#### **Update: Electronic Cigarettes**

4<sup>th</sup> Joint Meeting of the NCI Board of Scientific Advisors and the National Cancer Advisory Board December 2, 2014

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## **Overview of Presentation**

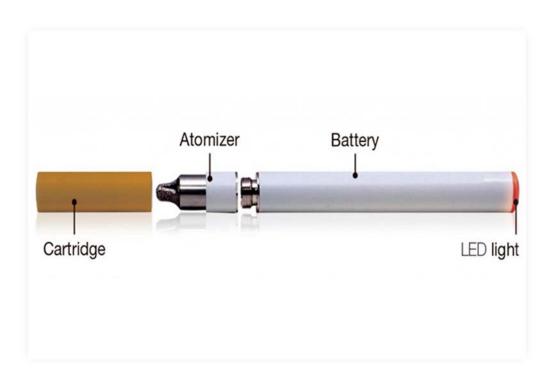
- Cigarettes vs. Electronic Cigarette
- Emissions and Health Effects
- Prevalence, Adults and Youth
- The Debate
- Marketing and "Vaping culture"
- Potential as Cessation Tool
- Regulatory Efforts, Federal and State level
- NIH Research

# What Is an Electronic Cigarette?





Electronic





Rechargeable e-cigarette



Pen-style, mediumsized rechargeable e-cigarette



Tank-style, rechargeable e-cigarette







# **E-cigarette Aerosol (not Vapor!)**





CHEMICAL	CHEMICAL EMISSIONS μG/150 puffs – 27 mL/puff	
	MINIMUM	MAXIMUM
ACETALDEHYDE	2.0	13.6
ACROLEIN	<0.02	41.9
FORMALDEHYDE	3.2	56.1
CADMIUM	< 0.04	0.22
LEAD	0.03	0.57
NICKEL	0.11	0.29
NICOTINE	5,770	19,060
NNK*	<0.0001	0.028
PROPYLENE GLYCOL	250,950	828,750

<sup>\*</sup>NNK = 4 (n-nitrosomethylamino)-1-(3-pyridyl)1-butanone

**Source**: F. Offerman. *The Hazards of E-Cigarettes*. ASHRAE Journal, June 2014.

# **Aerosol Composition**



e-liquid

**Device Characteristics** 



**User Topography** 



# **E-Cigarette Aerosol Hazards**

- Propylene glycol/vegetable glycerin
- Nicotine
- Metals
- Particle size distribution (nanoparticles)
- Flavorings

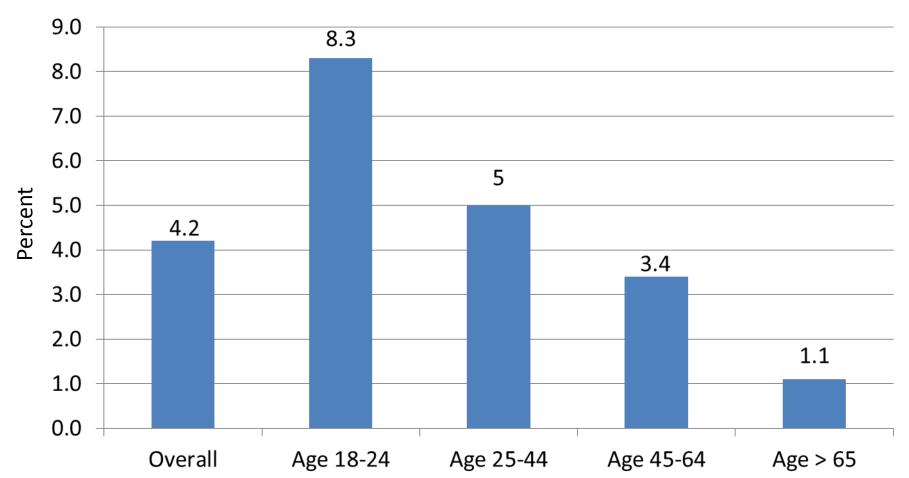
"..regardless of the potential long-term harm reduction benefits of [e-cigarettes], an important policy question is whether the still uncertain risk of potentially serious lung disease merits precautionary regulation of e-liquid composition in the face of considerable scientific uncertainty."

**Source**: Barrington-Trimis J, Samet JM, McConnell R. Flavorings in e-cigarettes. An unrecognized respiratory hazard? JAMA, November 10, 2014.

# E-cigarette Use, U.S. Adults

National Adult Tobacco Survey, 2012-2013

(compared to 18.0% Cigarette Use)

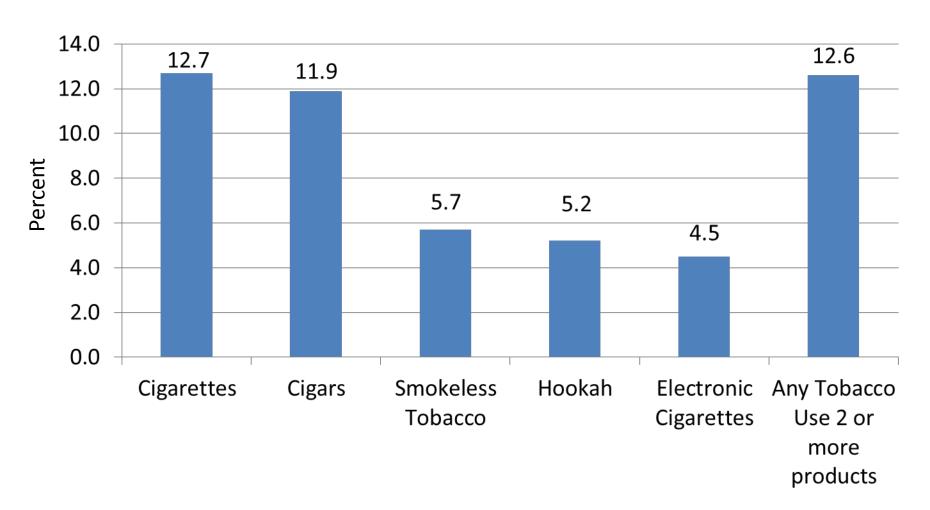


**Note**: Use = every day, someday, or rarely

Source: CDC. MMWR. June 27, 2014 / 63(25);542-547.

## Prevalence, U.S. High School Students

National Youth Tobacco Survey, 2013



**Note**: Use = past 30 day

**Source**: CDC. MMWR. November 14, 2014 / 63(45);1021-1026.

# Use by Non-smoking Youth

- U.S. youth who had never smoked use ecigarettes
  - 263,000 in 2013; 79,000 in 2011
- Intention to smoke conventional cigarettes was expressed by 44% of ever e-cigarette users and 22% of never e-cigarette users
- Key concerns: lead to nicotine addiction, and/or use of cigarettes among youth who would not otherwise become tobacco users

**Source:** Bunnell RE, et. al. 2014. *Nicotine and Tobacco Research.* 

# **E-cigarettes: Intense Debate**

"We've worked very hard to reduce smoking in this country, and I think its been a fantastic success. Now I think we're on the verge of destroying all the progress that we've [made]."

- Denise Kandel, Time Magazine, 09/03/14

"E-cigarette use has been a consumer led revolution...

The use of e-cigarettes could save millions of lives during this century, and have the most important public health impact in the history of tobacco use."

- Jacques le Houezec, 09/05/14

### Potential Benefit vs. Harm

#### Potential Benefit

 Harm reduction if smokers use them as a substitute (whole or in part) for cigarettes

#### Potential Harm

- Youth/Young adults: nicotine addiction, lead to use of other tobacco products, facilitate other drug use
- Former smokers: return to smoking
- Smokers: dual use, or deter quitting
- Long term use: hazards unknown
- Society: renormalize smoking behavior, erode gains in smoke-free air laws

# World Health Organization Position Statement

"Electronic Nicotine Delivery Systems (ENDS), therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates."

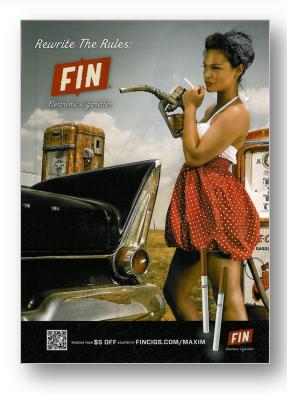
Source: Electronic nicotine delivery systems, Report by World Health Organization, 21 July 2014



























## **E-cigarettes and Smoking Cessation?**

- Studies have examined:
  - nicotine delivery
  - effect on withdrawal from nicotine
  - effect on smoking cessation
- Preliminary Conclusion: E-cigarettes can deliver nicotine, may reduce urge to smoke, and may facilitate quitting and reduced consumption.

# Vaping "Culture" and Testimonials

"I tried every single one of the FDA-approved smoking cessation products... One day I decided to try one more thing, the e-cigarette. The day I started it was the day I quit smoking for good."

- Former Smoker



# **FDA Proposed Deeming Rule**

- 2010: U.S. District Judge ruled that FDA may not regulate e-cigarettes as drugs or medical devices, unless marketed for therapeutic purposes
- 2014 Proposed Rule: deem products meeting the statutory definition of "tobacco product" including ecigarettes
  - Subject to FDA's authorities, including adulteration/misbranding, reporting HPHCs, registration, require premarket review, minimum age of purchase, health warnings, prohibit sales through vending machines
  - Requested comments on various topics

# **NO SMOKING**

WITHIN 15 FT OF ENTRYWAY





#### INCLUDING E-CIGARETTES

If you see someone smoking, please notify the manager. If the problem persists, please call 311 and report it.











If you weren't born on or before **TODAY'S DATE in** 

1996

Then you CAN'T buy E-CIG'S, Electronic Cigarettes, Liquids and Supplies.



18 is the Legal Age





#### Smoke Free!

N.D.C.C. 23-12-9 to 23-12-11

Smoking, including the use of e-cigarettes, is prohibited by law indoors and within 20 feet of entrances and windows.

## **Clinical Guidance**

- "There is not yet enough evidence for clinicians to counsel their patients who are using combustible tobacco products to use ecigarettes as a primary cessation aid."
- "If a patient has failed initial treatment, has been intolerant to or refused to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt."
- "However, subjects should be informed that these products are unregulated, may contain low levels of [toxicants], and have not been proven as cessation devices or safe over the long term."
- "Patients should quit smoking cigarettes entirely as soon as possible, because continued cigarette smoking, even at reduced levels, continues to impose health risks."

**Source:** Bhatnagar A, et al. Electronic Cigarettes: A Policy Statement from the American Heart Association. *Circulation*. August 2014.

### **NIH Research:**

#### **Tobacco Regulatory Science Program**

- Tobacco Centers of Regulatory Science (TCORS)
  - 11 of 14 TCORS
- Other Tobacco Regulatory Science
  - 5 NCl grants
  - 1 NHGRI grant
  - 3 NHLBI grants
  - 9 NIDA grants
- Research Topics: addiction, appeal, communication, marketing, and messaging, economics, health effects, initiation, point-of-sale, measures standardization, product characteristics, risk/harm perception, toxicity, vulnerable populations

**Source:** NIH Tobacco Regulatory Science Program, <a href="https://prevention.nih.gov/tobacco-regulatory-science-program">https://prevention.nih.gov/tobacco-regulatory-science-program</a>

# NIH Research: Research Project Grants



- NCI State and Community Tobacco Control Research Initiative (SCTC), RFA-CA-10-008
  - Electronic nicotine delivery systems (ENDS): New evidence from the State and Community Tobacco Control Research Initiative (9 articles, editorial)
- NIDA 3 grants within the RPG
  - Research Topics: topography and abuse liability in smokers, models of e-cigarette use among hospitalbased sample of smokers, identify new biomarkers of exposure to e-cigarettes

# Development of a Standardized Electronic Cigarette for Clinical Research

- Currently available research data on electronic cigarettes are insufficient to fully understand their impact on public health
- NIDA Small Business Innovation Research Contract Proposal, June 2014
- Standardized electronic cigarette that will have defined nicotine delivery characteristics and be available for 5+ years, sufficient for the full term of a multi-year study
- Drug Master File will be created to allow the device to obtain IND approval

Source: https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N43DA-15-8921/listing.html

# NIH Workshop on E-Cigarettes Research Questions

- Standards to measure contents and emissions
- Biomarkers of exposure and health effects
- Physiological effects on tissues and organ systems, including pulmonary and cardiovascular
- Information on users, how devices are used and identification of best tools to assess these measures
- Factors that drive use and influence patterns of use
- Appropriate methods to evaluate a potential role for e-cigarettes in smoking or nicotine cessation
- Vulnerable populations: youth, women of reproductive age

**Source**: Walton KM et al. NIH Electronic Cigarette Workshop: Developing a Research Agenda. *Nicotine & Tobacco Research*, 2014, 1-11.





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