

# Electronic Nicotine Delivery Systems

AKA Electronic Cigarettes or Vape Pens  
Fact or Hype?

---

Victoria Fehrmann Warren, Program Coordinator  
Comprehensive Tobacco Control Program, MoDHSS

522-2824

# Objectives of this ENDS/e-cigarette presentation



- Are they regulated? Tested?
- Who is using them and why?
- Are they safe?
- Are they a cessation device?
- What is the public health stance?

**More questions than answers!**

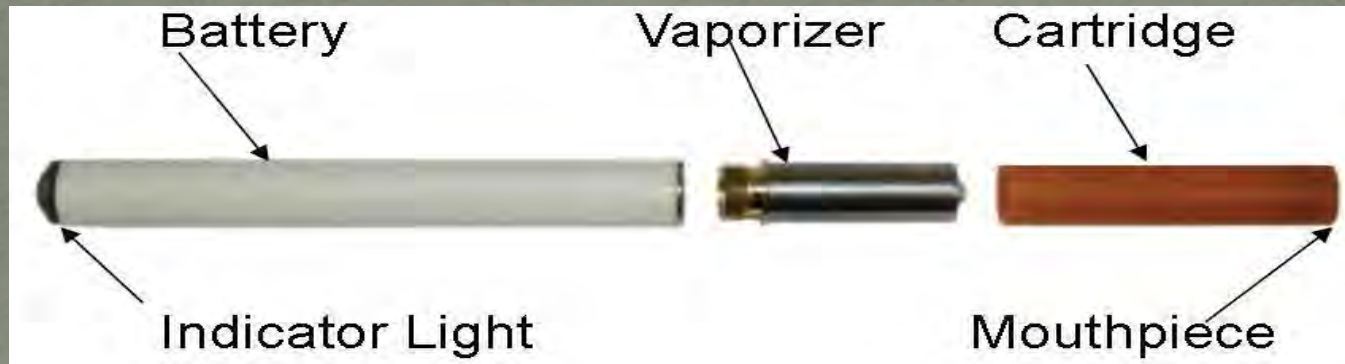
**What are electronic  
nicotine delivery systems  
(ENDS) or electronic  
cigarettes (e-cigarettes)?**

# Electronic Nicotine Delivery Systems (ENDS)

Many don't recognize (or use) the term "electronic cigarette" – they are known as "vape pens" or "mods" or ??



# Products designed to deliver nicotine to user in aerosol (“vapor”) form



- Battery: heating element, rechargeable
- Vaporizer (creates aerosol): converts cartridge contents into aerosol (vapor) inhaled by user
- Replaceable/refillable cartridge: contains nicotine and/or other chemicals—amount nicotine advertised from 0 - 20 mg/mL

# Electronic Nicotine Delivery Systems (ENDS)

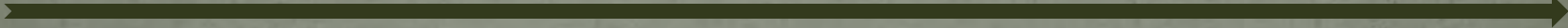
Made to look like cigarettes, cigars, pipes, hookahs, pens



# And many other things



# What have you heard about these products?



- ❑ What are users saying?
- ❑ What are sellers saying?
- ❑ What do manufacturers say?
- ❑ How are they advertised?



# From users, sellers, manufacturers



- ❑ Use of ENDS commonly called “vaping”
- ❑ Promoted by manufacturers, sellers and users as safe-producing *water* vapor not smoke

**No matter the name – sends nicotine to the brain through the lungs**

# Who makes ENDS and liquids?


---

- ❑ Lollilard
- ❑ Reynolds America
- ❑ Altria
- ❑ Njoy
- ❑ International
- ❑ Many others



**How are they regulated?**

# US Food & Drug Administration (FDA) regulation of tobacco products



Under the authority of the 2009 Family Smoking Prevention and Tobacco Control Act, the FDA Center for Tobacco Products currently regulates:

- cigarettes
- cigarette tobacco
- roll-your-own tobacco
- smokeless tobacco

# What is the status of ENDS with FDA?



In 2009, a federal court:

- ❑ denied FDA authority to regulate as cessation device
- ❑ but said could be regulated as a tobacco product

# ENDS status with FDA



- ❑ In April 2014, FDA issued proposed regulations identifying ENDS as tobacco products with:
  - restrictions on sales to minors
  - pre-market review
  - mandated ingredient listing
- ❑ Regulations are pending

## ENDS status with FDA



### Cessation Device?

No electronic nicotine delivery system can be marketed as a smoking cessation device without going through the rigorous approvals of FDA

## ENDS status with FDA



- ❑ FDA has not evaluated any ENDS for safety or effectiveness
- ❑ Early on, in limited laboratory studies, FDA found issues indicating poor quality control\*:
  - cartridges labeled 0 nicotine *did* contain nicotine
  - 3 different cartridges with the same label gave off very different amounts of nicotine with each puff

\*Subsequent studies by independent researchers have found the same



# From FDA's Tobacco Products' website

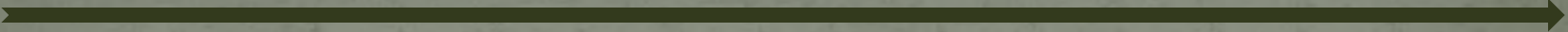


<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>

E-cigarettes have not been fully studied, so consumers currently don't know:

- ❑ the potential risks ... when used as intended
- ❑ how much nicotine or other potentially harmful chemicals are being inhaled
- ❑ whether there are any benefits ... using these products

## From FDA's website—Tobacco Products



**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**

# Missouri law



It is now illegal to sell ENDS products to anyone under 18

Or

For anyone under 18 to possess, use, buy

**Who is using them  
and why?**

## Adult (18+) use of ENDS in Missouri 2014



### Behavioral Risk Factor Surveillance System:

7% use every day or some days

- ❑ 45.7% to quit smoking
- ❑ 17% to try a new way of smoking
- ❑ 13.7% because friends or family use
- ❑ 4% to smoke in places that do not allow smoking

### Missouri Tobacco Quitline callers: 9%

- ❑ 44% to cut down
- ❑ 55% to quit
- ❑ 7% when can't use other products
- ❑ 39% use every day
- ❑ 58% use more than one cartridge a day

# Youth use of ENDS in Missouri 2015

- High school current use: 22%\* of all
  - 68% of current smokers
  - 9.6% of non-smokers
- Middle school current use: 7.2%\* of all
  - 83% of current smokers
  - 3% of non-smokers

*Youth Risk Behavior Survey & Youth Tobacco Survey*

\* Only 11% & 2.4% currently smoke cigarettes

Marketing & commercial appeal



Why do ENDS appeal to youth?

# Marketing & commercial appeal

Promoted heavily online & more widely searched than tobacco products or quitting products

The screenshot shows a Windows Internet Explorer browser window displaying the website "Electronic Cigarette Reviews and Blog". The address bar shows the URL "http://www.e-cig.org/category/products-updates/electron". The browser's menu bar includes "File", "Edit", "View", "Favorites", "Tools", and "Help". The Favorites bar shows several sites, including "Goo...", "100...", "Dic...", "Map...", "Wca...", "Fac...", "Tob...", "USP...", "Are...", "Mo-X", and "usa...". The website's navigation bar includes "E-Cigarette Blog", "Electronic Cigarettes for Sale", "Discount Coupons", "Reviews", "Affiliate Programs", and "Pages". A search bar is located on the right side of the navigation bar. The main content area features a banner for "BUY A STARTER KIT, SAVE 15% ON CARTS" with a "Shop Now" button. Below the banner, the article "Vapor4Life E-Cig Kit Discounts and Coupon Codes" is displayed, written by Jimmy Tank on July 17, 2013. The article text describes Vapor4Life's core brands and their products. Social media sharing icons for Facebook, Twitter, LinkedIn, and others are visible below the article. A second article, "Our New Recommended E-Cigarette Supplier: Vapor4Life", is also visible, written by Jimmy Tank on April 9, 2013. The browser's taskbar at the bottom shows the Start button, several open applications, and the system clock displaying 1:15 PM.



On-line availability



Languages:

Currencies: US Dollar

Shopping Cart: 0 items

- Home page
- New products
- Specials
- My account
- Contact us

Nothing to say here.... It's the ProVari (and Mini)... The "Cadillac" of Vaping.

**QUICK FIND**

Use keywords to find the product you are looking for.

[Advanced Search](#)

**READ WHAT OTHERS ARE SAYING**

Displaying 1 to 6 (of 1074 reviews)

Result Pages: 1 2 3 4 5 ... [\[Next >>\]](#)

1000ml DragonJuice - USA Made - (18mg) Medium      Date Added: Thursday 04



High  
tech



Glamorous

1.877.35.VAPOR  
1.877.958.2767  
Live Support is Online Need Order Help!

VAPOR COUTURE Batteries

SEARCH CONNECT WITH US TWITTER WEBSITE

Sparkling Crystal Tips  
SHOW BATTERIES

You'll Fall in Love...  
SLIM, ELEGANT E-CIGS  
PICK YOUR COLOR

View the Lookbook

What is VAPOR COUTURE?  
VAPOR COUTURE'S STARTER KITS  
SHOP NOW

Gorgeous Accessories  
SHOP NOW

VAPOR COUTURE Made for Women

FOLLOW US ON  
f t p

ANY MOOD. ANY STYLE. EVERY VAPE.



Stylish

world's first



VAPOR  
ZEUS  
VZ VAPOR4LIFE™



# Flavors

- The only flavor of cigarettes is menthol
- ENDS and e-juice are available in many flavors



4 Irresistible Flavors

- Rodeo Drive
- Fresh Mint
- Bombshell
- Passion Fruit

A woman in a red dress holding three e-juice boxes: Fresh Passion Fruit, Rodeo Drive, and Bombshell.

TRY NOW



BLISS COMES IN 2 NEW FLAVORS

Introducing...

Artic Mint & Strawberry Champagne

A champagne glass with ice and a strawberry, next to a glass of strawberry champagne.

# Marketed where cigarettes can't be

NEW!

## Take Back Your Freedom with Stephen Dorff



### Lady Slim Electronic Cigarette



*Our best seller model especially to women who like a slim e-cigarette. It is super thin and extremely light compared to any e-cigarette models.*

**DIMENS**  
Length: 1.4  
Diameter: 0.1  
Weight: 0.3 ounce

Using messaging reminiscent of the past

# WHY QUIT? SWITCH TO BLU

blu is the smart choice for smokers wanting a change. Take back your freedom to smoke when and where you want without ash or smell. blu is everything you enjoy about smoking and nothing else. Nobody likes a quitter, so make the switch today.

Visit [blucigs.com](http://blucigs.com)

**PREMIUM ELECTRONIC CIGARETTE**  
18+ only. CALIFORNIA PROPOSITION 65. Warning: This product contains nicotine, a chemical known to the state of California to cause birth defects or other reproductive harm.

**ENDS deliver nicotine  
to the brain through the  
lungs**

# Nicotine



- Is addictive
- Is toxic to developing fetuses
- Is a poison



# Nicotine is addictive

The DeNoble Files—Your Brain

[https://www.youtube.com/watch?v=4tg\\_rMiOLnA](https://www.youtube.com/watch?v=4tg_rMiOLnA)

# Nicotine affects the brain

The DeNoble Files–Earmuffs

<https://www.youtube.com/watch?v=uFX9F-KD7co>

# Youth using nicotine



- ❑ Are more vulnerable to addiction than adults
- ❑ Are more likely to continue use
- ❑ May become more heavily addicted
- ❑ May have a harder time quitting

# Liquid nicotine or “e-juice”



- ❑ Many of today's users refill their device with liquid nicotine
- ❑ Bottles come as large as 250 mL (about a cup) with nicotine concentrations of 0-72 mg/mL
- ❑ At the highest concentration a 250 mL bottle could have **18 grams** of nicotine

# Nicotine



- ❑ An average combustible cigarette yields ~**1 mg** of *absorbed* nicotine when smoked
- ❑ A 20 mg/mL cartridge has the nicotine **of** about **20 cigarettes**
- ❑ Studies and interviews show that an average ENDS user consumes **3-5** mL of liquid nicotine a day, with some using more than 15 mL a day
- ❑ Daily inhaling aerosol from 3 mL liquid nicotine is similar in nicotine content to smoking 30 to 40 cigarettes (depending on nicotine concentration)

# Liquid nicotine or “e-juice”

---

- ❑ The estimated fatal dose of nicotine for adults is 30-60 **mg**
- ❑ The estimated fatal dose of nicotine for children is only **10 mg**—approximately 4 drops of a maximum strength “e-juice” solution

This risk is more consistent with nicotine-based **pesticides**, rather than traditional tobacco products

It poses a danger by inhalation, ingestion, and skin contact

## Nicotine is a **POISON!**



- ❑ The number of poisoning cases linked to ENDS liquids was:
  - **1,543** in 2013, a *huge* increase from 460 in 2012
  - **3,783** in 2014
  - **2,452** from January-September 2015

# Why so many poisonings?



Can you find the candy?





# Common symptoms of nicotine overdose

---

- ❑ Extreme anxiety
- ❑ Cold sweats
- ❑ Dizziness
- ❑ Headache
- ❑ Muscle twitches
- ❑ Insomnia
- ❑ Tingling sensations
- ❑ Confusion
- ❑ Panic attacks
- ❑ Depression
- ❑ Palpitations, fast pulse
- ❑ Increased blood pressure
- ❑ Fatigue and weakness
- ❑ Reduced appetite
- ❑ Stomach ache and nausea
- ❑ Chest pain
- ❑ Hearing or vision problems
- ❑ Seizures

# Reported mild adverse effects of ENDS use

---

- ❑ Headache
- ❑ Chest pain/coughing
- ❑ Nausea/vomiting
- ❑ Dizziness
- ❑ Confusion
- ❑ Sore throat
- ❑ Blurry vision



# Reported strong adverse effects of ENDS use

---

- ❑ Pneumonia
- ❑ Congestive heart failure
- ❑ Disorientation
- ❑ Seizure
- ❑ Low blood pressure
- ❑ Chest pain
- ❑ Second degree burns to face
- ❑ Loss of vision



What are other potential  
safety issues?

# What's in the fluid?



- ❑ Quality of ingredients generally unknown
- ❑ No requirement to declare all ingredients
- ❑ Fluids are known to contain:
  - nicotine
  - humectants
  - flavorings

# Flavoring



- ❑ On **January 2014** there were at least 7,764 unique flavors
- ❑ Often the same chemicals “generally recognized as safe” for food & drugs
- ❑ But *not* known to be safe :
  - to inhale
  - to deliver nicotine

# Flavor & Extract Manufacturers Association (FEMA) of the US



- ❑ The primary route to FDA regulatory authority of flavor ingredients
- ❑ Determines “GRAS” status (generally recognized as safe)
- ❑ GRAS status applies only to human food, medicine (oral ingestion)

# FEMA GRAS Status



- ❑ No regulatory approval to use GRAS ingredients in ENDS
- ❑ Claims by manufacturers that the ingredients have GRAS status are “false and misleading”



## Some ingredients in flavoring



- ❑ Diacetyl (used to give foods a buttery or creamy flavor)
  - caused a severe & irreversible obstructive lung disease when inhaled by workers exposed to particles of it that were aerosolized (“popcorn lung”)
- ❑ Acetaldehyde (sugar) for sweetness
  - known to make nicotine more addictive
- ❑ Unknowns

# Humectant



- ❑ Allows aerosol (vapor) production
- ❑ Most common is propylene glycol
- ❑ Propylene glycol is FDA approved for use in some products, **but** inhaling aerosolized **nicotine** in propylene glycol is not
- ❑ Some studies show that heating propylene glycol changes its chemical composition, producing small amounts of propylene oxide, a known carcinogen

# Harmless water vapor?



- ❑ It is claimed ENDS emit “harmless water vapor” so they must be safe
  - Is it “just” water vapor?
- ❑ Research is showing.....

# What is in the aerosol (vapor)?



- ❑ Not a water vapor but an aerosol
- ❑ Aerosol has been found to contain:
  - nicotine
  - propylene glycol
  - fine & ultrafine (UF) particles
  - low levels of toxins known to cause cancer (at least 10 have been identified)
  - nanoparticles of chromium, nickel, tin
  - free radicals

# What is in the aerosol?

---

- ❑ Some with higher concentration of UF particles than cigarette smoke
  - UF particles cause respiratory problems, exacerbate asthma, impair lung function
  - fine & UF particles constrict arteries, can trigger heart attack
- ❑ WHY?

# Particulate Matter Sizes

**Fine particles**

● ~ 2.5 $\mu\text{m}$  or smaller



**Human  
Red  
Blood  
Cell**

5 $\mu\text{m}$

**Average  
Human Hair  
Diameter  
~100  $\mu\text{m}$**

● **Ultrafine or  
Nanoparticles**

~ >1 $\mu\text{m}$  or microns to  
<100nm or nanometers

# Secondhand aerosol?



- ❑ *May be* less polluting than cigarettes, but still pollutes the air
- ❑ Emissions expose non-users to:
  - nicotine at levels similar to secondhand smoke—a recent study showed the nicotine *was* absorbed by those around
  - fine and UF particles and volatile organic compounds (VOCs)
  - some levels of toxins known to cause cancer

# Secondhand aerosol?



Long term health effects on non-smokers are still unknown, but science on potential for negative consequences is mounting



# Risk assessment from American Industrial Hygiene Association

October 2014



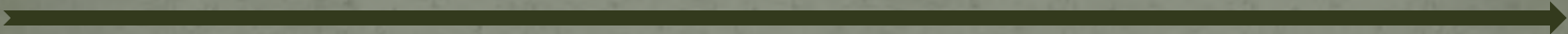
- ❑ Existing research does *not* appear to warrant the conclusion that ENDS are “safe” in *absolute* terms
- ❑ ENDS *not* emission-free; emit airborne contaminants that may be inhaled by both the user and those nearby
- ❑ ENDS should be considered a source of VOCs and particulates in the indoor environment that have *not* been thoroughly characterized or evaluated for safety

# ENDS are advertised as:

- ❑ A better-smelling, cheaper, guilt-free alternative to smoking
- ❑ A way to circumvent smokefree laws & policies



# Why be concerned about advertising to circumvent smokefree?



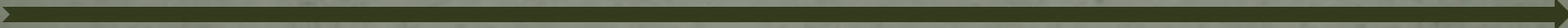
Using ENDS in public, smokefree areas can undermine smokefree policies & youth prevention efforts by:

- ❑ Making enforcement more difficult
- ❑ Giving the appearance that smoking is acceptable

People are being exposed in the belief that the aerosol is safe

# Vaping encourages tobacco smoking?

*Does vaping in e-cig ads affect tobacco smoking, urge, intentions, & perceptions in daily, intermittent, & former smokers? Health Communication, March 2015*

- 
- ❑ When see vaping in person or on TV:
    - daily smokers more likely to crave cigarettes
    - former smokers less able to refrain from smoking
  - ❑ As opposed to the same who did not see the behavior

# Time out for social norm activity



- ❑ Listen to each statement
- ❑ If it is true for you, stand up
- ❑ If it is not true or you don't know, stay seated
- ❑ Can sit down after each statement

# Cessation product?

---

- ❑ ENDS are **not** FDA-approved cessation products
- ❑ 4 prescription & 3 non-prescription smoking cessation products *are* FDA-approved:
  - RX: Varenicline, Bupropion, Nicotine Inhaler, Nicotine Nasal Spray
  - OTC: nicotine replacement patches, gum, lozenges
- ❑ These products have been scientifically shown to be effective for smoking cessation *and* are safe when used as directed

## U.S. Preventive Services Task Force Recommendation on ENDS for Smoking Cessation

- Thus far, the U.S. Preventive Services Task Force (USPSTF) has made the strongest stance about ENDS
- In September 2015, the USPSTF “found the evidence on ENDS use as a smoking cessation tool in adults or adolescents to be insufficient.”
- The USPSTF was only able to identify two randomized, controlled trials that evaluated the effect of e-cigarettes on smoking abstinence in adults. These two studies found mixed results.



# Recent research on ENDS cessation potential

*Use of Electronic Cigarettes Among State Tobacco Cessation Quitline Callers, Nicotine & Tobacco Research, May 2013*



*ENDS users were **significantly less likely to have quit smoking** 7 months after first calling the Quitline, compared with participants who had never tried  
ENDS*

*Note: Authors affiliated with Alere Wellbeing, Inc. a Quitline Provider*



# Recent research on quitting behaviors with ENDS

*E-Cigarette Use in the Past and Quitting Behavior in the Future: A Population-Based Study, American Journal of Public Health, June 2015*



- ❑ Compared with smokers who never used ENDS, the ENDS (ever) users were:
  - significantly less likely to smoke fewer cigarettes
  - and
  - significantly less likely to quit for 30 days or more
- ❑ Ever-users *were* more likely to report a quit attempt, although not statistically significant
- ❑ *Conclusion:* Smokers who have used ENDS may be at increased risk for not being able to quit smoking

# Other issues of initiation & cessation potential

---

- ❑ Surveys showing patterns of dual use (both ENDS & cigarettes) by both adults & youth
- ❑ Nicotine is addictive & hard to break:
  - current smokers may not realize they have not kicked the addiction
  - former smokers, believing ENDS are safe, may return to nicotine addiction
- ❑ The high-tech, attractive products & marketing are “glamorizing” & possibly making smoking again appear “normal”

# Public health approach—cessation



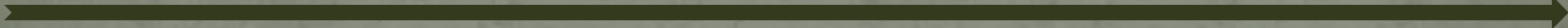
- ❑ *Can* say there is no scientific evidence that ENDS help smokers quit
- ❑ *Do* know they are a nicotine delivery device—and nicotine is addictive
- ❑ Recommend *only* known, tested, safe, products for those trying to quit

# Public health approach–safety



- ❑ Studies continue, but with many brands & too few studies yet, conclusions are not definite
- ❑ Cannot say they are safe, but it does appear as if it is not “harmless water vapor”
  - in fact, it is not “just” water
  - in fact, it is aerosol, not vapor
- ❑ We cannot say that they are unsafe—they may be safer than combustible cigarettes, but “safer” is not necessarily “safe”

# Public health approach—secondhand smoke (aerosol) exposure



- Because of the unknowns surrounding the aerosol

and

- Because ENDS mimic smoking

**Public health is taking a cautious approach**

- Most prohibit them in smokefree or tobacco-free policies for the organization
- And strive for inclusion in policies for communities

Why include in smokefree policies?



The standard is  
**Clean** Indoor Air  
*not*  
Less Dirty Air

# Recent research on awareness/beliefs

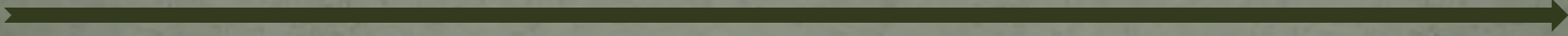
*Characteristics Associated With Awareness, Perceptions, and Use of Electronic Nicotine Delivery Systems Among Young US Midwestern Adults, AJPH, March 2013*



- ❑ More than  $\frac{2}{3}$  of young adults were aware of ENDS
- ❑ A small proportion had tried/used in past 30 days
- ❑ Despite the lack of scientific evidence, a large proportion of users & non-users thought they:
  - can help people quit smoking
  - are less harmful and less addictive than cigarettes

# Recent research on users' opinions

*Vaping profiles and preferences: an online survey of electronic cigarette users, Addiction Research, Feb. 2013*

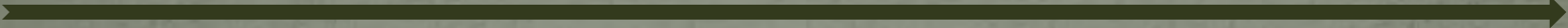


- ❑ Adults surveyed found ENDS:
  - satisfying to use
  - reduced cravings for tobacco cigarettes
  - associated with very few immediate side effects
  - tended to be used for a *longer* duration than NRT



# Recent research on safety

*Metal & Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette (EC) Cartomizer Fluid and Aerosol, PLOS One, March 2013*

- 
- ❑ Concentrations of 9 of 11 **metallic** elements in ENDS aerosol were **higher than or equal to** the concentrations in cigarette smoke
  - ❑ Presence of metal and silicate particles in aerosol demonstrates need for improved quality control in ENDS design and manufacture
  - ❑ Studies are **needed** on how aerosol impacts the health of users and bystanders

# Recent research on safety

Reported January 2015 in letter published in the *New England Journal of Medicine*



- ❑ Aerosol from ENDS products can contain high concentration of formaldehyde—a known carcinogen
  - Researchers conducted a detailed chemical analysis of the aerosol’s liquid droplets
  - Devices dialed up to highest settings had “masked” formaldehyde—could increase the likelihood of formaldehyde deposits in the lung
  - Concentration was significantly higher than regular cigarettes—5 to 15 times higher

# Recent research on effect on non-users

*Does e-cigarette consumption cause passive vaping? Indoor Air, April 2013*



- ❑ Fine particles, ultrafine particles, and volatile organic compounds were found *in the air* in **increased quantity** after the use of an ENDS
- ❑ This inhaled aerosol undergoes changes in the human lung
- ❑ Passive vaping must be expected from the use of ENDS

# Recent research on secondhand exposure

*Exhaled Electronic Cigarette Emissions: What's Your Secondhand Exposure? RTI Press, March 2015*



- ❑ Non-user may be exposed to aerosol particles smaller than 1,000 nanometers
  - similar in size to tobacco smoke and diesel engine smoke
- ❑ Exact exposure depends on:
  - chemical composition of liquid
  - operation of the device
  - user vaping preferences
- ❑ Aerosol and gases produced contain nicotine, glycerin/glycols, artificial flavorings, preservatives

# Recent research on what is in the aerosol

*Reactive Free Radicals in Electronic Cigarette Aerosols, Chemical Research in Toxicology, June 2015*



- ❑ Reactive free radicals found in ENDS aerosols
- ❑ These have been shown to be a causal factor in a variety of diseases.
- ❑ Currently insufficient data to determine the potential harm from exposure to ENDS generated radicals.
- ❑ Overall levels of radicals significantly lower than in combustible cigarette—degree of damage *might* be less, but depends on the identity and reactivity of the specific radicals produced

# Recent research on if ENDS use leads to smoking

*Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence,  
Journal of the American Medical Association, August 18, 2015*



- ❑ High school students who had ever used ENDS at baseline were *more* likely than nonusers to report initiation of combustible tobacco use over the next year.
- ❑ Past 6-month use of any combustible tobacco product: 30.7% for ENDS ever use vs. 8.1% for ENDS never use
- ❑ Greater likelihood of use of any combustible tobacco product with odds ratios of 2.65 for cigarette, 4.85 for cigar, 3.25 for hookah

# Use in pregnancy

*Nicotine & the developing human: A neglected element in the electronic cigarette debate, American Journal of Preventive Medicine, March 2015*



- ❑ Switching to ENDS from cigarettes is *not* safe because:
  - nicotine is harmful to developing fetus
  - nicotine contributes to smoking related preterm delivery
  - nicotine alters brain development
  - nicotine is thought to contribute to SIDS