

# Electronic Cigarette (“E-Cigarette”) Fact Sheet

Electronic cigarettes (“e-cigarettes”) are devices, about the size of a regular cigarette. They operate by electronically vaporizing a solution that often contains nicotine, creating a mist which is then inhaled. E-cigarettes are available in various flavors and claimed strengths of nicotine cartridges.

## How an Electronic Cigarette Works

- When a user inhales on the mouthpiece, the vaporizer is turned on and converts the liquid in the cartridge into a vapor. A rechargeable battery powers the vaporizer and has an indicator light to show when the device is in use.<sup>1</sup>
- The components of a typical e-cigarette are illustrated below:



- Cartridges generally contain nicotine, flavoring, and other chemicals.<sup>2</sup> Quality control of the ingredients is of concern.<sup>3</sup> For more details, see the section below, “Safety and Quality Control.”
- Cartridges are sold with various amounts of nicotine, from 0 mg to 18 mg of nicotine or more, although the U.S. Food and Drug Administration (FDA) testing has shown that these advertised strengths can be very different than the actual amount of nicotine in the cartridges.<sup>2</sup>
- Some users refill their own cartridges, which may be dangerous because it involves dealing with toxic levels of nicotine. Some refill bottles contain over 1,000 mg of nicotine, and the fatal dose for children is estimated at only 10 mg and for adults is estimated at 30-60 mg.<sup>4</sup>

## Manufacturers

- Ruyan, a Chinese company, claims to have originally invented and patented the e-cigarette.<sup>5</sup>
- There are now a number of companies selling e-cigarettes both on the internet and in retail mall locations in the U.S., including Ruyan, Crown 7, ePuffer, Gamucci, Janty, NJOY, PureSmoker, S.S. Choice, SmokeStik, and Smoking Everywhere.

## Legal Status

- The FDA has classified the e-cigarettes it has examined as combination drug-device products that would require FDA approval before being legally sold in the US.<sup>6</sup>
- The FDA has been challenged regarding its jurisdiction over e-cigarettes in a case currently pending in federal district court (Smoking Everywhere v. FDA No. 1:09-CV-0077-RJL (D.D.C.)).<sup>6</sup>
- Internationally, the legality of e-cigarettes varies; for example, they are banned in Canada and Australia.<sup>7,8</sup>

## Potential Youth Appeal

There is concern that electronic cigarettes may appeal to youth because of their high-tech design, easy availability online or via mall kiosks, and the wide array of flavors of cartridges including chocolate and mint.<sup>6</sup>

## Safety and Quality Control

While some manufacturers have funded research on electronic cigarettes, at this point the only independent research on e-cigarettes available has been done by the FDA and was released on July 22, 2009.<sup>1</sup>

The FDA's Division of Pharmaceutical Analysis analyzed the ingredients in a small sample of cartridges from two leading brands of electronic cigarettes, and found that the tested products contained detectable levels of known carcinogens (chemicals that cause cancer) and toxic chemicals.<sup>3</sup> In one sample, the FDA detected diethylene glycol, a chemical used in antifreeze that is toxic to humans.<sup>3</sup> In several other samples, the FDA detected carcinogens, including nitrosamines.<sup>3</sup>

The FDA's other important findings include the following:

- The testing suggested that the quality control processes used to manufacture these products are inconsistent or non-existent.<sup>3</sup> For example, three different e-cigarette cartridges with the same label were tested and each cartridge emitted a markedly different amount of nicotine with each puff.
- The e-cigarette cartridges that were labeled as containing no nicotine had low levels of nicotine in all cartridges tested, except one.<sup>3</sup>
- In addition to the known carcinogens and toxic chemicals, tobacco-specific impurities suspected of being harmful to humans, anabasine, myosmine, and  $\beta$ -nicotyrine, were detected in a majority of the samples tested.<sup>3</sup>
- One high-nicotine cartridge delivered twice as much nicotine to users when the vapor from that e-cigarette brand was inhaled than was delivered by a sample of the nicotine inhalation product approved by the FDA for use as a smoking cessation aid that was used as a control.<sup>3</sup>

## **SOURCES**

<sup>1</sup>Westenberger, B.J., Evaluation of e-cigarettes. 2009, FDA, Center for Drug Evaluation and Research, Division of Pharmaceutical Analysis: St. Louis, MO.

<sup>2</sup>FDA. *Consumer Updates: FDA Warns of Health Risks Posed by E-Cigarettes*. 2009 July 24, 2009 [cited 2009 August 12, 2009]; Available from: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>.

<sup>3</sup>FDA. *Summary of results: Laboratory analysis of electronic cigarettes conducted by FDA*. 2009 July 22, 2009 [cited 2009 August 12, 2009]; Available from: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.

<sup>4</sup>INCHEM, I.P.o.C.S.I. *Nicotine*. 1991 [cited 2009 August 12, 2009]; Available from: <http://www.inchem.org/documents/pims/chemical/nicotine.htm>.

<sup>5</sup>Ruyan. *Ruyan asserts patent rights to e-cigarette in key China court ruling*. 2009 [cited 2009 August 12, 2009]; Available from: <http://www.ruyanamerica.com/News/News.cfm?NewsID=1008>.

<sup>6</sup>FDA. *FDA and public health experts warn about electronic cigarettes [press release]*. 2009 July 22, 2009 [cited 2009 August 12, 2009]; Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>.

<sup>7</sup>Canada, H., Notice: To all persons interested in importing, advertising or selling electronic smoking products in Canada. 2009.

<sup>8</sup>Australian Government Department of Health and Ageing, N.D.a.P.S.C., *Record of Reasons, 54th Meeting, 14-15 October 2008*. 2008.