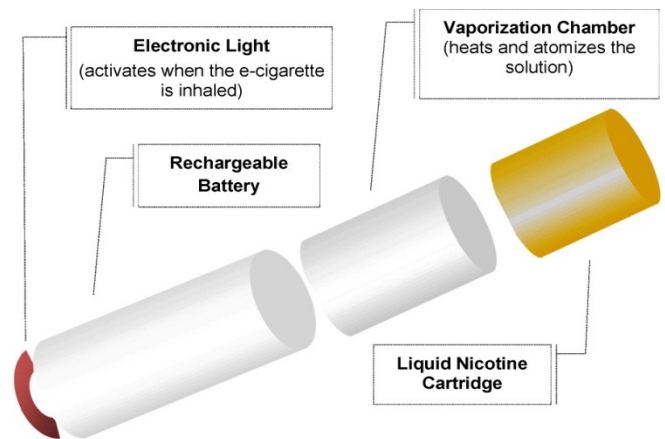




E-Cigarettes Fact Sheet

What are e-cigarettes?

“E-cigarettes”—or electronic cigarettes—are devices that allow users to mimic the ritual of smoking a cigarette while inhaling nicotine. Many glow at the end when activated as real cigarettes do.¹ Instead of smoke from burning tobacco, users inhale vapor containing nicotine (with the exception of versions which claim to be free of nicotine), flavor additives, and other chemicals.² When users inhale from the end of an e-cigarette, a battery-operated vaporizer heats a liquid solution into a vapor.³



The FDA has not approved e-cigarettes as smoking cessation devices. E-cigarette packaging is not required to include health warnings, unlike packaging for conventional cigarettes and U.S. Food and Drug Administration (FDA)-approved nicotine replacement therapy (NRT) products.⁴ Several e-cigarette marketers have advertised their products as smoking cessation tools,⁵ despite a lack of credible evidence that they are effective cessation aids.⁶

E-cigarettes are sold over the internet, in specialized mall kiosks, and by some tobacco retailers. Media reports price e-cigarette costs at approximately \$60, including the e-cigarette, a charger, and a liquid cartridge.⁷ Refills of the liquid cost \$7-\$10 for a 10-millimeter bottle.⁸

How dangerous are e-cigarettes?

The risks posed by e-cigarettes are currently unknown. The FDA, in 2009, released a study on e-cigarettes.⁹ The FDA’s Division of Pharmaceutical Analysis investigated the components of a small sample of cartridges from two e-cigarette brands.¹⁰ Test results of the sample of cartridges found them to contain nitrosamines (a known carcinogen), as well as other toxic chemicals, including diethylene glycol, which is found in anti-freeze.¹¹ Impurities found in tobacco which are suspected of causing adverse health effects were also detected, including anabasine, myosmine, and β -nicotyrine.¹² A 2011 German study examined secondhand emissions from several e-cigarette brands, finding that e-cigarettes users not only ingest, but also emit toxins and harmful ultrafine and fine particles, posing potential health risks to those nearby.¹³

Nicotine levels in e-cigarette cartridges are also of significant concern to health experts. The e-cigarette cartridges of liquid solution have been found to contain up to 18mg or more of nicotine.¹⁴ Additionally, bottles of solution sold to refill the cartridges vary considerably in nicotine content. Some refill bottles contained concentrations of nicotine as high as 500 to over 1000 mg of nicotine per 1 oz bottle of solution.¹⁵ A lethal dose of nicotine when ingested is 30 – 60 mg for adults and just 10 mg for children. Nicotine overdoses are a serious concern due to the



high concentration of nicotine in the e-cigarette solutions and the lack of protective packaging on the bottles and cartridges to prevent accidental ingestion.¹⁶

The FDA recommends that people seeking to quit smoking should use FDA-approved smoking cessation aids including nicotine gum and nicotine patches.¹⁷ There is insufficient evidence to support e-cigarette use as a cessation device.¹⁸

The FDA, the Centers for Disease Control and Prevention, and the American Academy of Pediatrics have all voiced their concern that electronic cigarettes could lead to an increase in nicotine addiction and youth tobacco use.¹⁹ Of particular concern is that e-cigarette cartridges are sold by some vendors in fruit and candy flavors that appeal to youth and that laws prohibiting the sale of cigarettes to minors may not be written broadly enough to cover e-cigarettes.²⁰

What is the legal status of e-cigarettes?

The FDA will regulate e-cigarettes under its authority to regulate other tobacco products. The FDA at one time detained or blocked incoming shipments of e-cigarettes from overseas manufacturers on the basis that e-cigarettes are unapproved drug delivery devices that must pass through the FDA's New Drug Application (NDA) process before they can legally be sold.²¹ Two e-cigarette importers and distributors, Smoking Everywhere, Inc. and Sottera, Inc., brought a lawsuit against the FDA and sought a preliminary injunction to prevent the FDA from regulating e-cigarettes as a drug delivery device and from stopping the importation of e-cigarettes into the U.S. while the case is ongoing.²² The e-cigarette distributors argued that because their products use nicotine derived from tobacco, e-cigarettes should be regulated as "tobacco products," subject to much more limited restrictions that do not require pre-approval by the FDA. The United States District Court for the District of Columbia granted the preliminary injunction. This ruling was affirmed by the United States Court of Appeals for the District of Columbia Circuit in December 2010.²³ In April of 2011, the FDA decided it would not seek further review of this decision, but rather will regulate e-cigarettes as tobacco products under the Family Smoking Prevention and Tobacco Control Act in accordance with the court's opinion.²⁴

In September 2009, the FDA announced that it will continue to bring enforcement actions against e-cigarette companies that make unsubstantiated health claims about their products.²⁵

E-cigarette sales are also subject to state law. Various state attorneys general have brought lawsuits alleging that e-cigarette distributors have violated state law by selling to minors or making unsubstantiated health claims.

For example:

- Oregon's attorney general has brought lawsuits against both Soterra, Inc. and Smoking Everywhere, Inc.²⁶ Both companies agreed to settlements barring them from selling e-cigarettes in the state, at least until local and national standards on e-cigarettes are established. Smoking Everywhere and its CEO also agreed to pay the state \$120,000 after admitting violations of state law.



- In 2010, former California Attorney General Jerry Brown’s office reached a settlement with Sottera, Inc. for \$85,000 in damages and an agreement to end sales and marketing to minors, discontinue sales of flavored cartridges, and stop marketing e-cigarettes as cessation devices unless approved by the FDA.²⁷ Soterra, Inc. also agreed to stop making claims that e-cigarettes are safer than cigarettes until reliable scientific evidence to support such a claim is available.

What Can State and Local Governments Do?

Regulate Marketing

As demonstrated above, state attorneys general can take action to ensure that e-cigarette marketing is not targeting youth or making unsubstantiated marketing claims.

Strengthen Smoke-Free Laws

State and local laws prohibiting smoking in public places may include definitions of “smoking” that do not include e-cigarette smoking (also referred to as “vaping”). It may be prudent to expand the definitions of smoke-free laws to cover e-cigarette use. As with the health effects of e-cigarettes on the users, the secondhand health effects on bystanders have not been established, however, it is known that e-cigarettes emit numerous toxins.²⁸ In addition, prohibiting e-cigarette use in public places would help to avoid the confusion that might ensue if e-cigarette use leads other smokers to believe that cigarette smoking is permitted. This in turn would strengthen the message of such laws that smoking and tobacco use in public places is not socially acceptable.

Strengthen Youth Access Laws

Similarly, the definitions in youth access laws may not be written specifically enough to prohibit e-cigarette sales to minors. E-cigarette sales to minors could lead to lifelong nicotine dependence and should be prohibited.

Legal Responses to E-Cigarettes in New York

New York State prohibits the sale of electronic cigarettes to individuals younger than 18 years of age.²⁹ Like tobacco products, sales of electronic cigarettes and smoking paraphernalia to minors are prohibited. ***Businesses offering electronic cigarettes for sale must post conspicuous signs indicating that such items may not be sold to persons under the age of 18.***³⁰

Suffolk County, New York prohibits the sale of e-cigarettes to persons under the age of 19 (the legal age for cigarette purchase in Suffolk County.)³¹ ***The law also prohibits the use of e-cigarettes in public places where conventional smoking is also prohibited.***³²

This work provides education materials and research support for Policy initiatives and does not and cannot be relied upon as legal advice.



Additional Resources

- [Tobacco Control Legal Consortium](http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regulatingecigs-2010.pdf): Guide to regulating e-cigarettes and links to other state laws. [http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regulatingecigs-2010.pdf]
- [U.S. Food and Drug Administration](http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm): Information about the FDA's enforcement actions against e-cigarette manufacturers and its analysis of the health risks posed by e-cigarettes. [http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm]
- [Americans for Nonsmokers' Rights](http://www.no-smoke.org/learnmore.php?id=645): Fact sheet on e-cigarettes and links to recent news articles. [http://www.no-smoke.org/learnmore.php?id=645]
- [Policy Guidance Document on E-Cigarettes \(ACSCAN, AHA, ALA, CFTEK\)](http://www.ttac.org/tcn/2010/may-2010/pdfs/Policy_Guidance_E-Cigarettes.pdf): Joint statement of health organizations supporting legislation to prohibit the sale of e-cigarettes without FDA approval. [http://www.ttac.org/tcn/2010/may-2010/pdfs/Policy_Guidance_E-Cigarettes.pdf]



References

- ¹. See Memorandum from B.J. Westenberger, Deputy Director, Ctr. For Drug Evaluation and Research, Div. of Pharm. Analysis, to Michael Levy, Supervisory Regulatory Counsel, Ctr. For Drug Evaluation and Research (May 4, 2009), available at <http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf> [hereinafter Westenberger Memo].
- ². U.S. Food and Drug Admin., FDA Warns of Health Risks Posed by E-Cigarettes (2009), available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173430.pdf> [hereinafter FDA Consumer Update].
- ³. Westenberger Memo, *supra* note 1, at 1.
- ⁴. FDA Consumer Update, *supra* note 2, at 2.
- ⁵. U.S. Food and Drug Admin., FDA Acts Against 5 Electronic Cigarette Distributors (Sept. 9, 2010), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225224.htm>.
- ⁶. World Health Organization, Marketers of Electronic Cigarettes Should Halt Unproven Therapy Claims (Sept. 19, 2008) available at <http://www.who.int/mediacentre/news/releases/2008/pr34/en/>.
- ⁷. Misha Davenport, *Electronic Cigarettes in Legal Limbo*, CHICAGO SUN-TIMES (Feb. 1, 2011, 11:32 AM), <http://www.suntimes.com/lifestyles/3490015-423/cigarette-cigarettes-smoking-traditional-tobacco.html>.
- ⁸. *Id.*
- ⁹. Westenberger Memo, *supra* note 1.
- ¹⁰. FDA Consumer Update, *supra* note 2, at 2.
- ¹¹. U.S. Food and Drug Admin., *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA*, Public Health Focus, FDA.GOV (July 22, 2009), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.
- ¹². *Id.*
- ¹³. Schripp, T., Markewitz, D., Uhde, E. and Salthammer, T., *Does e-cigarette consumption cause passive vaping?* INDOOR AIR (forthcoming), <http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0668.2012.00792.x/citedby>.
- ¹⁴. Westenberger Memo, *supra* note 1, at 3-4.
- ¹⁵. Indiana Tobacco Prevention and Cessation, Electronic Cigarettes Fact Sheet (2009), available at <http://www.in.gov/itpc/files/ECigarettes.pdf>.
- ¹⁶. American Cancer Society Cancer Action Network, E-Cigarettes Fact Sheet (2010), available at <http://www.acscan.org/content/wp-content/uploads/2010/10/e-cigarette.pdf>.
- ¹⁷. U.S. Food and Drug Admin., *E-Cigarettes: Questions and Answers*, Consumer Updates, FDA.GOV (Sept. 9, 2010), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm>.
- ¹⁸. Compare Thomas Eisenberg, *Electronic Nicotine Delivery Devices: Ineffective Nicotine Delivery and Craving Suppression After Acute Administration*, 19 TOBACCO CONTROL 87 (2010) (suggesting that e-cigarettes do not effectively suppress cigarette smokers' nicotine cravings) with C. Bullen et al., *Effect of an Electronic Nicotine Delivery Device (E Cigarette) on Desire to Smoke and Withdrawal, User Preferences and Nicotine Delivery: Randomised Cross-Over Trial*, 19 TOBACCO CONTROL 98 (2010) (finding that e-cigarettes helped to reduce the desire to smoke in study participants). Cf. C.O. Cobb et al., *Evaluating the Acute Effects of Oral, Non-Combustible Potential Reduced Exposure Products Marketed to Smokers*, 19 TOBACCO CONTROL 367 (2010) (calling to question the success of non-combustible potential reduced exposure products (PREPs) as smoking cessation aids).
- ¹⁹. U.S. Food and Drug Admin., FDA and Public Health Experts Warn About Electronic Cigarettes (July 22, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>.
- ²⁰. FDA Consumer Update, *supra* note 2, at 2.



- ²¹ *Smoking Everywhere, Inc. v. U.S. Food and Drug Admin.*, 680 F.Supp.2d 62, 63 (D.D.C. 2010), *aff'd*, *Sottera, Inc. v. U.S. Food and Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).
- ²² *Id.*
- ²³ *Sottera, Inc. v. U.S. Food and Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).
- ²⁴ Letter from Lawrence R. Deyton, Director, Center for Tobacco Products, U.S. Food and Drug Admin., to Stakeholders (April 25, 2011), *available at* <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm> (last visited May 18, 2011).
- ²⁵ U.S. Food and Drug Admin., *Electronic Cigarettes*, Public Health Focus, FDA.GOV (Sept. 13, 2010), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>.
- ²⁶ Oregon Dep't of Justice, Oregon Attorney General John Kroger Stops Sale of Unapproved Electronic Cigarettes (Aug. 18, 2009), *available at* <http://www.doj.state.or.us/releases/2009/rel081809.shtml>.
- ²⁷ California Dep't of Justice, Brown Announces Electronic Cigarette Marker's Agreement to Stop Deceptive Marketing and Sales to Minors (Aug. 3, 2010), *available at* http://oag.ca.gov/news/press_release?id=1965.
- ²⁸ *Supra* note 13.
- ²⁹ N.Y. PUBLIC HEALTH LAW §1399-cc(3) (McKinney).
- ³⁰ N.Y. PUBLIC HEALTH LAW §1399-cc(2) (McKinney).
- ³¹ SUFFOLK CNTY., N.Y., LOCAL LAW NO. 29-209 (2009) ("A Local Law Banning the Sale of E-Cigarettes to Persons Under the Age of 19"), *available at* <http://legis.suffolkcountyny.gov/Resos2009/i1347-09.pdf>.
- ³² *Id.*