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LEGAL RESOURCE CENTER
FOR PUBLIC HEALTH POLICY

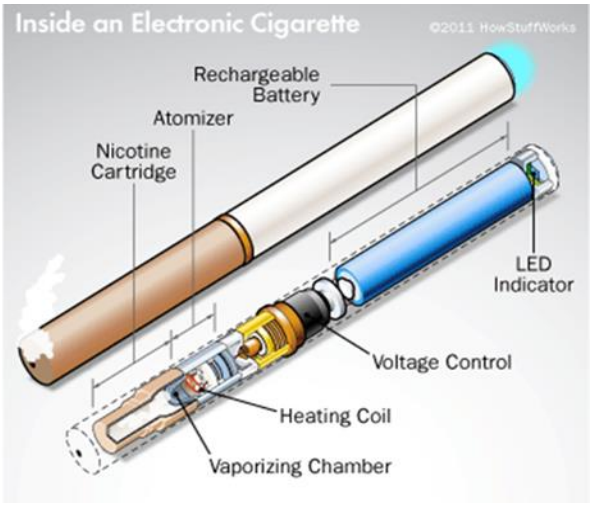


ELECTRONIC NICOTINE DELIVERY SYSTEMS
Fact Sheet

Frequently Asked Questions (FAQs)

What are Electronic Nicotine Delivery Systems (ENDS)?

- Battery-operated device containing a liquid nicotine solution that is vaporized and inhaled by the user.
- Often resemble cigarettes, cigars or pipes and come in a variety of flavors, including: cherry, chocolate, coffee, grape, menthol, mint, peach, piña colada, tobacco and vanilla.
- Sold online and in convenience stores, gas stations and specialty stores called "vape shops."
- Prices range from a few dollars for disposable devices to several hundred dollars for starter kits containing: a reusable device, a charger and replacement cartridges.
- Disposable ENDS contain up to "400 puffs" of vapor (equivalent to a pack and a half of traditional cigarettes)



ESDs contain three main components: a rechargeable lithium battery, a liquid nicotine cartridge and an atomizer that converts the liquid nicotine into a vapor.

What health risks are associated with these products?

- Because these products are relatively new to the market, long-term health effects are still largely unknown.[1] In 2011, the National Institutes of Health (NIH) and FDA announced a new study called the Population Assessment of Tobacco and Health Study (PATH), which will analyze tobacco use, including ENDS, and how it affects the health of Americans over a period of years and decades.
- Previously, the absence of federal or state regulation of ENDS made the toxicity of these products difficult to quantify. Cartridge ingredients and toxicant levels may vary greatly across brands. However, in May 2016, the FDA finalized and published the "Deeming Rule" which will require ENDS manufacturers to disclose product ingredients and concentrations, among other things.[2]
- The U.S. Food and Drug Administration (FDA) analyzed several ENDS brands and found the products contained carcinogens such as nitrosamines and "toxic chemicals such as diethylene glycol, an ingredient used in anti-freeze."[3]
- The World Health Organization determined that the value of ENDS as therapeutic aids for smoking cessation or safety as cigarette replacements could not be established, due to the lack of chemical studies and clinical trials.[4]
- Clinical studies indicate ENDS contain several toxic and carcinogenic compounds (although in far lower levels than traditional cigarettes) and may damage lungs.[5] Moreover, nicotine (the key ingredient in ENDS) is highly addictive, has immediate bio-chemical effects on the brain and body and is toxic in high doses.[6]

Are electronic smoking devices popular with youth?

- The FDA is concerned that ENDS may lead youth to try other tobacco products. Early data indicate youth e-cigarette users are more likely than non-users to initiate conventional tobacco use.
- ENDS sales doubled every year from 2008 to 2014. An $82 million market in 2010 expanded to nearly $3.5 billion in 2015. [7]
- In 2011 only 4.5% of high school youth had ever used ENDS.[8] By 2015 this figure increased to 44.9% – a nearly ten-fold increase.[9]
- In 2014, ENDS (16%) became the most commonly used tobacco product among middle and high school students, outpacing cigarettes (9.3%), cigars (8.6%), and smokeless tobacco (6.0%).

What existing laws and regulations govern electronic nicotine delivery systems?

- Maryland law prohibits the sale of "an electronic device that can be used to deliver nicotine" to a minor[10]; however, the sale of individual ESD components to a minor, including liquid nicotine cartridges, is not prohibited under the existing statute.
- On May 5th, 2016, the FDA adopted what is commonly referred to as the "Deeming Rule." The rule "deems" all other present and future products derived from tobacco subject to FDA authority, specifically including ESDs.

- **ENDS will now be subject to the following requirements, although compliance dates will be implemented on a staggered basis:**
    - Required disclosure of product ingredients
    - Premarket review*
    - Prohibition of reduced risk claims absent FDA approval
    - Age restriction to individuals 18 and over
    - Required age verification by photo ID
    - Ban on vending machines except for adult-only facilities
    - Ban on free samples
    - Required health warnings
    - Federal reporting requirements[11]

*Premarket review applies to products not commercially available on or before February 15, 2007. FDA will permit ENDS manufacturers to continue to sell their products for up to 24 months, by which time they must submit an application for pre-market review or substantial equivalence.

[1] Tan AS, Bigman CA. *E-cigarette awareness and perceived harmfulness: prevalence and association with smoking device outcomes.* AM J Prev Med. 2014; 47(2):141-149.
[2] 21 C.F.R. §§ 1100- 1150.17.
[3] U.S. Food and Drug Administration, Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA , http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm, updated 4/22/14, accessed 8/12/16.
[4] Tobacco Free Initiative, World Health Organization, *Questions and Answers on Electronic Cigarettes or Electronic Nicotine Delivery Systems*, *available at* http://www.who.int/tobacco/communications/statements/eletronic_cigarettes/en/ (March 30, 2015).
[5] Maciej Lulasz Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes*, BMJ (March 6, 2013).
[6] U.S. Surgeon General, U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction* (1988).
[7] Josh Sanburn, *Can Electronic Cigarettes Challenge Big Tobacco?*, Time.com, January 8, 2013, available at http://business.time.com/2013/01/08/can-electronic-cigarettes-challenge-big-tobacco/.
[8] U.S. Centers for Disease Control and Prevention, *E-cigarette use triples among middle and high school students in just one year* (2016), http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html.
[9] *Id*.
[10] MD. CODE ANN., Health-Gen. § 24-305 (West 2013).
[11] 21 C.F.R. §§ 1100-1150.17.

This document was developed by the Legal Resource Center for Public Health Policy at the University of Maryland Francis King Carey School of Law, with funding and support provided in part by the Centers for Disease Control and Prevention. The Legal Resource Center for Public Health Policy provides information and technical assistance on issues related to public health in Maryland. The legal information and assistance does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

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