

Report from the U.S.A. - 2018

NASEM Report and the JUUL Phenomenon

“Invasion” of the Pod-Mods?

Nancy Rigotti, MD

Director, Tobacco Research and Treatment Center

Massachusetts General Hospital

Professor of Medicine, Harvard Medical School, Boston, MA USA



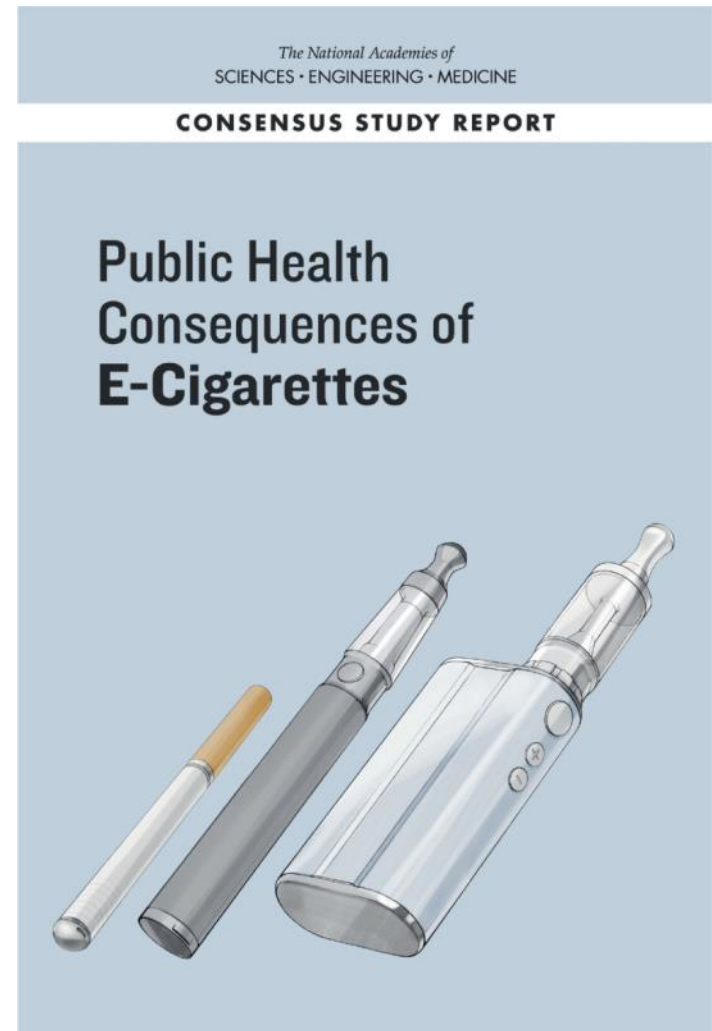
U.S. National Academies of Sciences, Engineering and Medicine (NASEM) Report

Released January 23, 2018

nationalacademies.org/eCigHealthEffects

#eCigHealthEffects

The National
Academies of
SCIENCES
ENGINEERING
MEDICINE



NASEM Report - Background

U.S. Congress → FDA Center for Tobacco Products → National Academies of Sciences, Engineering, and Medicine (NASEM) → Convene a committee

Statement of Task:

- Evaluate available evidence of the health effects related to the use of e-cigarettes*
- Identify future federally funded research needs

*Excluding heat not burn products



Committee Members

- David L. Eaton (Chair)
- Anthony J. Alberg
- Maciej Goniewicz
- Adam Leventhal
- José E. Manautou
- Sharon McGrath-Morrow
- David Mendez
- Richard Miech
- Ana Navas-Acien
- Kent E. Pinkerton
- Nancy A. Rigotti
- David A. Savitz
- Gideon St.Helen



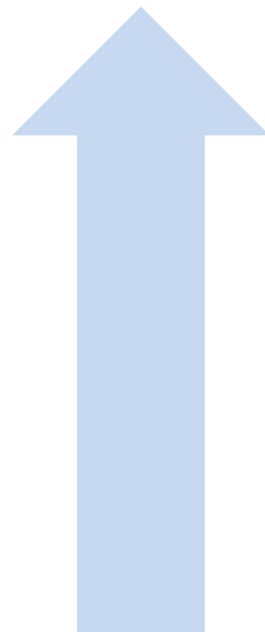
Methods

- **Literature Search**
 - February 1, 2017 - August 31, 2017
 - >800 studies reviewed
- **Approach to Assessing Causality**
 - Evidence Synthesis (“Hill criteria”)
- **Conclusions based on level of evidence**
 - Consensus of members required



Levels of Evidence Framework

- Conclusive
- Substantial
- Moderate
- Limited
- Insufficient
- No available
(\neq evidence of no effect)



Report Organization

Section I: E-Cigarette Devices, Constituents, and Exposures

Section II: Effects of E-Cigarettes on Health

Section III: Public Health Implications of E-Cigarettes



Public Health Effects of E-cigarettes

- The net public health effect of e-cigarettes will depend on the balance of 3 factors:
 - Potential to help current smokers to quit
 - Potential to increase the uptake of combustible tobacco product use
 - Inherent toxicity
 - Absolute (vs. nonsmoking) - youth
 - Relative to combustible tobacco - adult smokers



Overall Report Summary

- While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.
- E-cigarettes contain fewer numbers and lower levels of toxic substances than conventional cigarettes.
- The long-term health effects of e-cigarettes are not yet clear.



Overall Report Summary

- Using e-cigarettes may help adults who smoke combustible tobacco cigarettes quit smoking, but more research is needed.
- Among youth, e-cigarette use increases the risk of initiating smoking of combustible tobacco cigarettes.
- Modelling results indicate that, under likely scenarios, the use of e-cigarettes in the population will result in a net public health benefit.



Implications for Health Care Providers

- Patients are asking their doctors about e-cigs
- Physicians seek guidance but data do not provide a definitive answer - *not so unusual in medicine*
- Professional organizations could provide guidance but most have been slow to do so
 - Little evidence on key questions
 - “First do no harm” (*precautionary principle*)
 - Finding consensus may be challenging



How should you advise a smoker?

(Rigotti, *Ann Intern Med.* 2018)

- They are less harmful than continuing to smoke cigarettes
- Many questions remain about e-cigarettes' safety and effectiveness for quitting. They are not FDA approved.
- Recommend using approved treatments first
- *Recommend vs. do not discourage* use if a smoker insists and has failed other methods
 - If using, switch completely to e-cigarettes (avoid dual use)
 - Encourage a plan to stop e-cigarettes at some point in the future



Position Statement on Electronic Cigarettes

American Cancer Society – Feb. 2018

- Advise patients to use FDA-approved cessation aids.
- Support patients to quit combustibles (and eventually e-cigs)
- If a patient is not willing to quit “despite firm clinical advice,” encourage switch to “least harmful form of tobacco product,” including exclusive use of e-cigs.
- Strongly discourage dual use of e-cigs and combustible tobacco products



Expert Consensus Decision Pathway on Tobacco Cessation

— *American College of Cardiology* – Nov. 2018

- Emphasize the goal of complete cessation of all combustible tobacco products. Even a single cigarette per day increases cardiovascular risk.
- Recommend evidence-based, FDA-approved smoking cessation aids, which are known to be safe and effective.
- Be prepared to discuss the evidence about e-cigarettes' risks and benefits with patients who ask.
- If the smoker chooses to use e-cigarettes, provide evidence-based advice (avoid dual use, aim to quit e-cigs too)



“Invasion” of the Pod Mods?

MAY 14, 2018 ISSUE

THE PROMISE OF VAPING AND THE RISE OF JUUL

Teens have taken a technology that was supposed to help grownups stop smoking and invented a new kind of bad habit, molded in their own image.



Public Safety

Juuling: If you don't know what it is, ask your kids

‘I Can't Stop’: Schools Struggle With Vaping Explosion

1 MEDICINE

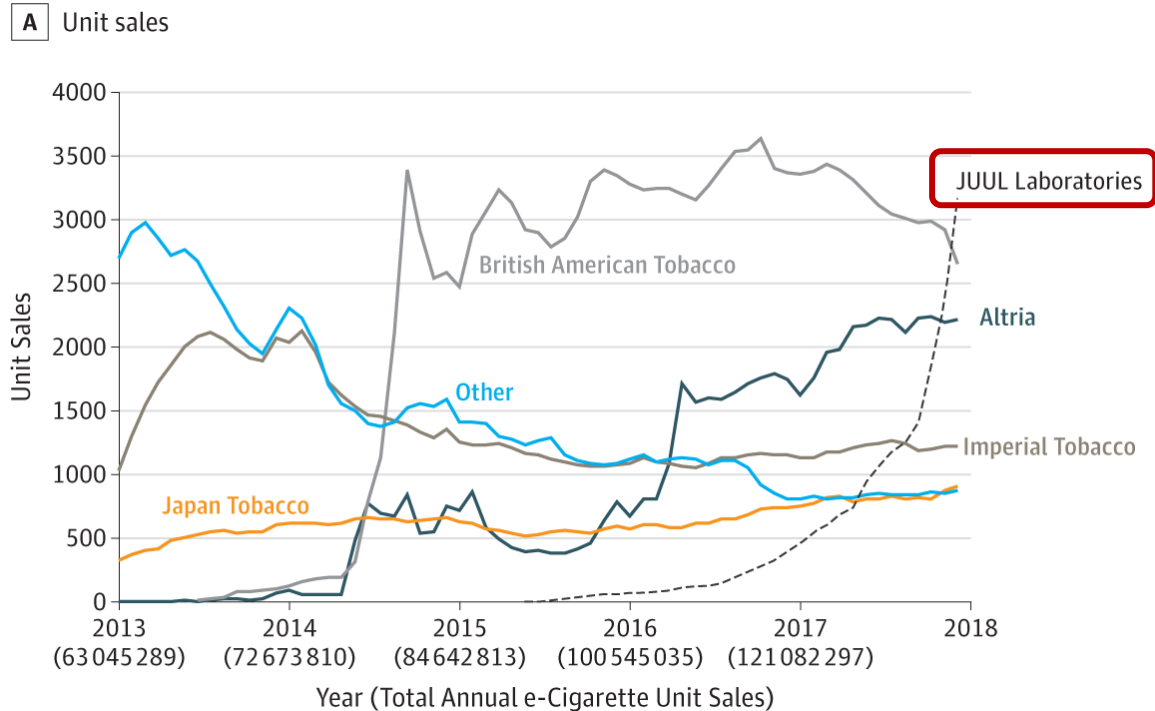
Did Juul Lure Teenagers and Get ‘Customers for Life’?

The JUUL Phenomenon

- Sleek high-tech design
- Better nicotine delivery
- Social media marketing



JUUL - now the U.S. market leader



Source: King B et al. JAMA 2018; 320:1379.



FDA Response - September 12, 2018

“The FDA now believes that youth use of e-cigarettes is reaching epidemic proportions.”

- Sales trends
- News coverage
- “Increased concerns among kids, parents and educators”
- Illegal sales to minors
 - >1300 retailers sold JUUL to minors in a “nationwide undercover blitz”
- “Preliminary data that will be finalized and released in coming months.”
2018 National Youth Tobacco Survey shows ~75% increase in e-cig use among high school students

FDA Actions - September 12, 2018

- Warn, fine >1300 retailers who sold JUUL to minors
 - 5 products were most often sold (have 97% of market)
 - JUUL
 - Vuse, MarkTen XL, blu, Logic (tobacco industry owned)
- Manufacturers of these 5 products have 60 days to show plans “describing how they will address the widespread youth use of their products.”

FDA Actions - September 12, 2018

■ OR What?

- FDA may reconsider its policy to allow these products on the market without FDA approval until 2022.
- “This could mean requiring these brands to remove some or all of their flavored products that may be contributing to the rise in youth use from the market until they...meet obligations under the law.”

Subsequent FDA Actions

- Seized documents from JUUL headquarters in SF
- Investigating reports that some e-cigarette manufacturers have introduced new products since 8/8/16 illegally
 - JUUL copycats made by others
- Expanded FDA's "Real Cost" public education campaign to increase messages focused on preventing youth use of e-cigs

FDA Actions - Summary

- **Supply reduction**
 - Stop sales to minors
 - Threaten to take some products off market
- **Demand reduction**
 - Make products less attractive
 - Educate public about risk

Expected FDA Actions - November 2018

- Ban sales of flavored e-cigarettes in retail stores and gas stations
 - Except tobacco, mint, and menthol flavors
- Require age-verification for online sales
- “An unfortunate trade-off” – *Scott Gottlieb*
 - “In order to close the on-ramp to e-cigarettes to kids, we have to put in place some speed bumps for adults.”

JUUL Response - November 2018

*Juul Will Stop Selling Most
E-Cigarette Flavors in Stores and
Halt Social Media Promotions*

NYTimes, 11/13/18

- Ban flavored e-cigarette sales in retail stores and gas stations (except tobacco, mint, and menthol flavors)
 - Might restart at retail stores with age-verification technology
- Discontinue social media promotions
- Require age-verification for online sales

Possible future FDA Actions

- Restrict marketing of JUUL copy-cats
- Re-start the effort to remove menthol in cigarettes
- Raise minimum age for buying tobacco products to 21 years?

Some critical questions

- What is the change in youth use of e-cigs (and cigarettes) 2017→ 2018?
 - National Youth Tobacco Survey
 - Monitoring the Future Survey (Dec 2018)
- If youth e-cigarette use (especially frequent use) rises
 - Models predict that long term net benefits of e-cigs will decline
 - Regulatory efforts to keep products from youths and young adults are warranted
 - How can regulation be done without losing the potential benefits of e-cigs to reduce combustible tobacco use among adults?

Some critical questions

- Natural history of the “cohort” of never smoking JUUL users
 - How many switch to combustible cigarettes?
 - Why would they switch to a “less desirable” product?
 - If few switch, how long will e-cig/JUUL use last?
 - If most users continue for many years, how harmful is that?
Is a higher prevalence of nicotine dependence worth helping current smokers to quit?
 - How many will many stop on their own?
 - How many will they need help to quit e-cigarettes?

Let's not forget cessation

- Are JUULs effective smoking cessation tools?
- They might be the best e-cigarette to promote cessation among current cigarette smokers.
 - How important are flavors to their appeal and success?
 - How can we (in the US) test their efficacy for cessation given FDA constraints?

Stay tuned....