



AGENDA REPORT

Meeting Date: November 5, 2013
Item Number: E-2
To: Honorable Mayor & City Council
From: Michelle S. Tse, Senior Management Analyst
Subject: AN INTERIM ORDINANCE OF THE CITY OF BEVERLY HILLS
DECLARING A MORATORIUM ON THE ESTABLISHMENT AND
FURTHER OPERATION OF ANY ELECTRONIC CIGARETTE
RETAILER AND DECLARING THE URGENCY THEREOF

Attachments: 1. Interim Urgency Ordinance with Exhibits

RECOMMENDATION

It is recommended that the City Council read the ordinance titled "AN INTERIM ORDINANCE OF THE CITY OF BEVERLY HILLS DECLARING A MORATORIUM ON THE ESTABLISHMENT AND FURTHER OPERATION OF ANY ELECTRONIC CIGARETTE RETAILER AND DECLARING THE URGENCY THEREOF" by title only, waive further reading and adopt the ordinance. A four-fifths vote is required to adopt the interim urgency ordinance.

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 report will address the sale of e-cigarettes. Staff review of relevant Federal and State laws and amending the regulation of smoking to include e-cigarettes in the City's municipal code is being addressed as a separate agenda item during the November 5th City Council formal meeting.

DISCUSSION

The attached interim urgency ordinance will place a temporary moratorium on the sales of e-cigarettes at any establishment. A preliminary assessment by staff confirmed there

are retailers within the city that are currently selling e-cigarettes. In order to allow retailers to amortize any investment in e-cigarettes made before the adoption of the ordinance, retailers who purchased e-cigarettes for resale prior to the date of adoption of the ordinance will be able to continue to sell such cigarettes for a period of two weeks after the adoption of the ordinance. Selling e-cigarettes beyond the two weeks is a misdemeanor and is punishable by a fine not to exceed \$1,000 or imprisonment for up to six months, or both.

If approved by the City Council, this interim urgency ordinance will be effective immediately, for up to 45 days. Interim urgency ordinances can be extended twice, for up to a maximum of two years. During the interim period, staff will further research this issue and provide a status update to the City Council within the 45-day period. The status update to the City Council may include recommendations based on findings or a request to extend the urgency ordinance for up to 10 months and 15 days for staff to further research and develop a permanent ordinance.

If approved by the City Council, staff will immediately conduct public education and outreach efforts during the 45-day interim period. Notifications will be sent to tobacco retailers operating in the city to inform them about the urgency ordinance and that sales of e-cigarettes is now prohibited two weeks after the ordinance adoption date.

Staff will be working closely with the Health and Safety Commission to solicit feedback and recommendations on how to best address e-cigarettes and smoking regulations in general. Staff introduced the e-cigarette issue during the October 28 Health and Safety Commission meeting, which will be followed by a more in-depth discussion on e-cigarettes and smoking during its November 25 meeting, after the installation of its three new Commissioners.

FISCAL IMPACT

Staff estimates there will be some fiscal impact to the City to conduct public education efforts and enforcement.

Mahdi Aluzri 
Approved By _____

Attachment 1

ORDINANCE NO. 13-O-

AN INTERIM ORDINANCE OF THE CITY OF BEVERLY HILLS DECLARING A MORATORIUM ON THE ESTABLISHMENT AND FURTHER OPERATION OF ANY ELECTRONIC CIGARETTE RETAILER 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

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.

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 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

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.

no way of knowing: 1) Whether electronic cigarettes are safe for their intended use; 2) What 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

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*.

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

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. Some existing businesses in the City are already advertising the sale of electronic cigarettes. Electronic cigarette retailers are not currently addressed in the Beverly Hills Municipal Code.

N. Some electronic cigarettes could be used to consume substances other than tobacco, as well as synthetic marijuana substitutes and other products that are potentially harmful to the public health and safety, and to the general quality of life. Anecdotal evidence suggests that electronic cigarette retailers can create harmful secondary effects in the neighborhoods in which they are located, but the City has not studied how to best manage and mitigate these impacts. Further study and consideration of the potential impacts that electronic cigarette retailers may have on the public’s health, safety, and welfare is required to ensure that any negative impacts can be addressed and mitigated.

O. If electronic cigarette retailers are established or are operating without appropriate review and regulation, they could have adverse secondary effects on the public health and on

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

neighborhoods and result in significant irreversible change to the neighborhood and community character.

P. The City intends to study, within a reasonable time, the adequacy of its existing ordinances and the potential need to adopt new regulations regarding electronic cigarette retailers. The City Council, the Health and Safety Commission, and the people of Beverly Hills require a sufficient and reasonably limited time to consider and study legally appropriate and reasonable policies regulating these businesses in order to prevent negative impacts on neighboring residents. Given the time required to undertake the necessary study and planning, the City Council finds that it is necessary to enact an interim moratorium to ensure that establishment and operation of businesses that may conflict with the contemplated new development policies are not permitted in the interim.

Q. The City Council has the authority to adopt an interim ordinance pursuant to Government Code Section 65858 in order to protect the public health, safety, or welfare. For the reasons set forth in paragraphs A through P, there is a current and immediate threat to the public health, safety, and welfare presented by the unregulated establishment and operation of smoke shops and electronic cigarette retailers, and the sale of electronic cigarettes. There is therefore an urgent necessity for the City to adopt a temporary moratorium on the establishment and operation of electronic cigarette retailers.

Section 2. The City hereby ordains that the establishment or continued operation of any electronic cigarette retailer is prohibited. The City shall not approve any new or pending application for any permit, license, or other entitlement for the establishment or operation of any electronic cigarette retailer. The sale of electronic cigarettes from other than a fixed location,

including, but not limited to, electronic cigarette retailing by persons on foot or from vehicles is prohibited.

A. For purposes of this ordinance, the term “electronic cigarette retailer” means any establishment, structure, facility, vehicle, stand or cart that devotes any floor space or display area to the sale, display, marketing, bartering, trading or exchange of electronic cigarettes or otherwise engages in these activities.

B. For purposes of this ordinance, the term “electronic cigarette” means 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 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.

C. The terms defined above shall be broadly and liberally interpreted to carry out the intent of this interim ordinance.

Section 3. Penalties and Enforcement. Violation of any provision of this ordinance shall constitute a misdemeanor and shall be punishable by a fine not to exceed \$1,000 or by imprisonment for a period not to exceed six months, or by both such fine and imprisonment. Each and every day such a violation exists shall constitute a separate and distinct violation of this ordinance. In addition to the foregoing, any violation of this ordinance shall constitute a public nuisance and shall be subject to abatement as provided by all applicable provisions of law. Any violation of this ordinance may also be prosecuted as an infraction or as a civil administrative action pursuant to Title 1, Chapter 3 of the Beverly Hills Municipal Code.

Section 4. Amortization. Any retailer that has purchased electronic cigarettes for retail sale prior to the date of adoption of this ordinance may engage in the retail sale of such electronic cigarettes within the City for a period of two weeks after the date of adoption of this ordinance. The sale of such electronic cigarettes shall be subject to the following conditions:

A. The sale of electronic cigarettes from other than a fixed location, including, but not limited to, electronic cigarette retailing by persons on foot or from vehicles is prohibited.

B. The retailer shall not sell an electronic cigarette to another person who appears to be under the age of thirty (30) years without first examining the identification of the recipient to confirm that the recipient is at least the minimum age under state law to purchase an electronic cigarette.

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 and establishment of the interim moratorium hereby, will have a significant effect on the environment, because the moratorium imposes greater limitations on electronic cigarette retailers and the sale of electronic cigarettes in the City than the limitations currently required under the Beverly Hills Municipal Code, and will thereby serve to reduce potential 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, paragraph, sentence, clause or phrase of this ordinance or any part thereof is for any reason held to be invalid, such invalidity shall not affect the validity of the remaining portions of this ordinance or any part hereof. The City Council hereby declares that it would have passed each section, subsection,

subdivision, paragraph, sentence, clause or phrase hereof, irrespective of the fact that any one or more sections, subsections, subdivisions, paragraphs, sentences, clauses or phrases be declared invalid.

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 his certification, together with proof of publication, to be entered in the Book of Ordinances of the Council of this City.

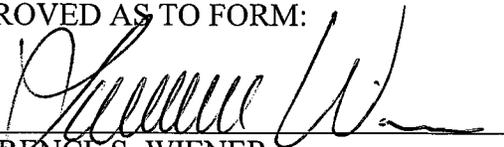
Section 8. Effective Date. This ordinance, being an interim ordinance adopted as an urgency measure for the immediate protection of the public safety, health, and general welfare, containing a declaration of the facts constituting the urgency, and passed by a minimum four-fifths (4/5) vote of the City Council, shall take effect immediately upon its adoption, and remain valid for forty-five (45) days, unless extended in accordance with Government Code Section 65858.

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

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

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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 Deyton, M.S.P.H., M.D.¹⁸ [ARCHIVED]
- FDA Modernizing Regulatory Science¹⁹

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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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Electronic Cigarettes

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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.

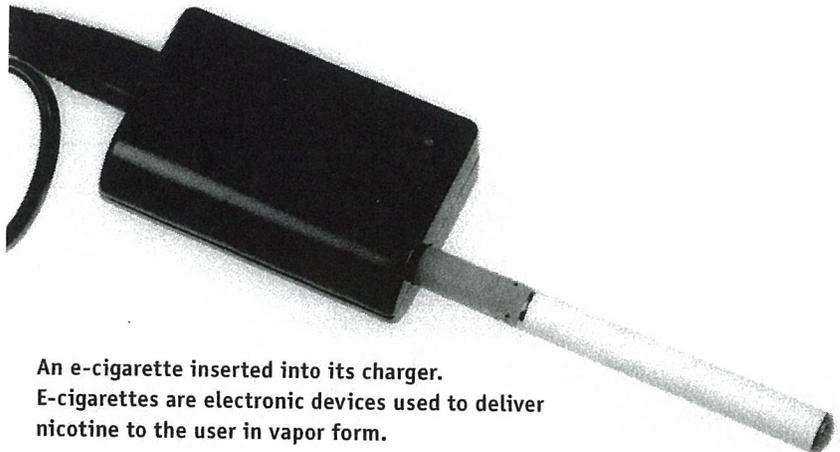
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

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.

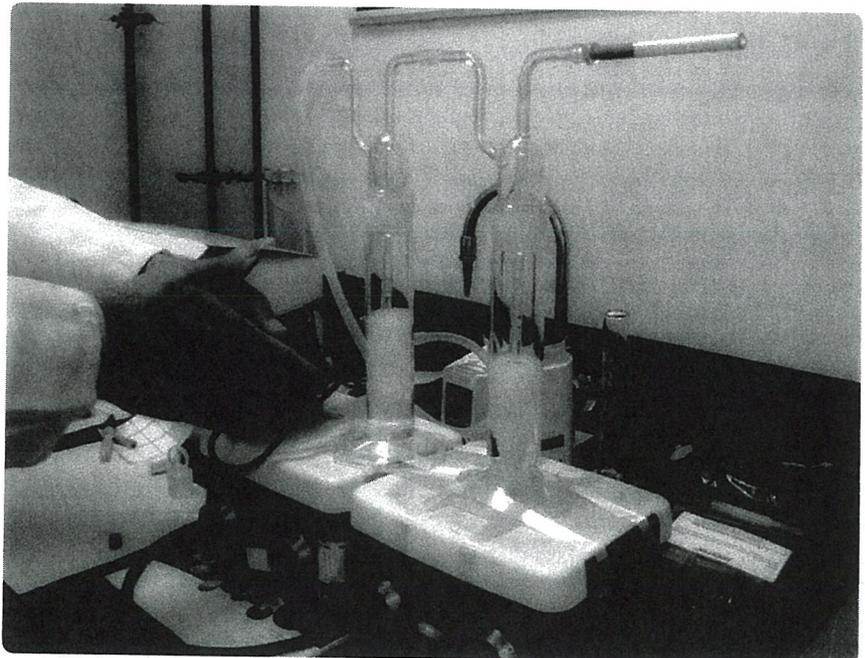
The agency is concerned that

- 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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