

Vapor inhaled by the user and exhaled into the environment

Cartridge contains a nicotine solution; typically also serves as the mouthpiece for inhaling vapor

Atomizer creates vapor from the nicotine solution in the cartridge

Battery is rechargeable, typically lithium-ion

LED light comes on during inhalation to mimic the glow of a traditional cigarette

Electronic Cigarettes: How They Are – and Could Be – Regulated

Electronic cigarettes, or e-cigarettes, are essentially nicotine-delivery products, relatively new to the market with a growing following. The battery-powered devices provide inhaled doses of nicotine through a vaporized solution contained in cartridges inserted into the apparatus. No smoke or combustion is involved; the device emits a vapor when used. For this reason, e-cigarette use is sometimes referred to as “vaping.” E-cigarettes may be legally sold in the United States under federal law.

After a federal court ruled the Food and Drug Administration (FDA) does not have the authority to regulate e-cigarettes as drugs or drug delivery devices,¹ in April 2011 the FDA announced plans to regulate e-cigarettes as a tobacco product under the Tobacco Control Act.²

The Tobacco Control Act expressly allows state and local governments to regulate the sale and use of tobacco products, and authorizes them to enact measures that are more restrictive than federal law.³ This fact sheet explains what the FDA’s decision means, and what additional steps state and local governments can take.

FDA’s Initial Attempt to Regulate E-Cigarettes

In 2008, the FDA moved to establish authority over e-cigarettes as drugs or drug delivery devices by blocking new e-cigarette shipments into the United States. (The FDA has authority to regulate “drugs,” “devices,” or drug/device combinations through the Food, Drug and Cosmetic Act.⁴)

In response, an e-cigarette manufacturer sued the FDA in federal court, claiming that the agency did not have authority over e-cigarettes as drugs or drug delivery devices and therefore could not stop the shipments.

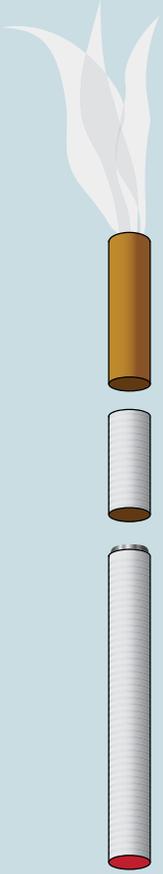
In 2010, the court ruled in favor of the manufacturer, holding that the FDA may not regulate e-cigarettes as drugs or drug delivery devices if they are not marketed as tobacco cessation aids (such as nicotine gum or patches). However, the court found that the FDA *does* have the authority to regulate e-cigarettes as tobacco products.

Limitations on New FDA Regulations

The FDA decided not to appeal the decision to the U.S. Supreme Court, instead announcing that it plans to issue regulations on e-cigarettes as a tobacco product under the Tobacco Control Act. Although the FDA has the authority to create restrictions on e-cigarettes, there are substantial limits to what it can do.

First, issuing a regulation is a lengthy process requiring several steps: drafting the regulation, providing a public comment period, and considering the submitted comments before issuing a final regulation. Given this process, it is uncertain when the regulations would take effect and how broad in scope they may be. (For more information about the federal regulatory process, see our fact sheet “[Getting Your Voice Heard: Commenting on Federal Regulations.](#)”)

In April 2011, the FDA announced plans to regulate e-cigarettes as a tobacco product under the 2009 Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act). This fact sheet explains what this announcement means, and what steps state and local governments can take to restrict e-cigarette sales and use.



How We Can Help

Our staff can consult with individual communities to help customize a new law restricting the use or sale of e-cigarettes. To contact us, go to www.changelabsolutions.org/tobaccoquestions.

This document is one in a series of FDA Law Notes addressing issues around the 2009 law. All of the FDA Law Notes are available at www.changelabsolutions.org/tobacco-control.

ChangeLab Solutions formerly existed under the name Public Health Law & Policy (PHLP), which included the Technical Assistance legal Center (TALC). Any references to PHLP or TALC in this publication should now be understood to refer to ChangeLab Solutions.

ChangeLab Solutions is a nonprofit organization that provides legal information on matters relating to public health. The legal information provided in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state. This material was made possible with funds received from the California Department of Public Health under contract #09-11182.

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Second, any regulations issued by the FDA would not ban the *use* of e-cigarettes (i.e., where people can “smoke” or “vape” e-cigarettes) and it’s unknown whether the FDA would propose banning or otherwise limiting the *sale* of e-cigarettes.

Third, any proposed new regulation at the federal level would almost certainly be met with vigorous opposition from the e-cigarette industry, which may weaken or even defeat the regulation. The industry may not oppose local regulations as vigorously.

State and Local Government Options

In contrast to the limitations the FDA faces, state and local governments have much more freedom to create their own restrictions on e-cigarettes.⁵ Some state and local governments have already passed laws to prohibit the sale of e-cigarettes to minors, and they have the power to go much further. (See the chart on the next page.)

Limiting use and exposure

Many communities are interested in limiting the public’s exposure to secondhand e-cigarette vapor. The FDA has found that e-cigarette cartridges contain carcinogens and toxic chemicals, such as diethylene glycol, an ingredient used in antifreeze.⁶ Bystanders could be exposed to those chemicals if they inhale e-cigarette vapor exhaled by someone else.

In many cases, a local government can limit potential exposure to these chemicals simply by amending the definitions of *smoke* and *smoking* in local smokefree laws to include e-cigarettes and e-cigarette vapor. For communities interested in amending a local law to prohibit the use of e-cigarettes in places where smoking is prohibited, see our model [smokefree housing, recreational areas, and beaches](#) ordinances contain language that could be adapted for that purpose. Alternatively, communities may create new laws specifically to limit where e-cigarettes may be used.

Restricting sales

State and local governments can also set restrictions on the *sale* of e-cigarettes, including banning them entirely, limiting availability to individuals over a certain age, or banning certain types or components, such as candy-flavored cartridges, that may be attractive to children.

Another approach is to regulate who may sell e-cigarettes by requiring such businesses to have a tobacco retailer license in order to sell e-cigarettes. This helps state and local governments ensure that retailers comply with restrictions on e-cigarette sales, as well as regulations on the sale of other tobacco products like traditional cigarettes, cigars, and smokeless tobacco. For more information about tobacco retailer licensing, see [“License to Kill? Tobacco Retailer Licensing as an Effective Enforcement Tool,”](#) as well as our model [tobacco retailer licensing ordinance](#).

For more about the state of the law with regard to e-cigarettes, see the chart on page 3, which lists some examples of jurisdictions that have adopted laws governing the use and/or sale of e-cigarettes. The information contained in the chart is current as of July 2011. Note that the list is not exhaustive, so additional jurisdictions may have laws affecting e-cigarettes.

E-Cigarette Law at a Glance

This chart outlines federal, state, and local restrictions on e-cigarette use and sales, as well as further regulatory opportunities at the state and local level.

	Federal Law	State and Local Law ⁷	Policy Options for State/Local Governments
Limiting Use and Exposure	<p>ChangeLab Solutions is aware of only two existing federal restrictions on e-cigarettes. The U.S. Department of Transportation interprets existing federal regulations against smoking on airplanes to apply to e-cigarettes.</p> <p>The U.S. Air Force stated that e-cigarette use would be governed by the same regulations that limit the use of tobacco products in the Air Force, including prohibitions on their use in workplaces and public spaces that are not designated smoking areas.⁸</p>	<p>Several state and local governments limit e-cigarette use in public places, including:</p> <ul style="list-style-type: none"> • New Jersey⁹ • Savannah, GA¹⁰ • Bardstown, KY¹¹ • Bullitt County, KY¹² • Glasgow, KY¹³ • Madison County, KY¹⁴ • Suffolk County, NY¹⁵ • King County, WA¹⁶ • Tacoma, WA¹⁷ 	<p>Just as they may regulate the use of cigarettes and other tobacco products, state and local governments may pass their own laws to regulate where e-cigarettes can be used to protect the public from exposure to secondhand e-cigarette vapors.</p> <p>For example, they may pass laws to prohibit the use of e-cigarettes in:</p> <ul style="list-style-type: none"> • public buildings • schools • workplaces • entryways • bus stops • recreational areas • public events • multi-unit housing complexes
Restricting Sales	<p>Does not prohibit the sale of e-cigarettes to minors.</p> <p>Does not regulate the types of e-cigarette cartridges that may be sold.</p> <p>Does not require retailers of e-cigarettes to be licensed.</p>	<p>Some state and local governments prohibit the sale of e-cigarettes to minors including:</p> <ul style="list-style-type: none"> • California¹⁸ • Colorado¹⁹ • Minnesota²⁰ • New Hampshire²¹ • New Jersey²² • Tennessee²³ • City of Spokane, WA²⁴ • King County, WA²⁵ • Spokane County, WA²⁶ • Spokane Valley, WA²⁷ • Suffolk County, NY²⁸ • Tacoma, WA²⁹ 	<p>Just as they may regulate the sale of traditional cigarettes and tobacco products, state and local governments may pass their own laws to regulate how e-cigarettes can be sold.</p> <p>For example, state and local governments may pass laws that:</p> <ul style="list-style-type: none"> • prohibit the sale of e-cigarettes entirely within their jurisdiction • prohibit the sale of e-cigarettes to minors • prohibit the sale of flavored e-cigarette cartridges • require retailers to obtain a license to sell e-cigarettes

¹ *Sottera, Inc. v. FDA*, No. 10-5032 (D.C. Cir. 2010). The ruling does not necessarily apply to all e-cigarettes on the market. If an e-cigarette company markets its products as a smoking cessation aid, the FDA may still have the authority to regulate it as a drug or drug delivery device.

² An explanation of the FDA's decision not to appeal the Sottera decision is available at: www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm.

³ 21 U.S.C. 387p.

⁴ 21 U.S.C. § 321(g) and (h).

⁵ 21 U.S.C. 387p.

⁶ An FDA press announcement warning of the hazards of e-cigarettes is available at: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm.

⁷ See www.njgasp.org/E-Cigs_White_Paper.pdf for more information about jurisdictions that have regulated the use and/or sale of e-cigarettes, produced by New Jersey GASP.

⁸ Memorandum from the U.S. Air Force Surgeon General, Charles B. Green to ALMAJCOM/CV regarding electronic cigarette use (Aug. 17, 2010). Available at: www.af.mil/shared/media/document/AFD-100818-044.pdf.

⁹ N.J. Stat. Ann. § 26:3D-57 (2010).

¹⁰ Savannah, Ga., Code of Ordinances div. II, § 9-3017 (2010).

¹¹ Bardstown, Ky., Code of Ordinances tit. XI, ch. 123 (2010).

¹² Bullitt County Board of Health Reg. No. 10-01 (2011).

¹³ Citation: Glasgow, Ky., Code of Ordinances § 38.01 (2010).

¹⁴ Madison County Health Reg.700 (2011).

¹⁵ Suffolk County, N.Y., Admin. Code §§ 754-1–754-4 (2009).

¹⁶ King County, Wash. Board of Health Code § 19.12.100 (2010).

¹⁷ Tacoma-Pierce County, Wash. Envtl. Health Code Ch. 9 § 9 (2011).

¹⁸ Cal. Health and Safety Code §119405 (2011).

¹⁹ Colo. Revised Stat. § 18-13-121 (2011).

²⁰ Minn. Tobacco Modernization and Compliance Act of 2010 § 609.6855 (2010).

²¹ State of New Hampshire Statutes, Title X, §126-K:4 (2010).

²² N.J. Stat. Ann. § 2C:33-13.1 (2010).

²³ 2011 Tennessee Laws Pub. Ch. 501 (2011).

²⁴ Spokane, Wash., Mun. Code §§ 10.08.500-590 (2011).

²⁵ Tacoma-Pierce County, Wash. Envtl. Health Code Ch. 9 § 6 (2011).

²⁶ Spokane County, Wash., Ordinance No. 11-0135 (2011).

²⁷ Spokane Valley, Wash., Mun. Code §§ 7.40.010-090 (2011).

²⁸ Suffolk County, N.Y., Admin. Code § 792-9 (2009).

²⁹ King County, Wash. Board of Health Code § 19.12.060 (2010).