

## POLICY BRIEF

### KEY TERMS

**ENDS** – Electronic Nicotine Delivery Systems are devices such as e-cigarettes, tank systems, and vape pens that heat a liquid to create aerosols that are inhaled by the user. These e-liquids usually contain nicotine (but not tobacco) as well as additives, flavors and chemicals that can be toxic to people’s health.

**Nicotine** – a naturally occurring toxic chemical found in tobacco plants. Cigarettes, cigars, other tobacco products, tobacco smoke, and ENDS contain nicotine. Nicotine affects the nervous system and the heart and is highly addictive.

**Tobacco Control Act** – The Family Smoking Prevention and Tobacco Control Act was legislation that provided the FDA with authority to regulate the manufacture, distribution, and marketing of tobacco products, with greater emphasis on limiting any marketing towards children.

### Background

Electronic nicotine delivery systems (ENDS) simulate traditional cigarette smoking via the heating of a vapor aerosol composed of propylene glycol or glycerol as well as nicotine, flavors, and various additives.<sup>1</sup> Often marketed as less toxic than combustible tobacco, ENDS now comprise a multibillion-dollar industry, and adoption of these products has skyrocketed over the past decade, contrasting with combustible tobacco’s continued descent towards historically low usage.<sup>2-3</sup> ENDS proliferation has sparked a new wave of concerns, and their wider impacts on health are still being closely researched.

National regulation of traditional tobacco products dates back to the 19<sup>th</sup> century, but ENDS were initially regulated only on the state level, with little federal oversight. The Food and Drug Administration (FDA) only gained the ability to regulate tobacco products in 2009 with the passage of the Family Smoking Prevention and Tobacco Control Act.<sup>4-5</sup> However, with concerns about the increased use of ENDS by youth alongside the advent of easily concealable vape pens, federal regulation began in earnest

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<sup>1</sup> Kaiser MA, Prasad S, Liles T, Cucullo L. A decade of e-cigarettes: Limited research & unresolved safety concerns. *Toxicology*. 2016;365:67-75. doi:10.1016/j.tox.2016.07.020

<sup>2</sup> Federal Trade Commission. The Federal Trade Commission’s First Report on E-Cigarette Sales and Advertising Reveals Disturbing Trends Affecting the Health of Young Americans. Federal Trade Commission. Published 2022. <https://www.ftc.gov/news-events/news/press-releases/2022/03/federal-trade-commissions-first-report-e-cigarette-sales-advertising-reveals-disturbing-trends>

<sup>3</sup> US Department of Health and Human Services. Smoking Cessation: A Report of the Surgeon General. Published online 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>

<sup>4</sup> Goldman. E-Cigarettes and Federal Regulation | Health Affairs. Published 2014. <https://www.healthaffairs.org/doi/10.1377/hpb20140710.351753/full/>

<sup>5</sup> Rep. Waxman HA [D C 30. H.R.1256 - 111th Congress (2009-2010): Family Smoking Prevention and Tobacco Control Act. Published June 22, 2009. <http://www.congress.gov/bill/111th-congress/house-bill/1256>

over the last half-decade.<sup>4-6</sup> In 2020, prompted by a pattern of acute lung injuries thought to be associated with ENDS, the FDA banned the sale of cartridge-based flavored e-cigarettes (exempting tobacco and menthol flavored ENDS), arguing that fruity and colorful offerings such as cotton candy were a contributing factor towards ENDS appealing so heavily to youth.<sup>7</sup> Currently, all 50 states, as well as Washington D.C., prevent minors from purchasing ENDS,<sup>8</sup> but bans on vaping in smokefree venues, government buildings, and school districts remain inconsistent, with just 17 states currently including ENDS among indoor smoking bans and tax laws on e-cigarettes varying by state.<sup>8</sup> Furthermore, some companies have circumvented FDA regulations on flavor bans by developing disposable ENDS products, prompting the FDA to issue warning letters in response.<sup>9</sup>

ENDS' status as a tobacco cessation tool remains a contentious subject; the American Medical Association<sup>10</sup> and the American College of Preventative Medicine<sup>11</sup> have released opposing statements regarding their efficacy in the past. Proponents of ENDS as a form of harm reduction argue that ENDS are an effective smoking cessation device, allowing regular tobacco smokers to utilize an alternative smoking product with fewer known health risks as they begin the process of weaning off these products altogether.<sup>11</sup>

In 2015, ASCO and the American Association for Cancer Research (AACR) released a policy statement with recommendations to curb uptake among youth while nevertheless recognizing ENDS as a potentially promising harm reduction tool for chronic smokers looking to quit.<sup>12</sup> In the years since, a growing body of literature has demonstrated that ENDS usage could be linked to adverse health outcomes such as DNA damage and inflammation, which can facilitate the development of various cancers.<sup>13-14</sup> Furthermore, there has been little institutional support for ENDS as a smoking cessation

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<sup>6</sup> Gottlieb S. Protecting American Families: Comprehensive Approach to Nicotine and Tobacco - 06/28/2017. Published 2017. <https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017>

<sup>7</sup> US Food and Drug Administration. Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry. Published online 2020. <https://www.fda.gov/media/133880/download>

<sup>8</sup> Centers for Disease Control and Prevention. STATE System E-Cigarette Fact Sheet. Published 2023. <https://www.cdc.gov/statesystem/factsheets/ecigarette/ECigarette.html>

<sup>9</sup> US Food and Drug Administration. FDA Warns Internet Retailers for Selling Illegal E-Cigarettes Popular Among Youth. FDA. Published online November 9, 2023. <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-internet-retailers-selling-illegal-e-cigarettes-popular-among-youth>

<sup>10</sup> American Medical Association. Electronic Cigarettes Are Drug Delivery Devices and Should Be Subject to FDA Regulations. Published 2010. <https://casaa.org/wp-content/uploads/2010-AMA-Electronic-Cigarettes-Are-Drug-Delivery-Devices-and-Should-Be-Subject-to-FDA-Regulations.pdf>

<sup>11</sup> Siegel MB, Tanwar KL, Wood KS. Electronic cigarettes as a smoking-cessation: tool results from an online survey. *Am J Prev Med.* 2011;40(4):472-475. doi:10.1016/j.amepre.2010.12.006

<sup>12</sup> Brandon TH, Goniewicz ML, Hanna NH, et al. Electronic nicotine delivery systems: a policy statement from the American Association for Cancer Research and the American Society of Clinical Oncology. *J Clin Oncol.* 2015;33(8):952-963. doi:10.1200/JCO.2014.59.4465

<sup>13</sup> Yu V, Rahimy M, Korrapati A, et al. Electronic cigarettes induce DNA strand breaks and cell death independently of nicotine in cell lines. *Oral Oncology.* 2016;52:58-65. doi:10.1016/j.oraloncology.2015.10.018

<sup>14</sup> Muthumalage T, Lamb T, Friedman MR, Rahman I. E-cigarette flavored pods induce inflammation, epithelial barrier dysfunction, and DNA damage in lung epithelial cells and monocytes. *Sci Rep.* 2019;9(1):19035. doi:10.1038/s41598-019-51643-6

tool, and the industry has not attempted to push for FDA-approved clinical trials to conclusively demonstrate efficacy as such.<sup>15</sup>

With the landscape around ENDS rapidly transforming as their usage remains worryingly high, this brief is intended to highlight current ENDS regulations in place, what is needed to curb their adoption among youth populations, and what actions are necessary to better understand the relationship between ENDS and tobacco-related disparities.

## Concerns for ASCO Members & the Cancer Community

While ENDS rely on electricity to heat the device and usually avoid burning tobacco (which produces harmful chemicals such as arsenic, tar, and acetone among many others when burned), nicotine is still delivered in high enough quantities to facilitate rates of addiction that are comparable to combustible tobacco cigarettes.<sup>16</sup> Nicotine consumption also causes the brain to release dopamine, which leads the user to feel a sense of pleasure or relief, and nicotine use at an early age can potentially alter the brain chemistry of the user.<sup>17</sup>

The addictive quality of nicotine coupled with repeated exposure to potential cancer-causing carcinogens remains a concern. Multiple studies have highlighted the risk of both damage to DNA and the inhibition of DNA repair processes due to compounds found in ENDS.<sup>14-14</sup> Nicotine and the vapors from ENDS have the capacity to override DNA checkpoints, which sense damage and regulate cell replication. This can lead cells to replicate damaged DNA. ENDS vapor can also promote inflammation and unregulated cellular replication,<sup>14</sup> a primary driver of cancer.

While there is an argument for ENDS as a cessation tool, a portion of ENDS users become or already are categorized as dual-use smokers: individuals who regularly smoke both combustible tobacco cigarettes as well as ENDS devices such as vape pens.<sup>18</sup> Considering the breadth of literature on the harms of traditional cigarette smoking, the carcinogen cocktail that dual smokers are exposed to, while not deeply investigated in combination, reasonably has the potential to cause long-term health problems in users. Absent formal approval as tobacco cessation devices, the role of ENDS for such purposes remains murky.

Of chief concern for ASCO is the proliferation of regular vaping amongst school age children. A national survey titled “Monitoring the Future” found a 73% increase in 12<sup>th</sup> grade students who used a vaping

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<sup>15</sup> Herbst RS, Hatsukami D, Acton D, et al. Electronic Nicotine Delivery Systems: An Updated Policy Statement From the American Association for Cancer Research and the American Society of Clinical Oncology. *JCO*. 2022;40(35):4144-4155. doi:10.1200/JCO.22.01749

<sup>16</sup> Centers for Disease Control and Prevention. About Electronic Cigarettes (E-Cigarettes). Centers for Disease Control and Prevention. Published 2023. [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/about-e-cigarettes.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html)

<sup>17</sup> Benowitz NL. Nicotine Addiction. *N Engl J Med*. 2010;362(24):2295-2303. doi:10.1056/NEJMra0809890

<sup>18</sup> Owusu D, Huang J, Weaver SR, et al. Patterns and trends of dual use of e-cigarettes and cigarettes among U.S. adults, 2015–2018. *Preventive Medicine Reports*. 2019;16:101009. doi:10.1016/j.pmedr.2019.101009

device within 30 days of the survey between 2015 and 2020,<sup>19</sup> and multiple studies have highlighted that the advertising of these products increases the probability that youth will start using ENDS.<sup>2,20-21</sup> Understanding the full breadth of consequences that ENDS use carries when used from adolescence to middle and old age is currently not possible due to the lack of long-term data associated with this relatively new technology. Nevertheless, the evidence has developed sufficiently to identify multiple risks in the short and long-term associated with youth uptake of ENDS.

## Where ASCO Stands on ENDS

ASCO acknowledges that despite numerous studies showing the presence of harmful carcinogens in ENDS, the evidence from biomarker studies show *lower* relative carcinogen exposure as users are not inhaling combustible tobacco.<sup>15</sup> What is widely recognized is that smoking combustible tobacco (cigarettes, cigars, hookah pipes, etc.) can increase the risk of various cancers by many magnitudes. As such, it will likely take many more years of study to effectively understand the link between ENDS usage and the risk of cancer. ASCO supports the continued undertaking of these studies, chief among them being FDA-backed randomized clinical trials. These trials would best assist in closing the knowledge gap regarding ENDS' ability to serve as cessation or harm reduction tools.

ASCO and the AACR strongly believe that ENDS require further regulation and that flavored electronic nicotine products, with their potential to addict new users who previously never smoked, should be unilaterally banned if they contain natural or synthetic nicotine. ASCO also opposes any advertisements for nicotine products that have the potential to reach underage users, though it should be acknowledged that influencers and other forms of social media advertisement make comprehensive regulation of ENDS marketing a challenge. However, ASCO remains open to a role for ENDS as tobacco cessation devices if data can demonstrate efficacy comparable to existing cessation methods and the FDA grants formal approval.

## For More Information

[Electronic Nicotine Delivery Systems: An Updated Policy Statement From the American Association for Cancer Research and the American Society of Clinical Oncology](#)

[Electronic Nicotine Delivery Systems: A Policy Statement From the American Association for Cancer Research and the American Society of Clinical Oncology](#)

[Tobacco Cessation and Control a Decade Later: American Society of Clinical Oncology Policy Statement Update](#)

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<sup>19</sup> Johnston LD, Miech RA, O'Malley PM, Bachman JG, Schulenberg JE, Patrick ME. Monitoring the Future National Survey Results on Drug Use, 1975-2020: Overview, Key Findings on Adolescent Drug Use. Institute for Social Research; 2021. <https://eric.ed.gov/?id=ED611736>

<sup>20</sup> Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174

<sup>21</sup> Pierce JP, Sargent JD, Portnoy DB, et al. Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study. *JAMA Pediatr*. 2018;172(5):444-451. doi:10.1001/jamapediatrics.2017.5756