Electronic Cigarettes

Potential Harms & Benefits

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9/22/14

Includes slides courtesy of M. Brad Drummond, MD, MHS
Johns Hopkins University School of Medicine

Objectives – for me

* Discuss the mechanisms of e-cigarettes
* Review current data
  * Potential adverse health effects
  * Efficacy as smoking cessation aid
* Highlight current social and regulatory issues
* No financial relationships to disclose
* Member: American Thoracic Society Tobacco Action Committee and the American Lung Association Sub-committee on Electronic Cigarettes

Objectives – for you

Following the presentation, attendees will be able to:

* Discuss potential adverse health effects & benefits of electronic cigarettes for individual users
* Discuss potential adverse public health effects of electronic cigarettes
* Describe the interplay between use of conventional cigarettes and electronic cigarettes
* Cite the evidence on use of electronic cigarettes as a tool for cessation of conventional cigarettes

US Department of Health & Human Services

* Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine, flavor and other chemicals.
* They turn chemicals, including highly addictive nicotine, into an aerosol that is inhaled by the user.
* Most e-cigarettes are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble everyday items such as pens and USB memory sticks.

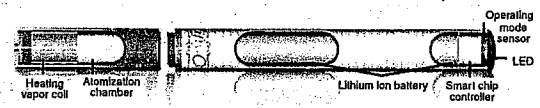
Electronic cigarette

* Nomenclature
  * Electronic cigarette (eCig or e-cig)
  * Electronic nicotine delivery system (ENDS)
  * Hookah stick
  * Personal vaporizer (PV)
    * "Vaping"
* Delivers aerosolized/atomized nicotine in a vapor
* Different from nicotine inhaler

Nicotine inhalers vs e-cigarettes

* Nicotine inhalers
  * Deliver non-combusted aerosolized nicotine, absorbed in oropharyngeal mucosa
  * FDA-approved and regulated for treatment of tobacco dependence
* E-cigarettes
  * Heating element atomizes the liquid, resulting in aerosolized nicotine vapor and a visible plume
  * Vapor inhaled into the lungs, where nicotine is absorbed
  * E-cigarettes currently lack FDA oversight – no standardized production, marketing or safety assessments

Devices that deliver a nicotine-containing vapor



Amer J Health Sys Pharm 2009; 66:1740-42

E-cigarette nicotine cartridge

* Replaceable
* Approximately 250 puffs/cartridge
  * Equivalent to 1 pack (20 cigarettes)
* "Smoke juice"
  * Propylene glycol, vegetable glycerin, polyethylene glycol
  * Varying amount of nicotine
  * Various flavors

Vapor

* Variable amounts of nicotine & potentially harmful toxins, lower levels than in conventional cigarette smoke
  * Study of 16 different e-cigarettes found that the total amount of nicotine in 15 puffs of vapor (generated by an automatic smoking machine) varied from 0.5 to 15.4 mg
  * Typical amount from one smoked conventional cigarette ranges from 1.54 to 2.60 mg
* Possible role of e-cigarettes in establishing nicotine addiction, especially in youth

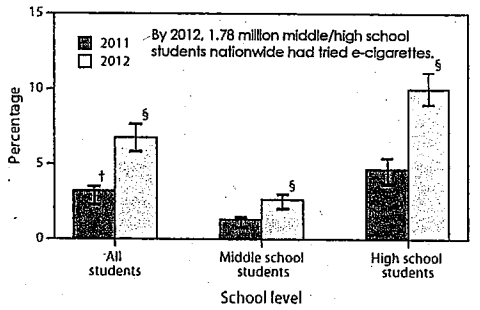
Implications for lung health

* Marketed and perceived as a "healthier alternative" to conventional cigarettes
* Few data exist on the safety of these devices or efficacy in harm reduction & treatment of tobacco dependence
  * Studies limited by small sample sizes, lack of control groups & significant loss to follow-up
* Even less known about overall impacts on population health

Changing social norms

* Concern that e-cigarette marketing, ads and use re-normalize and re-glamorize smoking
  * Potentially reversing decades of efforts by public health and medical groups
* Potential benefits – related to cessation or reduction of conventional cigarette smoking due to e-cigarette use by individuals – may be outweighed by societal increases in nicotine dependence associated with e-cigarette initiation, and with a renewed acceptance of smoking in general

Use of e-cigarettes among US middle & high school students increasing rapidly



Ever electronic cigarette use among middle and high school students, by year — National Youth Tobacco Survey, United States, 2011–2012

CDC MMWR – September 6, 2013 / 62(35);729-730

The JAMA Network

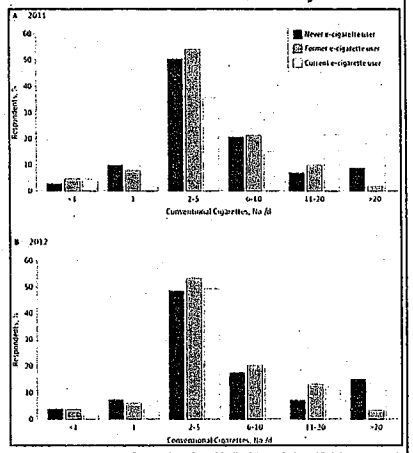
Electronic cigarettes and conventional cigarette use among US adolescents: a cross-sectional study

Current e-cigarette use was associated with heavier smoking among conventional smokers

For those who had ever used e-cigarettes, 9.3% reported never smoking conventional cigarettes

76.3% of current e-cigarette users were also smoking conventional cigarettes

Adolescents consider e-cigarettes as high-tech, accessible, and convenient, especially in places where smoking is not allowed



Dutra L, Glantz S. JAMA Pediatr. doi:10.1001/jamapediatrics.2013.5488

Nicotine

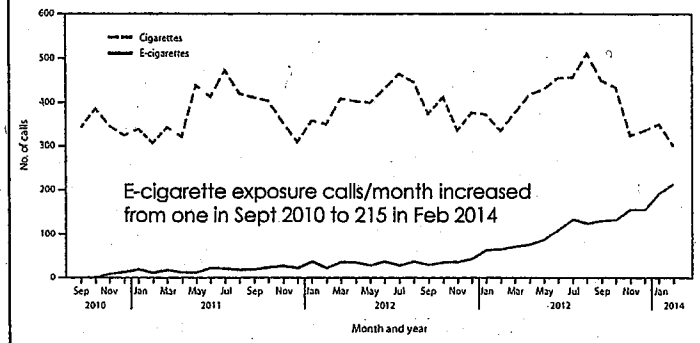
* Nicotine has negative impacts on brain development, including the adolescent brain, and the fetal brain, with implications for use during pregnancy
* Nicotine causes constriction of blood vessels – can lead to low birth weight babies – at increased risk for illness & death
* Evidence that *in utero* exposure can influence later occurrence of impaired fertility, type 2 diabetes, obesity, hypertension, neurobehavioral defects, and respiratory dysfunction

Bruin JE et al. Toxicological sciences 2010; 116: 364-374.

Acute nicotine poisoning

* Poisoning from e-cigarettes from the liquid containing nicotine
  * Ingestion, inhalation or absorption (skin, eyes)
  * Poisoning from conventional cigarettes mostly due to being eaten by young children
* 0.5-1.0 mg per kg body weight can be lethal
* Replacement cartridge typically contains 6-24 mg of nicotine, some may contain >100 mg
  * 30-kg child who swallows the contents of a 24-mg cartridge at high risk of acute and lethal poisoning

Number of calls to US poison centers for cigarette or e-cigarette exposures, by month 9/2010 - 2/2014



Chatham-Stephens K et al. MMWR April 4, 2014 / 63(13);292-293

Nicotine poisoning

* 51.1% of e-cigarette-related poisonings were children 0-5 years; 42% adults age ≥20
* E-cigarette calls as a proportion of total calls increased dramatically
  * 0.3% in 9/2010 to 41.7% in 2/2014
  * Total: 2,405 e-cigarette & 16,248 cigarette calls
* E-cigarette calls more likely to report an adverse effect
  * Vomiting, nausea, eye irritation

Chatham-Stephens K et al. MMWR April 4, 2014 / 63(13):292-293

Nicotine – a gateway drug

* Gateway drug – a drug that lowers the threshold for addiction to other agents
* A well-defined developmental sequence of drug use occurs that starts with a legal drug and proceeds to illegal drugs
  * Use of tobacco or alcohol precedes the use of marijuana, which in turn precedes the use of cocaine and other illicit drugs
  * Priming with nicotine enhances the effects of cocaine
* Nicotine use is a gateway to marijuana and cocaine
  * Strong epidemiologic and molecular evidence

Kandel and Kandel. N Engl J Med 2014;371:932-43.
DOI: 10.1056/NEJMsa1405092

Nicotine – other adverse effects

* Significant cardiovascular effects
  * May play a major role in development of coronary artery disease, atherosclerosis and aortic aneurysms
* Affects neuroregulation and structural changes in the brain and lung
  * Can disturb a wide variety of reflexes and responses; may increase vulnerability to hypoxemia
  * Nicotine addiction may cause deleterious effects in women's brains by inhibiting estrogen signaling, which may make the brain more susceptible to ischemia
* Associated with development of peptic ulcer & gastrointestinal cancers
* May promote tumor angiogenesis

More toxins

* FDA detected low levels of toxic substances in e-cigs
  * Tobacco specific nitrosamines and diethylene glycol
  * 4 carbonyl compounds, 2 volatile organic compounds
  * Heavy metals – lead, cadmium, nickel
* Long-term carcinogenic effects unknown

Table 2. Comparison of toxin levels in conventional and electronic cigarettes

Toxin	Conventional cigarette (µg/cigarette in mainstream smoke)	Electronic cigarette (µg per 15 puffs)	Average ratio (conventional: electronic)
Carbonyl compounds			
formaldehyde	1.6–52	0.20–5.61	9
acetaldehyde	52–140	0.11–1.36	450
acrolein	2.4–62	0.07–4.19	15
Toluene	8.3–70	0.02–0.63	120
Nitrosamines			
N'-nitrosonornicotine	0.005–0.19	0.00008–0.00043	380
NNK	0.012–0.11	0.00011–0.00283	40

Definition of abbreviation: NNK = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.
Adapted by permission from Reference 40.

Goniewicz ML et al. Tobacco Control 2013
Drummond & Upson. Ann Am Thorac Soc Vol 11, No 2, pp 236–242, Feb 2014

Lung function

* Additives in liquid nicotine cartridges (glycol derivatives) similar to theatrical smokes & fogs
* Acute exposure to propylene glycol for one minute in 27 healthy non-asthmatics resulted in a 2% reduction in FEV_1/FVC ($p=0.049$) – measure of airway obstruction
* In a longitudinal study of 101 employees at sites using theatrical fog, those usually ≤ 10 feet from fog-generating machines had 5% reductions in adjusted FEV_1 and FVC compared with those working farther away

Lung function

* Increased airway obstruction
  * In 30 healthy smokers, use of e-cigarettes for 5 minutes caused increased total respiratory impedance, respiratory flow resistance and overall peripheral airway resistance
* E-cigarette use was associated with increasing oxidative stress as measured by lower levels of the fraction of exhaled nitric oxide
* Smaller acute effects on lung function than conventional cigarettes
* Long-term effects unknown

More on lung function

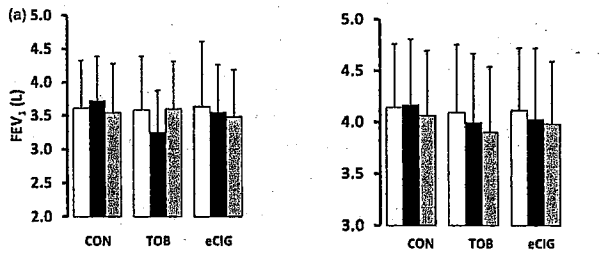
* Acute impact of active and passive electronic cigarette smoking on lung function and cotinine
* 15 smokers and 15 never-smokers
* 3 visits
  * Control, tobacco exposure, e-cig exposure
    * 30 min active or 1 hr passive
    * 7 day wash-out between visits
  * Spirometry: before, immediately after, 1 hour after

Flouris AD et al. Inhalation toxicology 2013; 25(2):91-101.

Vapor did not reduce FEV_1

White: Before
Black: Immediate
Grey: 1 hr

FEV_1 – forced expiratory volume in 1 second



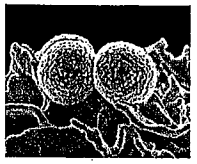
Flouris AD et al. Inhalation toxicology 2013; 25(2):91-101.

E-cigarettes and lung function

* Conclusions – for active and passive exposure
  * Smaller acute effects on lung function than conventional cigarettes
  * Result in measurable serum cotinine levels (metabolite of nicotine)
  * Data limited by small sample sizes
  * No information about long term effects, or on people with lung disease, including asthma

Effects on methicillin-resistant Staphylococcus aureus (MRSA)

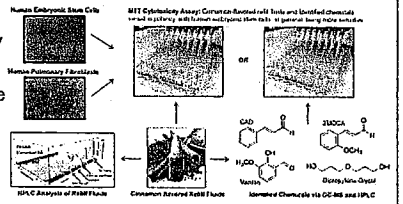
* MRSA becomes more resistant when exposed to electronic cigarette vapors – harder to kill
  * Forms thicker protective biofilms
  * Increased resistance to human antimicrobial peptides
* Exposure to e-cigarette vapor may decrease body's ability to fight infection
  * Reduces ability of human epithelial cells to kill MRSA (in cell culture)



EM of MRSA

Toxic cinnamon?

* Most cinnamon-flavored refill fluids were cytotoxic to embryonic and adult cells
* Human embryonic stem cells were more sensitive than adult pulmonary fibroblasts
* 4 chemicals identified in cinnamon-flavored refills
  * Dipropylene glycol & vanillin had low cytotoxicity
  * Cinnamaldehyde & 2-methoxycinnamaldehyde were cytotoxic (in MTT assay)



Behar RZ et al. Toxicology in Vitro 28 (2014) 198–208 http://dx.doi.org/10.1016/j.tiv.2013.10.008

Reasons that adults use electronic cigarettes

* Four-country survey of people who smoked conventional cigarettes and used electronic cigarettes
  * United States, United Kingdom, Canada, Australia
* 80% because they considered them less harmful than combustible cigarettes
* 75% to reduce their smoking of conventional cigarettes
* 85% to quit smoking

Adkison SE et al. Am J Prev Med 2013; 44: 207–215

Do eCigs reduce cigarette use?

* 40 people who smoke, not interested in quitting
* Given electronic cigarettes & supplies
* No encouragement, motivation or reward for smoking cessation
* Followed over 24 weeks
* Primary outcome
  * 50% reduction in cigarettes from baseline to 24 weeks

Polosa R et al. BMC Public Health 2011; 11:786

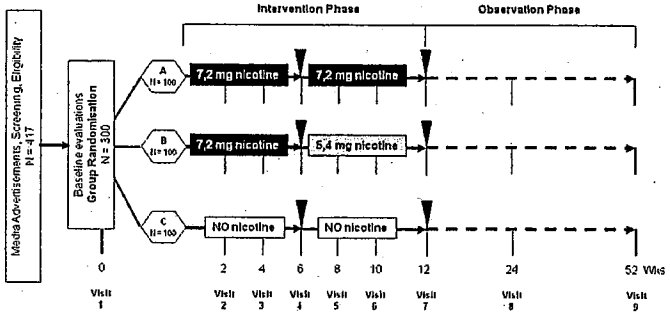
eCigs can reduce cigarette use

* 27(68%) completed 24-week follow-up
  * 13/40 (33%) reported 50% reduction
  * 9/40 (23%) quit conventional cigarettes
    * 6 of whom continued to use e-cigarettes
    * Not statistically significant
* Cigs/day dropped from 25 to 5 ($p<0.001$)
* Adverse events
  * Throat irritation: 33% Cough: 32%
  * Mouth irritation: 21%

Polosa R et al. BMC Public Health 2011; 11:786

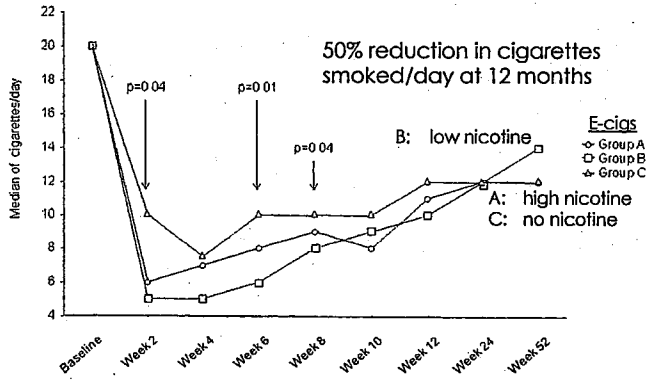
Do eCigs reduce cigarette use?

* 300 people who smoke, not interested in quitting



Caponnetto P et al. PLOS One 2013; 8(6):e66317

No difference between groups



Caponnetto P et al. PLOS One 2013; 8(6):e66317

Impact on smoking conventional cigarettes

* Confirmed quit rate at 52 weeks (exhaled CO)
  * High nicotine eCig: 13%
  * Low nicotine eCig: 9%
  * Placebo eCig: 4%
* Conclusion
  * Favorable modification in smoking habits and trend in cessation rates in unmotivated smokers
  * Possible confounder – participants received a lot of attention

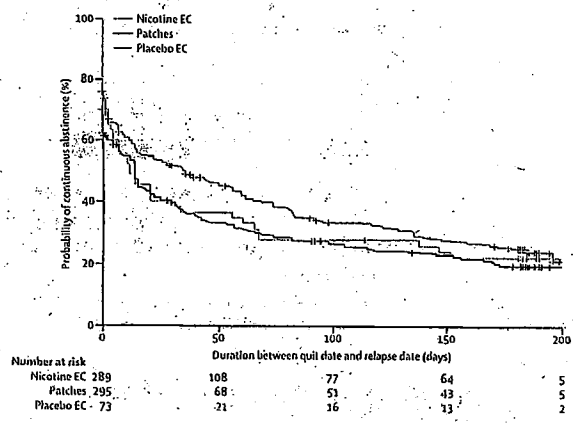
Caponnetto P et al. PLOS One 2013; 8(6):e66317.

E-cigarettes vs. nicotine patch

* 657 people who wanted to quit smoking conventional cigarettes
* Randomized interventions for 3 months after quit date
  * E-cigarette
  * 21-mg nicotine patch (no taper; no adjunct lozenges, gum)
  * Placebo e-cigarette, no nicotine patch
  * All received telephone counseling
* Outcome: 6 months confirmed cessation (exhaled CO)

Bullen C et al. Lancet 2013; online Sep 7, 2013

E-cigarettes delayed time to relapse



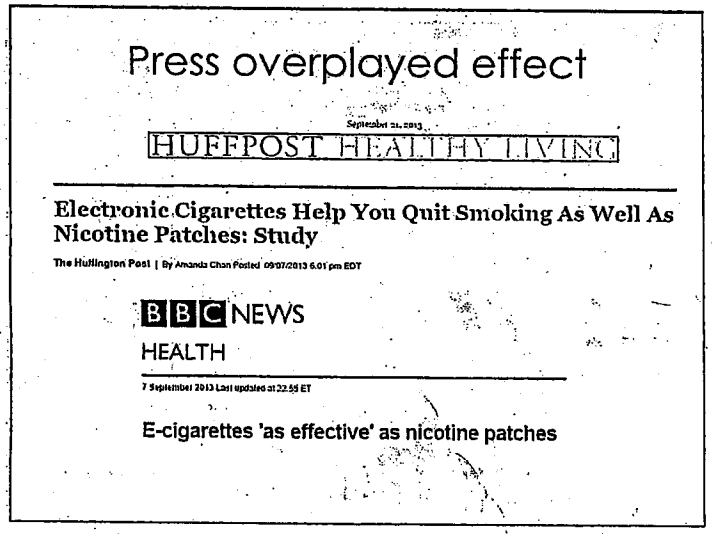
Bullen C et al. Lancet 2013; online 9/7/13

No significant difference

* 22% lost to follow-up
* 6-month quit rate – low for everyone
  * 7.3% e-cigarette
  * 5.8% nicotine patch
  * 4.1% placebo e-cigarette
* Dual use persisted at 6 months in approximately 1/3 of e-cig participants

Bullen C et al. Lancet 2013; online Sep 7, 2013.

Press overplayed effect



September 21, 2013

HUFFPOST HEALTHY LIVING

Electronic Cigarettes Help You Quit Smoking As Well As Nicotine Patches: Study

The Huffington Post | By Amanda Chan Posted: 09/07/2013 6:01 pm EDT

BBC NEWS

HEALTH

7 September 2013 Last updated at 22:55 ET

E-cigarettes 'as effective' as nicotine patches

Role in harm reduction unclear

* Some data demonstrate effectiveness in reducing conventional cigarette consumption.
* Instead of quitting, more people are moving toward dual use
  * May cut down on conventional cigarette use but not quitting and they're adding electronic cigarettes into the mix
  * No cardiovascular benefit without total cessation of conventional tobacco use
  * Heart disease leading cause of death among smokers

Over-the-counter use of tools for smoking cessation

5863 adults who had smoked within the previous 12 months and made at least one quit attempt

* E-cigarette only (n=464) – used for cessation
* NRT bought over-the-counter only (n=1922)
* No aid (n=3477)

Reported abstinence at 6 months

* E-cigarette vs NRT
  * Adjusted OR 1.63 (95% CI 1.17 - 2.27)
* E-cigarette vs no aid
  * Adjusted OR 1.61 (95% CI 1.19 - 2.18)
* Still using e-cigs; no data on dosing of NRT

Confounded by a self-selection bias in that respondents are often e-cigarette enthusiasts

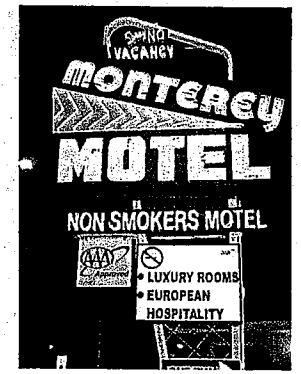
Brown J. doi: 10.1111/add.12623

Conclusions from clinical trials

* E-cigarettes contain much lower levels of potential carcinogens
* Smaller acute lung effects than conventional cigarettes
  * No long term data on lung function or cancer risk
* No data demonstrate efficacy as a tool for cessation
  * Equally ineffective as nicotine patch
  * Patches were not dosed optimally

Nicotine dependence

* E-cigs may perpetuate nicotine dependence in those who smoke conventional cigarettes, and decrease incentives for cessation, because they can be used where conventional cigarettes are not allowed
  * 70% of people who use e-cigarettes regularly do so because they are allowed in places where smoking is banned – convenience



Adkison SE et al. Am J Prev Med 2013; 44: 207–215

Not only used by smokers

* Concern that electronic cigarettes may serve as a gateway to conventional cigarettes for youth
* 7.4% of former smokers now using e-cigarettes

CDC 2012

* 20.3% of middle school ever e-cigarette users, and 7.2% of high school ever e-cigarette users, reported never smoking conventional cigarettes
* An estimated 160,000 students who reported ever using e-cigarettes had never smoked conventional cigarettes
* Dual use – among current e-cigarette users, 61.1% of middle schoolers & 80.5% of high schoolers also reported current smoking of conventional cigarettes

Manufacturers

Altria (Marlboro)

Reynolds (Camel)

Lorillard Inc (Newport)

Tobacco industry heavily involved

* Historical behavior of the tobacco industry has included:
  * Deceit about the health effects of tobacco
  * Intentional marketing to children
  * Manipulating nicotine levels in cigarettes to maintain or increase addiction

Companies claim they do not market to youth

Flavors – cherry, strawberry, vanilla, cookies & cream milkshake...

"Fun flavors" attract kids

Industry leader Lorillard:

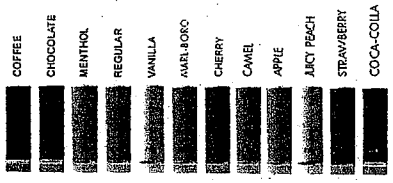
* "Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry."
* "Youth smoking prevention" website of Lorillard, manufacturer of blu eCigs, the best-selling e-cigarette brand

http://www.tobaccofreekids.org/tobacco_unfiltered/post/2014_06_11_ecigarettes

More choices than Starbucks...

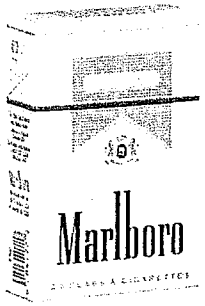
7764 unique flavors

CHOOSE FROM
16 GREAT FLAVORS!



Vapor Level	Outstanding	Excellent	Very Good	Excellent	Outstanding
Choice of Nicotine Level	5 strengths 0-24mg	5 strengths 0-24mg	4 strengths 0-16mg	5 strengths 0-24mg	5 strengths 0-24mg
Choice of tobacco flavors	Three	Two	Two	Three	Three
Choice of Fruit Flavors	No fruit flavors	Peach,Pineapple Pear, Orange, Apple, Cherry, Strawberry, Watermelon, Blueberry, Grape	Cherry,Apple, Grape, Banana, Orange,Peach, Pinaapple, Strawberry, Blueberry, Watermelon,	Cherry, Pina Colada, Peach	Cherry
Choice of Other Flavors	Chocolate, Mocha, Vanilla, Menthol, Clove	Menthol,Vanilla, Chocolate,Coffee, Clove, RedEnergy,Cola, Caramel, Irish Cream	Menthol,Mild Menthol, Vanilla, Almond, Chocolate, Peppermint Cinnamon, Clove Coffee	Chocolate, Vanilla, Menthol, Peppermint,	Menthol, Peppermint, Coffee, Vanilla, Chocolate, Cherry, Cola Mint Tea Pumpkin Spice (seasonal)
Battery Colors	White, Pink, designer styles	White, choice of colors and patterns; custom designs	White	White or Black	White, Black, Stainless Steel, Blue,Pink VC Sims
Battery length (without filter cartridge)	Standard 2.5", Long- 3.2"	Standard 2.5", Long- 4.2"	Standard or 4"	Standard 2.5", Long 3.25"	Shorty-2.83" Standard- 3.11" Long-4.4"

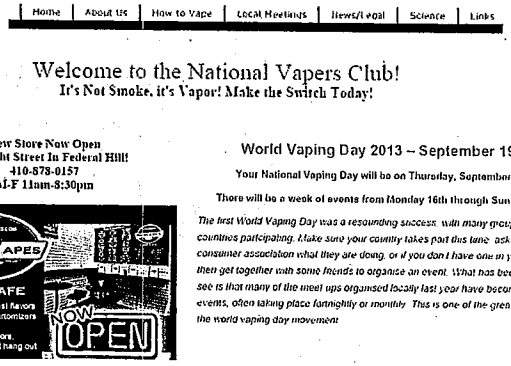
Cheaper than conventional cigarettes



$6.00/pack

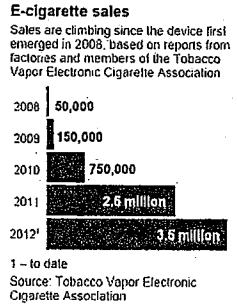
Starter pack: $49.99
Cartridge: $ 2.40

Vaping... the new Friday night



Most major US & European tobacco companies heavily invested in e-cigarette market

* Industry advertising spending increased to $20.8 million in 2012, from $2.7 million in 2010
* 2013 Super Bowl ad for NJoy e-cigarettes generated a 40% increase in sales in the 5 markets where it aired
* Studies by the U.S. attorney general found that e-cigarette sales have doubled every year since 2008
* The percentage of US adult smokers trying e-cigarettes increased from 10% in 2010 to 21% in 2011



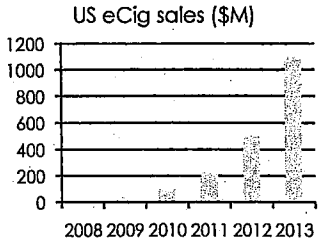
The NJOY e-cigarette story

* NJOY e-cigarette
  * Independent start-up
    * Silicon Valley investors
    * 40% US market

Richard Carmona
US Surgeon General
2002-2006
NJOY Board of Directors

Increasing advertising and sales

* Blu eCig advertising
  * $992,000 first quarter 2012
  * $12.4M first quarter 2013
* Annual sales
  * $1.3B in 2013
    * $700M retail
    * $600M online
  * Conventional tobacco: $80B



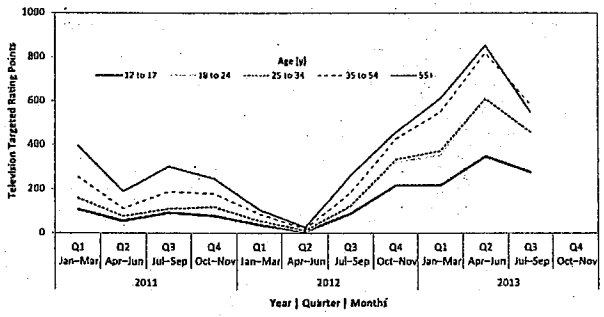
NYTimes.com 8/29/13
Rstreet.org 12/20/12

Television ads

* E-cigarette companies market using TV ads
  * Broad audience includes 24 million youth
* Ad content may appeal to young people – emphasizes independence and maturity
* The reach and frequency of ads increased dramatically between 2011 and 2013
  * 256% for youth, 321% for young adults
* Absence of evidence-based public health messaging
* If current trends continue, youth awareness and use of e-cigarettes are likely to increase

Duke JC et al. Pediatrics 2014;134:1–8

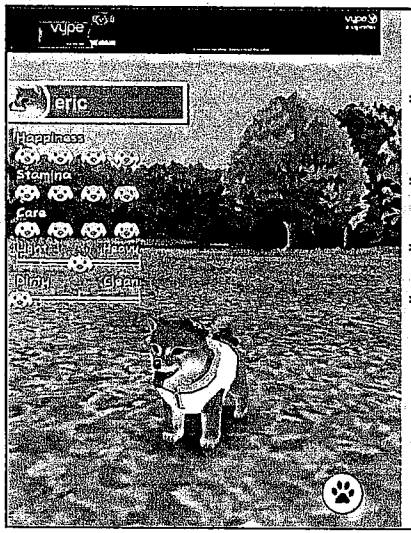
Exposure to e-cigarette television advertisements, 1/2011 – 9/2013



Duke JC et al. Pediatrics 2014;134:1–8

Youth-oriented ads

* http://www.youtube.com/watch?v=grWEhJ63OQ0
* http://www.youtube.com/watch?v=zvUFgVxs_7k
* http://www.youtube.com/watch?v=gqC5lg74xhY
* http://www.youtube.com/watch?v=mUJ5W2pz1XI



* British American Tobacco has apologized for running an ad for its Vype e-cigarette in an ipad game aimed at children.
* The ad drew attention after GB, a UK-based author, tweeted a picture.
* It's not clear how the ad ended up in the game.
* BAT: "We apologise that an advert has ended up on an channel that it clearly wasn't intended or appropriate for. As soon as this was brought to our attention, we pulled all our online advertising whilst we look into this matter further and establish how it happened."

7 Ways E-Cigarette Companies Are Copying Big Tobacco's Playbook

(or 7 reasons FDA should quickly regulate e-cigarettes)

The CDC recently reported that rates of electronic cigarette use among U.S. youth more than doubled from 2011 to 2012, when 10 percent of high school students reported ever having used e-cigarettes.

These numbers are troubling but not surprising. There has been an explosion in e-cigarette marketing in recent years, and e-cigarette manufacturers are using the same slick tactics long used to market regular cigarettes to kids.

Here's how. →

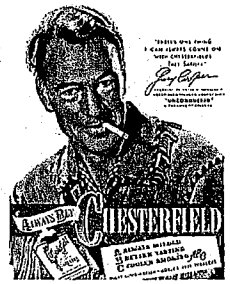
October 2, 2013

1. They have celebrity spokespeople

Like cigarette ads of old, television, online and print ads for e-cigarettes feature catchy slogans and celebrity endorsers, including actor **Stephen Dorff**

Stephen Dorff's Rise From the Ashes- Brought to you by blu Cigs

https://www.youtube.com/watch?v=VZlshwAt_RU



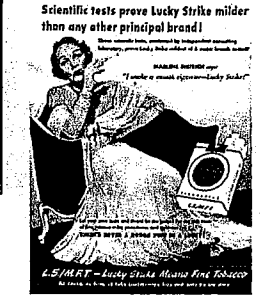
http://tobacco.stanford.edu/tobacco_main/main.php

... and TV personality **Jenny McCarthy** for blu eCigs ...

blu eCigs 2013 TV Commercial "Freedom" featuring Jenny McCarthy for blu Electronic Cigarettes

306 views

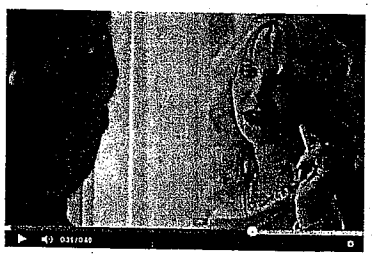
https://www.youtube.com/watch?v=A5rBDaiN8E



http://tobacco.stanford.edu/tobacco_main/main.php

... and rock musician **Courtney Love** for NJOY.

The message: Using these products is trendy and cool.



NJOY Presents: Relax...It's Courtney Love!

2. Their magazine ads feature rugged men ...

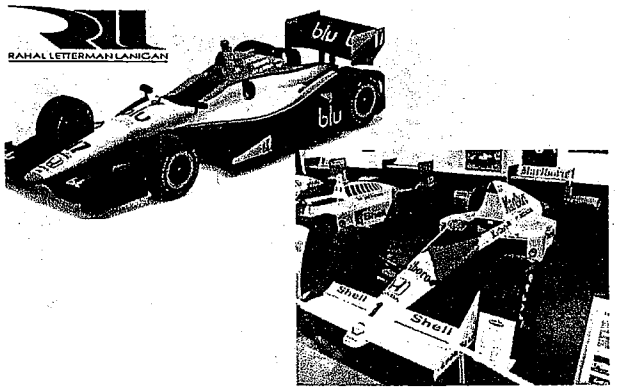
... and glamorous women

These ads feature today's equivalents of the Marlboro Man and the Virginia Slims woman, depicting e-cigarette use as masculine, sexy or rebellious. E-cigarette ads have appeared in magazines that reach millions of teens, including *Rolling Stone, Sports Illustrated, InStyle* and *Us Weekly.*

3. They know sex sells

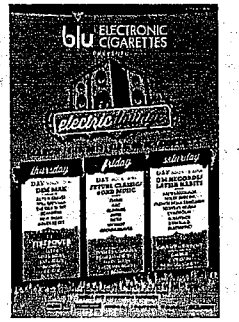
Like cigarette companies have long done, e-cigarette makers portray use of their products as sexually attractive.

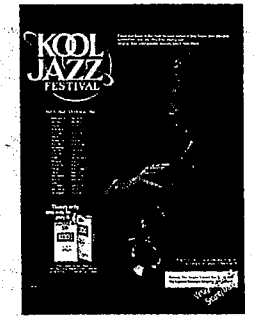
4. They sponsor sports ...



... and music festivals

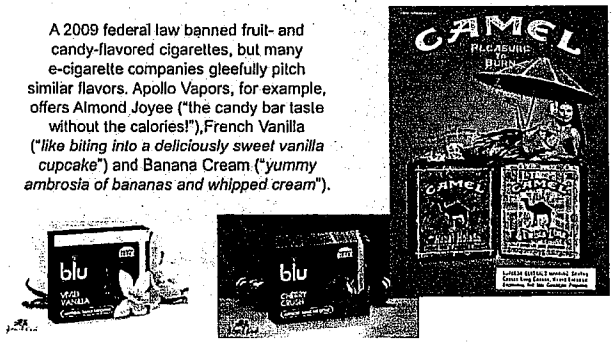
For decades tobacco companies used sponsorships of sports and entertainment events, especially auto racing and music festivals, to promote cigarettes to huge audiences, including kids. Cigarette sponsorships are now banned, but e-cigarette brands have auto racing sponsorships of their own.





5. Their products come in sweet flavors

A 2009 federal law banned fruit- and candy-flavored cigarettes, but many e-cigarette companies gleefully pitch similar flavors. Apollo Vapors, for example, offers Almond Joyee ("the candy bar taste without the calories!"),French Vanilla ("*like biting into a deliciously sweet vanilla cupcake*") and Banana Cream ("*yummy ambrosia of bananas and whipped cream*").



6. They use cartoons

The web site for Blu e-Cigs has featured a cartoon pitchman named "Mr. Cool." It was reminiscent of the Joe Camel cartoon character that so Effectively marketed cigarettes to kids in the 1990s.

7. Their ads say, "Switch, Don't Quit."

Tobacco companies have long tried to discourage smokers from quitting by marketing cigarette changes as reducing health risk. Some e-cigarette ads carry a similar message.

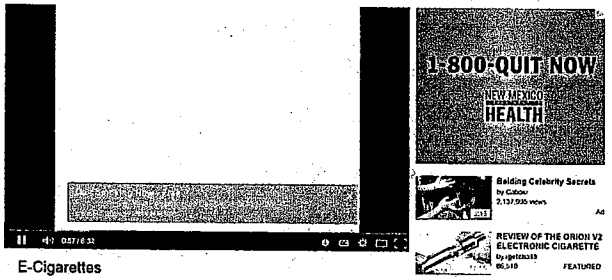
No wonder youth e-cigarette use is on the rise.

These developments underscore the need for the FDA to quickly regulate e-cigarettes and take steps to prevent their marketing and sale to kids.

CAMPAIGN for TOBACCO-FREE Kids

www.TobaccoFreeKids.org

Good job DOH!



E-Cigarettes

FDA

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

* The potential risks of e-cigarettes when used as intended
* How much nicotine or other potentially harmful chemicals are being inhaled during use, or whether there are any benefits associated with using these products

Not known whether 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

FDA regulation

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

AMERICAN LUNG ASSOCIATION.
Fighting for Air

ACP

ACPM
American College of Preventive Medicine

American Heart Association.

American Public Health Association

LEGACY
FOR LONGER HEALTHIER LIVES

NACCHO

ONS

Partnership for Prevention

SAHM
SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE

September 19, 2013

The President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

We write you today to ask for your leadership in ensuring that the Food and Drug Administration (FDA) moves forward promptly with a rule that would assert the agency's authority over all tobacco products, including e-cigarettes, little cigars, cigars and other tobacco products not currently under its jurisdiction. More than two years ago, FDA announced its intent to take this action, yet no progress has been made. This delay is having very real public health consequences.

http://action.lung.org/site/DocServer/need-fda-regulations-all-tobacco-09192013.pdf

FDA

Anticipated that the FDA will regulate e-cigarettes as tobacco products, not as tools for the treatment of tobacco dependence

Table 1. Tobacco regulatory roles by the United States Food and Drug Administration

Center for Tobacco Products:
Implementation of Family Smoking Prevention and Tobacco Control Act
Require disclosure of tobacco products
Create standards for tobacco products
Review premarket applications for new or modified risk tobacco products
Establish and enforce tobacco sales and marketing restrictions
Require strong health warnings on tobacco packaging
Center for Drug Evaluation and Research:
Regulate smoking-related products marketed for therapeutic benefit
Ensure that health benefits of therapies outweigh known risks
Ensure truth in advertising
Oversee research, development, manufacture, and marketing of drugs

FDA proposed regulations

* Prohibit the sales of tobacco products to anyone under the age of 18
* Prohibit vending machine sales (except in places where only adults have access)
* Registration by all manufactures with FDA, including a list of all tobacco products they sell
* Disclosure of ingredients by manufacturers to FDA

http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm

FDA proposed regulations

* Eliminate free sampling of all tobacco products
* Good manufacturing practice requirements
* Premarket review for any "new" tobacco product
* Premarket review of any product wishing to make a "modified risk or harm" claim
* User fees for all newly deemed products

Rules would not outlaw flavors or advertising

http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm

Regulation

* States can include e-cigarettes with all their tobacco regulation
  * Legally they are tobacco products
* Need research evaluating the efficacy and health implications of electronic cigarettes, to determine if they reduce, or reinforce smoking behaviors
* Strong recommendations from medical and health associations, including the American Lung Association and the American Thoracic Society, to regulate e-cigarettes the same as conventional cigarettes

American Heart Association

* Calls for strong regulations regarding the potential marketability of e-cigarettes to youth
* Recommends a federal ban on the sale of e-cigarettes to minors, warning that the devices could become a gateway to actual cigarettes for young people who see e-cigarettes as "high-tech, accessible, and convenient," according to a JAMA Pediatrics study of 40,000 middle and high school students
* Recommends that all existing rules and regulations in place for tobacco-related products apply to e-cigarettes

Electronic Cigarettes: A Policy Statement from the American Heart Association

(Circulation. August 24, 2014)

* Clinicians should tell their patients who use e-cigarettes to set a firm quit date, warning that any device that delivers nicotine into the body is harmful and likely lethal.
* "Nicotine is a dangerous and highly addictive chemical no matter what form it takes – conventional cigarettes or some other tobacco product," Dr. Elliott Antman, AHA president

Summary – electronic cigarettes

* Safety has not been demonstrated
* Pure nicotine-delivery devices – pose the same risk of addiction to other drugs
* Benefits have not been proven
  * Few studies have assessed role for harm reduction and cessation, with conflicting findings

Bam TS et al. Position statement on electronic cigarettes or electronic nicotine delivery systems. Int J Tuberc Lung Dis. 2014 Jan;18(1):5–7. doi.org/10.5588/ijtld.13.0815

Summary – electronic cigarettes

* Adverse health effects for third parties exposed (second-hand exposure) cannot be excluded
  * Emission of fine and ultrafine inhalable liquid particles, nicotine and cancer-causing substances
* Marketing, awareness and use growing rapidly
* Use increasing exponentially among adolescents/ young adults
  * Use of e-cigarettes does not discourage, and may encourage, conventional cigarette use

Bam TS et al. Position statement on electronic cigarettes or electronic nicotine delivery systems. Int J Tuberc Lung Dis. 2014 Jan;18(1):5–7. doi.org/10.5588/ijtld.13.0815

Sales of e-cigarettes prohibited in:
Australia, Brazil, Canada, Mexico, Panama, Singapore, and Switzerland

Nicotine references

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Additional resource

* Seminar from University of California 10/2013 available at http://www.trdrp.org/event-link.php

ATS
We help the world breathe
PULMONARY • CRITICAL CARE • SLEEP

For Immediate Release

Contact: Nathaniel Dunford
212-315-8620
ndunford@thoracic.org

Given that the electronic cigarette is intended to deliver nicotine to the user while reproducing many of the salient cues of smoking, the ATS recommends that federal, state and municipal authorities should assert jurisdiction and effectively regulate e-cigarettes. Regulation must include:

1. States should regulate e-cigarettes as tobacco products. E-cigarettes should not be sold to those younger than 18, and regulations requiring identification and proof of age at the time of purchase should apply.

2. Internet sales of e-cigarettes should be strictly regulated.

3. E-cigarettes should be taxed at rates equivalent with traditional cigarettes and other tobacco products.

4. E-cigarettes should be subject to the same restrictions regarding public use as combustible tobacco products, and e-cigarettes should not be used in smoke-free areas.

5. The FDA should deem regulatory authority over e-cigarettes.

6. Candy and menthol flavored e-cigarettes should banned.

7. E-cigarette packaging should include warning labels, similar in size and scope to those required of combustible tobacco packaging. Where risks are known, the consumer should be informed of those risks in clear and direct language. Where data regarding risk is unavailable or inconclusive, the consumer should be informed of the lack of reliable safety testing data.

8. The FDA should regulate the form and content of e-cigarette advertising.

9. Both direct and implied health and safety claims by e-cigarette manufacturers should be subject to the same evidentiary review process currently required for other products making such claims.

10. The FDA should require e-cigarette manufacturers to adopt Good Manufacturing Processes similar to those that exist for other regulated products, including lot numbers, securing packaging, etc

11. Given that nicotine is an addictive drug, with the dependence liability related to the pharmacokinetic characteristics of the delivery device, delivery characteristics of the e-cigarette should be evaluated and disclosed, and periodically monitored to ensure consistency of the product's dependence potential over time.

12. Content of e-cigarette cartridges should be disclosed and regulated.

13. The nicotine content of the e-cigarette cartridge should not exceed that of a similar user volume of combustible tobacco.

14. Deliverable nicotine levels should be consistent between cartridges.

15. Researchers and clinicians, along with scientific societies and publications, receiving funding from e-cigarette manufacturers should disclose this relationship and the potential for conflict of interest in a manner equivalent to disclosures required for funding from the remainder of the tobacco industry.

The American Heart Association

1. Supports the inclusion of e-cigarettes in smoke-free air laws.

2. Supports the inclusion of e-cigarettes in state and federal laws and regulations that prohibit the sale of e-cigarettes to minors.

3. Supports the inclusion of e-cigarettes in laws that restrict the marketing and advertising of e-cigarettes to minors.

4. Supports effective FDA regulation of e-cigarettes that addresses marketing, youth access, labeling, quality control over manufacturing, free sampling, and standards for contaminants.The regulation should allow for quality-controlled products for adults who want to transition from conventional cigarettes to e-cigarettes or to quit or reduce smoking. Bottles containing nicotine refill liquids can be toxic if swallowed, so cartridges and bottles should have proper warning labeling and child-proof packaging. It is important that the relevant government agency monitor whether these devices are used for delivery of other drugs and medications. Companies should not be able to claim that e-cigarettes are a cessation aid unless they are approved by the FDA for that purpose.

5. Supports including e-cigarettes in the definition of tobacco products (or tobacco-derived products) and smoking, not by creating a separate definition for e-cigarettes, because a separate definition can create a risk of e-cigarettes being exempted from other tobacco control laws, including smokefree laws. E-cigarettes defined as tobacco products could still be treated differently within taxation legislation and regulation.