#### E-Cigarettes: What We Know and Don't Know

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## **Presentation Outline**



Components and Use of E-cigarette Devices

**Prevalence Data** 

Scientific Health Assessments and Findings



Policy and Legal Response

Marketing Implications



The Future of E-cigarettes

#### OVERVIEW AND HISTORY OF ELECTRONIC NICOTINE DELIVERY SYSTEMS

## What's in a Name?

- Electronic Nicotine Delivery Systems (ENDS)
  Electronic Nicotine Delivery Device (ENDD)
  Electronic Cigarette
- •E-cigarette
- •E-cig•Personal Vaporizer



"Smokers" are now "vapers," who, instead of identifying themselves with a particular brand of cigarette, identify themselves by the type of e-cigarette they use and the flavors they prefer.

Barbeau, A., Burda, J., Siegel, M. (2013). Perceived efficacy of e-cigarettes versus nicotine replacement therapy among successful ecigarette users: a qualitative approach. Addiction Science & Clinical Practice , 8(5).

#### Who Invented the E-Cigarette?

•Hon Lik, a Chinese pharmacist from Beijing, is generally credited with inventing e-cigarettes as they exist in their current form in 2003 while working for Golden Dragon Holdings, which later changed its name to Ruyan, which means "Resembling smoking."



•Ruyan began marketing e-cigs in China in 2004, and soon after began exporting them to Europe and the US.

> Foulds, J., Veldheer, S., Berg, A. (2011). Electronic cigarettes (e-cigs): views of aficionados and clinical/public health perspectives. International Journal of Clinical Practice<u>i</u>, 65(10):1037-42. Henningfield, J. E., Zaatan, G. S. (2010) Electronic nicotine delivery systems: emerging science foundation for policy. Tobacco Control, 19(2):89-90.

#### Little-Known Trivia...Who ELSE (Maybe Invented the E-Cigarette?

•In 1963, Herbert A. Gilbert filed a patent for a smokeless nontobacco cigarette with the US Patent Office, and two years later, his patent was accepted.



Tenk, J. (2009). New Invention of 1963: The Smokeless Non-Tobacco Cigarette. Retrieved 5/27/13 from http://www.ecig.org/2009/11/07/new-invention-of-1963-the-smokeless-non-tobacco-cigarette/

# COMPONENTS AND USE OF E-CIGARETTE DEVICES

#### What's in an E-Cigarette?





Cobb, N. K., Abrams, D. B. (2011). E-cigarette or drug-delivery device? Regulating novel nicotine products. The New England Journal of Medicine, 365(193-195).

Kuschner, W. G., Reddy, S., Mehrotra, N., Paintal, H.S. (2011). Electronic cigarettes and thirdhand tobacco smoke: two emerging health care challenges for the primary care provider. International Journal of General Medicine, 4(115-120).

#### How Does an E-Cigarette Work?

•The user inhales on the mouthpiece, which activates the flow trigger (and LED light as applicable) in the device.

• The battery sends a current to the heating element, which heats and vaporizes the contents of the cartridge.

•The user breathes in the vapor mist.



Cobb, N. K., Abrams, D. B. (2011). E-cigarette or drug-delivery device? Regulating novel nicotine products. The New England Journal of Medicine, 365(193-195).

Kuschner, W. G., Reddy, S., Mehrotra, N., Paintal, H.S. (2011). Electronic cigarettes and thirdhand tobacco smoke: two emerging health care challenges for the primary care provider. International Journal of General Medicine, 4(115-120).

# **PREVALENCE DATA**

#### **Adult Awareness and Use**

#### **US Population**



Zhu S-H, Gamst A, Lee M, Cummins S, Yin L, et al. (2013) The Use and Perception of Electronic Cigarettes and Snus among the U.S. Population . PLoS ONE 8(10): e79332. doi:10.1371/journal.pone.0079332 King, B. B., Alam, S., Promoff, G, Arrazola, R., Dube, S. R. (2013) Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults,

2010-2011. Nicotine Tobacco Research, 15(9): 1623-7.

#### **Adult Awareness and Use**

#### **US Current Smokers**



Zhu S-H, Gamst A, Lee M, Cummins S, Yin L, et al. (2013) The Use and Perception of Electronic Cigarettes and Snus among the U.S. Population . PLoS ONE 8(10): e79332. doi:10.1371/journal.pone.0079332

#### U.S. Youth Use

#### **Ever Tried**



Centers for Disease Control and Prevention. (2013) E-cigarette use more than doubles among U.S. middle and high school students from 2011-2012. Retrieved from http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html

#### Florida Youth Use

#### **High School Students**



2012 Florida Youth Tobacco Survey, http://www.floridahealth.gov/reports-and-data/survey-data/fl-youth-tobacco-survey/reports/index.html

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#### Where Have You Seen E-cigs for Sale?

# Online Convenience Stores Pharmacies Big Box Stores Malls Tobacco Specialty Shops Liquor/Beverage Stores Grocery Stores Television



# SCIENTIFIC HEALTH ASSESSMENTS AND FINDINGS

•Still in need of safety and efficacy data – no long-term controlled clinical trials. Most research studies conclude by noting the need for further research

•Inconsistent nicotine delivery and craving suppression •In a study on pulmonary effects (Vardavas et al.), 5 minutes of ecigarette use led to an increase of impedence, peripheral airway flow resistance, and oxidative stress among healthy smokers.

Eissenberg, T. (2010) Electronic nicotine delivery devices: ineffective nicotine delivery and craving suppression after acute administration. (Tobacco Control, 19(87-88).

Popova, L., Ling, P. M. (2013) Alternative Tobacco Product Use and Smoking Cessation: A National Study. American Journal of Public Health, In Press.

Vardavas, C. I., Anagnostopoulos, N., Kougia, M., Evangelopoulou, V, Connolly, G. N., Behrakis, P. K. (2012) Impact of Respiratory Flow Resistance, Impedance, and Exhaled Nitric Oxide. Chest, 141(6)), 1400-1406.

Metal and silicate particles found in cartomizer and aerosol
One study found variations in design; ambiguous amounts of nicotine per cartridge; insufficient labeling of cartridges, wrappers, packs; leakiness of cartridges; defective parts and operation; errors in orders filled; incomplete/inaccurate instruction manual

42-year old woman – lipoid pneumonia due to recurrent exposure to glycerin-based oils in e-cigarette nicotine vapor
Not legally approved as a smoking cessation aid, but some smokers view/purchase it as such, and evidence is mounting against that.

McCauley, L., Markin, C., Hosmer, D. (2012). An Unexpected Consequence of Electronic Digarette Use. (2012). Chest, 141(4), 1110-1113.

Trtchounian, A., Talbot, P. (2011). Electronic nicotine delivery systems: is there a need for regulation? Tobacco Control, 20(47-52). Vickerman, K. A., Carpenter, K. M., Altman, T., Nash, C. M., Zbikowski, S. M. (2013). Use of Electronic Cigarettes Among State Tobacco Cessation Quitline Callers. Nicotine & Tobacco Research, In Press.

Williams, M., Villarreal, A., Bozhilov, K., Lin, S., Tablot, P. (2013). Metal and Silicate Particles Including Nano Fluid and Aerosol. PLoS One, 8(3), e57987.

#### •Anecdotal reports of injuries from malfunction of e-cigarettes



•Because of mounting concerns, FDA did preliminary research of its own in 2009.

<u>FDA Research</u>
<u>http://www.youtube.com/watch?v=t8PqKqlmO4c</u>

# POLICY AND LEGAL RESPONSE

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U.S. Department of Health & Human Services           U.S. Department of Health & Human Services         A to Z Index   Follow FDA             U.S. Food and Drug Administration         Most Popular Searches           Protecting and Promoting Your Health         Most Popular Searches		a A <b>A</b>
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Information and Adverse Event Reporting Program           Safety Information           Safety Alerts for Human Medical Products           2013 Safety Alerts for Human Medical Products           2012 Safety Alerts for Human Medical Products           2011 Safety Alerts for Human Medical Products           2011 Safety Alerts for Human Medical Products           2010 Safety Alerts for Human Medical Products           2010 Safety Alerts for Human Medical Products           2009 Safety Alerts for Human Medical Products           2008 Safety Alerts for Human Medical Products           2007 Safety Alerts for Human Medical Products           2007 Safety Alerts for Human Medical Products	[Posted 07/22/2009] FDA notified healthcare profession cigarette samples has found that they contain carcinoge ingredient used in antifreeze. Electronic cigarettes, also generally contain cartridges filled with nicotine, flavor an nicotine, which is highly addictive, and other chemicals i are marketed and sold to young people and are readily i available in different flavors, such as chocolate and mint The FDA's Division of Pharmaceutical Analysis analyzed two leading brands of electronic cigarettes. In one samp chemical used in antifreze that is toxic to humans, and carcinogens, including nitrosamines. These products of approved nicotine replacement products or conventiona submitted to the FDA for evaluation or approval, at this til limited testing it has performed, the levels of nicotine or various brands of these products deliver to the user. Health care professionals and consumers may report s problems with the use of e-cigarettes to the FDA's MedV by regular mail, fax or phone. [07/22/2009 - Information on E-cigarettes - FDA]	als and patients that a laboratory analysis of electronic ins and toxic chemicals such as diethylene glycol, an called "e-cigarettes," are battery-operated devices that d other chemicals. The electronic cigarette turns nto a vapor that is inhaled by the user. These products available online and in shopping malls. They are also t, which may appeal to young people. It the ingredients in a small sample of cartridges from le, the FDA's analyses detected diethylene glycol, a in several other samples, the FDA analyses detected o not contain any health warnings comparable to FDA- l cigarettes. Because these products have not been me the agency has no way of knowing, except for the the amounts or kinds of other chemicals that the erious adverse events (side effects) or product quality Vatch Adverse Event Reporting program either online,

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For Immediate Release: Sept. 9, 2010	
Media Inquiries: Siobhan DeLancey, 301-796-4668, siobhan.delancey@fda.hhs.gov Consumer Inquiries: 888-INFO-FDA	
FDA acts against 5 electronic cigarette distributors	
Agency cites unsubstantiated claims, poor manufacturing practices The LLS. Enod and Drun Administration today issued warning letters to five electronic cigarette distributors	s for various violations of the Federal Food, Drug, and Cosmetic Act
(FDCA) including unsubstantiated claims and poor manufacturing practices.	s to various violations of the rederar rood, brug, and dosineate Ad
Also today, in a letter to the Electronic Cigarette Association, FDA said the agency intends to regulate electr mission of protecting the public health. The letter outlines the regulatory pathway for marketing drug produ	tronic cigarette and related products in a manner consistent with its ucts in compliance with the FDCA.
For a drug product to gain FDA approval, a company must demonstrate to the agency that the product is sa	afe and effective for its intended use. The company must also
demonstrate that manufacturing methods are adequate to preserve the strength, quality and purity of the p	product.
marketed," the letter to the association read.	nat electronic organettes solu in the Onited States alle lawiully
FDA has determined that the electronic cigarette products addressed in the warning letters to the distribute	tors, and similar products, are subject to FDA regulation as drugs.
proven. Yet all five companies claim without FDA review of relevant evidence that the products help users of	quit smoking cigarettes.
The companies receiving warning letters today are: E. CigaratteDirect LLC, Duyan America Inc., Comucci A	Amorica (Smokov Boyou Inc.) E Cia Technology Inc. and Johnson's

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<b>U.S. Food and Drug Administration</b> Protecting and Promoting <i>Your</i> Health	A to Z Index I Follow FDA I FDA Voice Blog SEARCH Most Popular Searches
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Electronic Cigarettes (e-Cigarettes)	
As the safety and efficacy of e-cigarettes have not been fully studied, consumers of e-cigarette products currently have no way of knowing: whether e-cigarettes are safe for their intended use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or if there are any benefits associated with using these products.	What are electronic cigarettes? Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine, flavor and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.
Additionally, it is not known if e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.	Image of an e-Cigarette inserted into a charger.
Report Adverse Events	
Please report adverse events with e-cigarettes by: filling out the online form or calling 1-800-FDA-1088.	
FDA Regulation of e-Cigarettes Currently, e-cigarettes that are marketed for therapeutic purposes are regulated by the FDA Center for Drug Evaluation and Research (CDER). The FDA Center for Tobacco Products (CTP) currently regulates	Most e-cigarettes are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble everyday items such as pens and USB memory sticks.
<ul> <li>cigarettes,</li> <li>cigarette tobacco,</li> <li>roll-your-own tobacco, and</li> <li>smokeless tobacco.</li> </ul>	v
FDA has stated its intent to issue a proposed rule that would extend FDA's tobacco product authorities to products	s that meet the statutory definition of "tobacco product." For

•FDA attempted to block the import of e-cigarettes, claiming that they were "adulterated, misbranded, or unapproved drug-device combinations" and should fall under the FDA's regulatory authority as medical devices under the Food, Drug, and Cosmetics Act (FDCA) •Sottera, a major importer and distributer of e-cigarettes filed for an injunction (Sottera, Inc. v FDA) to block the FDA from regulating ecigarettes as drug-device combination products and prevent the importation block, arguing that e-cigarettes are tobacco products. •End Result: Sottera got the injunction and the FDA only has regulatory authority under the Family Smoking Prevention and Control Act of 2009 (a.k.a. Tobacco Act).

Tebor, J. (2011). Recent Case Developments. American Journal of Law & Medicine, 37 (2011): 194-198.

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#### **Subsequent Responses**

#### •Frequent/Various/State of Flux

- Countries
- States
- Counties/Municipalities
- E-cigarette Industry

#### **E-cigarette Industry/Consumer Responses**



#### **E-cigarette Industry/Consumer Responses**





#### **E-cigarette Industry/Consumer Responses**

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## MARKETING IMPLICATIONS

# Marketing of Tobacco Products

•Tobacco products have been banned from advertising in all but certain venues for a long time.

•E-cigarettes are showing up everywhere (television, radio, internet, magazines, etc.)



#### **Free Promotion**



# THE FUTURE OF E-CIGARETTES



# What Will the Future Hold?

Steps tobacco companies could be/are takingSteps the FDA could takeTobacco Free Florida Statement





