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#### Today's cigarette and e-cigarette landscape

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#### Today's cigarette and e-cigarette landscape

Richard C. Wender, MD
Professor of Family and Community Medicine
Thomas Jefferson University



E-cigarettes are one of the most difficult and complex public health issues most of us have confronted.

Most anti-tobacco experts and advocates line up on a spectrum from embracing e-cigarettes as a promising way to reduce the harm of tobacco products all the way to being the greatest threat to progress in our 60 year war on big tobacco.

#### What Do You Believe?

- E-cigarettes are a gateway to smoking.
- After years of decline, smoking rates are going up in teens.
- E-cigarettes are a little less harmful than smoking.
- Many middle and high schoolers think e-cigarettes are completely safe.
- E-cigarettes cause some cases of acute lung injury resulting in deaths in some cases
- E-cigarettes help some people completely quit smoking.

#### What Do You Believe?

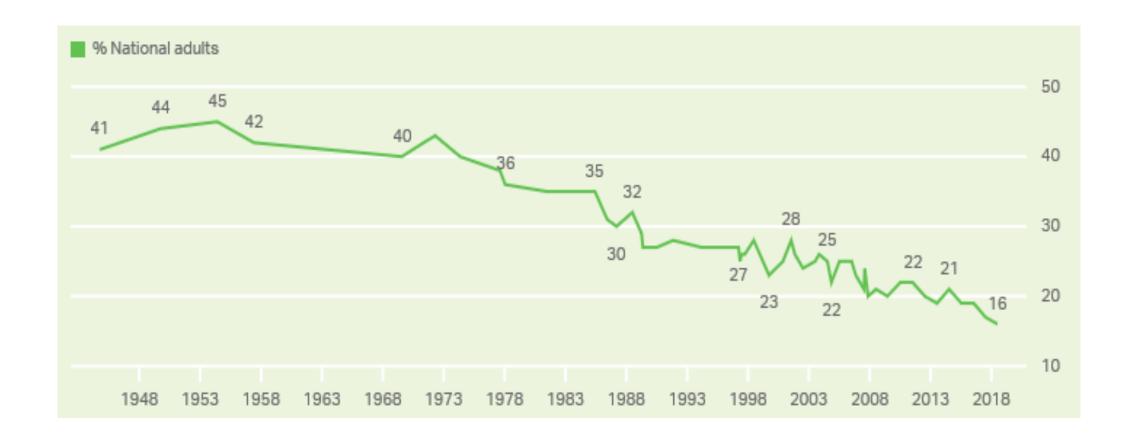
- Banning flavors in e-cigarettes is a very smart policy.
- Raising the legal purchase age to 21 is opposed by all tobacco product companies.
- Sale of e-cigarettes and vaps should be banned.
- IQOS is going to become an increasing issue.

#### The tobacco product landscape today.

## Cigarette smoking is at an all-time low.



#### **Smoking among US adults**



# Cigarette and e-Cigarette use are closely linked to/correlated with social determinants of health

#### **Smoking and Education**

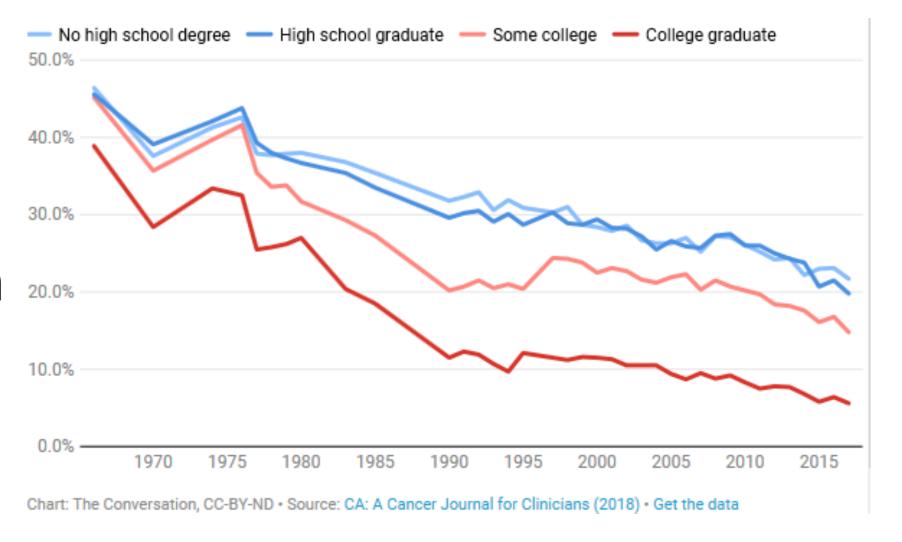
40.6%

of US adults with a GED smoke

4.5%

of US adults with a graduate degree smoke

# Smoking Rates by Education Level



## Tobacco use remains the leading cause of preventable death in US

- About half of all Americans who keep smoking will die because of the habit.
- In 2018, 16% of US adults were current smokers, compared to 42.4% in 1965.

#### **Cigarettes and Death**

- More than 480,000 people will die from smoking related problems in the US every year
  - 278,544 deaths in men
  - 201,773 deaths in women
- 46,802 opiod-related deaths in US in 2018

Source: cdc.gov

#### **Smoking and Poverty**

25.3%

of US adults
living below the
poverty level smoke

14.3%

of US adults living at or above the poverty level smoke

Cigarette smoking is down, but about

#### 34 MILLION

American adults still smoke

#### Cigarette smoking remains high among certain groups







Adults 25-64 years old



Lower education



Below poverty level



Midwest and South









Serious psychological distress



American Indians, Alaska Natives and Multiracial



Lesbians, gays, and bisexuals

#### Strategies essential to continue reducing cigarette smoking overall





Run mass media campaigns



Raise tobacco prices



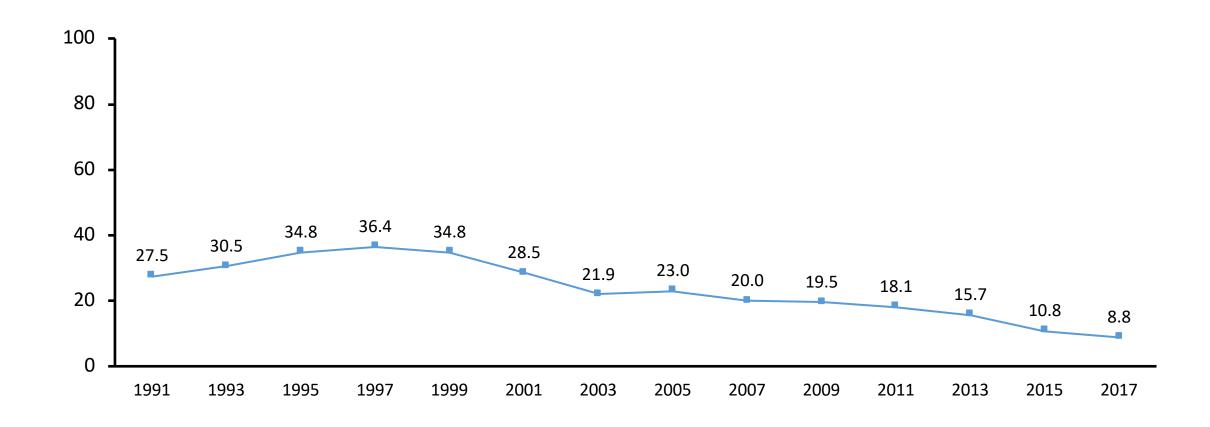
Make quit help easy to access



## Teen cigarette smoking is at an all-time low.

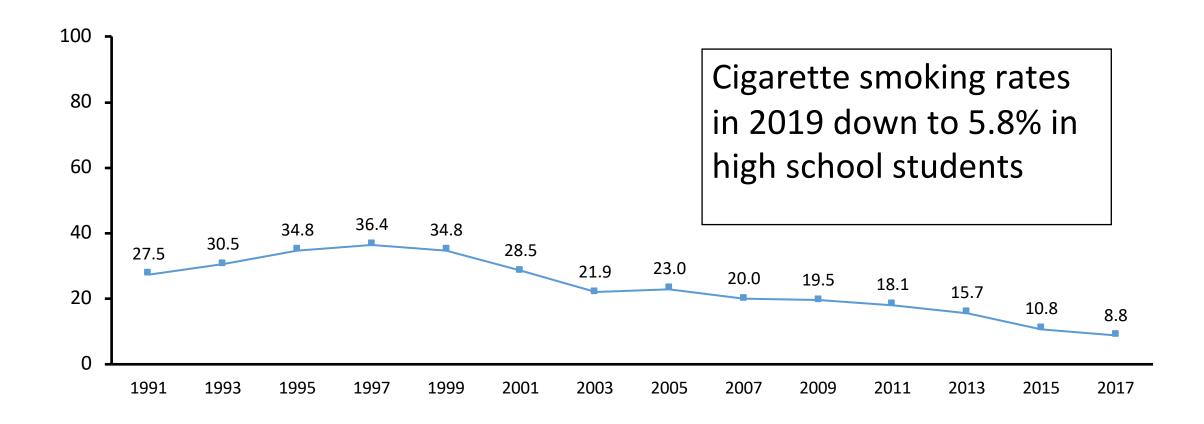


#### Smoking among high schoolers





#### Smoking among high schoolers



## But there are new threats in our battle against tobacco

#### What are E-cigarettes?

- An electronic cigarette is an electronic device that simulates tobacco smoking. It consists of an atomizer, a power source such as a battery, and a container such as a cartridge, tank, or pod. Instead of cigarette smoke, the user inhales vapor, so using an e-cigarette is called "vaping"
- Virtually all e-cigarettes are flavored. Even "tobacco flavor" is a flavoring.

## Why are E-cigs Classified as Tobacco Products?

 The nicotine in eliquid is the same as that used in pharmaceutical NRT. It is extracted from a member of the tobacco family but not the same plant as used for smoking tobacco as that has much less nicotine in the leaves than the rustica type of tobacco plant. Rustica has much more nicotine in each leaf so is not suitable for smoking unless you have a high tolerance.

#### Classifying E-Cigarettes, or Vaping, Products

#### How to Classify the User's E-Cigarette, or Vaping, Product

For an accessible explanation of schematic below on how to classify e-digarettes, go to <u>Appendix</u>, page 25.

#### Important notes:

- 1. E-liquids can contain nicotine, THC, CBD, flavors, or other solvents.
- Marijuana herb, hash oil, dab wax are used with vaporizers.

#### QUESTION 1:

Is the e-liquid contained in a disposable e-cigarette, cartridge, tank, or pod? Disposable e-cigarette (no cartridge, tank or pod)







Cartridge (Prefilled or refillable) QUESTION 2: Is the cartridge

also called a pod cartridge or contains nicotine salts?

YES

,

NO

2nd GENERATION

(Battery Pen)





Tank/ Sub-Ohm (Refillable) 3rd GENERATION

(Modifiable-allows variable voltage/watts)





Pod (Prefilled or refillable) 4th
GENERATION
(Pod Mod)







Vaporizer, Dab rig, Dab pen



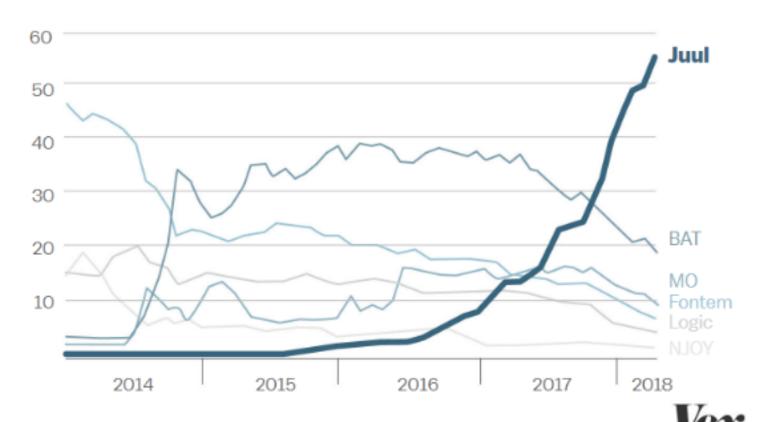




Source: Gentzke AS, Creamer M, Cullen KA, et al. Vital signs: Tobacco product use among middle and high school students - United States, 2011-2018. MMWR Morb Mortal Wkly Rep. 2019 Feb;68(6):157-64. PMID: 30763302

#### **Juul Sales are Booming**

Dollar share percentage of the e-cigarette traditional retail market, as of March 2018



Source: Nielsen Total US xAOC/Convenience Database and Wells Fargo Securities, LLC



## Adolescents' and Young Adults' Use and Perceptions of Pod-Based Electronic Cigarettes

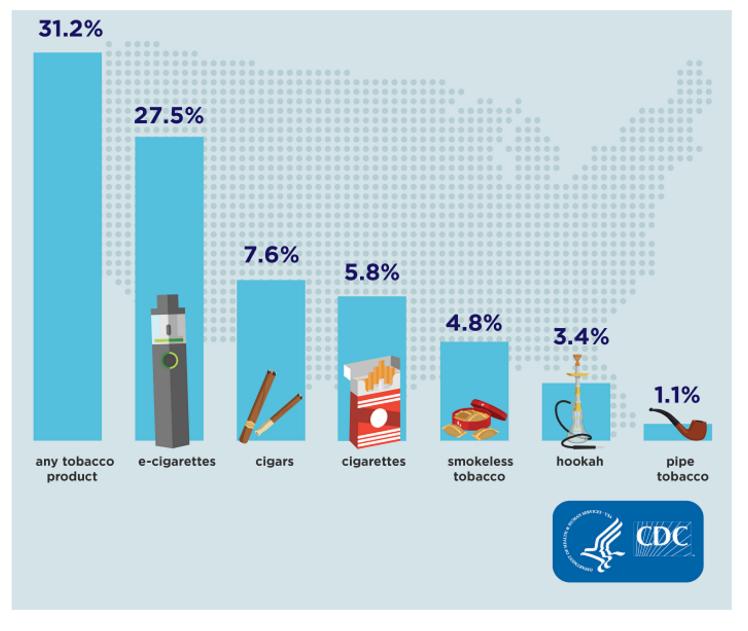
This survey study of 445 adolescents and young adults revealed similar chances (40%) of experiencing negative health and social consequences from using pod-based and/or other types of e-cigarettes.

Among 34 adolescents and young adults reporting any loss of autonomy from nicotine, there was no difference in mean Hooked On Nicotine Checklist scores between those using pod-based and other e-cigarettes

#### **Use the Right Language**

- Ask every middle school and high school age patient about vaping exposure and use.
- Language varies
  - Vaping more common language than e-cig
  - "Juuling" was used as a generic term for all vaping but is varying to some extent now.

# Tobacco Product Use Among High School Students



### Vaping Threatens Progress on Tobacco, Nicotine

Daily cigarette smoking		Daily nicotine vaping
8 <sup>th</sup>	0.8%	1.9%
<b>10</b> <sup>th</sup>	1.3%	6.9%
12 <sup>th</sup>	2.4%	11.7%

Significant 5-year declines in cigarette smoking (lifetime use)

	2014	2019	% decline
8 <sup>th</sup>	13.5%	10.0%	26%
<b>10</b> <sup>th</sup>	22.6%	14.2%	37%
<b>12</b> <sup>th</sup>	34.4%	22.3%	35%



#### Harms of E-cigs and Vapes

- Growing consensus that use by adults of currentgeneration ENDS is likely to be less harmful than smoking conventional cigarettes or other combusted tobacco products.
- Currently, ENDS contain and produce substantially lower levels of toxicants than combustible tobacco products.
- They are likely to have physical risks.
- Potential as a pathway to combustible use.

#### **Estimating the Harms of ENDS**

 Estimating the population health impact of recently introduced modified risk tobacco products: a comparison of different approaches

Peter N Lee, MA, David Abrams, PhD, Annette Bachand, PhD et.al. Nicotine & Tobacco Research

https://doi.org/10.1093/ntr/ntaa102

#### **Results of Models**

 Despite methodological differences, most modelers have assumed that the increase in risk of mortality from MRTP use, relative to that from cigarette smoking, is very low and have concluded that MRTP introduction is likely to have a beneficial impact.

## But Individual Studies Suggest That Risks May Be Substantial

- Cardiovascular disease may be the greatest risk but far from certain.
- Pulmonary disease is possible.
- A few studies suggest that vapor may include some carcinogens but cancer risk likely to be substantially lower than smoking.

Original Investigation | Substance Use and Addiction

## Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths

Kaitlyn M. Berry, MPH; Jessica L. Fetterman, PhD; Emelia J. Benjamin, MD, ScM; Aruni Bhatnagar, PhD; Jessica L. Barrington-Trimis, PhD; Adam M. Leventhal, PhD; Andrew Stokes, PhD

#### Abstract

**IMPORTANCE** The use of electronic cigarettes (e-cigarettes) and other noncigarette tobacco products may increase the odds of cigarette initiation, even among low-risk youths.

**OBJECTIVE** To evaluate the associations of prior e-cigarette use and other tobacco product use with subsequent cigarette initiation within 2 years of follow-up.

**DESIGN, SETTING, AND PARTICIPANTS** In this prospective cohort study, data from waves 1 through 3 of the Population Assessment of Tobacco and Health Study (2013-2016) were used to assess youths aged 12 to 15 years who had never used cigarettes, e-cigarettes, or other tobacco

products at ways 1. This was a nationally consecontative study of the UE population. Data analysis was

#### **Key Points**

Question Is electronic cigarette (e-cigarette) use among tobacco-naive youths associated with subsequent risk of cigarette initiation?

Findings In this cohort study using data from the Population Assessment of Tobacco and Health Study (2013-2016), youths whose first tobacco product was an e-cigarette were more likely to

initiate cigarettes over 2 years of

#### E-Cigarettes as a Gateway to Smoking

- Cigarette smoking was much higher, 20.5%, in prior ecigarette users vs. adolescents without prior tobacco product use, 3.8%.
- E-cigarette users were 4 times as likely to try smoking and 3 times more likely to become a regular smoker than non-users.
- The association with prior e-cigarette use and smoking initiation was higher for low-risk youth than high-risk.
   This is a pattern not previously seen.



# Taking on the e-cigarette Epidemic



"We're beyond speculating that this could all be very experimental use by kids. The data is in, and it's showing that between 800,000 and 900,000 kids who use these e-cigarette products are using them regularly -- 20 days out of a 30-day month," Henigan said. "That's not experimental. That suggests mass addiction."

https://www.webmd.com/smoking-cessation/news/20190131/what-works-to-help-teens-quit-vaping#1

## Summary of E-cig/Vaping Recommendations for Youth

- E-cigarettes are not safe.
- Most contain nicotine and are addictive.
- The best strategy is to not use any type of vap or ecigarette.
- If you're vaping now, give serious thought to quitting.
- If you want to quit, help is available.
- Smoking is even more dangerous than vaping. Don't smoke and vap and don't substitute smoking for vaping.

#### ARE E-CIGARETTES LESS HARMFUL THAN REGULAR CIGARETTES?

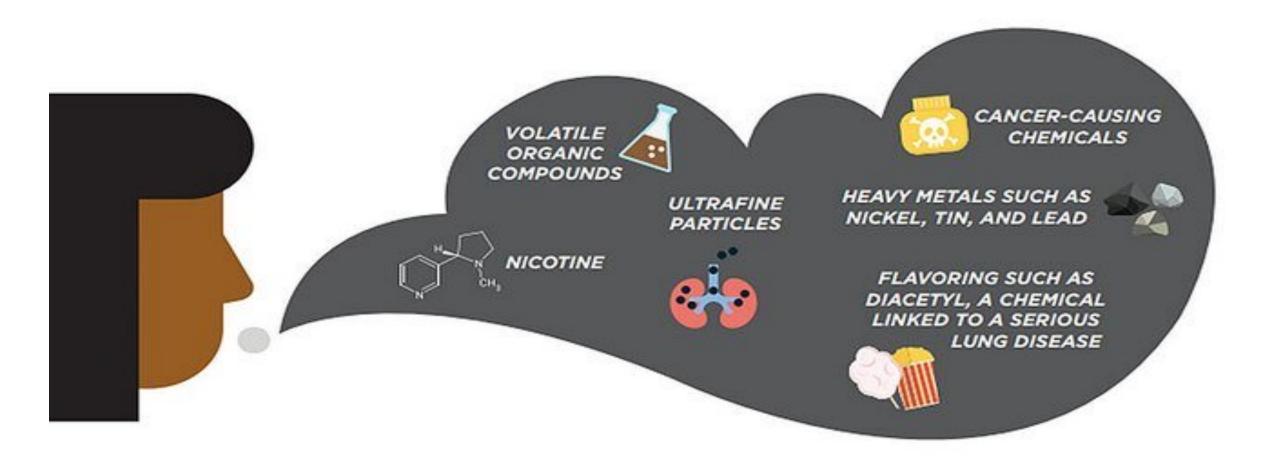


YES, but that doesn't mean e-cigarettes are safe.

E-cigarette aerosol generally contains fewer toxic chemicals than the deadly mix of 7,000 chemicals in smoke from regular cigarettes. However, e-cigarette aerosol is not harmless. It can contain harmful and potentially harmful substances, including nicotine, heavy metals like lead, volatile organic compounds, and cancer-causing agents.

#### WHAT IS IN E-CIGARETTE AEROSOL?

THE E-CIGARETTE AEROSOL THAT USERS BREATHE FROM THE DEVICE AND EXHALE CAN CONTAIN HARMFUL AND POTENTIALLY HARMFUL SUBSTANCES:



### **How to Quit Vaping**



### First Day Without Vaping

- 1. Do not vape
- 2. Stay busy
- 3. Avoid vaping triggers
- 4. Ask for help
- 5. Reward yourself

### **Deal with Vape Cravings**

- Do something else. When a craving hits, stop what you're doing and do something different. Sometimes, just changing your routine helps you shake off a craving.
- **Get active.** Take a quick walk or go up and down the stairs a few times. Physical activity, even in short bursts, can help boost your energy and beat a craving.
- Stop and breathe. Breathe in slowly through your nose and breathe out slowly through your mouth. Repeat this 10 times to help you relax until the craving passes.
- Text with or talk to someone. Supportive people in your life can help you stay strong in moments when the urges are tough to handle.
- Play a game on your phone. Keep your phone handy! Games can be a good distraction when you're having a craving.
- Call or chat with an expert.

#### Other CDC Modules

- 3. Dealing with vaping triggers
- 4. Vaping addiction and nicotine withdrawal
- 5. Anxiety, stress, and vaping
- 6. Depression and vaping

#### Can Adolescents Use NRT

- Not FDA approved
- Mixed efficacy in studies
- No evidence of serious harm
- AAP recommends consideration of off label use of NRT

#### **Reducing E-cigarette Use**

- Empower (or force) FDA to exercise its full authority.
  - Reduce nicotine content in all tobacco products.
  - Demand testing of new products and validation of modified risk claims.
  - Encourage testing and approval of new cessation aids.
- Raise the price of legal purchase to 21.
- Ban all added flavors, including menthol.
- Find messages that works with parents and kids.



#### **E-cigarettes in Adult Smokers**

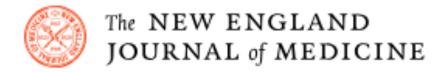
- Do e-cigarettes help smokers completely quit smoking?
- Are e-cigarettes a useful pathway to end all tobacco use, including e-cigs?
- Is it possible to support use of e-cig use in adult smokers while discouraging use in all teens?
- What will happen as we ban flavors?

Harm reduction has been shown to be effective for numerous risky adolescent and adult behaviors and is fully embraced for opiod addiction.

More people die from nicotine addiction each year than from opiod addiction.

# Why Won't We Embrace Harm Reduction in Tobacco Use?

- Lack of trust. The tobacco industry has made huge investments in Electronic Nicotine Delivery Systems, (ENDS)
- Altria owns more than 50% of Juul
- Phillip Morris has made a huge investment in IQOS
  - heat not burn tobacco



#### A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy

Peter Hajek, Ph.D., Anna Phillips-Waller, B.Sc., Dunja Przulj, Ph.D., Francesca Pesola, Ph.D., Katie Myers Smith, D.Psych., Natalie Bisal, M.Sc., Jinshuo Li, M.Phil., Steve Parrott, M.Sc., Peter Sasieni, Ph.D., Lynne Dawkins, Ph.D., Louise Ross, Maciej Goniewicz, Ph.D., Pharm.D., et al.

Article Figures/Media Metrics

January 30, 2019

DOI: 10.1056/NEJMoa1808779

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#### Abstract

**BACKGROUND** E-cigarettes are commonly used in attempts to stop smoking, but evidence is limited regarding their effectiveness as compared with that of nicotine products approved as smoking-cessation treatments.

METHODS We randomly assigned adults attending U.K. National Health Service stop-smoking services

### E-cigarettes Are the Preferred Quitting Aid for Adults – and May Be More Effective Than Approved NRT

- Hajek et. al. randomly assigned 886 smokers to either 3 months of NRT or an e-cigarette vape products.
- The e-cig group was then instructed to use the e-cig strength and flavor of their choice
- At 1 year, 18.0% were abstinent in the e-cig group vs.
   9.9% in the NRT group



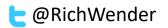
### Banning Flavors – Effect on Adult Smokers

- There are NO flavors that appeal to adults but not kids. Teens and adults like the same flavors
- This includes menthol and mint (which are derived from identical sources).
- Allowing "tobacco" flavor unlikely to do much to protect kids
  - There is no one tobacco flavor! Companies will find a way to make tobacco flavor appealing to youth

### Dangers of Menthol Cigarettes

- Menthol makes cigarettes easier to smoke and harder to quit.
  - Creates a cooling effect
  - Reduces the harshness of cigarette smoke
  - Suppresses coughing





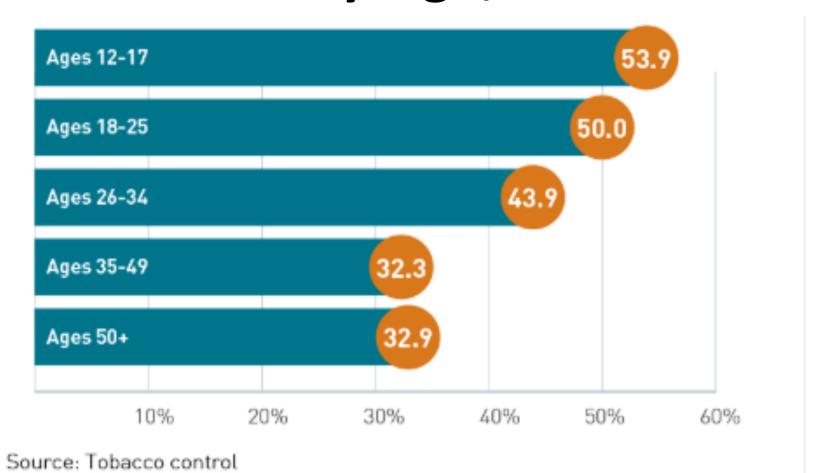
#### Menthol Cigarettes and Youth

- Research shows menthol cigarettes are more likely to addict youth.
- Initiation with menthol cigarettes facilitates progression to established cigarette use among young smokers.
- The youngest smokers use menthol cigarettes at the highest rates.

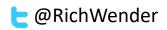




## Menthol Cigarette Use Among Current Smokers in the US by Age, 2012-2014







#### Menthol Cigarettes and Minority Groups

- Nearly 9 in 10 African-American smokers aged 12 and older use menthol cigarettes.
- From 2008 to 2010, 94.9 percent of African-American youth smokers used menthol cigarettes.
  - Compared to 51.3% of white youth smokers.
- Tobacco industry has a history of marketing menthol brands to African Americans.





### **Ban on Menthol Cigarettes?**

- Only 1.71% of the US is covered by a menthol cigarette ban.
- If menthol cigarettes were banned:
  - 38.9% of all menthol smokers would try to quit.
  - 44.5% of African American menthol smokers would try to quit.
- If a menthol cigarette ban had gone into effect in 2011, an estimated 320,000 smoking-attributable deaths would be averted by 2050, almost a third of them among African Americans.





## IQOS – A New Addition to the Tobacco Landscape

- IQOS is a Phillip Morris product that heats tobacco.
- The user inhales the vapor coming from the device.
- Already in use in Europe.









## Phillip Morris will Attempt to Get FDA Approval as a Modified Risk Product

- Phillip Morris' own data show that IQOS significantly reduces emissions and exposure to several harmful and potentially harmful constituents compared with combustible cigarettes.
- However PM's data also show that IQOS emissions contain higher levels of many other substances compared to combustible cigarettes.
- The impact of these substances on IQOS toxicity and harm are not known.



#### IQOS and Risk to Health

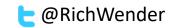
- Great concern about the health risks of IQOS but we know frighteningly little today.
- Strongly suspected that IQOS is substantially more harmful than e-cigs.
- The health risks are likely to be different than smoking cigarettes – unknown if net health effects will be the same or less.



The US launch of IQOS occurred at the Lenox Square Mall ...







in Atlanta, Ga., ...







... home of the American Cancer Society and the CDC.









#### Anyone think this is a coincidence??





#### Discourage Use of IQOS!

- As if Juul were not enough of a challenge, now we have to cope with IQOS.
- Discourage use!
- If a smoker wants to try an electronic nicotine device instead of smoking, direct them to a traditional cannister like vape product with options to decrease nicotine content over time.



# Lung Injury Associated with Vaping or E-cigarette Use



### **EVALI** Cases Have Sharply Declined

<u>"Emergency department (ED) visits related to e-cigarette, or vaping, products</u> continue to decline, after sharply increasing in August 2019 and peaking in September 2019"

### From CDC Final Report on EVALI

"Vitamin E acetate is strongly linked to the EVALI outbreak. Vitamin E acetate has been found in product samples tested by FDA and state laboratories and in patient lung fluid samples tested by CDC from geographically diverse states. Vitamin E acetate has not been found in the lung fluid of people that do not have EVALI."

# We Believe We've Found the Cause of EVALI

- Since removal of Vitamin E acetate from vaping pods of any kind, EVALI has largely disappeared.
- The emergence of EVALI was used by anti-ecigarette advocates to suggest that e-cigs might be the cause of acute lung injury.
- They're not

