

## **E-Cigarettes**

### Are they safe? Will they help smokers quit?

Electronic cigarettes or "e-cigarettes" are battery-operated devices that allow the user to inhale a vapor produced from cartridges filled with nicotine, flavor and other chemicals. E-cigarette companies promote them as both alternatives to traditional cigarettes and tobacco cessation tools.

There is <u>no</u> scientific evidence that e-cigarettes are safe or that they can help smokers quit.

### What are E-Cigarettes?

- According to the U.S. Food and Drug Administration (FDA), e-cigarettes are combination drug-device products designed to deliver nicotine or other substances to a user in the form of a vapor.<sup>1</sup> FDA does not consider e-cigarettes to be tobacco products.
- E-cigarettes are not traditional cigarettes. They are typically composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that uses heat to convert the contents of the cartridge into a vapor, which is then inhaled by the user.<sup>2</sup>
- Some e-cigarettes contain nicotine, a highly addictive drug<sup>3</sup>.

#### Safety and Cessation Concerns

- There is currently no scientific evidence about the safety of e-cigarettes. In initial lab tests, FDA found detectable levels of carcinogens (nitrosamines) and toxic chemicals, including an ingredient used in anti-freeze, in two brands of e-cigarettes and numerous cartridges. FDA determined that users could potentially be exposed to these chemicals. This contradicts manufacturers' claims that their products are safe alternatives to tobacco.
- E-cigarettes have not been approved by the FDA for use in smoking cessation. No evidence exists to show they help people quit smoking.<sup>8</sup>
- More research on e-cigarettes is needed to determine what ingredients they contain, how they are being used, and what effect they have on users.

### Marketing and Youth Access Concerns

- Despite the fact that e-cigarettes have not been shown to be effective tobacco cessation tools and are not FDA approved, some distributors are marketing them for smoking cessation.<sup>9</sup>
- In one study, FDA found that some e-cigarette cartridges claiming not to contain nicotine actually did. 10
- Government agencies and medical organizations, such as the FDA, the Centers for Disease Control and Prevention, and the American Academy of Pediatrics have also expressed concern that electronic cigarettes could increase nicotine addiction and tobacco use in young people.<sup>11</sup>
- E-cigarettes are often made to resemble cigarettes and available in flavors that may appeal
  to youth. E-cigarettes may also lead youth to try traditional cigarettes or other tobacco
  products, which are known to cause disease and premature death.<sup>12</sup>
- Many nicotine refill bottles or cartridges are not adequately packaged to prevent children's access or accidental ingestion of toxic amounts of nicotine.

#### ACS CAN's Current Views

- ACS CAN strongly supports FDA's assertion that e-cigarettes should be regulated as drugdelivery devices and not as tobacco products. We support the authority of the FDA to take action to protect and advance the public health to the full extent of the law.
- ACS CAN supports including e-cigarettes in new smoke-free laws or amendments to

# Recent FDA Action on E-Cigarettes

In September 2010, FDA began enforcing its authority to regulate e-cigarettes as combination drug-devices and issued warming letters against five electronic cigarette distributors for making unsubstantiated claims and marketing their products illegally. FDA requested that the companies in violation of the law correct their violations or stop selling their products within 15 working days.

- existing laws. However, since FDA does not consider e-cigarettes to be tobacco products, they should clearly be defined as different from tobacco products and addressed separately in the law.
- Regardless of the marketing tactics that ecigarette companies use, ACS CAN supports restricting the sale of e-cigarettes until they are approved by the FDA and evidence shows that these products are not harmful.
- Laws that only prohibit sales to minors do not go far enough to protect public health.

#### References

<sup>&</sup>lt;sup>1</sup> U.S. Food and Drug Administration. FDA and Public Health Experts Warn About Electronic Cigarettes. July 22, 2009. Available online at <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm</a>.

<sup>&</sup>lt;sup>2</sup> U.S. Food and Drug Administration. E-Cigarettes: Questions and Answers. September 17, 2010. Available online at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm.

<sup>&</sup>lt;sup>3</sup> National Institute on Drug Abuse. Tobacco/Nicotine. Available at http://www.nida.nih.gov/drugpages/nicotine.html.

<sup>&</sup>lt;sup>4</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <a href="http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm">http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm</a>.

<sup>&</sup>lt;sup>5</sup> The E-Cigarettes Shop. Electronic Cigarettes - A Healthier Alternative to Smoking. Available online at http://theecigarettes.com/electronic-cigarettes-a-healthier-alternative-to-smoking/.

<sup>&</sup>lt;sup>6</sup> ECigarettesUSA, Inc. ECigarettes...a healthier alternative to cigarettes. Available at <a href="http://www.ecigarettesusa.com/">http://www.ecigarettesusa.com/</a>.

<sup>&</sup>lt;sup>7</sup> The Safe Cig. Electronic Cigarette FAQs. Available online at http://www.thesafecig.com/contactus.php.

<sup>&</sup>lt;sup>8</sup> World Health Organization. Marketers of Electronic Cigarettes Should Halt Unproven Therapy Claims. September 19, 2008. Available online at <a href="http://www.who.int/mediacentre/news/releases/2008/pr34/en/">http://www.who.int/mediacentre/news/releases/2008/pr34/en/</a>.

<sup>&</sup>lt;sup>9</sup> U.S. Food and Drug Administration. FDA Acts Against 5 Electronic Cigarette Distributors. September 9, 2010. Available online at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225224.htm.

<sup>&</sup>lt;sup>10</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at

 $<sup>\</sup>underline{http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm}.$ 

<sup>11</sup> U.S. Food and Drug Administration. FDA and Public Health Experts Warn About Electronic Cigarettes.

<sup>&</sup>lt;sup>12</sup> U.S. Food and Drug Administration. FDA Warns of Health Risks Posed by E-Cigarettes. July 23, 2009. Available online at <a href="http://www.fda.gov/ForConsumers/Consumer-Updates/ucm173401.htm">http://www.fda.gov/ForConsumers/Consumer-Updates/ucm173401.htm</a>.