What Employers Need to Know About Electronic Cigarettes

National Business Group on Health

Quick Facts About E-Cigarettes

- Not an FDA-approved tobacco cessation device.
- Contain nicotine and detectable levels of known carcinogens and toxic chemicals.
- Look very similar to regular cigarettes (especially from a distance).
- Manufactured using inconsistent or non-existent quality control processes.

Actions for Employers

- Determine whether the use of e-cigarettes is allowed in their jurisdictions, including in the workplace.
- Understand whether unions, works councils, or other laws can raise barriers to implementing workplace policies regulating e-cigarettes.
- Stay informed on any new laws and emerging scientific evidence regarding e-cigarettes.

What are electronic cigarettes (e-cigarettes)?

Electronic cigarettes, more commonly called "e-cigarettes," are a type of electronic nicotine delivery systems (ENDS). They look very similar to regular cigarettes. The Food and Drug Administration (FDA) does not consider e-cigarettes as tobacco cessation devices.[1]

There is no standard definition of an e-cigarette since different manufacturers use different designs and incorporate a range of ingredients. Most e-cigarettes consist of the following:[2]

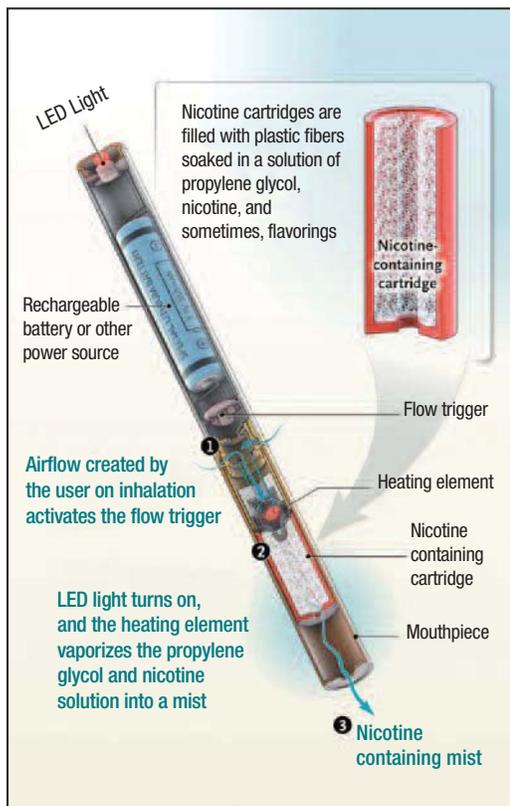- A cartridge containing a humectant (a substance to attract and absorb water molecules from the air) carrier, such as propylene glycol, and often with nicotine solution in different concentrations, but not necessarily derived from tobacco;

- A tube into which a cartridge is inserted and through which the user inhales; and

- A battery powered heating element from which the solution is drawn, causing the humectant to vaporize and form a mist.

When a user 'lights' the e-cigarette, a computer-aided sensor activates a heating element in the device that releases the liquid in aerosol form for inhalation. When users inhale, an LED at the end of the metal tube glows making the tip of the e-cigarette appear as if it was burning.[3] A visible vapor is emitted that disappears within a few seconds. The process of using an e-cigarette is known as "vaping" or "e-smoking."

Figure. Diagram of an Electronic Cigarette

LED Light

Nicotine cartridges are filled with plastic fibers soaked in a solution of propylene glycol, nicotine, and sometimes, flavorings

Nicotine-containing cartridge

Rechargeable battery or other power source

Flow trigger

Airflow created by the user on inhalation activates the flow trigger ❶

Heating element

Nicotine containing cartridge ❷

LED light turns on, and the heating element vaporizes the propylene glycol and nicotine solution into a mist

Mouthpiece

❸ Nicotine containing mist

Source: Reprinted with permission from the Massachusetts Medical Society. Cobb NK, Abrams DB. E-cigarette or drug-delivery device? Regulating novel nicotine products. *N Engl J Med*. 2011;365(3):194. Copyright 2011, Massachusetts Medical Society.

Currently, three related products are being sold: delivery devices, cartridges and refill solutions, sometimes referred to as "juice." Cartridges generally contain up to 20 mg of nicotine and are device-specific.[4] Starter cartridges are included with each device sold but are primarily sold separately by the device manufacturer or other suppliers. Refill kits allow the consumer to fill used cartridges with replacement solution at higher nicotine amounts than they originally contained.[4]

Created in China and first marketed internationally in 2002, e-cigarettes were not readily available in the United States until late 2006. The industry has grown from approximately a few thousand users in 2006 to several million worldwide, with tens of thousands of new e-cigarette users every week.[5] Industry estimates put U.S. sales of the devices and accessories at more than $200 million annually.[6,7]

Why would an employer consider banning e-cigarettes from the workplace?[3,8]

- Nicotine is addictive in any form.

- E-cigarettes look very similar to regular cigarettes (especially from a distance), making it harder for an employer to monitor employee cigarette use.

- The vapor emitted from e-cigarettes could be an annoyance to non-smoking employees. Also, allowing employees to smoke e-cigarettes in a tobacco-free workplace may encourage non-smoking employees to try to smoke real cigarettes in the workplace or at least question why they cannot do so.

- Some state and local governments currently ban or regulate the use of e-cigarettes in the workplace.

- There may be environmental and/or practical issues regarding the disposal of e-cigarettes.

What should employers do before implementing a workplace e-cigarette ban?[3]

- Determine whether the use of e-cigarettes is allowed in their jurisdictions, including in the workplace;

- Understand whether unions, work councils, or other laws can raise barriers to implementing workplace policies regulating e-cigarettes; and

- Stay informed on any new laws and emerging scientific evidence regarding e-cigarettes.

What are some employers doing about e-cigarettes?

Currently, many private employers are beginning to review the use of e-cigarettes in their workplaces. Several federal employers have banned e-cigarettes. The U.S. Air Force bans the use of e-cigarettes in most of its facilities based on the categorization by its Surgeon General's office in 2010 of e-cigarettes as "tobacco

products." Additionally, the U.S. Department of Transportation prohibited the use of electronic cigarettes on airplanes, and plans to issue an official ban.[9]

How should employers create or revise tobacco-free workplace policies and tobacco cessation programs to address e-cigarettes?

Employers may want to revise their tobacco-free workplace policies to include e-cigarettes as a form of tobacco. An employer that bans the use of e-cigarettes should indicate that smoking in any form through the use of tobacco products (pipes, cigars and cigarettes) or "vaping" with e-cigarettes is prohibited.[8]

Furthermore, since e-cigarettes are not FDA-approved cessation devices, employees using e-cigarettes are still considered smokers.[4] As a result, they may not be eligible for "non-tobacco user" status for health plans with premium differentials for tobacco users and non-tobacco users.

In order for employees to be considered non-tobacco users, they must be free of all tobacco products or enrolled in cessation programs with FDA-approved cessation methods and devices. Smokers and e-cigarette users can use multiple nicotine replacement products that are approved, regulated and deemed to be safe and effective by the FDA, such as patches, gum, lozenges, nasal sprays and FDA-approved inhalers.

Does the FDA regulate e-cigarettes?

In April 2011, the FDA stated that e-cigarettes and other similar products cannot be regulated unless they are marketed for therapeutic purposes. However, products "made or derived from tobacco" can be regulated as "tobacco products" under the *Federal Food, Drug, and Cosmetic Act*.[10] Currently, electronic cigarettes are not subject to pre-market review requirements of the *Family Smoking Prevention and Tobacco Control Act*. The FDA is developing a strategy to regulate this emerging class of products as tobacco products. Products that are marketed for therapeutic purposes will continue to be regulated as drugs and/or devices.
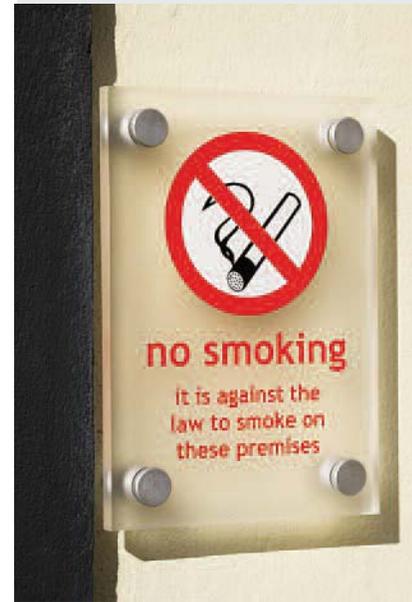
Highlights of the Family Smoking Prevention and Tobacco Control Act (2009), U.S. Food and Drug Administration (FDA)

- Orders a study on the public health implications of raising the minimum age to purchase tobacco products.
- Requires the Secretary of Health and Human Services to create a plan relating to enforcing restrictions on the advertising and promotion of menthol and other cigarettes to minors.
- Mandates larger, more varied and more prominent warning labels on tobacco products.
- Prohibits the FDA from banning existing tobacco products or requiring that they eliminate nicotine.
- Requires FDA review of new tobacco products before they can go to market unless they are similar to products marketed before February 15, 2007.
- Requires tobacco product manufacturers to:
  – Not promote products as lower-risk alternatives to traditional tobacco unless the FDA certifies that it is likely to improve public health;
  – Release all marketing research documents to the FDA;
  – Disclose all ingredients in its products;
  – Identify the form and delivery method of nicotine;
  – Disclose any research into the health, toxicological, behavioral, or physiologic effects of tobacco products to the FDA; and
  – Notify the FDA of any future changes to the ingredients of their products.

Source: GovTrack.us. *H.R. 1256: Family Smoking Prevention and Tobacco Control Act.* http://www.govtrack.us/congress/bill.xpd?bill=h111-1256&tab=summary. Accessed August 29, 2011.

What have scientific studies concluded about the value and harms of e-cigarettes?

In 2009, the FDA conducted limited laboratory studies of certain e-cigarette samples. Testing of e-cigarette cartridges revealed quality control processes used to manufacture these products were "inconsistent or non-existent."[11] Among its findings, cartridges labeled as containing no nicotine contained nicotine, as well as deviations from the content claimed on the label.[4] Furthermore, vapor testing from the devices revealed similar variability, including "puff-to-puff" variation.[12] In addition, the FDA found that e-cigarettes "...contained detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed."[11] More research is necessary to determine the risks of e-cigarette use.

What are the state government policies/laws surrounding e-cigarettes?

Currently, no states have completely banned e-cigarettes. However, several states have prohibited e-cigarette sales to minors and included them in their indoor smoking bans. California, Colorado, Minnesota, New Hampshire, New Jersey and Utah have prohibited the sale of e-cigarettes to minors since March 2011.[13,14] In New Jersey, e-cigarette use is banned in areas where smoking is banned.[15,16] Currently, New Jersey is the only state that has this law.[15,16] New York is considering a complete ban on electronic cigarettes.[13]

Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by the FDA

Due to the variability among products, this analysis should not be used to draw conclusions about what substances are or are not present in particular electronic cigarettes or brands of e-cigarettes.

ABOUT THE SAMPLES
- Electronic cigarettes and components from two leading brands.
- 18 various flavored, nicotine and no-nicotine cartridges offered for use with these products.

CARTRIDGES WERE TESTED FOR
- Nicotine content
- Presence of other tobacco constituents, and
- Substances known to be harmful to humans, including those that are potentially carcinogenic or mutagenic.

RESULTS
- Quality control processes used to manufacture these products are inconsistent or non-existent.
- Analysis revealed the following:
  - Diethylene glycol, an ingredient used in antifreeze, was detected in one cartridge. This substance is toxic to humans.
  - Certain tobacco-specific carcinogens (substances directly involved in causing cancer) were detected in half of the samples tested.
  - The electronic cigarette cartridges that were labeled as containing no nicotine had low levels of nicotine present in all cartridges tested, except one.
  - Three different electronic cigarette cartridges with the same label were tested and each cartridge emitted a markedly different amount of nicotine with each puff. The nicotine levels per puff ranged from 26.8 to 43.2 mcg nicotine/100 mL puff.
  - 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 the FDA-approved smoking cessation nicotine inhaler.

Source: U.S. Food and Drug Administration. Summary of results: laboratory analysis of electronic cigarettes conducted by FDA. http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm. Updated July 22, 2009. Accessed August 29, 2011.

What are some concerns voiced by public health professional associations about e-cigarettes?

The American Medical Association, American Cancer Society, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and the American Academy of Pediatrics all advocate for a strong regulatory role by the FDA and recommend that smoke-free laws and policies prohibit the use of e-cigarettes.[17,18] These organizations are concerned because there is no demonstrated public health benefit from e-cigarettes.[19] Furthermore, they have also raised concerns that the marketing and flavors of e-cigarettes (such as coffee, chocolate, mint and apple) may appeal to minors.[19]

What are other countries doing about e-cigarettes?

The World Health Organization (WHO) convened a Regulatory Consultation on the Safety of Electronic Nicotine Delivery Systems in May 2010. Delegates from Australia, Brazil, Canada, the European Commission, New Zealand, Saudi Arabia, Singapore, South Africa, Switzerland, Thailand, Turkey, Ukraine and the United States attended the meeting.[20] They stated that "overall it is evident that there is growing concern internationally about the quality, safety, and 'regulatory gap' of these emerging products broadly called Electronic Nicotine Delivery Systems as they continue to penetrate new markets."[20]

The delegates concluded that:

- Nicotine and nicotine products for human use should be regulated.

- Electronic Nicotine Delivery Systems may be used to deliver other potentially toxic chemicals and ingredients.

- Electronic Nicotine Delivery Systems are often accompanied by inaccurate information.

- The quality and safety of these products need to be established.

As a result, they recommend that "Regulators of medical and tobacco products should collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating (or possibly banning) Electronic Nicotine Delivery Systems to protect public health."[20]

Where can employers find additional information about e-cigarettes and tobacco programs and policies?

- National Business Group on Health:
  Tobacco: The Business of Quitting, An Employer's Website for Tobacco Cessation

  Moving Science into Coverage: An Employer's Guide to Clinical Preventive Services

- U.S. Food and Drug Administration:
  Public Health Focus: Electronic Cigarettes

- America's Health Insurance Plans (AHIP) and Center for Health Research Kaiser Permanente:
  Tobacco ROI Calculator

- American Lung Association
  State Legislated Actions on Tobacco Issues 2010

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