



# Preventing e-Cigarette Poisonings among Children and Youth: Policy and Practice

December 14<sup>th</sup>, 2016

# Tech Tips



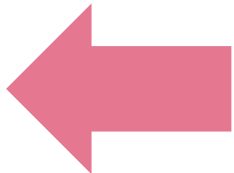
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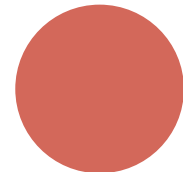
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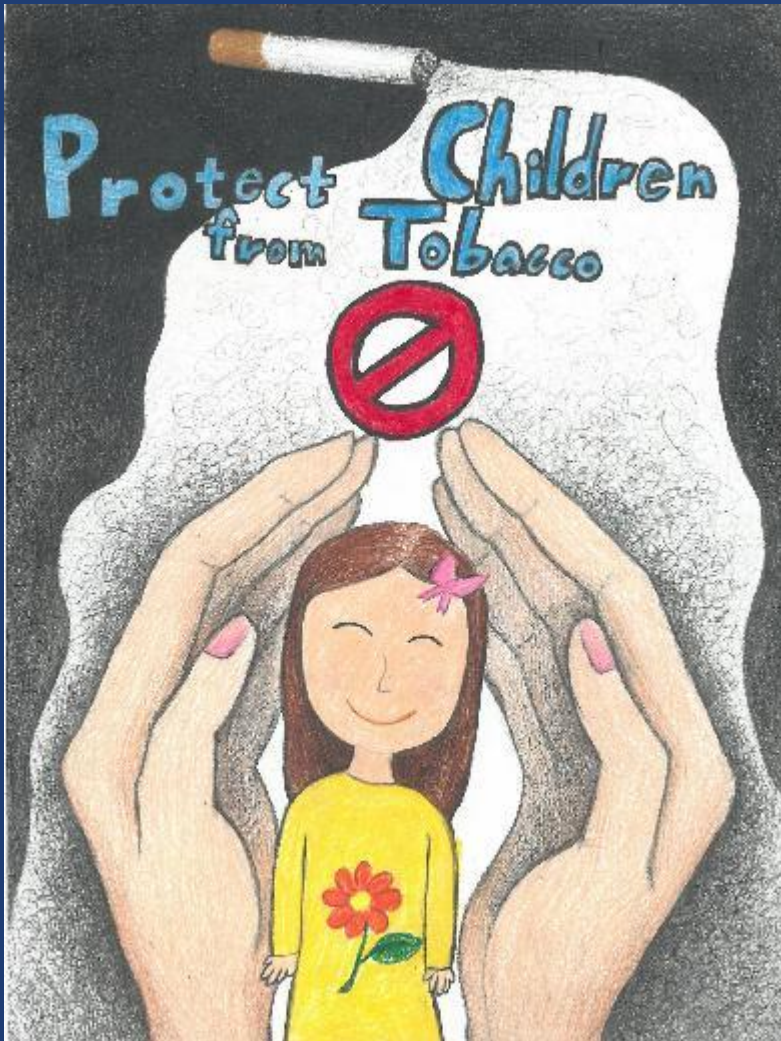
# Presenters

Jonathan Klein



Michael Freiberg





# E-cigarettes and Electronic Nicotine Delivery Systems

**Jonathan D. Klein, MD, MPH, FAAP**  
American Academy of Pediatrics

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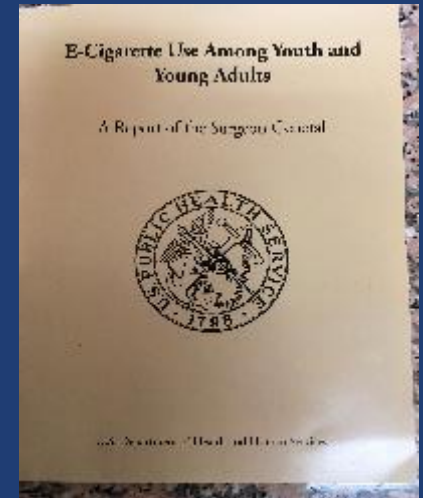
December, 2016

# Objectives

- I have no conflicts of interest.
- *I do not intend to but may* discuss unapproved use of a commercial product/device-use of Nicotine replacement therapy for smoking cessation by young people under age 18.

# *Objectives – e-cigarettes and “vaping” devices*

- What are they
- Who is using them
- Public and individual health concerns
  - Safety of devices/poisoning risk
  - Potential for adolescent nicotine addiction
  - Potential to glamourize and re-normalize smoking
  - Evidence for cessation/dual use
  - Evidence for effects of second-hand vapor exposure





# Why care about e-cigs?



They look cool and appeal to adolescents and young adults

# Why care about e-cigs?



They come in kid-friendly flavors



# Oxford Word of the Year, 2014

2012: GIF (the verb..)

2013: Selfie

2014: Vape

2015: 😊

2016: Should be announced this week!

Interest over time ?

Google Trends: “Vape”

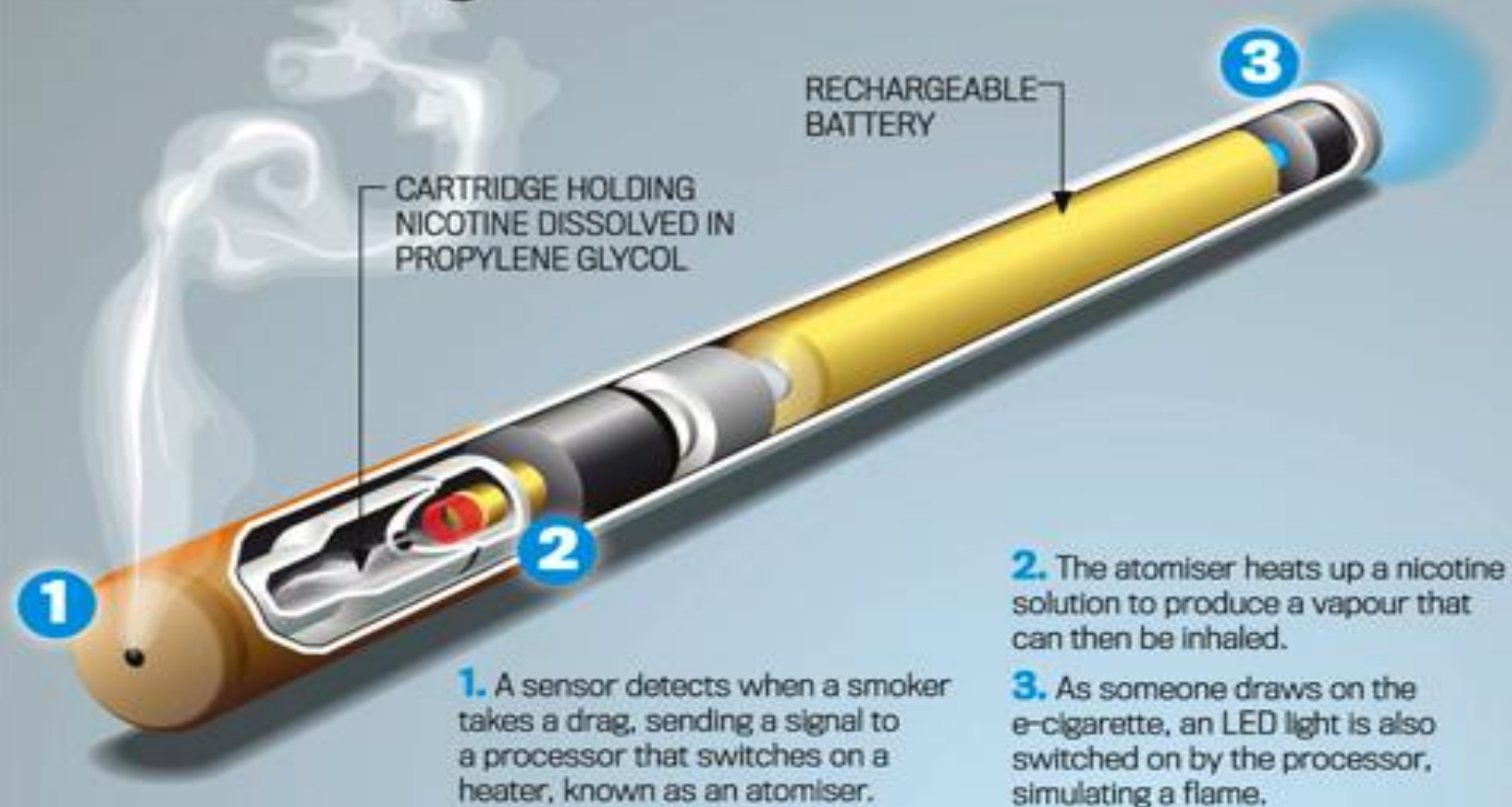


# From Cigarette to Vapor Pen: evolving terms and technology

- Electronic cigarettes or e-cigarettes
- Electronic cigars or e-cigars
- E-hookah or hookah sticks
- Vaping devices, vape pens, and personal vaporizers
- Mechanical mods or tanks
- ANDS: Alternative nicotine delivery systems
- ENNDS: non-nicotine...

# What are e-cigarettes?

## Inside the e-cigarette







# ENDS are Sold Everywhere

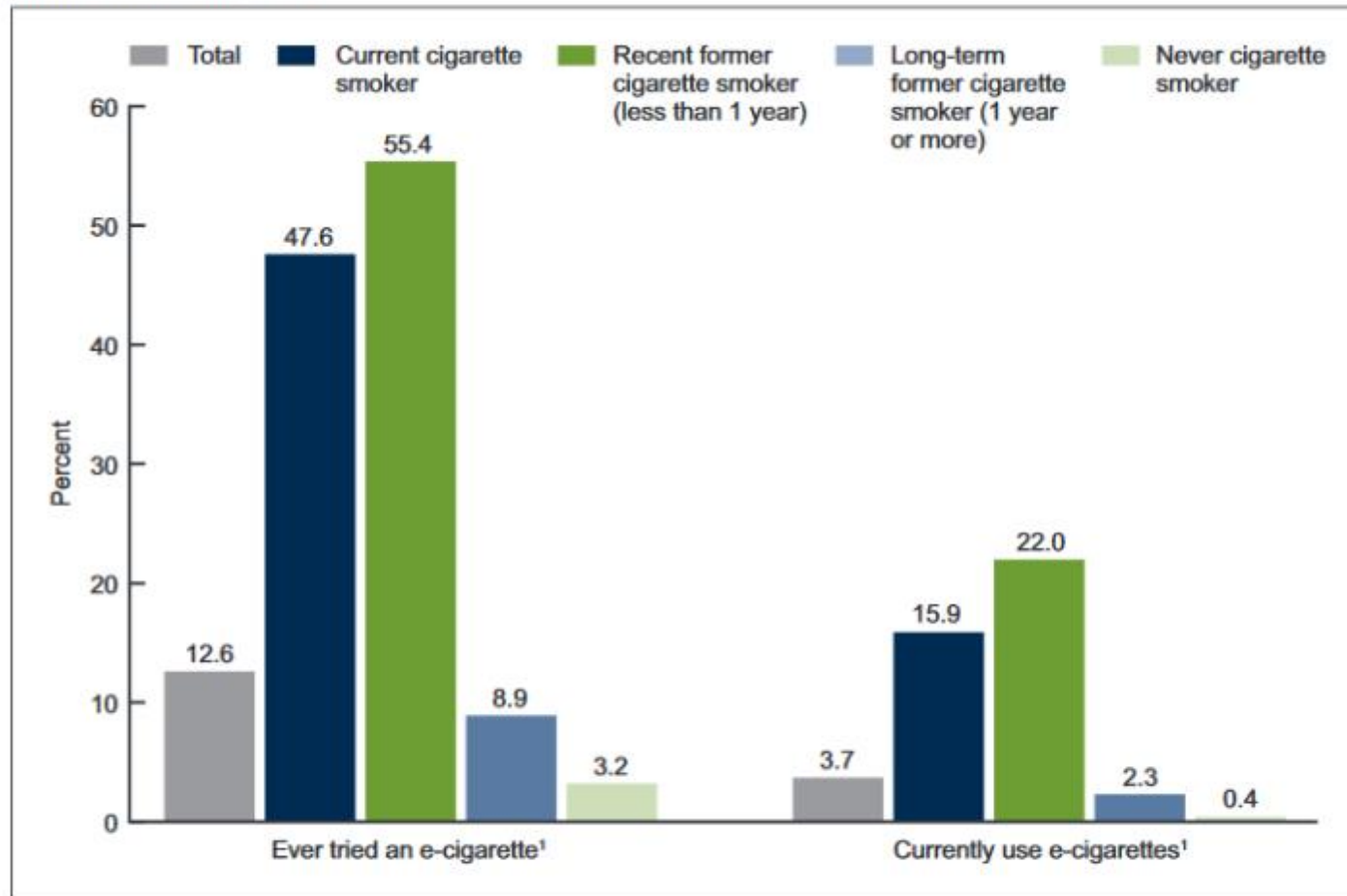
- “Vape” shops
- Convenience stores
- Gas stations
- Retail outlets
- Mall kiosks
- Grocery stores
- Internet vendors





# 2014 Adults and ENDS Use

Figure 3. Percentage of adults who had ever tried and percentage who currently use e-cigarettes, by cigarette smoking status: United States, 2014

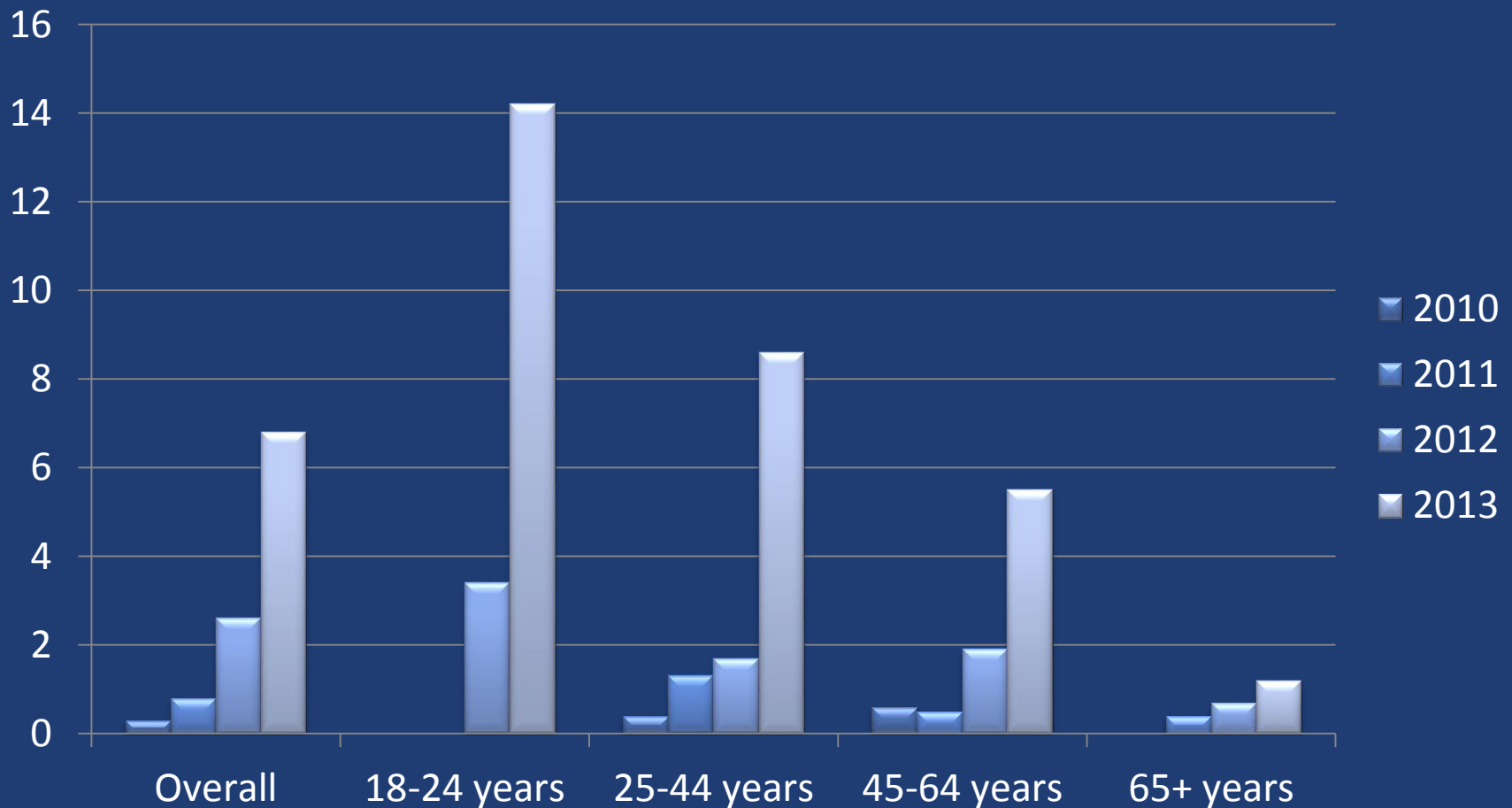


¹Percentages were significantly different across all smoking status groups.

NOTES: Current e-cigarette users have ever tried an e-cigarette, even once, and currently use them every day or some days. Current cigarette smokers have ever smoked 100 cigarettes in their lifetime and currently smoke every day or some days. Based on household interviews with adults aged 18 and over.

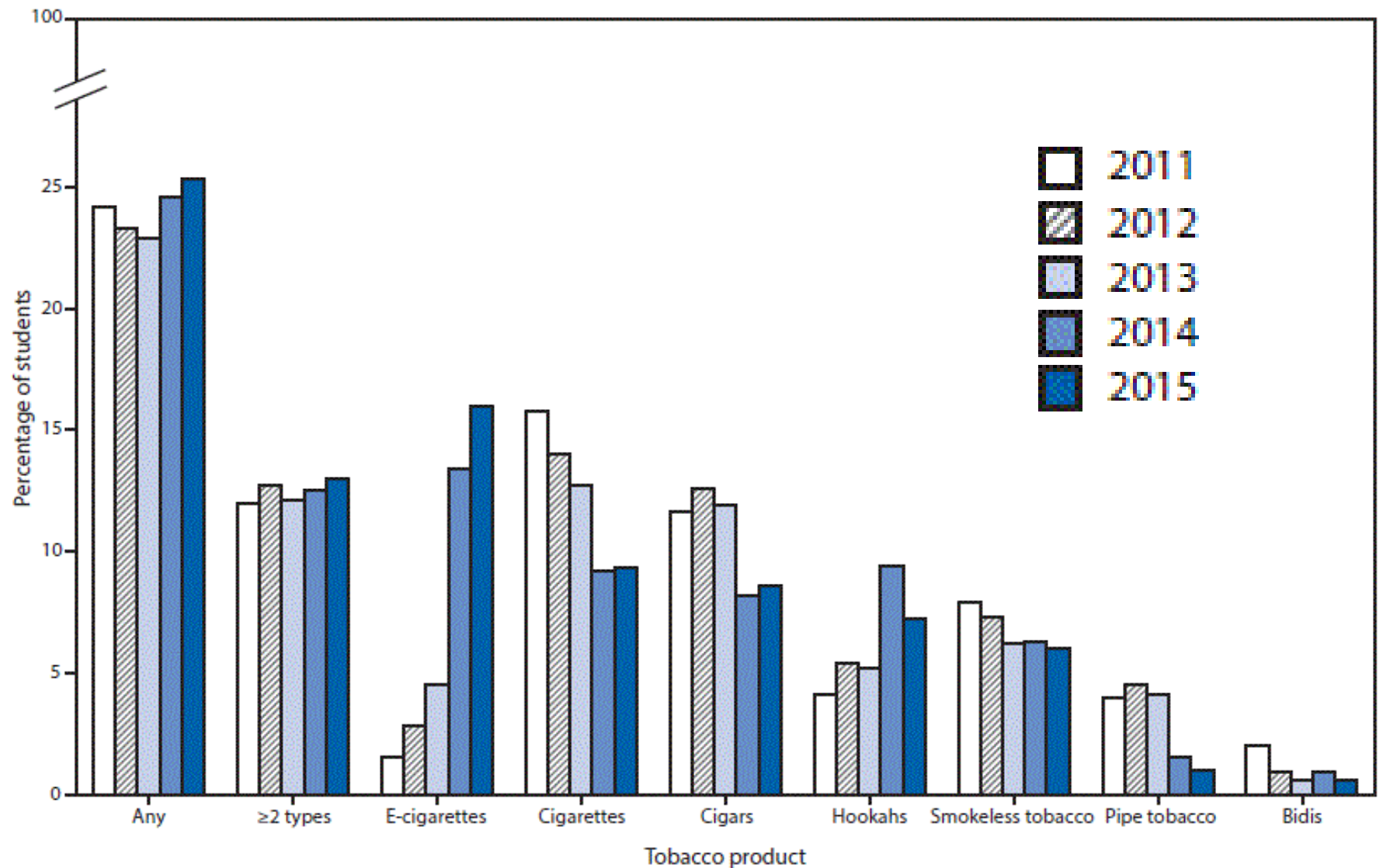
SOURCE: CDC/NCHS, National Health Interview Survey, 2014.

# Trends in adult current use of e-cigarettes 2010-2013

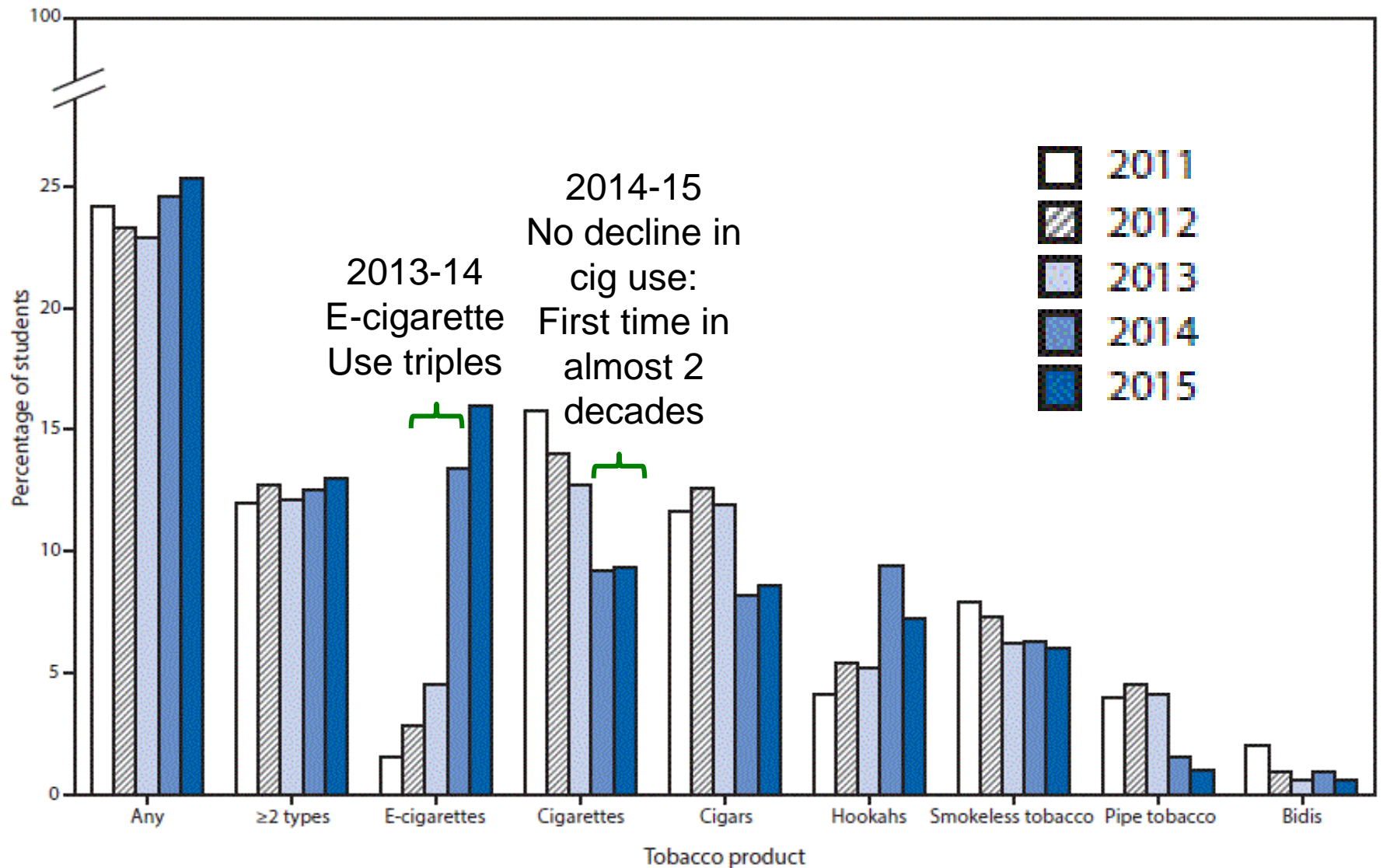


McMillen, et al. "Trends in electronic cigarette use among US adults. In press, 2014

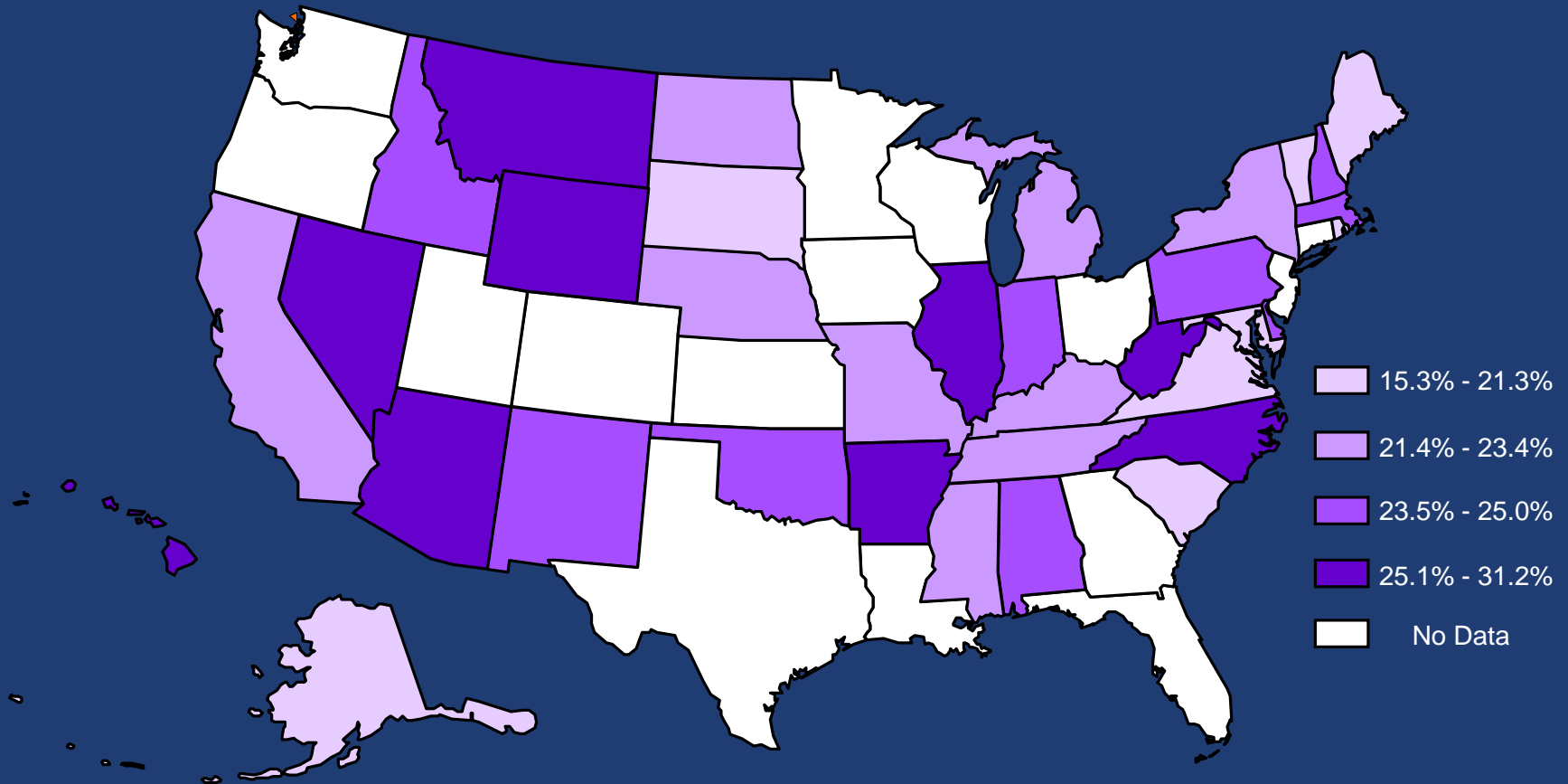
# High School Student Tobacco Use National Youth Tobacco Survey (NYTS)



# High School Student Tobacco Use National Youth Tobacco Survey (NYTS)



# Percentage of High School Students Who Currently Used Electronic Vapor Products\*



\*E-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens such as blu, njoy, or starbuzz on at least 1 day during the 30 days before the survey



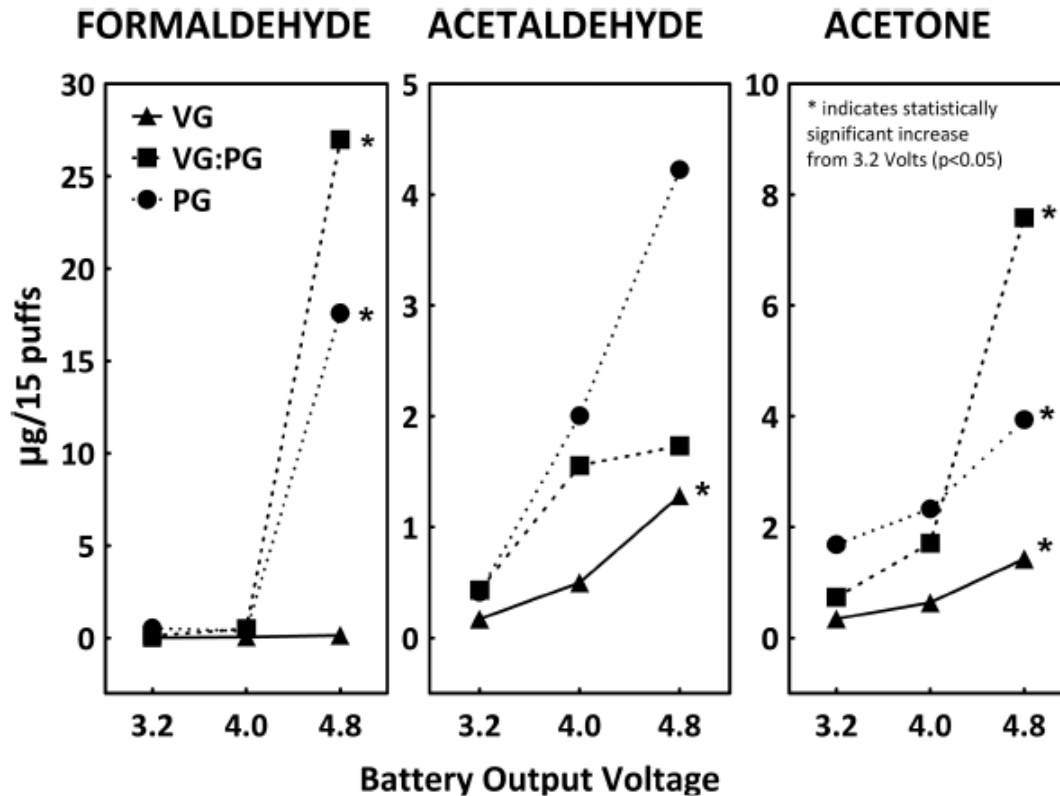
# Constituents of “e-juice”: humectant, flavoring, +/- nicotine

- GRAS classification:
  - Generally recognized as safe for use IN FOOD
  - Based on scientific evidence or use before 1958
- GRAS means safe for certain populations, in certain quantities, for ingestion or topical use
- Have NOT been assessed for safety as inhalants

# Constituents of e-juice: Humectants

- Propylene glycol: general recognized as safe
  - Few human studies for inhalation, used as a tobacco humectant historically
    - Can cause eye and respiratory irritation
    - Dow Chemical states “inhalation exposure to mists should be avoided”
    - Altria published a study in rats and dogs in 2011, stating a plan to conduct “first-time-in-man” human exposure studies
- Vegetable glycerin: generally recognized as safe
  - When heated and vaporized, can form acrolein, which can cause upper respiratory irritation
- Unknown long-term health effects

# Humectant Toxicity – heating creates carcinogenic compounds



**Figure 1.** Effects of nicotine solvent and battery output voltage on levels of carbonyl compounds released from ECs (µg/15 puffs;  $N = 3$ ; puff duration 1.8 s, puff volume 70 ml, puff intervals 17 s).

# Constituents of e-juice: Flavors

- Product flavors contain menthol in concentrations similar to menthol cigarettes
- Menthol found in 40% of the tobacco-flavored non-menthol products
- Various chemicals – irritant or toxic and carcinogens when heated

# Constituents of e-juice: Nicotine

- Nicotine effects
  - Complex pharmacodynamics – neural stimulant at low doses and a depressant at high doses
    - Stimulates memory and alertness.
    - Many people feel a sense of well-being.
    - Decreases appetite; may relieve minor depression.
    - Increases heart rate and blood pressure



# Constituents of e-juice: Nicotine

- Nicotine overdose
  - Excess: nausea and vomiting, excessive salivation, abdominal pain,, sweating, hypertension, tachycardia, ataxia, tremor, headache, dizziness and seizures
  - Death: several case reports of suicide by nicotine
    - Two child deaths SO FAR from e-juice reported
- Lethal dose in Humans - stated as 0.8mg/kg (60mg)
  - Multiple literature reports of survival at 6 mg/kg
  - Recent review suggests LD50 = 6.5-13mg/kg
  - = to 2 ½ teaspoons for an medium sized adult

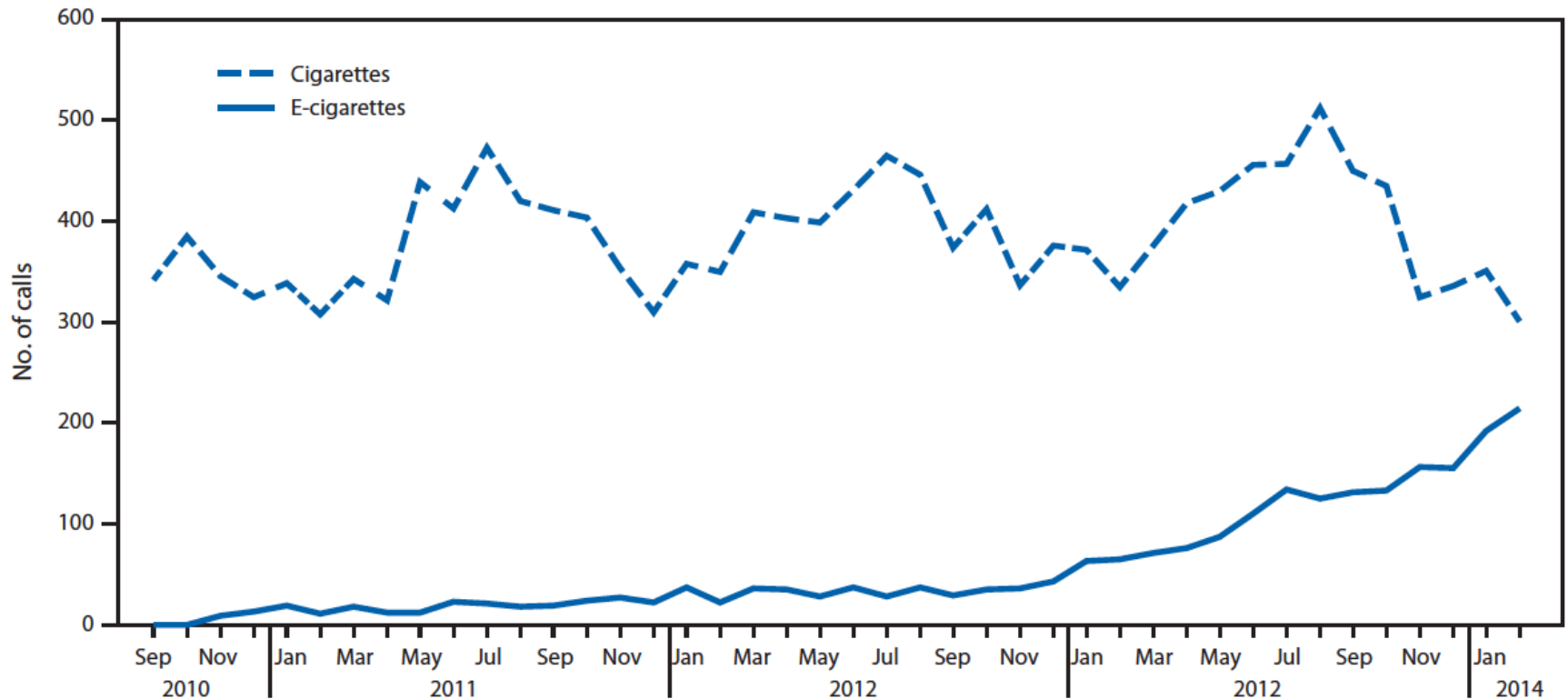


18mg/ml is standard – 6 oz = 3280 mg

Toxic dose for 60kg person = 6.5-13mg/kg=6-12 ml

# Poison Control Calls

FIGURE. Number of calls to poison centers for cigarette or e-cigarette exposures, by month — United States, September 2010–February 2014



# Child Nicotine Poisoning Prevention Act of 2015

- Child Nicotine Poisoning Prevention Act of 2015 (S. 142)
  - Re-introduced by Sen. Nelson (D-FL) and Sen. Ayotte (R-NH) and 10 other Senators
  - Grants Consumer Product Safety Commission (CPSC) authority to require child-proof packaging for nicotine refill solutions sold to consumers (current law prohibits CPSC from regulating *any* tobacco products)
  - The bill is crafted narrowly to focus only on liquid nicotine and its safe containment from children, and does not affect the manufacture of the substance nor the products they are designed to refill

# What are the health harms?

- Relative to smoked tobacco, less harmful
  - No tar
  - Variable levels of nicotine
- Relative to NO tobacco or medical NRT
  - Growing concerns for decreased lung function (aldehydes)
  - Quality control – adulterated products have been found
- Safety of flavor when heated and inhaled is unknown
- Non- and former smokers may become addicted
- May maintain combusted tobacco use
- Still mostly unregulated

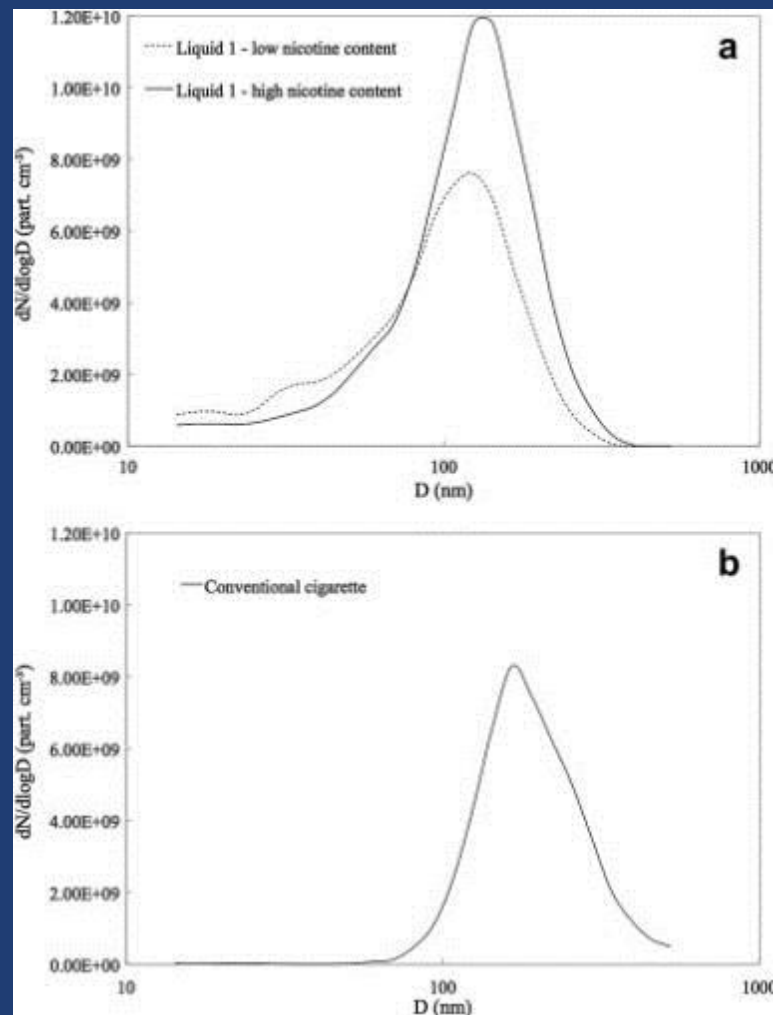


# New Addiction?

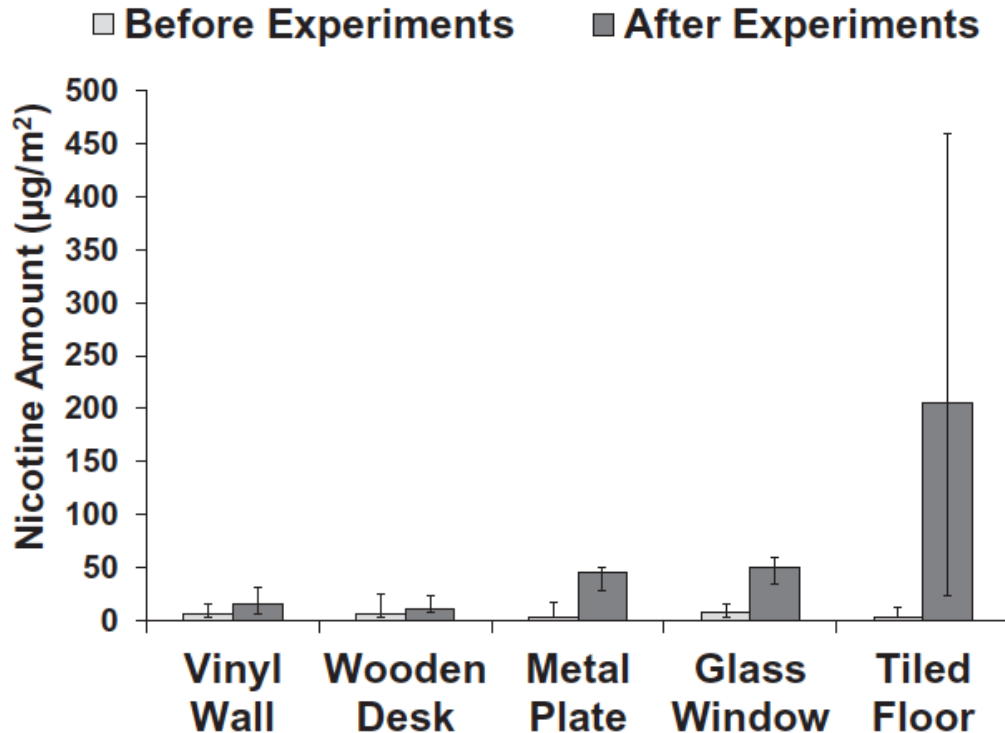
- The adolescent brain appears uniquely susceptible to nicotine addiction
- Animal studies show that nicotine exposure during adolescence period has long-standing effects in the brain including cell damage that leads to both immediate and persistent behavior changes.

# Public Health Harms

- Second-hand vapor is NOT just water vapor
  - Emit variable levels of nicotine (1/10<sup>th</sup> that of cigarettes), plus fine particles of similar size to that of cigarettes, and comparable concentration of fine particles
  - Emit low levels of other toxins: formaldehyde, acetaldehyde, metals



# Surface Contamination



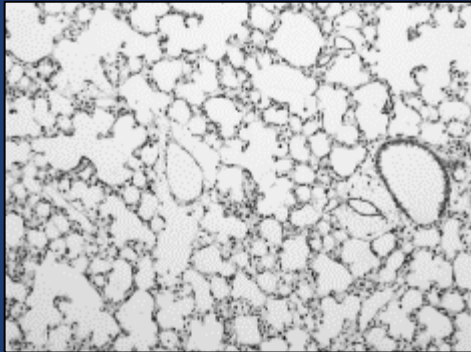
**Figure 1.** Amounts of nicotine deposited on various surfaces before and after exposure to e-cigarette vapors (median values; bars show interquartile ranges;  $N = 4$ ).

Nicotine on surfaces  
from e-cigarette use

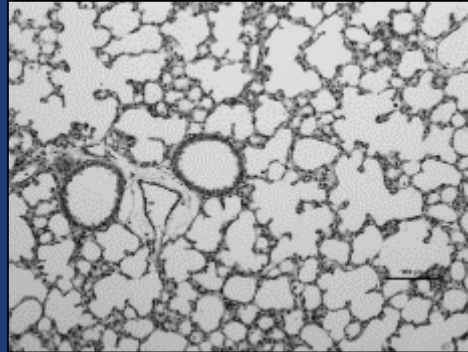
Combines with indoor  
substances such as  
ozone and nitrous oxide  
to make irritants and  
carcinogens (Tobacco  
Specific Nitrosamines)

# Alveolar growth, lung function and overall growth is impaired in newborn mice exposed to E-cigarette emissions

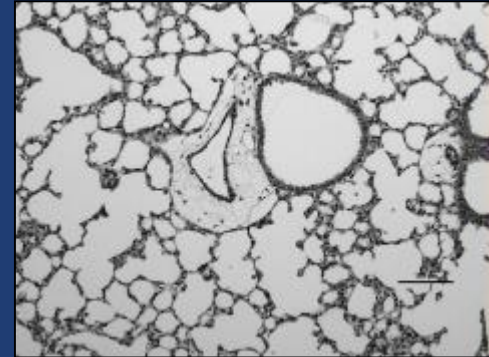
Room air



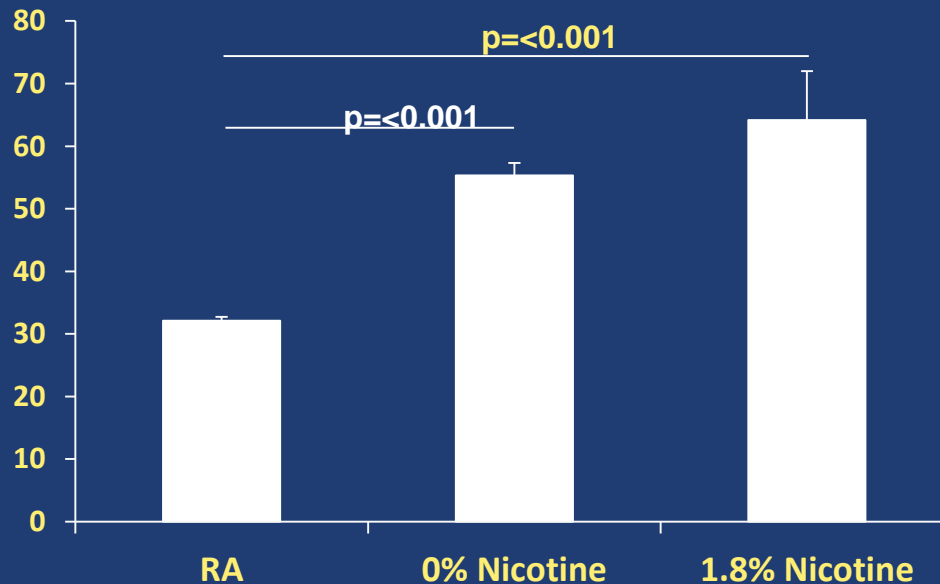
0% nicotine



1.8% nicotine



Mean linear intercept  
(arbitrary units)



McGrrath-Morrow S, et al.  
PLoS One, Feb. 2015

# Re-normalizing the image of smoking

- In places where smoking is not allowed
- Advertising is completely unrestricted
  - TV ads for the first time since 1971
- Largely indistinguishable from cigarettes





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# Battery issues?

**A 17-year-old says he suffered third-degree burns to his leg when a vape pen battery exploded in his pocket.**



Go Fund Me / Via [gofundme.com](https://www.gofundme.com)



KDVR / Via [kdvr.com](https://www.kdvr.com)



**The teenager's left leg was charred from his thigh to his calf, and he suffered second- and third-degree burns.**



KDVR / Via [kdvr.com](https://www.kdvr.com)

<http://www.buzzfeed.com/stephaniemcneal/vape-pen-horror#.fj0pJ906Z>

Feb 29, 2016



# Marijuana



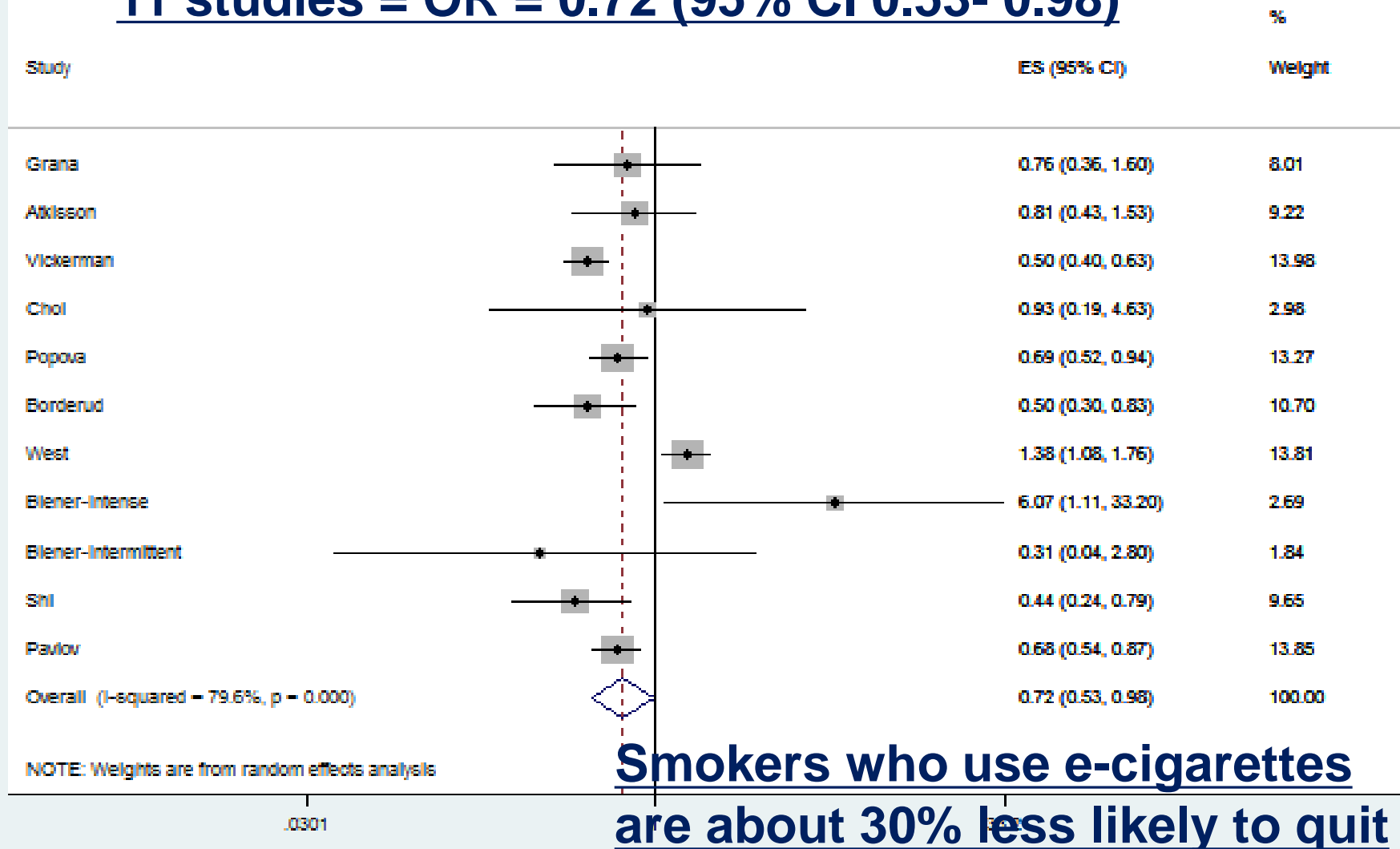
<h2>SATIVA Complete Set</h2> <p>DAYTIME • 500MG</p> <p>An uplifting and stimulating sativa dominant blend of all-natural organic cannabis oil. Perfect for daytime, sativa provides an energetic and enhanced state of well-being.</p> <p>Includes battery, 500mg cartridge, and USB charger. Everything you need to get started with a 100% lifetime guarantee.</p>	<h2>INDICA Complete Set</h2> <p>NIGHTTIME • 500MG</p> <p>A calm and relaxing indica dominant blend. Perfect for nighttime, indica provides a relaxation, pain relief, and can be a powerful tool for inducing deep sleep.</p> <p>Includes battery, 500mg cartridge, and USB charger. Everything you need to get started with a 100% lifetime guarantee.</p>

# Is there evidence for e-cigarettes for smoking cessation?

Limited: most suggests that people cut  
down and don't stop completely...


# Meta-analysis – Glantz et al 2015

**11 studies = OR = 0.72 (95% CI 0.53- 0.98)**



# E-cigarettes and Nonsmoking Youth

**Among nonsmoking youth, those that have ever used e-cigarettes have greater intentions to smoke conventional cigarettes than those who have never used e-cigarettes**



In 2013, more than **a quarter million** middle and high school students **never** smoked regular cigarettes but **had** used e-cigarettes...

**3 times**  
**as many as 2011!**



# What happens now?

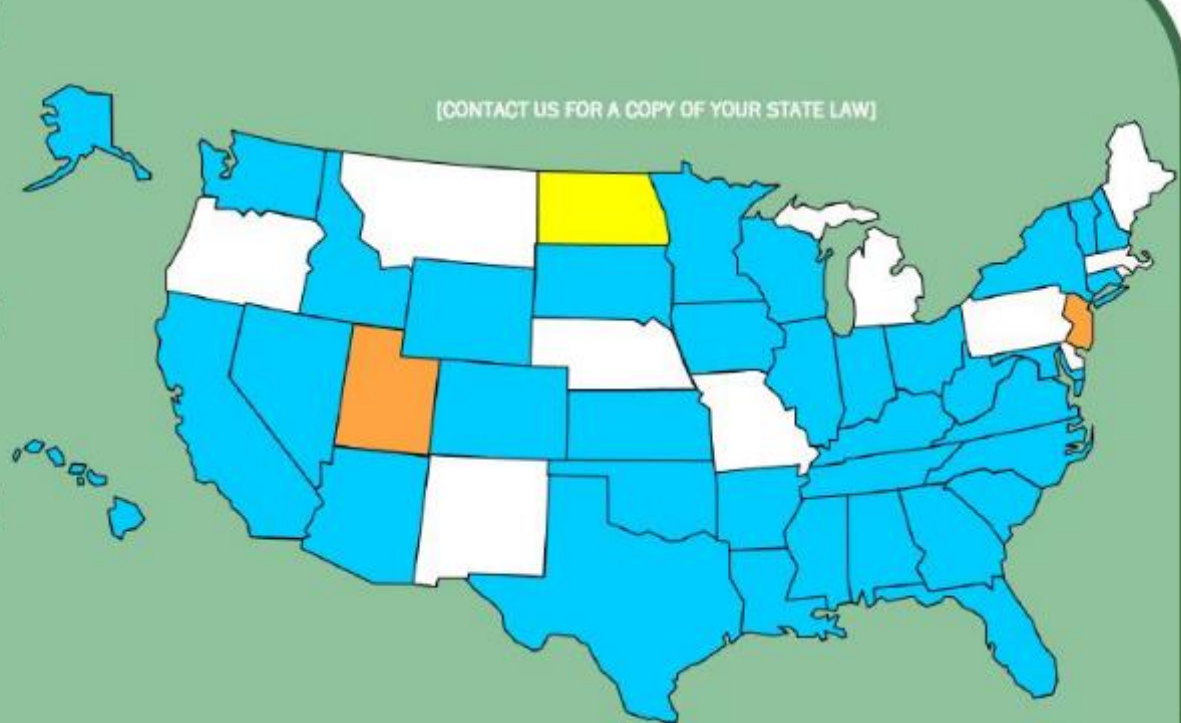
- Expected that the market will continue to explode
- FDA deeming rule – May 2016
  - Improved quality control and production standards
  - No sales <18 years
  - Health warning labels
  - No vending machine sales
  - No marketing implying “healthy” or “safe”
  - Would go into effect 2 years AFTER final rule
  - Misses several aspects: flavors, child-proof packaging, marketing, online sales
  - Legal challenges pending



# E-Cigarette Laws by State

- 2 states—laws banning purchase of e-cigarettes for minors <18 years; use prohibited in all work places, bars, and restaurants
- 37 states—laws banning purchase of e-cigarettes for minors <18 years
- 1 state—law banning use of e-cigarettes in all workplaces, bars, and restaurants

## Pending Legislation: 2014 StateTrack Profile: E-Cigarettes





# AAP Position – E-cigarettes

- Sales to youth should be prohibited
- Flavors should be banned
- Smoke free environments should include e-cigarettes and their vapor in all workplace and clean air rules
- Child proof packaging should be required for E-liquids

- - -

- Parent/child and adolescent prevention screening and cessation counseling must ask the right questions about e-cigs and secondhand vapor

# 2016 Surgeon General Report

## E-cigarette use among youth and young adults

- E-cigarette use among youth and young adults has become a public health concern.
- use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. Nicotine in any form among youth is unsafe.
- E-cigarette aerosol (secondhand vapor) is not harmless. It contains harmful constituents, including nicotine, which can harm the developing adolescent brain.

<https://e-cigarettes.surgeongeneral.gov/>

# 2016 Surgeon General Report

## E-cigarette use among youth and young adults

- E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used for marketing conventional tobacco products to youth.
- Actions could include incorporating e-cigarettes into smoke-free policies, preventing access to e-cigarettes by youth, price and tax policies, retail licensure, regulation of e-cigarette marketing likely to attract youth, and educational initiatives targeting youth and young adults.

# So what should we do?

- Until we know more about “e-anything” and cessation, recommend medicinal NRT, quit lines and cessation support to tobacco/nicotine users
- Until there is regulation of marketing, flavoring, and promotion to youth, “debate” over possible harm reduction benefits of e-cigarettes supports industry efforts to delay effective regulation and to create a new generation addicted to nicotine

American Academy  
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**Thank you**

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# PREVENTING E-CIGARETTE POISONINGS AMONG CHILDREN AND YOUTH

CHILDREN'S SAFETY NETWORK WEBINAR



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# ROAD MAP FOR THIS PRESENTATION

- My Organization(s)
- Federal E-Cigarette Regulations
- State E-Cigarette Regulations
- Child Nicotine Poisoning Prevention Act (CNPPA)
- Resources



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# LEGAL TECHNICAL ASSISTANCE



Legal Research



Policy Development, Implementation, Defense



Publications



Training



Direct Representation



Lobby



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# THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009



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## Final deeming regulation provisions

	Cigarettes	Smokeless tobacco	Cigars	E-cigarettes and others
Minimum sales age of 18 and age verification under 27	✓	✓	✓	✓
Prohibition on vending machine sales	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities
Prohibition on self-service displays	Allowed in adults-only facilities	Allowed in adults-only facilities		
Minimum package size requirements	✓			
Prohibition on breaking packages by retailers (e.g., sales of loosies)	✓	✓		
Prohibition on free samples	✓	Allowed in qualified adults-only facilities	✓	✓
Prohibition on characterizing flavors	Menthol and tobacco allowed			
Mandatory warning labels on packages and advertisements	Nine rotating warnings	Four rotating warnings	Six rotating warnings*	One static warning
Prohibition on brand names on non-tobacco products and brand name sponsorship of sporting and cultural events	✓	✓		
Required notice of advertising in any non-traditional medium	✓	✓		



# STATE REGULATION OF LIQUID NICOTINE PACKAGING



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# EXAMPLE: MINNESOTA'S LAW



## **461.20 SALE OF ELECTRONIC DELIVERY DEVICE; PACKAGING.**

(a) For purposes of this section, "child-resistant packaging" is defined as set forth in Code of Federal Regulations, title 16, section 1700.15 (b)(1), as in effect on January 1, 2015, when tested in accordance with the method described in Code of Federal Regulations, title 16, section 1700.20, as in effect on January 1, 2015.

(b) The sale of any liquid, whether or not such liquid contains nicotine, that is intended for human consumption and use in an electronic delivery device, as defined in section 609.685, subdivision 1, that is not contained in packaging that is child-resistant, is prohibited. All licensees under this chapter must ensure that any liquid intended for human consumption and use in an electronic delivery device is sold in child-resistant packaging.

(c) A licensee that fails to comply with this section is subject to administrative penalties under section 461.12, subdivision 2.

# CHILD NICOTINE POISONING PREVENTION ACT OF 2015

“... any nicotine provided in a liquid nicotine container sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States shall be packaged in accordance with the standards provided in section 1700.15 of title 16, Code of Federal Regulations, as determined through testing in accordance with the method described in section 1700.20 of title 16, Code of Federal Regulations, and any subsequent changes to such sections adopted by the Commission.”



<https://www.govtrack.us/congress/bills/114/s142/text>



# CHILD NICOTINE POISONING PREVENTION ACT OF 2015

- Savings Clause
  - No mention of effect on existing state laws
- Exclusion: “The term liquid nicotine container does not include a sealed, pre-filled, and disposable container of nicotine in a solution or other form in which such container is inserted directly into an electronic cigarette, electronic nicotine delivery system, or other similar product, if the nicotine in the container is inaccessible through customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion or other contact by children.”

<https://www.govtrack.us/congress/bills/114/s142/text>



# CHILD NICOTINE POISONING PREVENTION ACT OF 2015



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# RESOURCES

① [www.publichealthlawcenter.org/topics/tobacco-control/e-cigarettes](http://www.publichealthlawcenter.org/topics/tobacco-control/e-cigarettes)

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## E-Cigarettes

Electronic cigarettes (e-cigarettes) are devices, often resembling cigarettes, cigars or pipes, designed to deliver nicotine or related substances to users in the form of a vapor. Over the last few years, these products have enjoyed a boom in popularity, thanks largely to marketing claims that promote them as less hazardous alternatives to combustible cigarettes and tout their safety, convenience and cost-effectiveness over traditional tobacco products. Because of the lack of clinical research on e-cigarettes, many public health organizations and policymakers are concerned about their safety and health impact on users. Also, because the federal government has yet to exercise its regulatory authority over these products, e-cigarettes are manufactured without regulatory oversight or quality controls, and promoted and advertised broadly without appropriate health warnings or legal age restrictions.

A growing number of state and local governments have taken steps to regulate the sale, marketing and use of e-cigarettes to protect the health of users, reduce youth initiation to nicotine and tobacco products, and promote enforcement of tobacco-free laws. This section provides background information and resources on e-cigarettes, as well as options and considerations for communities and policy makers to

### Related Topics

- [Advertising and Marketing](#)
- [Federal Regulation of Other Tobacco Products](#)
- [Flavored Products](#)
- [Sales Restrictions](#)

### Related Publications

- [U.S. E-Cigarette Regulations - 50 State Review \(2016\)](#)
- [State and Local Tobacco Regulation in a Post-Deeming World \(2016\)](#)

# RESOURCES

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Home » U.S. E-Cigarette Regulations - 50 State Review (2016)

## U.S. E-Cigarette Regulations - 50 State Review (2016)

The following is a snapshot of the U.S. landscape of e-cigarette regulation, prepared by the Consortium and the [Public Health and Tobacco Policy Center](#) at Northeastern University. The information below was based on a 50-state (plus Washington, D.C.) survey of current state statutes pertaining to e-cigarette regulations in the following areas: definition of "tobacco product," taxation, product packaging, youth access/other retail restrictions, and smoke-free air legislation. Please note that some links go to legislative websites or portals because the laws have not yet been codified or are not otherwise available. The N/A designation refers to the lack of state laws or regulations related to e-cigarettes as of September 15, 2016; however, many local laws in these states (and throughout the U.S.) address e-cigarettes.

Please click on a state to see the regulations in place as of September 15, 2016.

[Click here to download the complete data set \(PDF\)](#)   Map not working? [Click here](#) to reload!

[Click here to view Washington D.C.](#)





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**E-Cigarette Poisonings**

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# RESOURCES



Improving health through the power of law

## 2014 Legislative Spotlight: Electronic Cigarettes E-Liquids and Child-Resistant Packaging

On May 21, 2014, Governor Mark Dayton signed into law [new legislation](#) to address "electronic delivery devices" – products more commonly known as electronic cigarettes or e-cigarettes.

Electronic cigarettes are battery-powered devices, often resembling cigarettes, cigars, or pipes, designed to deliver nicotine or other substances to users in the form of an inhaled aerosol or vapor. Once primarily sold through the Internet or at mall kiosks, electronic cigarettes are now widely available in convenience stores, gas stations, tobacco stores and increasingly, at stand-alone, exclusive e-cigarette shops. Many public health advocates support the regulation of electronic cigarettes to reduce youth initiation to nicotine and tobacco products, protect the health of their users, and to promote the enforcement of smoke-free laws.

Included within the new legislation are a number of provisions that impact the retail sale of electronic cigarettes. Existing retail tobacco regulations were, for the most part, amended and/or expanded to address the sale of electronic cigarettes. One new provision, however, is specific to this type of product.



### 461.20 SALE OF ELECTRONIC DELIVERY DEVICE; PACKAGING.

(a) For purposes of this section, "child-resistant packaging" is defined as set forth in [Code of Federal Regulations, title 16, section 1200.15 \(b\)\(1\)](#), as in effect on January 1, 2015, when tested in accordance with the method described in [Code of Federal Regulations, title 16, section 1200.25](#), as in effect on January 1, 2015.

(b) The sale of any liquid, whether or not such liquid contains nicotine, that is intended for human consumption and use in an electronic delivery device, as defined in [section 608.685, subdivision 1](#), that is not contained in packaging that is child resistant, is prohibited. All licensees under this chapter must ensure that any liquid intended for human consumption and use in an electronic delivery device is sold in child-resistant packaging.

(c) A licensee that fails to comply with this section is subject to administrative penalties under [section 661.12, subdivision 2](#).

An important regulation – one of the first of its kind in the United States. But, one that also raises a number of questions.

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Fact Sheet

## Policy Approaches to Prevent Liquid Nicotine Poisonings

The increasing use of electronic cigarettes and similar e-devices, such as vape pens, mods, tanks, and personal vaporizers, along with e-liquid refills has created several public health problems requiring policy solutions.<sup>1</sup> One such problem, which governments at all levels have only recently started to consider, is the poisonings caused by the concentrated liquid nicotine used in these products. This fact sheet takes a brief look at this problem and possible policy approaches for addressing it.<sup>2</sup>

### Overview

Although e-cigarette use is not yet at the level of conventional cigarette use, it is increasing dramatically. Approximately one in five U.S. smokers has tried e-cigarettes.<sup>3</sup> Some studies have even shown that teens use e-cigarettes more than traditional tobacco products.<sup>4</sup> Thousands of shops specialize in e-cigarettes and e-liquid in the U.S., and these shops were projected to have over \$1 billion in sales in 2014.<sup>5</sup> Many non-specialty stores, such as gas stations and convenience stores, also sell e-liquid.



E-liquid comes in a variety of enticing flavors, such as cherry, chocolate, gummy bear, and bubble gum, many of which appeal to children.<sup>6</sup> According to one source, approximately 7,764 flavors of e-liquid are available through e-cigarette websites.<sup>7</sup> Many of these websites do not attempt to verify the age of their customers.<sup>8</sup>

The problem is that much of the e-liquid on the market contains nicotine, which depending on the concentration, can be extremely dangerous. Nicotine is an acute toxin;<sup>9</sup> exposure to nicotine by swallowing or contact with the skin can result in nausea and vomiting, as well as respiratory arrest, seizures, or even death.<sup>10</sup> A lethal dosage of nicotine is estimated to be between 1 and 13 milligrams per kilogram of bodyweight.<sup>11</sup> The nicotine level in most e-liquid ranges between 1.8 and 2.4 percent,<sup>12</sup> though the nicotine concentration in a vial of e-liquid can be as high as 10 percent.<sup>13</sup> For a 200-pound person, a teaspoon of 1.8 percent nicotine concentrated e-liquid could be fatal.<sup>14</sup> Children, drawn to e-liquid because of its many kid-friendly flavors, are especially vulnerable to nicotine poisoning.<sup>15</sup>

## E-Cigarette Poisonings

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# Questions



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