



AGENDA REPORT

- Meeting Date:** November 5, 2013
- Item Number:** E-1
- To:** Honorable Mayor & City Council
- From:** Michelle S. Tse, Senior Management Analyst
- Subject:**
- A. AN ORDINANCE OF THE CITY OF BEVERLY HILLS INCLUDING ELECTRONIC CIGARETTES WITHIN THE CITY'S SMOKING REGULATIONS AND DECLARING THE URGENCY THEREOF; AND
 - B. AN ORDINANCE OF THE CITY OF BEVERLY HILLS INCLUDING ELECTRONIC CIGARETTES WITHIN THE CITY'S SMOKING REGULATIONS; AND
 - C. AMENDMENT TO THE CITY OF BEVERLY HILLS PARK RULES AND REGULATIONS TO EXTEND THE PROHIBITION OF SMOKING TO INCLUDE ELECTRONIC CIGARETTES
- Attachments:**
- 1. Urgency Ordinance with Exhibits
 - 2. Ordinance with Exhibits
 - 3. Beverly Hills Recreation and Park Rules and Regulations Regarding Smoking

RECOMMENDATION

Staff recommends that the City Council read the ordinance titled "AN ORDINANCE OF THE CITY OF BEVERLY HILLS INCLUDING ELECTRONIC CIGARETTES WITHIN THE CITY'S SMOKING REGULATIONS AND DECLARING THE URGENCY THEREOF" by title only, waive further reading and adopt the ordinance. A four-fifths vote is required to adopt the urgency ordinance.

Staff also recommends that the City Council read the ordinance titled "AN ORDINANCE OF THE CITY OF BEVERLY HILLS INCLUDING ELECTRONIC CIGARETTES WITHIN THE CITY'S SMOKING REGULATIONS" by title only, waive further reading and introduce this ordinance.

Finally, staff recommends that the City Council approve the amendment to the City of Beverly Hills Park and Rules Regulations to extend the prohibition of smoking to include electronic cigarettes (“e-cigarettes”).

INTRODUCTION

At the October 15, 2013 Study Session, staff received direction from the City Council to review existing State and Federal e-cigarette regulations and proceed with the following: (1) amend the definition of smoking in the City’s municipal code to include electronic cigarettes (“e-cigarettes”); and (2) formulate regulations on the sale of e-cigarettes.

This agenda item will address amending the definition of smoking in the City’s existing regulation to include e-cigarettes. Regulations prohibiting the sales of e-cigarettes will be addressed as a separate agenda item during the November 5th City Council formal meeting.

Currently, there are minimal Federal and State regulations on e-cigarette use. The Federal Drug Administration’s website states its intent to issue a proposed rule that would extend its tobacco product regulations to include e-cigarettes in the near future.

State laws pertaining to public smoking, as currently worded, do not appear to include e-cigarettes. California Government Code Section 7597(a) prohibits smoking of any tobacco product inside a public building, or outdoor area within 20 feet of a main entrance or operable window of a public building. Labor Code Section 6404.5 only prohibits the smoking of all tobacco products in all enclosed places of employment in the state. Enclosed place is defined to include “lobbies, lounges, waiting areas, elevators, stairwells, and restrooms that are a structural part of the building...” Labor Code § 6404.5(b). State law does, however, prohibit the sale of e-cigarettes to minors under the age of 18.

Due to the increasing popularity of e-cigarettes and minimal federal and state oversight, cities such as Temple City, Duarte, Pico Rivera and Seal Beach have formulated regulations at the local level to address this growing issue.

DISCUSSION

Staff conducted a review of the City’s existing smoking and tobacco regulations to draft an urgency ordinance that amends the definition of smoking to include e-cigarettes.

The urgency ordinance includes the following changes to the City’s smoking and tobacco regulations:

- The City’s “90²10 Fresh Air Dining” ordinance will also prohibit the use of e-cigarettes.
- Prohibition on the establishment and operation of cigarette vending machines will also include e-cigarettes.
- This urgency ordinance expands on the State’s existing law by prohibiting the use of e-cigarettes inside and near public buildings.

If adopted by the City Council, this urgency ordinance will be effective immediately and the listed changes will be permanently reflected in the City’s Municipal Code.

In addition to the urgency ordinance, staff has presented an identical ordinance without the urgency declaration. Typically, the City Attorney's office recommends that the adoption of urgency ordinances (other interim zoning moratoria) be accompanied by the introduction of the same ordinance without the urgency declaration. Thus, to the extent that there is any question about the adequacy of the urgency declaration, an ordinance following the non-urgency procedure for adoption has been introduced and may be processed in accordance with the non-urgency procedures. As part of the non-urgency procedure, a second reading of the ordinance is required and if approved by the City Council, becomes effective 30 days thereafter.

Staff has also amended the City's Recreation and Park Rules and Regulations to extend its No Smoking policy to include e-cigarettes. This item is a separate document from the urgency ordinance because the prohibition on smoking in parks is promulgated as a parks rule issued by the Director of Recreation and Parks and is not an ordinance. "Upon Council approval of such rules and regulations, the director is authorized and empowered to enforce such rules and regulations." (BHMC 8-1-7).

As directed by the City Council, staff will be working closely with the Health and Safety Commission to explore future smoking regulations. Staff introduced the e-cigarette and smoking issue during the October 28 Health and Safety Commission meeting, with a more in-depth discussion scheduled for their November 25 meeting, after the installation of its three new Commissioners.

FISCAL IMPACT

Staff estimates there will be costs associated with education outreach and enforcement given these changes to the City's Municipal Code and the City's Recreation and Parks Rules and Regulations.

Mahdi Aluzri *MA*
Approved By

Attachment 1

ORDINANCE NO. 13-O-

AN ORDINANCE OF THE CITY OF BEVERLY HILLS
INCLUDING ELECTRONIC CIGARETTES WITHIN THE
CITY'S SMOKING REGULATIONS; AND DECLARING THE
URGENCY THEREOF

THE CITY COUNCIL OF THE CITY OF BEVERLY HILLS HEREBY ORDAINS AS
FOLLOWS:

Section 1. On November 5, 2013, the City Council considered the adoption of this Ordinance at a duly noticed public meeting and on the basis of the record thereof finds the following facts to be true:

A. Electronic cigarettes, commonly known as e-cigarettes, e-cigars, e-cigarillos, e-pipes, e-hookahs, are battery operated devices designed to look like and be used in the same manner as conventional tobacco products. Electronic cigarettes employ the use of a cartridge, generally containing up to 20 mg of nicotine, to deliver vaporized nicotine to users. Some cartridges used by electronic cigarettes can be re-filled with liquid nicotine solution, creating the potential for exposure to dangerous concentrations of nicotine;¹ and

B. The U.S. Food and Drug Administration ("FDA") conducted laboratory analysis of electronic cigarettes and found the following: 1) Diethylene glycol, an ingredient used in antifreeze and toxic to humans, was found in one cartridge; 2) Certain tobacco-specific nitrosamines, which are human carcinogens, were detected in half of the samples tested; 3) Tobacco-specific impurities suspected of being harmful to humans—anabasine, myosmine, and β-nicotyrine—were detected in a majority of the samples tested; 4) All but one tested cartridge labeled as containing no nicotine did in fact contain low levels of nicotine; 5) Three identically

¹ Yamin, C.K., Bitton A., and Bates, D.W. "E-Cigarettes: A Rapidly Growing Internet Phenomenon." *Annals of Internal Medicine*, 153:607-609, 2010.

labeled cartridges emitted markedly different amounts of nicotine with each puff. Nicotine levels per 100 mL puff ranged dramatically from 26.8 to 43.2 mcg nicotine; and 6) One high-nicotine cartridge delivered twice as much nicotine to users as was delivered by a nicotine inhalation product approved by FDA for use as a smoking cessation aid which was used as a control; and

C. The FDA has raised concerns that electronic cigarettes, which are often marketed in appealing flavors, can increase nicotine addiction among young people and may lead youth to try conventional tobacco products;² and

D. The FDA has also raised concerns that electronic cigarettes are marketed and sold to young people and are readily accessible online and via mall kiosks;³ and

E. A study published in the American Journal of Public Health found similar results to the FDA testing and concluded that the electronic cigarettes tested so far have demonstrated “poor quality control; toxic contaminants, albeit at low levels; misrepresentation of the nicotine delivered; and insufficient evidence of the overall public health benefit”;⁴ and

F. Clinical studies about the safety and efficacy of electronic cigarettes for their intended use have not been submitted to the FDA, and for this reason, consumers currently have no way of knowing: 1) Whether electronic cigarettes are safe for their intended use; 2) What

² U.S. Food and Drug Administration. *E-Cigarette: Questions and Answers*. 2010. www.fda.gov/forconsumers/consumerupdates/ucm225210.htm

³ U.S. Food and Drug Administration. *News Release, FDA and Public Health Experts Warn About Electronic Cigarettes*. July 22, 2009. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

⁴ Cobb, N.K., Byron, J., and Abrams, D.B., et al. “Novel Nicotine Delivery Systems and Public Health: The Rise of the ‘E-Cigarette.’” *American Journal of Public Health*, 100 (12): 2340-2342, 2010.

types or concentrations of potentially harmful chemicals the products contain; and 3) What dose of nicotine the products deliver;⁵ and

G. The World Medical Association has determined that electronic cigarettes “are not comparable to scientifically-proven methods of smoking cessation” and that “neither their value as therapeutic aids for smoking cessation nor their safety as cigarette replacements is established”;⁶ and

H. The federal law restricting the sale of tobacco products to minors currently applies only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, not electronic cigarettes (21 U.S.C. § 387a(b)); and

I. Between 2010 and 2011, rates of both awareness and use of unregulated electronic cigarettes by adults increased significantly;⁷ and

J. Electronic cigarettes often mimic conventional tobacco products in shape, size, and color, with the user exhaling a smoke-like vapor similar in appearance to the exhaled smoke from cigarettes and other conventional tobacco products; and

K. A study published in the *Journal of Environmental and Public Health* suggests that electronic cigarettes “may have the capacity to ‘re-normalize’ tobacco use in a demographic that has had significant denormalization of tobacco use previously”;⁸ and

⁵ U.S. Food and Drug Administration. *FDA Warns Of Health Risk Posed By E-Cigarettes*. 2009. www.fda.gov/downloads/forconsumers/consumerupdates/UCM173430.pdf

⁶ World Medical Association. *Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems*. October 2012. [www.wma.net/en/30publications/10policies/e19/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/e19/index.html.pdf?print-media-type&footer-right=[page]/[toPage])

⁷ King, B.A., Alam, S., and Promoff, G., et al. “Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011.” *Nicotine and Tobacco Research*.

⁸ McMillen, R., Maduka, J., and Winickoff, J. “Use of Emerging Tobacco Products in the United States.” *Journal of Environmental and Public Health*.

L. The use of electronic cigarettes in smoke free locations threatens to undermine compliance with smoking regulations and reverse the progress that has been made in establishing a social norm that smoking is not permitted in public places and places of employment; and

M. Government Code Section 7597(a) provides in pertinent part that no "...member of the public shall smoke any tobacco product inside a public building, or in an outdoor area within 20 feet of a main exit, entrance, or operable window of a public building..." Public building is defined as "a building owned and occupied, or leased and occupied, by the state, a county, a city, a city and county, or a California community college district." Government Code § 7596(a). Pursuant to this Government Code authority, the City has prohibited smoking in all public buildings in the City. Also, Labor Code Section 6404.5 prohibits the smoking of all tobacco products in all enclosed places of employment in the state. Enclosed place is defined to include "lobbies, lounges, waiting areas, elevators, stairwells, and restrooms that are a structural part of the building..." Labor Code § 6404.5(b).

N. Government Code Section 7597(b) provides a city is not preempted from adopting and enforcing additional smoking and tobacco control ordinances, regulations, or policies that are more restrictive than the applicable standards required by Government Code Section 7596 *et. seq.* The terms "smoke," "tobacco product," and "electronic cigarette" are not further defined in these Government Code Sections. Pursuant to Government Code Section 7597(b), the City may adopt a more restrictive ordinance, regulation or policy that provides definitions for these terms, and expressly prohibits the use of electronic cigarettes in public buildings in the City.

O. Labor Code Section 6404.5 prohibits the smoking of all tobacco products in all enclosed places of employment in the state. However, the smoking of electronic cigarettes is not

regulated by this Labor Code section and the City is not expressly preempted from regulating the smoking of electronic cigarettes within the City.

P. The City of Beverly Hills has been among a growing list of progressive cities throughout the nation which have adopted more stringent local smoking and tobacco control ordinances to protect public health. In 2008, the City Council adopted the “90210 Fresh Air Dining Ordinance” (BHMC Title 5, Chapter 4), which banned smoking in all outdoor dining areas. In 2010, the City Council passed an ordinance to regulate tobacco retailers through an annual permitting process (BHMC Title 4, Chapter 2, Section 2101, *et seq*). These two ordinances refer to the terms “smoke,” “smoking,” and “tobacco paraphernalia,” but do not explicitly include electronic cigarettes.

Q. It is the intent of the City Council of the City of Beverly Hills in enacting this ordinance, to provide for the public health, safety, and welfare by regulating the potentially dangerous behavior of smoking electronic cigarettes.

R. This ordinance is necessary for the immediate preservation of the public peace, health, or safety of the people of the City of Beverly Hills. Although the full health impacts of electronic cigarettes are still unclear, various studies suggest that electronic cigarettes pose significant public health and safety risks similar to those associated with traditional cigarettes and tobacco products, and therefore, should be regulated in the same manner.

Section 2. The City Council hereby amends Section 5-4-1 (“Definitions”) of Chapter 4 (“Smoking Regulations”) of Title 5 (“Public Health, Welfare, and Sanitation”) of the Beverly Hills Municipal Code to read as follows:

“5-4-1: Definitions:

ELECTRONIC CIGARETTE: an electronic and/or battery-operated device, the use of which may resemble smoking, which can be used to deliver an inhaled dose of nicotine or other substances. The term includes any such device, whether manufactured, distributed, marketed, or sold as an electronic cigarette, an e-cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, an electronic hookah, or any other product name or descriptor. The term does not include any medical inhaler prescribed by a licensed doctor.

ENCLOSED: Closed in by a roof and walls with appropriate openings for ingress and egress.

HOTEL: Shall have the same definition as that set forth in Title 10, Chapter 3 of this code.

NONENCLOSED: A predominantly outdoor area that does not meet the definition of “enclosed,” including, but not limited to, open air dining areas.

OPEN AIR DINING AREA: Any nonenclosed area located on private or public property made available to or customarily used by the general public that is designed, established or regularly used for consuming food and/or beverages or where food and/or beverages are served whether or not for compensation. This includes, but is not limited to, restaurants, hotels, bar standing and seating areas, patios, and coffee shops. An open air dining area does not include open air dining areas that are immediately adjacent to and accessory to a private smokers' lounge, as that term is defined in Labor Code Section 6404.5 or its successor statute.

SMOKE OR SMOKING: The carrying, holding, or operating of a lighted pipe, cigar, cigarette, electronic cigarette, or other kind of smoking equipment. Smoke also means the lighting,

operating, emitting, or exhaling of the smoke or vapor of a pipe, cigar, cigarette, electronic cigarette or other kind of smoking equipment. Smoke also means the gaseous or vaporous products and particles created by the use of a lighted or operated pipe, cigar, cigarette, electronic cigarette or other kind of smoking equipment.”

Section 3. The City Council hereby amends Section 5-4-5 (“Prohibition of Cigarette Vending Machines”) of Chapter 4 (“Smoking Regulations”) of Title 5 (“Public Health, Welfare, and Sanitation”) of the Beverly Hills Municipal Code to read as follows:

“5-4-5: Prohibition of Cigarette or Electronic Cigarette Vending Machines:

Unless otherwise prohibited by state or federal law, no person shall install, place, operate, or maintain within the City any cigarette vending machine. “Cigarette vending machine” shall mean any self-service device which, upon insertion of money or tokens, dispenses cigarettes or electronic cigarettes without the necessity of replenishing the device between each vending operation.”

Section 4. The City Council hereby adds new Section 5-4-7 (“Prohibition of Smoking Electronic Cigarettes in Public Buildings”) of Chapter 4 (“Smoking Regulations”) of Title 5 (“Public Health, Welfare, and Sanitation”) of the Beverly Hills Municipal Code to read as follows:

“5-4-7: Prohibition of Smoking Electronic Cigarettes in Public Buildings:

Smoking electronic cigarettes is prohibited in all buildings and areas where smoking of tobacco products is prohibited by California Government Code Section 7597 or any successor statute thereto.”

Section 5. CEQA. The City Council hereby finds that it can be seen with certainty that there is no possibility the adoption of this Ordinance will have a significant effect on the environment because the Ordinance only includes electronic cigarettes within tobacco retailer permitting regulations and smoking regulations currently in force under the Beverly Hills Municipal Code, and will thereby serve to reduce potential significant adverse environmental impacts. It is therefore exempt from California Environmental Quality Act review pursuant to Title 14, Section 15061(b)(3) of the California Code of Regulations.

Section 6. Severability. If any section, subsection, subdivision, sentence, clause, phrase, or portion of this Ordinance or the application thereof to any person or place, is for any reason held to be invalid or unconstitutional by the final decision of any court of competent jurisdiction, the remainder of this Ordinance shall remain in full force and effect.

Section 7. Publication. The City Clerk shall cause this Ordinance to be published at least once in a newspaper of general circulation published and circulated in the City within fifteen (15) days after its passage in accordance with Section 36933 of the Government Code, shall certify to the adoption of this Ordinance and shall cause this Ordinance and the City Clerk's certification, together with proof of publication, to be entered in the Book of Ordinances of the Council of this City.

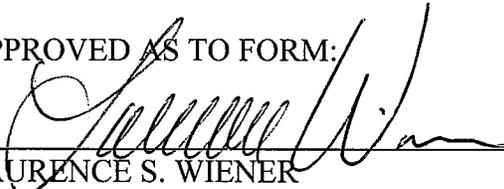
Section 8. Effective Date. This Ordinance, being an Urgency Ordinance adopted as an urgency measure for the immediate preservation of the public peace, health or safety, containing a declaration of the facts constituting the urgency, and passed by a minimum four-fifths (4/5) vote of the City Council, shall take effect immediately upon its adoption pursuant to Government Code Section 36937(b).

JOHN A. MIRISCH
Mayor of the City of
Beverly Hills, California

ATTEST:

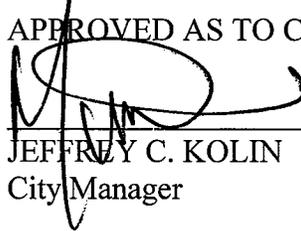
(SEAL)
BYRON POPE
City Clerk

APPROVED AS TO FORM:



LAURENCE S. WIENER
City Attorney

APPROVED AS TO CONTENT:



JEFFREY C. KOLIN
City Manager

for Jm

EXHIBITS

Various online articles as referenced in the ordinance

[Home For Consumers](#) [Consumer Updates](#)

For Consumers

E-Cigarettes: Questions and Answers

 [Get Consumer Updates by E-mail](#)¹

 [Consumer Updates RSS Feed](#)²

Q: What are electronic cigarettes?

A: Electronic cigarettes are products designed to deliver nicotine or other substances to a user in the form of a vapor. Typically, they are composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor. This vapor can then be inhaled by the user. These products are often made to look like such products as cigarettes, cigars, and pipes. They are also sometimes made to look like everyday items such as pens and USB memory sticks, for people who wish to use the product without others noticing.

Q: What concerns does FDA have regarding electronic cigarettes?

A: FDA has not evaluated any e-cigarettes for safety or effectiveness. When FDA conducted limited laboratory studies of certain samples, FDA found significant quality issues that indicate that quality control processes used to manufacture these products are substandard or non-existent. FDA found that cartridges labeled as containing no nicotine contained nicotine and that three different electronic cigarette cartridges with the same label emitted a markedly different amount of nicotine with each puff. Experts have also raised concerns that the marketing of products such as e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products.

Visit FDA's Electronic Cigarettes webpage³ for additional information.

Q: What action did FDA take today on electronic cigarettes?

A: FDA issued warning letters to five distributors of electronic cigarettes for violations of the Federal Food, Drug, and Cosmetic Act (FDCA). These violations included unsubstantiated claims and poor manufacturing practices.

Q: Would it be possible for an electronic cigarette to receive FDA approval?

A: Yes. FDA issued a letter to the Electronic Cigarette Association inviting electronic cigarette firms to work in cooperation with the agency toward the goal of assuring that electronic cigarettes sold in the United States are lawfully marketed. The agency intends to regulate electronic cigarettes and related products in a manner consistent with its mission of protecting the public health.

Q: What products should people who want to quit smoking use?

A: There are a number of FDA-approved smoking cessation aids, including nicotine gum, nicotine skin patches, nicotine lozenges, nicotine oral inhaled products, and nicotine nasal spray that are available for smokers to use to reduce their dependence on nicotine. Free help is available to all smokers who want to quit at 1-800-QUIT-NOW or by visiting www.smokefree.gov⁴.

This article appears on FDA's Consumer Updates page⁵, which features the latest on all FDA-regulated products.

Posted September 9, 2010

[back to top](#)

For More Information

- [Family Smoking Prevention and Tobacco Control Act](#)⁶
- [FDA Acts Against 5 Electronic Cigarette Distributors](#)⁷ [ARCHIVED]

- FDA's Electronic Cigarettes web page⁸
- Letter to the Electronic Cigarette Association (PDF - 43KB)⁹

Related Consumer Updates

- FDA Warns of Health Risks Posed by E-Cigarettes¹⁰
- FDA 101: Smoking Cessation Products¹¹ [ARCHIVED]
- "Light" Tobacco Products Pose Heavy Health Risks¹²
- What Are You Smoking (or Chewing or Inhaling)?¹³
- Less Risky Tobacco Product? Only if the Science Says So¹⁴
- Why Do People Use Tobacco? Looking for Answers¹⁵
- Why is the Great American Smokeout Important?¹⁶
- FDA Unveils New Cigarette Health Warnings¹⁷
- Regulating Tobacco: Q&A with Former CTP Director Lawrence Deyton, M.S.P.H., M.D.¹⁸ [ARCHIVED]
- FDA Modernizing Regulatory Science¹⁹

Page Last Updated: 09/24/2013

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News & Events

FDA NEWS RELEASE

For Immediate Release: July 22, 2009

Media Inquiries: Siobhan DeLancey, 301-796-4668, siobhan.delancey@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA and Public Health Experts Warn About Electronic Cigarettes

The U.S. Food and Drug Administration today announced that a laboratory analysis of electronic cigarette samples has found that they contain carcinogens and toxic chemicals such as diethylene glycol, an ingredient used in antifreeze.

Electronic cigarettes, also called "e-cigarettes," are battery-operated devices that generally contain cartridges filled with nicotine, flavor and other chemicals. The electronic cigarette turns nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

These products are marketed and sold to young people and are readily available online and in shopping malls. In addition, these products do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes. They are also available in different flavors, such as chocolate and mint, which may appeal to young people.

Public health experts expressed concern that electronic cigarettes could increase nicotine addiction and tobacco use in young people. Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium and Jonathan Samet, M.D., director of the Institute for Global Health at the University of Southern California, joined Joshua Sharfstein, M.D., principal deputy commissioner of the FDA, and Matthew McKenna, M.D., director of the Office of Smoking and Health for the Centers for Disease Control and Prevention, to discuss the potential risks associated with the use of electronic cigarettes.

"The FDA is concerned about the safety of these products and how they are marketed to the public," said Margaret A. Hamburg, M.D., commissioner of food and drugs.

Because these products have not been submitted to the FDA for evaluation or approval, at this time the agency has no way of knowing, except for the limited testing it has performed, the levels of nicotine or the amounts or kinds of other chemicals that the various brands of these products deliver to the user.

The FDA's Division of Pharmaceutical Analysis analyzed the ingredients in a small sample of cartridges from two leading brands of electronic cigarettes. In one sample, the FDA's analyses detected diethylene glycol, a chemical used in antifreeze that is toxic to humans, and in several other samples, the FDA analyses detected carcinogens, including nitrosamines. These tests indicate that these products contained detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed.

The FDA has been examining and detaining shipments of e-cigarettes at the border and the products it has examined thus far meet the definition of a combination drug-device product under the Federal Food, Drug, and Cosmetic Act. The FDA has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court. The agency is also planning additional activities to address its concerns about these products.

Health care professionals and consumers may report serious adverse events (side effects) or product

quality problems with the use of e-cigarettes to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

- Online: <http://www.fda.gov/Safety/MedWatch/default.htm>¹
- Regular Mail: use postage-paid FDA form 3500 available at: <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>² and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: (800) FDA-0178
- Phone: (800) FDA-1088

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For More Information

Electronic Cigarettes

3

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Page Last Updated: 04/17/2013

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FDA Warns of Health Risks Posed by E-Cigarettes

The Food and Drug Administration (FDA) has joined other health experts to warn consumers about potential health risks associated with electronic cigarettes.

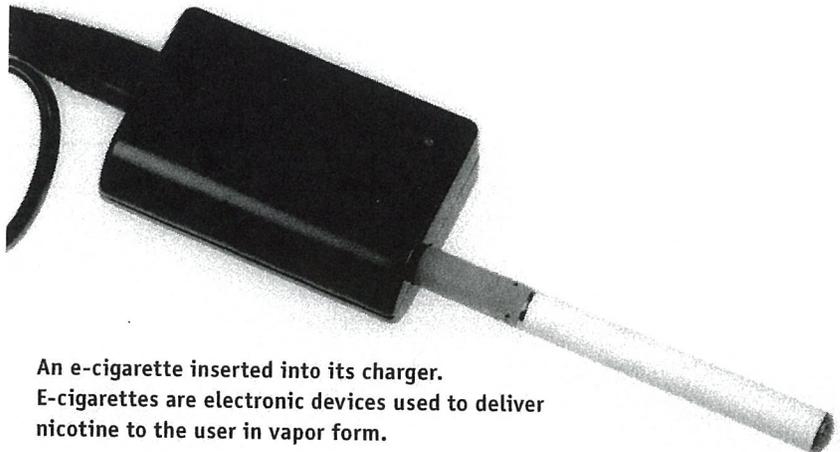
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

Sold online and in many shopping malls, the devices generally contain cartridges filled with nicotine, flavor, and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

"The FDA is concerned about the safety of these products and how they are marketed to the public," says Margaret A. Hamburg, M.D., commissioner of food and drugs.

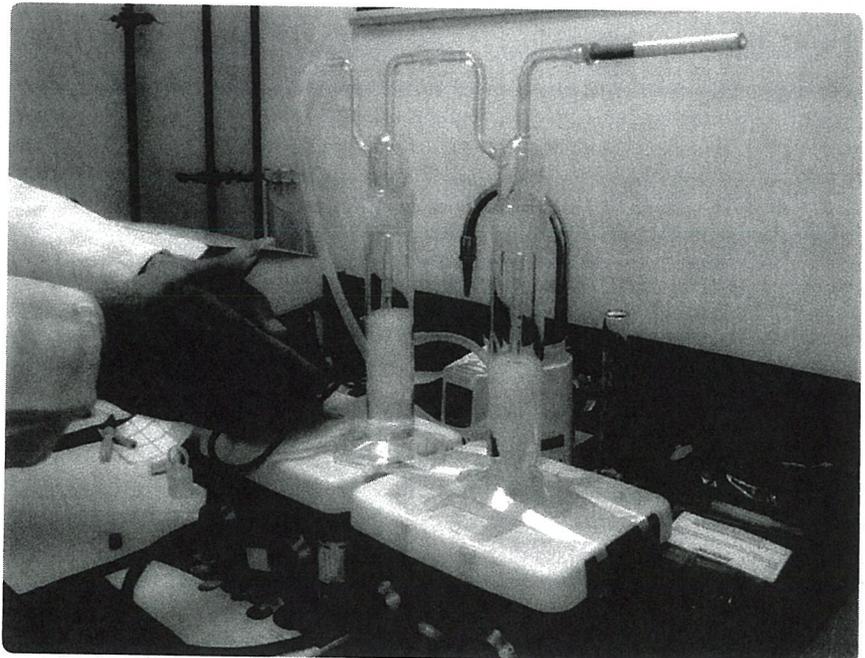
The agency is concerned that

- e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death
- the products may contain ingredients that are known to be toxic to humans
- because clinical studies about the safety and efficacy of these products for their intended use have not been



An e-cigarette inserted into its charger. E-cigarettes are electronic devices used to deliver nicotine to the user in vapor form.

FDA



Air is drawn through an e-cigarette during a laboratory procedure that simulates a smoker taking a puff. The resulting vapor is tested.

FDA

submitted to FDA, consumers currently have no way of knowing

- whether e-cigarettes are safe for their intended use
- about what types or concentrations of potentially harmful chemicals, or what dose of nicotine they are inhaling when they use these products

The potential health risks posed by the use of e-cigarettes were addressed in a July 22, 2009, phone conference between Joshua M. Sharfstein, M.D., principal deputy commissioner of food and drugs; Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium; Jonathan Samet, M.D., director of the University of Southern California's Institute for Global Health; and Matthew T. McKenna, M.D., director of the Office on Smoking and Health at the national Centers for Disease Control and Prevention.

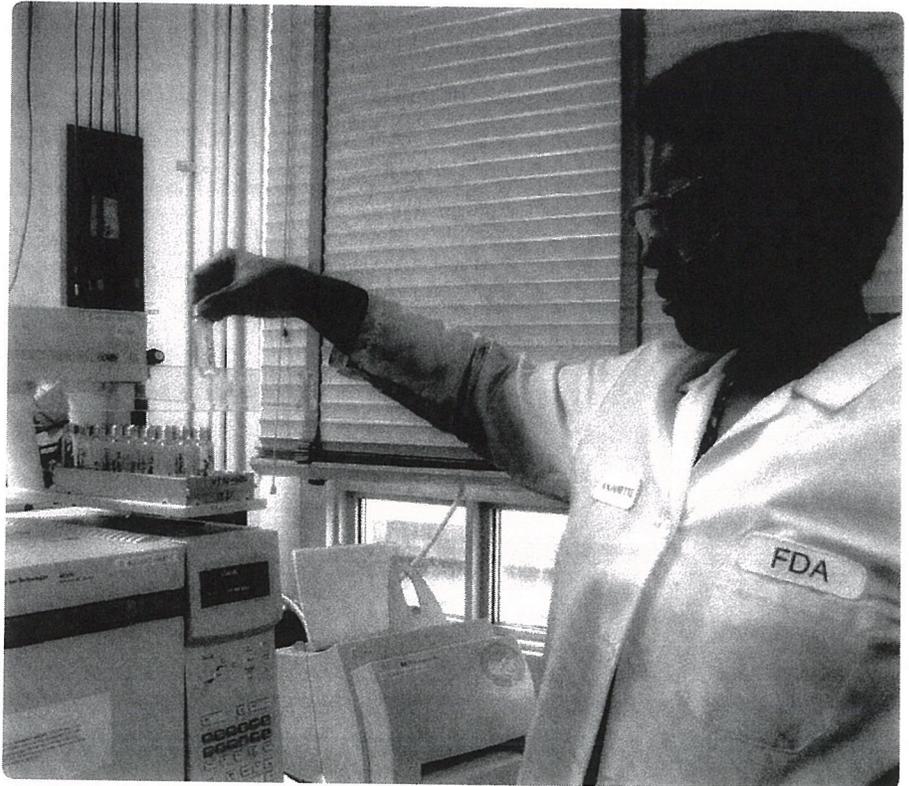
Conference participants stressed the importance of parents being aware of the health and marketing concerns associated with e-cigarettes. It was stated that parents may want to tell their children and teenagers that these products are not safe to use.

Of particular concern to parents is that e-cigarettes are sold without any legal age restrictions, and are available in different flavors (such as chocolate, strawberry and mint) which may appeal to young people.

In addition, the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes.

During the phone conference, which was shared with the news media, FDA announced findings from a laboratory analysis that indicates that electronic cigarettes expose users to harmful chemical ingredients.

FDA's Division of Pharmaceutical Analysis—part of the agency's Center for Drug Evaluation and Research—analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarette samples.



FDA

An FDA chemist uses a device set to the same temperature as an activated e-cigarette. This helps determine what might be inhaled by users of these products.

One sample was found to contain diethylene glycol, a toxic chemical used in antifreeze. Several other samples were found to contain carcinogens, including nitrosamines.

Agency Actions

FDA has been examining and detaining shipments of e-cigarettes at the border and has found that the products it has examined thus far meet the definition of a combination drug device product under the Federal Food, Drug, and Cosmetic Act.

The agency has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court.

FDA is planning additional activities to address its concerns about electronic cigarettes.

Meanwhile, health care professionals and consumers may report seri-

ous adverse events or product quality problems with the use of e-cigarettes to FDA through the MedWatch program, either online at www.fda.gov/Safety/MedWatch/default.htm or by phone at 1-800-FDA-1088.

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

For More Information

FDA Press Release
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

E-Cigarettes: FDA Web page
www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm



WMA Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems

Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012

INTRODUCTION

Electronic cigarettes (e-cigarettes) are products designed to deliver nicotine to a user in the form of a vapor. They are usually composed of a rechargeable battery-operated heating element, a replaceable cartridge that contains nicotine and/or other chemicals, and an atomizer that, when heated, turns the contents of the cartridge into a vapor (not smoke). This vapor is then inhaled by the user. These products are often made to look like other tobacco-derived products like cigarettes, cigars, and pipes. They can also be made to look like everyday items such as pens and USB memory sticks.

No standard definition of e-cigarettes exists and different manufacturers use different designs and different ingredients. Quality control processes used to manufacture these products are substandard or non-existent. Few studies have been done to analyze the level of nicotine delivered to the user and the composition of the vapor produced.

Manufacturers and marketers of e-cigarettes often claim that use of their products is a safe alternative to smoking, particularly since they do not produce carcinogenic smoke. However, no studies have been conducted to determine that the vapor is not carcinogenic, and there are other potential risks associated with these devices: Appeal to children, especially when flavors like strawberry or chocolate are added to the cartridges. E-cigarettes can increase nicotine addiction among young people and their use may lead to experimenting with other tobacco products.

Manufacturers and distributors mislead people into believing these devices are acceptable alternatives to scientifically proven cessation techniques, thus delaying actual smoking cessation. E-cigarettes are not comparable to scientifically-proven methods of smoking cessation. Their dosage, manufacture, and ingredients are not

consistent or clearly labelled. Brand stretching by using known cigarette logos is to be deplored.

Unknown amounts of nicotine are delivered to the user, and the level of absorption is unclear, leading to potentially toxic levels of nicotine in the system. These products may also contain other ingredients toxic to humans.

High potential of toxic exposure to nicotine by children, either by ingestion or dermal absorption, because the nicotine cartridges and refill liquid are readily available over the Internet and are not sold in child resistant packaging.

Due to the lack of rigorous chemical and animal studies, as well as clinical trials on commercially available e-cigarettes, neither their value as therapeutic aids for smoking cessation nor their safety as cigarette replacements is established. Lack of product testing does not permit the conclusion that e-cigarettes do not produce any harmful products even if they produce fewer dangerous substances than conventional cigarettes.

Clinical testing, large population studies and full analyses of e-cigarette ingredients and manufacturing processes need to be conducted before their safety, viability and impacts can be determined as either clinical tools or as widely available effective alternatives to tobacco use.

RECOMMENDATIONS

That the manufacture and sale of e-cigarettes and other electronic nicotine delivery systems be subject to national regulatory bodies prior approval based on testing and research as either a new form of tobacco product or as a drug delivery device.

That the marketing of e-cigarettes and other electronic nicotine delivery systems as a valid method for smoking cessation must be based on evidence and must be approved by appropriate regulatory bodies based on safety and efficacy data.

That e-cigarettes and other electronic nicotine delivery systems be included in smoke free laws.

Physicians should inform their patients of the risks of using e-cigarettes even if regulatory authorities have not taken a position on the efficacy and safety of these products.

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Attachment 2

ORDINANCE NO. 13-O-

AN ORDINANCE OF THE CITY OF BEVERLY HILLS
INCLUDING ELECTRONIC CIGARETTES WITHIN THE
CITY'S SMOKING REGULATIONS

THE CITY COUNCIL OF THE CITY OF BEVERLY HILLS HEREBY ORDAINS AS
FOLLOWS:

Section 1. On November 5, 2013, the City Council considered the adoption of this ordinance at a duly noticed public meeting and on the basis of the record thereof finds the following facts to be true:

A. Electronic cigarettes, commonly known as e-cigarettes, e-cigars, e-cigarillos, e-pipes, e-hookahs, are battery operated devices designed to look like and be used in the same manner as conventional tobacco products. Electronic cigarettes employ the use of a cartridge, generally containing up to 20 mg of nicotine, to deliver vaporized nicotine to users. Some cartridges used by electronic cigarettes can be re-filled with liquid nicotine solution, creating the potential for exposure to dangerous concentrations of nicotine;¹ and

B. The U.S. Food and Drug Administration ("FDA") conducted laboratory analysis of electronic cigarettes and found the following: 1) Diethylene glycol, an ingredient used in antifreeze and toxic to humans, was found in one cartridge; 2) Certain tobacco-specific nitrosamines, which are human carcinogens, were detected in half of the samples tested; 3) Tobacco-specific impurities suspected of being harmful to humans—anabasine, myosmine, and β-nicotyrine—were detected in a majority of the samples tested; 4) All but one tested cartridge labeled as containing no nicotine did in fact contain low levels of nicotine; 5) Three identically

¹ Yamin, C.K., Bitton A., and Bates, D.W. "E-Cigarettes: A Rapidly Growing Internet Phenomenon." *Annals of Internal Medicine*, 153:607-609, 2010.

labeled cartridges emitted markedly different amounts of nicotine with each puff. Nicotine levels per 100 mL puff ranged dramatically from 26.8 to 43.2 mcg nicotine; and 6) One high-nicotine cartridge delivered twice as much nicotine to users as was delivered by a nicotine inhalation product approved by FDA for use as a smoking cessation aid which was used as a control; and

C. The FDA has raised concerns that electronic cigarettes, which are often marketed in appealing flavors, can increase nicotine addiction among young people and may lead youth to try conventional tobacco products;² and

D. The FDA has also raised concerns that electronic cigarettes are marketed and sold to young people and are readily accessible online and via mall kiosks;³ and

E. A study published in the American Journal of Public Health found similar results to the FDA testing and concluded that the electronic cigarettes tested so far have demonstrated “poor quality control; toxic contaminants, albeit at low levels; misrepresentation of the nicotine delivered; and insufficient evidence of the overall public health benefit”;⁴ and

F. Clinical studies about the safety and efficacy of electronic cigarettes for their intended use have not been submitted to the FDA, and for this reason, consumers currently have no way of knowing: 1) Whether electronic cigarettes are safe for their intended use; 2) What

² U.S. Food and Drug Administration. *E-Cigarette: Questions and Answers*. 2010. www.fda.gov/forconsumers/consumerupdates/ucm225210.htm

³ U.S. Food and Drug Administration. *News Release, FDA and Public Health Experts Warn About Electronic Cigarettes*. July 22, 2009. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

⁴ Cobb, N.K., Byron, J., and Abrams, D.B., et al. “Novel Nicotine Delivery Systems and Public Health: The Rise of the ‘E-Cigarette.’” *American Journal of Public Health*, 100 (12): 2340-2342, 2010.

types or concentrations of potentially harmful chemicals the products contain; and 3) What dose of nicotine the products deliver;⁵ and

G. The World Medical Association has determined that electronic cigarettes “are not comparable to scientifically-proven methods of smoking cessation” and that “neither their value as therapeutic aids for smoking cessation nor their safety as cigarette replacements is established”;⁶ and

H. The federal law restricting the sale of tobacco products to minors currently applies only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, not electronic cigarettes (21 U.S.C. § 387a(b)); and

I. Between 2010 and 2011, rates of both awareness and use of unregulated electronic cigarettes by adults increased significantly;⁷ and

J. Electronic cigarettes often mimic conventional tobacco products in shape, size, and color, with the user exhaling a smoke-like vapor similar in appearance to the exhaled smoke from cigarettes and other conventional tobacco products; and

K. A study published in the *Journal of Environmental and Public Health* suggests that electronic cigarettes “may have the capacity to ‘re-normalize’ tobacco use in a demographic that has had significant denormalization of tobacco use previously”;⁸ and

⁵ U.S. Food and Drug Administration. *FDA Warns Of Health Risk Posed By E-Cigarettes*. 2009. www.fda.gov/downloads/forconsumers/consumerupdates/UCM173430.pdf

⁶ World Medical Association. *Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems*. October 2012. [www.wma.net/en/30publications/10policies/e19/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/e19/index.html.pdf?print-media-type&footer-right=[page]/[toPage])

⁷ King, B.A., Alam, S., and Promoff, G., et al. “Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011.” *Nicotine and Tobacco Research*.

⁸ McMillen, R., Maduka, J., and Winickoff, .J. “Use of Emerging Tobacco Products in the United States.” *Journal of Environmental and Public Health*.

L. The use of electronic cigarettes in smoke free locations threatens to undermine compliance with smoking regulations and reverse the progress that has been made in establishing a social norm that smoking is not permitted in public places and places of employment; and

M. Government Code Section 7597(a) provides in pertinent part that no "...member of the public shall smoke any tobacco product inside a public building, or in an outdoor area within 20 feet of a main exit, entrance, or operable window of a public building...." Public building is defined as "a building owned and occupied, or leased and occupied, by the state, a county, a city, a city and county, or a California community college district." Government Code § 7596(a). Pursuant to this Government Code authority, the City has prohibited smoking in all public buildings in the City. Also, Labor Code Section 6404.5 prohibits the smoking of all tobacco products in all enclosed places of employment in the state. Enclosed place is defined to include "lobbies, lounges, waiting areas, elevators, stairwells, and restrooms that are a structural part of the building...." Labor Code § 6404.5(b).

N. Government Code Section 7597(b) provides a city is not preempted from adopting and enforcing additional smoking and tobacco control ordinances, regulations, or policies that are more restrictive than the applicable standards required by Government Code Section 7596 *et. seq.* The terms "smoke," "tobacco product," and "electronic cigarette" are not further defined in these Government Code Sections. Pursuant to Government Code Section 7597(b), the City may adopt a more restrictive ordinance, regulation or policy that provides definitions for these terms, and expressly prohibits the use of electronic cigarettes in public buildings in the City.

O. Labor Code Section 6404.5 prohibits the smoking of all tobacco products in all enclosed places of employment in the state. However, the smoking of electronic cigarettes is not

regulated by this Labor Code section and the City is not expressly preempted from regulating the smoking of electronic cigarettes within the City.

P. The City of Beverly Hills has been among a growing list of progressive cities throughout the nation which have adopted more stringent local smoking and tobacco control ordinances to protect public health. In 2008, the City Council adopted the “90210 Fresh Air Dining Ordinance” (BHMC Title 5, Chapter 4), which banned smoking in all outdoor dining areas. In 2010, the City Council passed an ordinance to regulate tobacco retailers through an annual permitting process (BHMC Title 4, Chapter 2, Section 2101, *et seq*). These two ordinances refer to the terms “smoke,” “smoking,” and “tobacco paraphernalia,” but do not explicitly include electronic cigarettes.

Section 2. The City Council hereby amends Section 5-4-1 (“Definitions”) of Chapter 4 (“Smoking Regulations”) of Title 5 (“Public Health, Welfare, and Sanitation”) of the Beverly Hills Municipal Code to read as follows:

“5-4-1: Definitions:

ELECTRONIC CIGARETTE: an electronic and/or battery-operated device, the use of which may resemble smoking, which can be used to deliver an inhaled dose of nicotine or other substances. The term includes any such device, whether manufactured, distributed, marketed, or sold as an electronic cigarette, an e-cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, an electronic hookah, or any other product name or descriptor. The term does not include any medical inhaler prescribed by a licensed doctor.

ENCLOSED: Closed in by a roof and walls with appropriate openings for ingress and egress.

HOTEL: Shall have the same definition as that set forth in Title 10, Chapter 3 of this code.

NONENCLOSED: A predominantly outdoor area that does not meet the definition of “enclosed,” including, but not limited to, open air dining areas.

OPEN AIR DINING AREA: Any nonenclosed area located on private or public property made available to or customarily used by the general public that is designed, established or regularly used for consuming food and/or beverages or where food and/or beverages are served whether or not for compensation. This includes, but is not limited to, restaurants, hotels, bar standing and seating areas, patios, and coffee shops. An open air dining area does not include open air dining areas that are immediately adjacent to and accessory to a private smokers' lounge, as that term is defined in Labor Code Section 6404.5 or its successor statute.

SMOKE OR SMOKING: The carrying, holding, or operating of a lighted pipe, cigar, cigarette, electronic cigarette, or other kind of smoking equipment. Smoke also means the lighting, operating, emitting, or exhaling of the smoke or vapor of a pipe, cigar, cigarette, electronic cigarette or other kind of smoking equipment. Smoke also means the gaseous or vaporous products and particles created by the use of a lighted or operated pipe, cigar, cigarette, electronic cigarette or other kind of smoking equipment.”

Section 3. The City Council hereby amends Section 5-4-5 (“Prohibition of Cigarette Vending Machines”) of Chapter 4 (“Smoking Regulations”) of Title 5 (“Public Health, Welfare, and Sanitation”) of the Beverly Hills Municipal Code to read as follows:

“5-4-5: Prohibition of Cigarette or Electronic Cigarette Vending Machines:

Unless otherwise prohibited by state or federal law, no person shall install, place, operate, or maintain within the City any cigarette vending machine. “Cigarette vending machine” shall mean

any self-service device which, upon insertion of money or tokens, dispenses cigarettes or electronic cigarettes without the necessity of replenishing the device between each vending operation.”

Section 4. The City Council hereby adds new Section 5-4-7 (“Prohibition of Smoking Electronic Cigarettes in Public Buildings”) of Chapter 4 (“Smoking Regulations”) of Title 5 (“Public Health, Welfare, and Sanitation”) of the Beverly Hills Municipal Code to read as follows:

“5-4-7: Prohibition of Smoking Electronic Cigarettes in and Near Public Buildings:

Smoking electronic cigarettes is prohibited in all buildings and areas where smoking of tobacco products is prohibited by California Government Code Section 7597 or any successor statute thereto.”

Section 5. CEQA. The City Council hereby finds that it can be seen with certainty that there is no possibility the adoption of this ordinance will have a significant effect on the environment because the ordinance only includes electronic cigarettes within tobacco retailer permitting regulations and smoking regulations currently in force under the Beverly Hills Municipal Code, and will thereby serve to reduce potential significant adverse environmental impacts. It is therefore exempt from California Environmental Quality Act review pursuant to Title 14, Section 15061(b)(3) of the California Code of Regulations.

Section 6. Severability. If any section, subsection, subdivision, sentence, clause, phrase, or portion of this ordinance or the application thereof to any person or place, is for any reason held to be invalid or unconstitutional by the final decision of any court of competent jurisdiction, the remainder of this ordinance shall remain in full force and effect.

Section 7. Publication. The City Clerk shall cause this ordinance to be published at least once in a newspaper of general circulation published and circulated in the City within fifteen (15) days after its passage in accordance with Section 36933 of the Government Code, shall certify to the adoption of this ordinance and shall cause this ordinance and the City Clerk's certification, together with proof of publication, to be entered in the Book of Ordinances of the Council of this City.

Section 8. Effective Date. This ordinance shall go into effect and be in full force and effect at 12:01 a.m. on the thirty-first (31st) day after its passage

JOHN A. MIRISCH
Mayor of the City of
Beverly Hills, California

ATTEST:

(SEAL)
BYRON POPE
City Clerk

APPROVED AS TO FORM:

APPROVED AS TO CONTENT:



LAURENCE S. WIENER
City Attorney

JEFFREY C. KOLIN
City Manager

EXHIBITS

Various online articles as referenced in the ordinance

[Home](#) [For Consumers](#) [Consumer Updates](#)

For Consumers

E-Cigarettes: Questions and Answers

 [Get Consumer Updates by E-mail¹](#)

 [Consumer Updates RSS Feed²](#)

Q: What are electronic cigarettes?

A: Electronic cigarettes are products designed to deliver nicotine or other substances to a user in the form of a vapor. Typically, they are composed of a rechargeable, battery-operated heating element, a replaceable cartridge that may contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor. This vapor can then be inhaled by the user. These products are often made to look like such products as cigarettes, cigars, and pipes. They are also sometimes made to look like everyday items such as pens and USB memory sticks, for people who wish to use the product without others noticing.

Q: What concerns does FDA have regarding electronic cigarettes?

A: FDA has not evaluated any e-cigarettes for safety or effectiveness. When FDA conducted limited laboratory studies of certain samples, FDA found significant quality issues that indicate that quality control processes used to manufacture these products are substandard or non-existent. FDA found that cartridges labeled as containing no nicotine contained nicotine and that three different electronic cigarette cartridges with the same label emitted a markedly different amount of nicotine with each puff. Experts have also raised concerns that the marketing of products such as e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products. Visit FDA's Electronic Cigarettes webpage³ for additional information.

Q: What action did FDA take today on electronic cigarettes?

A: FDA issued warning letters to five distributors of electronic cigarettes for violations of the Federal Food, Drug, and Cosmetic Act (FDCA). These violations included unsubstantiated claims and poor manufacturing practices.

Q: Would it be possible for an electronic cigarette to receive FDA approval?

A: Yes. FDA issued a letter to the Electronic Cigarette Association inviting electronic cigarette firms to work in cooperation with the agency toward the goal of assuring that electronic cigarettes sold in the United States are lawfully marketed. The agency intends to regulate electronic cigarettes and related products in a manner consistent with its mission of protecting the public health.

Q: What products should people who want to quit smoking use?

A: There are a number of FDA-approved smoking cessation aids, including nicotine gum, nicotine skin patches, nicotine lozenges, nicotine oral inhaled products, and nicotine nasal spray that are available for smokers to use to reduce their dependence on nicotine. Free help is available to all smokers who want to quit at 1-800-QUIT-NOW or by visiting www.smokefree.gov⁴.

This article appears on FDA's Consumer Updates page⁵, which features the latest on all FDA-regulated products.

Posted September 9, 2010

[back to top](#)

For More Information

- [Family Smoking Prevention and Tobacco Control Act⁶](#)
- [FDA Acts Against 5 Electronic Cigarette Distributors⁷ \[ARCHIVED\]](#)

- FDA's Electronic Cigarettes web page⁸
- Letter to the Electronic Cigarette Association (PDF - 43KB)⁹

Related Consumer Updates

- FDA Warns of Health Risks Posed by E-Cigarettes¹⁰
- FDA 101: Smoking Cessation Products¹¹ [ARCHIVED]
- "Light" Tobacco Products Pose Heavy Health Risks¹²
- What Are You Smoking (or Chewing or Inhaling)?¹³
- Less Risky Tobacco Product? Only if the Science Says So¹⁴
- Why Do People Use Tobacco? Looking for Answers¹⁵
- Why is the Great American Smokeout Important?¹⁶
- FDA Unveils New Cigarette Health Warnings¹⁷
- Regulating Tobacco: Q&A with Former CTP Director Lawrence Dayton, M.S.P.H., M.D.¹⁸ [ARCHIVED]
- FDA Modernizing Regulatory Science¹⁹

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3. </NewsEvents/PublicHealthFocus/ucm172906.htm>
4. <http://www.smokefree.gov>
5. </ForConsumers/ConsumerUpdates/default.htm>
6. <http://www.accessdata.fda.gov/scripts/tobaccocontrol/index.cfm>

7. </NewsEvents/Newsroom/PressAnnouncements/2010/ucm225224.htm>
8. </NewsEvents/PublicHealthFocus/ucm172906.htm>
9. </downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM225263.pdf>
10. </ForConsumers/ConsumerUpdates/ucm173401.htm>
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13. </ForConsumers/ConsumerUpdates/ucm297878.htm>
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News & Events

FDA NEWS RELEASE

For Immediate Release: July 22, 2009

Media Inquiries: Siobhan DeLancey, 301-796-4668, siobhan.delancey@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA and Public Health Experts Warn About Electronic Cigarettes

The U.S. Food and Drug Administration today announced that a laboratory analysis of electronic cigarette samples has found that they contain carcinogens and toxic chemicals such as diethylene glycol, an ingredient used in antifreeze.

Electronic cigarettes, also called "e-cigarettes," are battery-operated devices that generally contain cartridges filled with nicotine, flavor and other chemicals. The electronic cigarette turns nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

These products are marketed and sold to young people and are readily available online and in shopping malls. In addition, these products do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes. They are also available in different flavors, such as chocolate and mint, which may appeal to young people.

Public health experts expressed concern that electronic cigarettes could increase nicotine addiction and tobacco use in young people. Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium and Jonathan Samet, M.D., director of the Institute for Global Health at the University of Southern California, joined Joshua Sharfstein, M.D., principal deputy commissioner of the FDA, and Matthew McKenna, M.D., director of the Office of Smoking and Health for the Centers for Disease Control and Prevention, to discuss the potential risks associated with the use of electronic cigarettes.

"The FDA is concerned about the safety of these products and how they are marketed to the public," said Margaret A. Hamburg, M.D., commissioner of food and drugs.

Because these products have not been submitted to the FDA for evaluation or approval, at this time the agency has no way of knowing, except for the limited testing it has performed, the levels of nicotine or the amounts or kinds of other chemicals that the various brands of these products deliver to the user.

The FDA's Division of Pharmaceutical Analysis analyzed the ingredients in a small sample of cartridges from two leading brands of electronic cigarettes. In one sample, the FDA's analyses detected diethylene glycol, a chemical used in antifreeze that is toxic to humans, and in several other samples, the FDA analyses detected carcinogens, including nitrosamines. These tests indicate that these products contained detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed.

The FDA has been examining and detaining shipments of e-cigarettes at the border and the products it has examined thus far meet the definition of a combination drug-device product under the Federal Food, Drug, and Cosmetic Act. The FDA has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court. The agency is also planning additional activities to address its concerns about these products.

Health care professionals and consumers may report serious adverse events (side effects) or product

quality problems with the use of e-cigarettes to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

- Online: <http://www.fda.gov/Safety/MedWatch/default.htm>¹
- Regular Mail: use postage-paid FDA form 3500 available at: <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>² and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: (800) FDA-0178
- Phone: (800) FDA-1088

#

For More Information

Electronic Cigarettes

3

RSS Feed for FDA News Releases⁴ [what is RSS?⁵]

Page Last Updated: 04/17/2013

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FDA Warns of Health Risks Posed by E-Cigarettes

The Food and Drug Administration (FDA) has joined other health experts to warn consumers about potential health risks associated with electronic cigarettes.

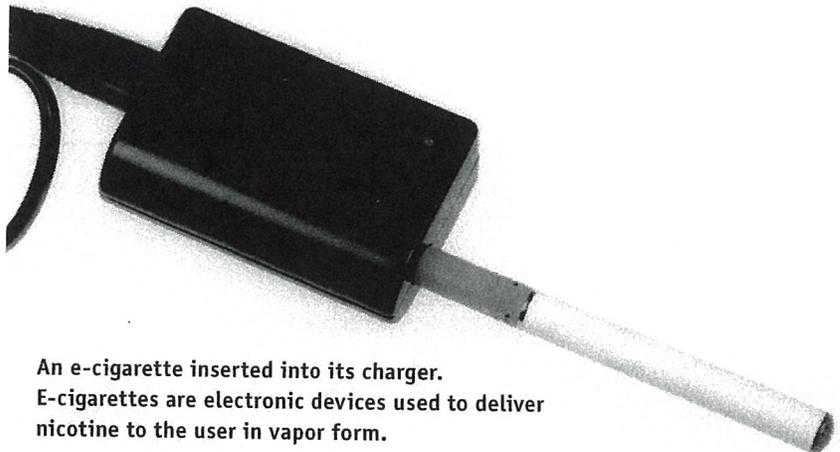
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

Sold online and in many shopping malls, the devices generally contain cartridges filled with nicotine, flavor, and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

"The FDA is concerned about the safety of these products and how they are marketed to the public," says Margaret A. Hamburg, M.D., commissioner of food and drugs.

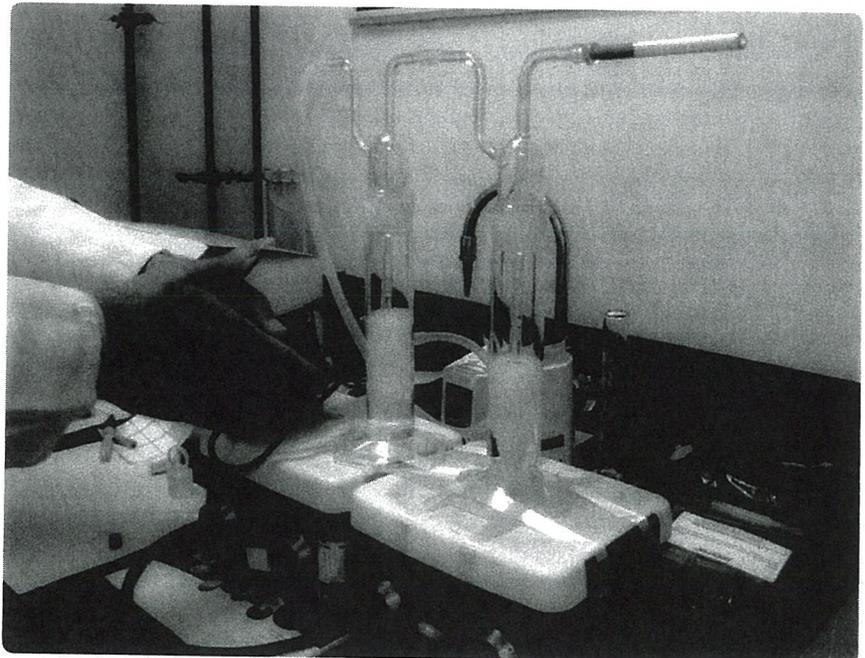
The agency is concerned that

- e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death
- the products may contain ingredients that are known to be toxic to humans
- because clinical studies about the safety and efficacy of these products for their intended use have not been



An e-cigarette inserted into its charger. E-cigarettes are electronic devices used to deliver nicotine to the user in vapor form.

FDA



Air is drawn through an e-cigarette during a laboratory procedure that simulates a smoker taking a puff. The resulting vapor is tested.

FDA

submitted to FDA, consumers currently have no way of knowing

- whether e-cigarettes are safe for their intended use
- about what types or concentrations of potentially harmful chemicals, or what dose of nicotine they are inhaling when they use these products

The potential health risks posed by the use of e-cigarettes were addressed in a July 22, 2009, phone conference between Joshua M. Sharfstein, M.D., principal deputy commissioner of food and drugs; Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium; Jonathan Samet, M.D., director of the University of Southern California's Institute for Global Health; and Matthew T. McKenna, M.D., director of the Office on Smoking and Health at the national Centers for Disease Control and Prevention.

Conference participants stressed the importance of parents being aware of the health and marketing concerns associated with e-cigarettes. It was stated that parents may want to tell their children and teenagers that these products are not safe to use.

Of particular concern to parents is that e-cigarettes are sold without any legal age restrictions, and are available in different flavors (such as chocolate, strawberry and mint) which may appeal to young people.

In addition, the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes.

During the phone conference, which was shared with the news media, FDA announced findings from a laboratory analysis that indicates that electronic cigarettes expose users to harmful chemical ingredients.

FDA's Division of Pharmaceutical Analysis—part of the agency's Center for Drug Evaluation and Research—analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarette samples.



FDA

An FDA chemist uses a device set to the same temperature as an activated e-cigarette. This helps determine what might be inhaled by users of these products.

One sample was found to contain diethylene glycol, a toxic chemical used in antifreeze. Several other samples were found to contain carcinogens, including nitrosamines.

Agency Actions

FDA has been examining and detaining shipments of e-cigarettes at the border and has found that the products it has examined thus far meet the definition of a combination drug device product under the Federal Food, Drug, and Cosmetic Act.

The agency has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court.

FDA is planning additional activities to address its concerns about electronic cigarettes.

Meanwhile, health care professionals and consumers may report seri-

ous adverse events or product quality problems with the use of e-cigarettes to FDA through the MedWatch program, either online at www.fda.gov/Safety/MedWatch/default.htm or by phone at 1-800-FDA-1088.

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

For More Information

FDA Press Release
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

E-Cigarettes: FDA Web page
www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm



WMA Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems

Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012

INTRODUCTION

Electronic cigarettes (e-cigarettes) are products designed to deliver nicotine to a user in the form of a vapor. They are usually composed of a rechargeable battery-operated heating element, a replaceable cartridge that contains nicotine and/or other chemicals, and an atomizer that, when heated, turns the contents of the cartridge into a vapor (not smoke). This vapor is then inhaled by the user. These products are often made to look like other tobacco-derived products like cigarettes, cigars, and pipes. They can also be made to look like everyday items such as pens and USB memory sticks.

No standard definition of e-cigarettes exists and different manufacturers use different designs and different ingredients. Quality control processes used to manufacture these products are substandard or non-existent. Few studies have been done to analyze the level of nicotine delivered to the user and the composition of the vapor produced.

Manufacturers and marketers of e-cigarettes often claim that use of their products is a safe alternative to smoking, particularly since they do not produce carcinogenic smoke. However, no studies have been conducted to determine that the vapor is not carcinogenic, and there are other potential risks associated with these devices: Appeal to children, especially when flavors like strawberry or chocolate are added to the cartridges. E-cigarettes can increase nicotine addiction among young people and their use may lead to experimenting with other tobacco products.

Manufacturers and distributors mislead people into believing these devices are acceptable alternatives to scientifically proven cessation techniques, thus delaying actual smoking cessation. E-cigarettes are not comparable to scientifically-proven methods of smoking cessation. Their dosage, manufacture, and ingredients are not

consistent or clearly labelled. Brand stretching by using known cigarette logos is to be deplored.

Unknown amounts of nicotine are delivered to the user, and the level of absorption is unclear, leading to potentially toxic levels of nicotine in the system. These products may also contain other ingredients toxic to humans.

High potential of toxic exposure to nicotine by children, either by ingestion or dermal absorption, because the nicotine cartridges and refill liquid are readily available over the Internet and are not sold in child resistant packaging.

Due to the lack of rigorous chemical and animal studies, as well as clinical trials on commercially available e-cigarettes, neither their value as therapeutic aids for smoking cessation nor their safety as cigarette replacements is established. Lack of product testing does not permit the conclusion that e-cigarettes do not produce any harmful products even if they produce fewer dangerous substances than conventional cigarettes.

Clinical testing, large population studies and full analyses of e-cigarette ingredients and manufacturing processes need to be conducted before their safety, viability and impacts can be determined as either clinical tools or as widely available effective alternatives to tobacco use.

RECOMMENDATIONS

That the manufacture and sale of e-cigarettes and other electronic nicotine delivery systems be subject to national regulatory bodies prior approval based on testing and research as either a new form of tobacco product or as a drug delivery device.

That the marketing of e-cigarettes and other electronic nicotine delivery systems as a valid method for smoking cessation must be based on evidence and must be approved by appropriate regulatory bodies based on safety and efficacy data.

That e-cigarettes and other electronic nicotine delivery systems be included in smoke free laws.

Physicians should inform their patients of the risks of using e-cigarettes even if regulatory authorities have not taken a position on the efficacy and safety of these products.

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Attachment 3

Beverly Hills Recreation and Parks Rule & Regulation Regarding Smoking

Pursuant to Beverly Hills Municipal Code (“BHMC”) Section 8-1-7, the Director of Recreation and Parks has designated the following rule and regulation:

“Smoking is prohibited in all City parks and recreation facilities.

For purposes of this rule and regulation, the term “smoking” means the carrying, holding, or operating of a lighted pipe, cigar, cigarette, electronic cigarette, or other kind of smoking equipment. Smoking also means the lighting, operating, emitting, or exhaling of the smoke or vapor of a pipe, cigar, cigarette, electronic cigarette or other kind of smoking equipment. Smoking also means the gaseous or vaporous products and particles created by the use of a lighted or operated pipe, cigar, cigarette, electronic cigarette or other kind of smoking equipment.

For purposes of this rule and regulation, the term “electronic cigarette” means an electronic and/or battery-operated device, the use of which may resemble smoking, that can be used to deliver an inhaled dose of nicotine or other substances. The term includes any such device, whether manufactured, distributed, marketed, or sold as an electronic cigarette, an e-cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, an electronic hookah, or any other product name or descriptor. The term does not include any medical inhaler prescribed by a licensed doctor.”