TBD

- PMTAs
  - Continued MDO litigation
  - Menthol-flavored e-cigs?
  - How do evolving use trends impact application of the standard for initial reviews, re-submissions, and the threshold for FDA withdrawal of MGOs?
- Menthol cigarette and flavored cigar product standards
  - APPH application in the final rule compared to proposed rule
  - Litigation
- Nicotine product standard?

The Goal of FDA Tobacco Regulation

CTP Vision:

To make tobacco-related disease and death part of America's past, not America's future, and, by doing so, ensure a healthier life for every family.