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Electronic Cigarettes: Facts & Myths

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Objectives



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- Identify the working parts of an e-cigarette, how they vary from model to model, and how those variations effect the user
- Identify current concerns and best practices in regards to e-cigarette usage
- Be knowledgeable in current FDA initiatives to address e-cigarette usage and identify trends towards the future

History

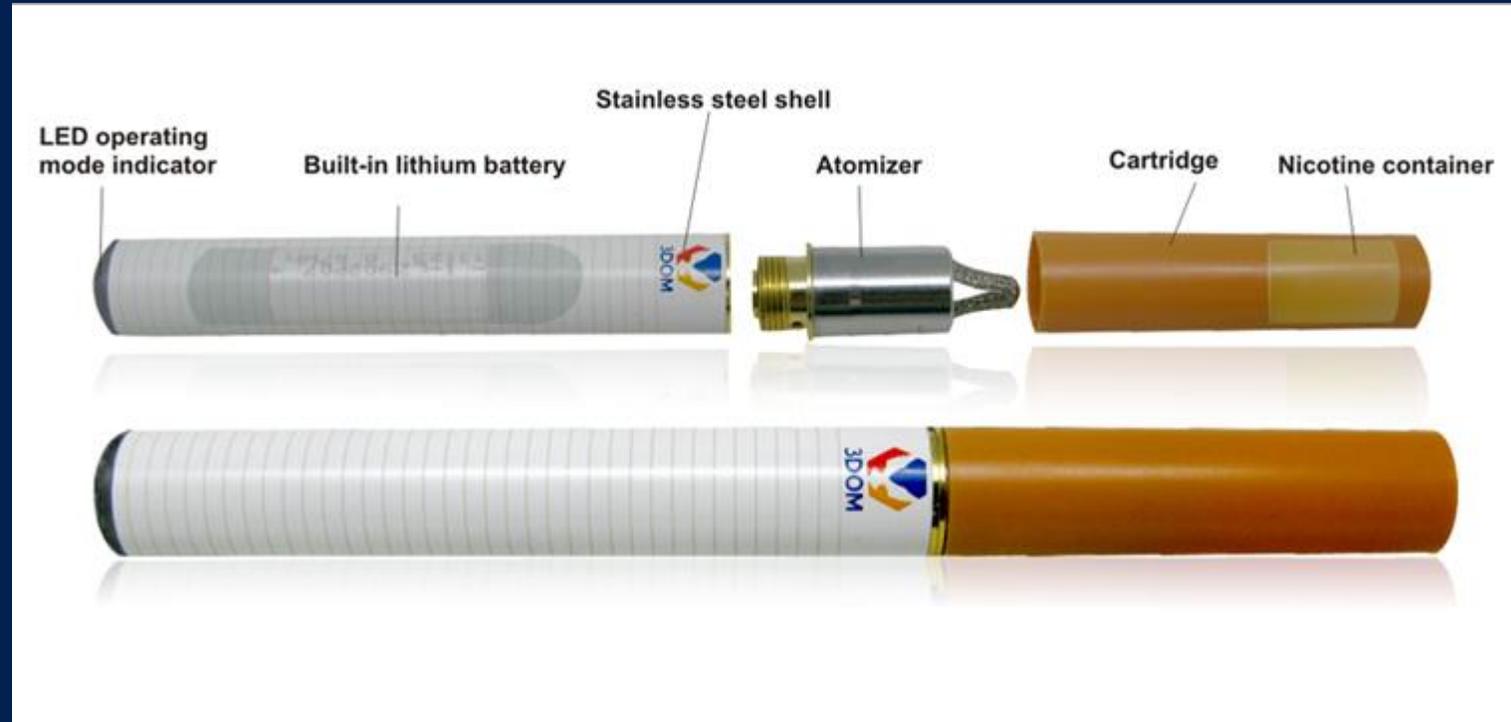
- Invented by Hon Lik, an accredited and licensed Chinese pharmacist in 2003
- First available only in China; started exporting in 2005-2006, and received the first international patent in 2007
- Tobacco companies started purchasing rights to e-cigarettes in 2012, with Blu being the first commercial brand purchased and marketed by big tobacco



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What Are E-Cigarettes?



1. Also known as a personal vaporizer (PV), vape, or electronic nicotine delivery system (ENDS)



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Model Variations

First Gen
(cig-a-like)



Second Gen
(vape pens)



Model Variations



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Third Gen
(mods)



Fourth Gen
(pod devices)



Model Variations

E-Cigs are evolving with time to become more “efficient” at delivering nicotine

- “E-Juice” is the substance inhaled by the user
- It contains 4 components:
 - Propylene glycol
 - Vegetable glycerin
 - Nicotine
 - Flavoring



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Nicotine

1. Responsible for the addictive properties of tobacco
 - a. When used as directed, it is a safe compound (extremely high doses are toxic)
2. Has a half-life of approximately 2 hours
3. Metabolized by the liver
4. Is harsh to inhale
5. First, 2nd, and 3rd generation e-cig devices were not efficient at providing nicotine to the user
 - a. Lead to development of nicotine salts and the rise of pod devices



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Conventional Cigarettes

1. Tobacco companies have been adding and refining levels of nicotine in cigarettes for decades
 - a. Conventional cigarettes use freebase nicotine that occurs naturally in tobacco
 - b. Many additives in conventional cigarettes are used to make both nicotine and tobacco more palatable to the user



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Freebase Nicotine vs Salts

1. Freebase nicotine was the “standard” for vape products up until 4th gen pod devices
 - Chemical nicotine is added to propylene glycol and vegetable glycerin, which carries the nicotine to the lungs
 - Nicotine at it’s “purest”
 - Freebase nicotine is incredibly harsh due to high alkalinity
 - Vape products deliver lower and ineffective doses of nicotine due to the harshness of freebase nicotine



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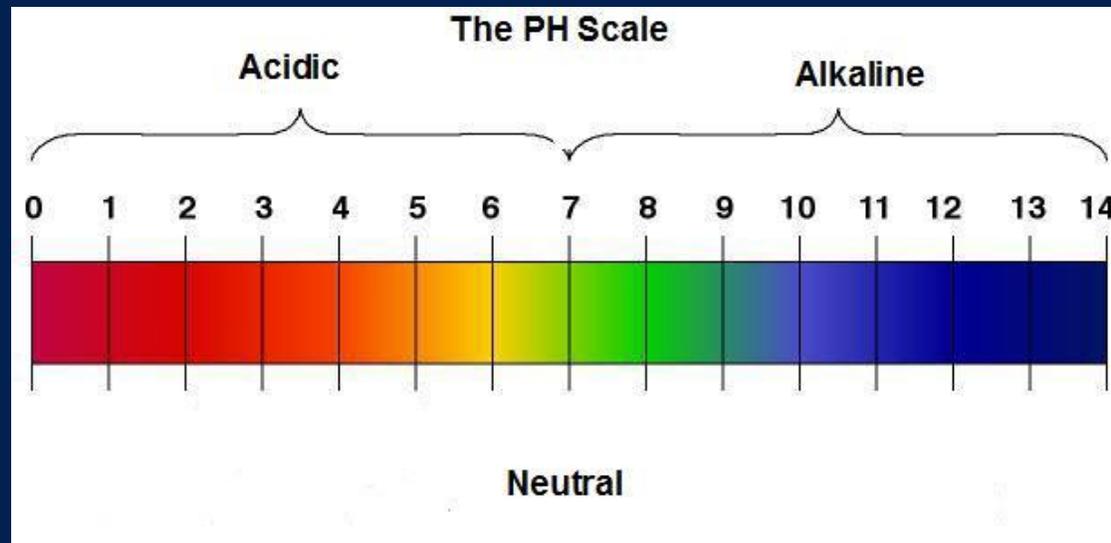
Freebase Nicotine vs Salts

1. Nicotine salts are freebase nicotine with benzoic acid added
 - a. Lowers pH level of freebase nicotine, which lowers alkalinity
 - b. Creates a much “smoother” hit and allows a higher level of nicotine to be used



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Pod Devices

- Thought to be leading to an increase in youth usage
- Portable and discrete
- New standard for vaping devices
- Easily accessible

Pod Devices

- Use disposable pods that come in various flavors
- Contain nicotine salts; one pod = 1 pack of cigarettes
- Discrete, available in gas stations, and rechargeable
- Very popular with youth



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Pod Devices

- Refillable pod
- Designed to be used with nicotine salt solutions
- Discrete
- Gaining popularity



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Youth Usage

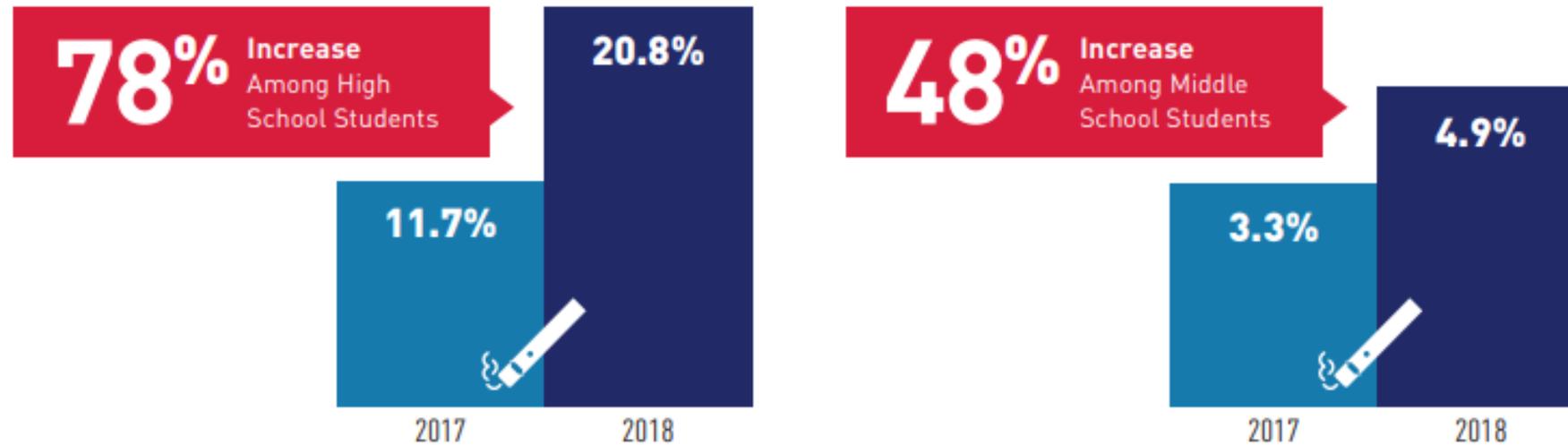
Youth Usage



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SURGE IN YOUTH CURRENT E-CIGARETTE USE — 1.5 Million More Students Used E-Cigarettes in 2018 vs 2017



Youth Usage



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AMONG HIGH SCHOOL CURRENT E-CIGARETTE USERS — Rise in Frequency and Use of Flavors

More Used
E-Cigarettes on
20 or More Days

28%

in 2018
vs
20% in 2017

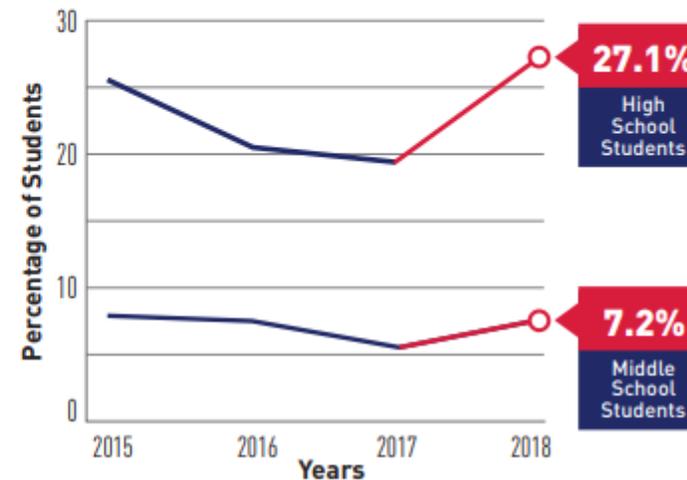
More Used
Flavored
E-Cigarettes

68%

in 2018
vs
61% in 2017

E-CIGARETTE USE SURGE LED TO UPTICK IN OVERALL TOBACCO USE — Reversing Previous Declines

Current Use of Any Tobacco Product



Note: All numbers in this document are estimates.

IN 2018



Almost **5M**
youth currently used
any tobacco product.



About **40%**
of youth who used
tobacco products used
two or more products.



Over **3.6M**
youth used e-cigs, making
them the most commonly
used tobacco product.

Restrictions: Flavorings

1. The FDA enacted a ban on all flavored cigarettes on September 22, 2009
 - a. Authorized by the Family Smoking Prevention & Control Act
 - b. In 2004, 22.8% of 17-year-old smokers reported using flavored cigarettes over the past month, compared to 6.7% of smokers over the age of 25
 - c. Studies of youth expectations around flavored tobacco products have found that young smokers report choosing flavored products because they “taste better” and are perceived to be “safer”



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TOBACCO

555
B-Mix
Clove
Cool
Crazy Grass
Crazy Hump
Crazy Hump Crush
Cuban Cigar
Cured Tobacco
DK-Tab
Havana Cigar
Mild Cigar
M-Mix
M-Mix House Blend
M-Mix Red
M-Mix Special Blend
M-Mix USA Blend
N-Mix
Peach Tobacco
P-Mix
RY4
Skinny V
S-Mix
Smooth
Tobacco
W-Mix
Winter Green Chew

MENTHOL

Alpine Fresh
B-Mix Menthol
Blazing Frost
Crazy Chill
Crazy Freeze
Crazy Hump Menthol
Extreme Ice
Menthol
M-Mix Menthol
M-Mix USA Blend Ment.
P-Mix Menthol
Skinny V Menthol

CANDY

Almond Coconut Bar
Blueberry Cotton
Candy
Blueberry Delight
Bubble Gum
Buttered Popcorn
Butterscotch
Candy Apple
Candy Cane
Caramel
Circus Cotton Candy
Coconut Candy
Cotton Candy
Crazy Rainbow
Cream De Menthe
Double Chocolate
English Toffee
Fresh-N-Fruity
Goblin Goo
Graham Cracker
Gummy Candy
Hot Cinnamon Candy
Kettle Corn
Mint Patty
Licorice
Peppermint
Peppermint Frost
Purple People Eater
Red Hots
Snick-Snack
Sour Apple
Sour Applicious
Spearmint
Super Red Hots
Sweet-N-Sour Kiss
Sweet Tart
Tutti Fruitti
Twin Mint
Twisted Grape
Winter Cool
Volcano
Zombie Blood
Zombie Juice
Zombie Mint

DESERTS

Apple Pie
Apple Pie Ala Mode
Banana Nut Bread
Banana Pudding
Banana Split
Bavarian Cream
Belgian Waffle
Black Honey
Blueberry Cheesecake
Blueberry Cinn. Crumble
Butter Pecan
Butter Rum
Cake Batter
Cheesecake
Cinnamon Coffee Cake
Cinnamon Danish
Cinnamon Sugar Cookie
Cream Cheese Frosting
Cream De Menthe
French Toast
French Vanilla
French Vanilla Deluxe
Fudge Brownie
Gingerbread
Lemon Meringue Pie
Key Lime
Marshmallow
NY Cheesecake
Peanut Butter
Peanut Buttercup
Pie Crust
Red Velvet Cake
Strawberry Short Cake
Sweet Cream
Sugar Cookie
Toasted Almond
Toasted Marshmallow
Vanilla Bean Ice Cream
Vanilla Butternut
Vanilla Cupcake
Vanilla Custard
Whipped Cream
White Chocolate
Yellow Cake

DRINKS

Amaretto
Brandy
Butter Rum
Cafe Latte
Cappuccino
Carmel Cappuccino
Champagne
Coffee
Coffee Cream
Cognac
Cola
Crazy Dew
Crazy Pep
Creamy Fruit Smoothie
Dulce De Leche
Eggnog
Espresso
Green Tea
Hot Chocolate
Hypnotic
Irish Cream
Island Gateway
Jamaican Rum
Java Shake
Jungle Juice
Kahlua & Cream
Kentucky Bourbon
Margarita
Mocha
Mojito
Munster
Pina Colada
Pink Champagne
Orange Cognac
Raging Bull
Root Beer
Rum
Shipwreck
Shipwreck Berry
Strawberry Daquiri
Strawberry Lemonade
Sweet Tea
Tropical Punch
Twisted Java
Wicked Brew

FRUITS

Banana
Banana Cream
Banana Graham
Berry Blast
Blackberry
Black Cherry
Blueberry
Cantaloupe
Chocolate Covered
Raspberries
Coconut
Cranberry
Crazy Berry
Crazy Watermelon
Dragon's Blood
Dragon Fruit
Flaming Peach
Fresh Apple
Fruit Rocket
Georgia Peach
Golden Pineapple
Green Apple
Harvest Berry
Hazelnut
Honey Dew Melon
Kiwi
Mango
Melon
Lemon
Lemon Lime
Orange Creamsicle
Papaya
Papa Granate
Passion Fruit
Pear
Pineapple
Pistachio
Plum
Pomegranate
Pop Star
Pumpkin
Pumpkin Spice
Raisin
Raspberry
Raspberry Lemonade
Swamp Frog
Strawberries & Cream
Strawberry
Strawberry Banana
Strawberry Kiwi
Strawberry Lemonade
Sweet Raspberry
Sweet Strawberry
Sweet Tangerine
Sweet Tangy Melon
Sweet Watermelon
Tutti Fruitti
Watermelon

**WE CAN
CREATE CUSTOM
FLAVOR MIXES**

Liquid Available in
70/30 and 50/50 PG/VG

Restrictions: Advertising

1. There is a view that public usage of e-cigarettes serves to make smoking “trendy” and “cool” again, undoing 50 years of public health initiatives and education.
2. *“Vaping” is making smoking acceptable—even cool—once again as the tobacco industry returns to it’s old ways, putting e-cigarette commercials back on the airwaves for the first time since the 1970s. - Forbes Magazine*
3. Sex appeal, celebrity endorsements, and cartoons are being used to appeal to a young demographic of users



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Advertising



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- Social media is the new television ad
 - Snapchat
 - Twitter
 - YouTube
 - Instagram
- Influencers promote brands and products in ways that are not overt
- Selling a lifestyle over a brand is the goal



Advertising



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- Subtle product placement
- Celebrity endorsements
- Most people are not even aware that it is an advertisement
- #ad within the comments is usually the only indication

Advertising



1. Influencers are the number one drive on social media
 - a. Over 23 million followers
 - b. Promotes products as an extension of their lifestyle



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Advertising

1. Paid for reviews for products by popular YouTube creators
 - a. Often have “how to vape with your parents not knowing” videos linked to product reviews



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Culture of Vaping



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[Redacted] • Follow
Narnia

[Redacted] Just an icon living.
#thesearemyfriends #hayeahihavefriends
#juulgang #juulpods #juulcouples #juul
#juulrelationships #juuling #juulvapor
#juulgang #juulgang #juulgang #di4juul #di4j
I'm proud to say I did most of the work on
the poster for my friend in need.



123 likes

1 DAY AGO

Add a comment...



Culture of Vaping



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Culture of Vaping



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Impact on Youth

1. Most e-cigarettes contain nicotine—the addictive drug in regular cigarettes, cigars, and other tobacco products.
2. Nicotine can harm the developing adolescent brain. The brain keeps developing until about age 25.
3. Using nicotine in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control.
4. Each time a new memory is created or a new skill is learned, stronger connections – or synapses – are built between brain cells. Young people’s brains build synapses faster than adult brains. Nicotine changes the way these synapses are formed.
5. Using nicotine in adolescence may also increase risk for future addiction to other drugs.



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Facts & Myths



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Facts & Myths

- Are e-cigarettes a viable alternative for adult smokers?
- Do they pose a risk to users exposed to secondhand vapor?
- Do they have any measurable health risk and are they a viable cessation tool?

Misconceptions

1. E-cigarettes are safe
 - a. E-cigarettes are not entirely “risk free”
 - b. Because of the inherent danger that comes with lack of regulation, e-cigarettes cannot be considered a risk free alternative
 - c. No studies have been conducted on long-term usage and respiratory illness
 - d. Some dangers are still present

2. E-cigs are better for you than regular cigarettes
 - a. E-cigs can be considered an initiative in harm reduction
 - b. However**, harm reduction does not equal “healthy”



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E-cigs vs. Conventional Cigarettes

1. Conventional cigarette secondhand smoke is proven to have over 7,000 chemicals, with at least 70 being carcinogens
2. E-cigarettes contain trace amounts of VOCs and other aerosol emissions
 - a. E-cigs do leave trace amounts of freebase nicotine in the air at 10 times the rate of a conventional cigarette
 - b. This could pose problems for specific populations, such as pregnant women and children, or people who have a high sensitivity to nicotine



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E-cigs vs. Conventional Cigarettes

1. Exhaled e-cigarette aerosol contained propylene glycol, glycerol, flavorings, and nicotine, along with acetone, formaldehyde, acetaldehyde, propanal, diacetyl, and triacetyl
 - a. Formaldehyde can be produced if certain conditions are met, such as vaping at too high a voltage
 - b. “Mods” are the most likely to produce large amount of chemicals
 - c. Each mod and flavoring is capable of delivering different chemicals



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E-cig Particles

1. E-cigarette aerosol is made up of a high concentration of ultrafine particles, and the particle concentration is higher than in conventional tobacco cigarette smoke
1. Exposure to fine and ultrafine particles may exacerbate respiratory ailments like asthma, and constrict arteries which could trigger a heart attack



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Respiratory Problems

1. Many of the elements identified in the aerosol are known to cause respiratory distress and disease
 - a. The concentrations of 9 of 11 elements in e-cigarette aerosol were higher than or equal to the corresponding concentrations in conventional cigarette smoke, including tin, nickel silver, silicate, and iron
2. Short term use of e-cigarettes has been shown to increase respiratory resistance and impair lung function, which may result in difficulty breathing.
 - a. Using an e-cigarette caused an instant increase in airway resistance that lasted for 10 minutes in the majority of the participants in an independent study



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E-cig Particles

1. At least 10 chemicals identified in e-cigarette aerosol are on California's Proposition 65 list of carcinogens and reproductive toxins, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986.
2. The compounds that have already been identified in mainstream (MS) or secondhand (SS) e-cigarette aerosol include:
 - a. Acetaldehyde (MS),
 - b. Benzene (SS)
 - c. Cadmium (MS)
 - d. Formaldehyde (MS,SS)
 - e. Isoprene (SS)
 - f. Lead (MS)
 - g. Nickel (MS)
 - h. Nicotine (MS, SS)
 - i. N-Nitrosonornicotine (MS, SS)
 - j. Toluene (MS, SS)



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Why Variation?

1. E-cigarette particles are chemically and structurally different than cigarette particles, with some compounds being present in e-cigs that are not in conventional cigarettes
2. Each e-cigarette itself is different
3. Over 170,000 flavorings have individual and unique chemical compounds



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Nicotine Poisoning

1. E-cigarettes are thought to be responsible for a dramatic increase in poison control calls and admissions to the hospital
 - a. 30mg to 60mg is the lethal dosage (ingestion of 5+ cigarettes or 10ml+ of diluted nicotine solution)
 - b. 1 person to date has committed suicide through e-juice
2. CDC analysis compared total monthly poison center calls involving e-cigarettes and conventional cigarettes, and found the proportion of e-cigarette calls jumped from 0.3 percent in September 2010 to 41.7 percent in February 2014



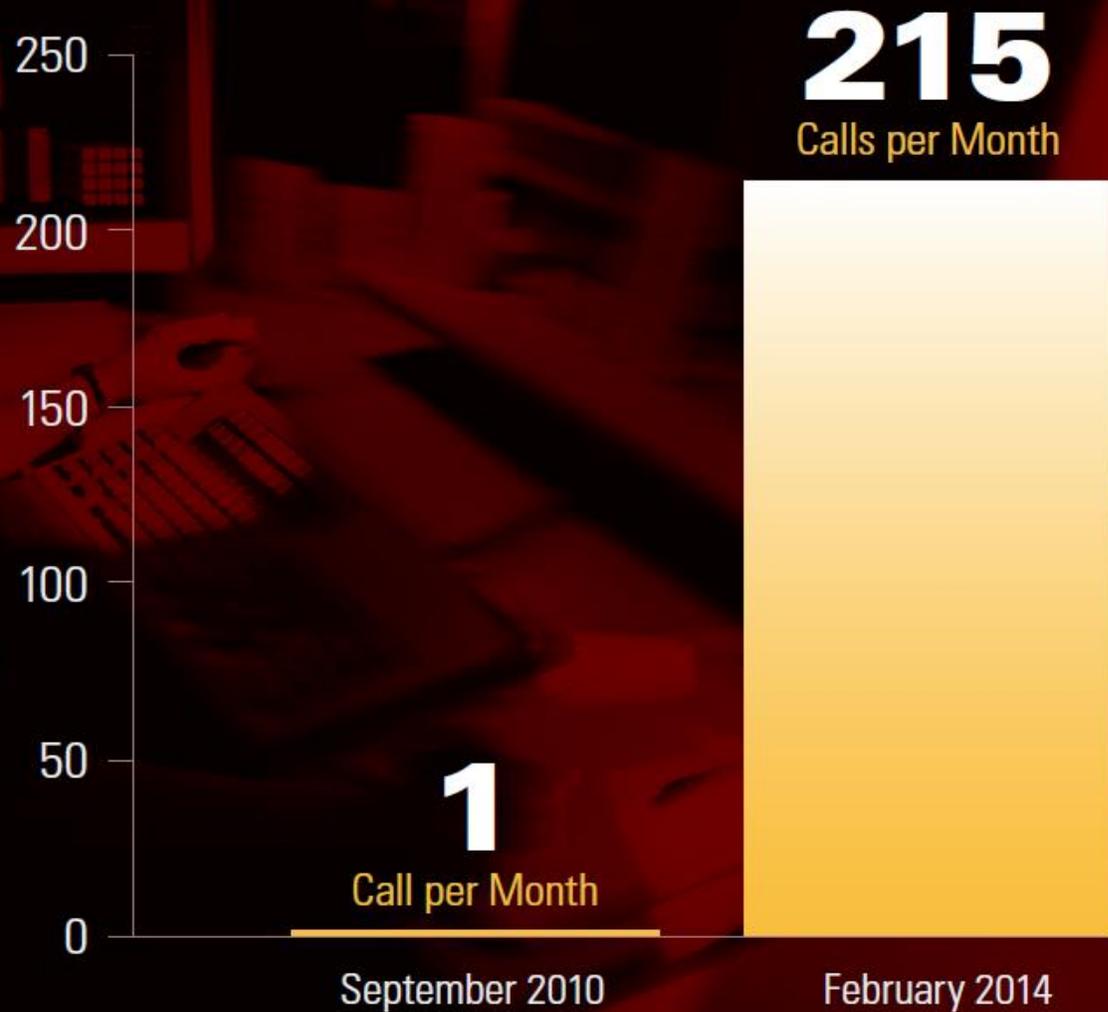
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Source: Mayer, Benard. Arch Toxicol. 2014; 88(1): 5-7. *How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century.* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/>

Center for Disease Control. *New CDC study finds dramatic increase in e-cigarette-related calls to poison centers.* <http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html>

Poison center calls involving e-cigarettes



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Where Do We Go From Here: FDA Regulation

Current policy initiatives

1. FDA Regulations:

- a. Only e-cigarettes that are marketed for therapeutic purposes are currently regulated by the FDA Center for Drug Evaluation and Research (CDER)
- b. The FDA has initiated a proposal to regulate all e-cigarettes as a tobacco derivative product (in effect as of August 2016)
- c. This would categorize e-cigarettes as “tobacco” and subject them to the same regulations as smokeless and conventional cigarettes



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Current policy initiatives

1. The proposed ruling is active on Aug 8th, 2016:
 - a. Register with the FDA and report product and ingredient listings
 - b. Only market products after FDA review
 - c. Only make direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole; and
 - d. Not distribute free samples
 - e. Minimum age and identification restrictions to prevent sales to underage youth
 - f. Requirements to include health warnings



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Current policy initiatives

1. The final rules will apply to all manufacturers, importers and/or retailers of e-cigarettes
 - a. Manufacturing is covered within FDA initiatives, so import and export of e-cigarettes should be regulated

HOWEVER...

These regulations are currently being delayed and fought for repeal in Congress by lobbyist groups and businesses.



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Current policy initiatives

1. Currently in effect:

- a. Not distribute free samples
- b. Minimum age and identification restrictions to prevent sales to underage youth
- c. Manufactures of e-juice and e-cigarette “mods” must undergo the following:
 - i. Pay user fee
 - ii. Register establishment with FDA
 - iii. Submit tobacco health documents



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Current policy initiatives

1. In effect in 2018:

a. Warning label with "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

2. Originally by May 2018; extended to Aug 2022:

a. Flavor listings of products produced

b. Submit "new" products (flavors) or exception for consideration due to Substantial Equivalence ruling

c. Delay was introduced in order to give the FDA more time to research and evaluate the risk of e-cigarettes vs conventional tobacco products



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Thank you

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