



## E-Cigarettes – Not a Safe Alternative to Smoking

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.

### 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> The 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, the FDA found detectable levels of carcinogens (nitrosamines) in half of the samples tested. They found other tobacco specific impurities (anabasine, mysomine, beta-nicotyrine) in a majority of the samples and an ingredient used in anti-freeze in two brands of e-cigarettes and numerous cartridges.<sup>4</sup> The FDA determined that users could potentially be exposed to these chemicals.<sup>5</sup> This contradicts manufacturers’ claims that their products are safe alternatives to tobacco.<sup>6, 7, 8</sup>

Electronic cigarettes are made overseas, mainly in China, and have not previously been tested for safety.<sup>9</sup> They have not been approved by the FDA for use in smoking cessation. No evidence exists to show they help people quit smoking.<sup>10</sup> More research on e-cigarettes is needed to determine, more specifically, the ingredients they contain, how they are being used, and what effect they have on users. In fact, the FDA recently sent letters to

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

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

<sup>4</sup> American Academy of Family Physicians, *FDA Analysis Finds Toxins, Carcinogens in Electronic Cigarettes*, David Mitchell, 7/28/2009, Available online at <http://www.aafp.org/online/en/home/publications/news/news-now/health-of-the-public/20090728e-cigarettes.printerview.html>

<sup>5</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.

<sup>6</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>7</sup> ECigarettesUSA, Inc. ECigarettes...a healthier alternative to cigarettes. Available at <http://www.ecigarettesusa.com/>.

<sup>8</sup> The Safe Cig. Electronic Cigarette FAQs. Available online at <http://www.thesafecig.com/contactus.php>.

<sup>9</sup> American Academy of Family Physicians (see footnote 4) and Tom Houston, M.D., Director of Ohio Health's Nicotine Dependence Program, Clinical Professor, Family Medicine Department, Ohio State University, Columbus, OH.

<sup>10</sup> World Health Organization. Marketers of Electronic Cigarettes Should Halt Unproven Therapy Claims. September 19, 2008. Available online at <http://www.who.int/mediacentre/news/releases/2008/pr34/en/>.

five companies that market and distribute e-cigarettes for violating the Federal Food, Drug, and Cosmetic Act. The FDA warned them of violations regarding marketing statements that make claims which are not based in research or science.<sup>11</sup> These violations include poor manufacturing practices and claims that the products help people quit smoking.

E-cigarettes are currently sold without legal age restrictions and do not contain health warnings comparable to those found on FDA-approved nicotine replacement products or conventional cigarettes.

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>12</sup> In one study, the FDA found that some e-cigarette cartridges claiming not to contain nicotine actually did.<sup>13</sup>

At its annual meeting in June of this year, the American Medical Association adopted a policy recommending that e-cigarettes be classified as a drug delivery device and should be subject to regulation by the FDA.<sup>14</sup>

### Marketing and Youth Access Concerns

Government agencies and medical organizations, such as the FDA, the Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the American Cancer Society – Cancer Action Network (ACS-CAN) have also expressed concern that electronic cigarettes could increase nicotine addiction and tobacco use in young people.<sup>15</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>16</sup> Many nicotine refill bottles or cartridges are not adequately packaged to prevent children's access or accidental ingestion of toxic amounts of nicotine.

The ACS-CAN strongly supports the FDA's assertion that e-cigarettes should be regulated as drug delivery devices and not as tobacco products. In addition, they state that:

- The FDA now has the authority and should take action to protect and advance the public health to the full extent of the law.
- E-cigarettes should be included in new smoke-free laws or amendments to existing laws.
- Since FDA does not consider e-cigarettes to be tobacco products, they should clearly be defined as different from tobacco products and be addressed separately in the law.

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<sup>11</sup> U.S. Food and Drug Administration. Available online at:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225178.htm>;

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225187.htm> ;

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225177.htm> ;

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm>

<sup>12</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>13</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.

<sup>14</sup> American Medical Association, AMNews, Available online at <http://www.ama-assn.org/amednews/2010/09/20/prbf0920.htm>

<sup>15</sup> U.S. Food and Drug Administration. FDA and Public Health Experts Warn About Electronic Cigarettes.

<sup>16</sup> U.S. Food and Drug Administration. FDA Warns of Health Risks Posed by E-Cigarettes. July 23, 2009. Available online at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>

- Regardless of the marketing tactics that e-cigarette companies use, the sale of e-cigarettes should be restricted 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.

### What Does this Mean for Hospitals?

OHA staff, in their activities working with hospitals statewide, are seeing several trends:

- 1) Patients who use tobacco are sometimes using e-cigarettes while they are in the hospital. Because of the newness of this product, there are no policies against their use.
- 2) Hospital personnel are often not familiar with what e-cigarettes are or the potential health dangers they pose.
- 3) Most hospitals that have already passed tobacco free campus policies do not include e-cigarettes in their policies.

Until more information or evidence is available about the safety of these products, it is recommended that hospitals do the following:

- 1) Amend tobacco free campus policies to include e-cigarettes as potentially harmful and that they are prohibited from being used on their property.
- 2) Inform patients at admission that e-cigarettes are prohibited from use, along with all tobacco products, and that other options are available to assist them in with their nicotine withdrawal while they are hospitalized, including medications and the Oklahoma Tobacco Helpline.
- 3) Educate hospital employees about what e-cigarettes are and the potential risks they pose. Provide them with the tools they need to discuss this with patients.
- 4) Advise employees who use tobacco that, along with other tobacco products, they are not permitted to use these devices on campus and other options are available to assist them in quitting tobacco use.
- 5) Provide employees, addicted to nicotine, with health benefits that include paid medications and referral to the Oklahoma Tobacco Helpline.

### Effective Tobacco Use Cessation

Leading health and tobacco treatment specialists, nationwide, support evidence-based treatment for nicotine addiction based upon the clinical practice guideline, *Treating Tobacco Use and Dependence*. The most effective means for stopping tobacco use include all of the following:

- 1) Talk to your doctor about quitting tobacco use and options available to quit.
- 2) Ask your doctor if you qualify for medications to assist in managing cravings and withdrawal symptoms, such as nicotine replacement therapy (NRT), Chantix or Zyban.
- 3) Call the Oklahoma Tobacco Helpline and talk to a trained Quit Coach who will assist in many ways.



### **These three things combined are the most effective tools we now have for quitting tobacco use!**

These three actions combined = 35% chance of success.

Quitting with no assistance = 5% chance of success.

For more information contact:

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*Hospitals Helping Patients Quit: Advancing Tobacco Treatment*