


# The Role of Government, Public Health, Industry, and Academia in Combatting Youth Vaping

**David Abrams**, Professor of Social and Behavioral Sciences, New York University College of Global Public Health

**James Baumberger**, Senior Director, Federal Advocacy, American Academy of Pediatrics

**Parker David Kasmer**, Regulatory Counsel, JUUL Labs

*Moderated by J. Benneville (Ben) Haas*, Partner, Latham & Watkins LLP



# The Role of Government, Public Health, Industry, and Academia in Combatting Youth Vaping

*Moderated by J. Benneville (Ben) Haas, Partner, Latham & Watkins LLP*

# FDA's Statutory Toolkit for Combatting Youth Vaping

## Section 906(d)

- Regulations governing sale and distribution; advertising and promotion
  - “appropriate for the protection of the public health”
  - Advertising restrictions “consistent with and to the full extent permitted by the First Amendment”
- Remote sales (March 2011 ANPRM)

## Section 907

- Tobacco product standard requiring the reduction or elimination of constituents/ingredients (e.g., flavors)
  - Must account for technical achievability
  - Must account for potential contraband
- Lengthy process (notice-and-comment rulemaking; at least 1 year delayed effective date)
- March 2018 ANPRM re: regulations of flavors in tobacco products

## Section 911

- Prohibition on “modified risk” claims

# FDA's Statutory Toolkit for Combatting Youth Vaping

## Section 905(j) and 910 Premarket Review

- Significance of February 15, 2007 and August 8, 2016 dates
- “Ban” or change in enforcement priorities? What does that mean?
- PMTA
  - PMTA Order may impose sale and distribution restrictions “only to the extent” permitted under 906(d)
  - FDA wants PMTAs to propose specific restrictions on sale and distribution in order make the APPH showing necessary for approval
  - IQOS Order placed “stringent restrictions” on marketing, particularly on the internet/social media
    - Lengthy memo issued in connection with approval provides roadmap for future applicants
    - Significant recordkeeping and reporting obligations



# The Role of Government, Public Health, Industry, and Academia in Combating Youth Vaping

## The Science

David B. Abrams, PhD  
New York University College of Global Public Health

Email: [da94@nyu.edu](mailto:da94@nyu.edu)





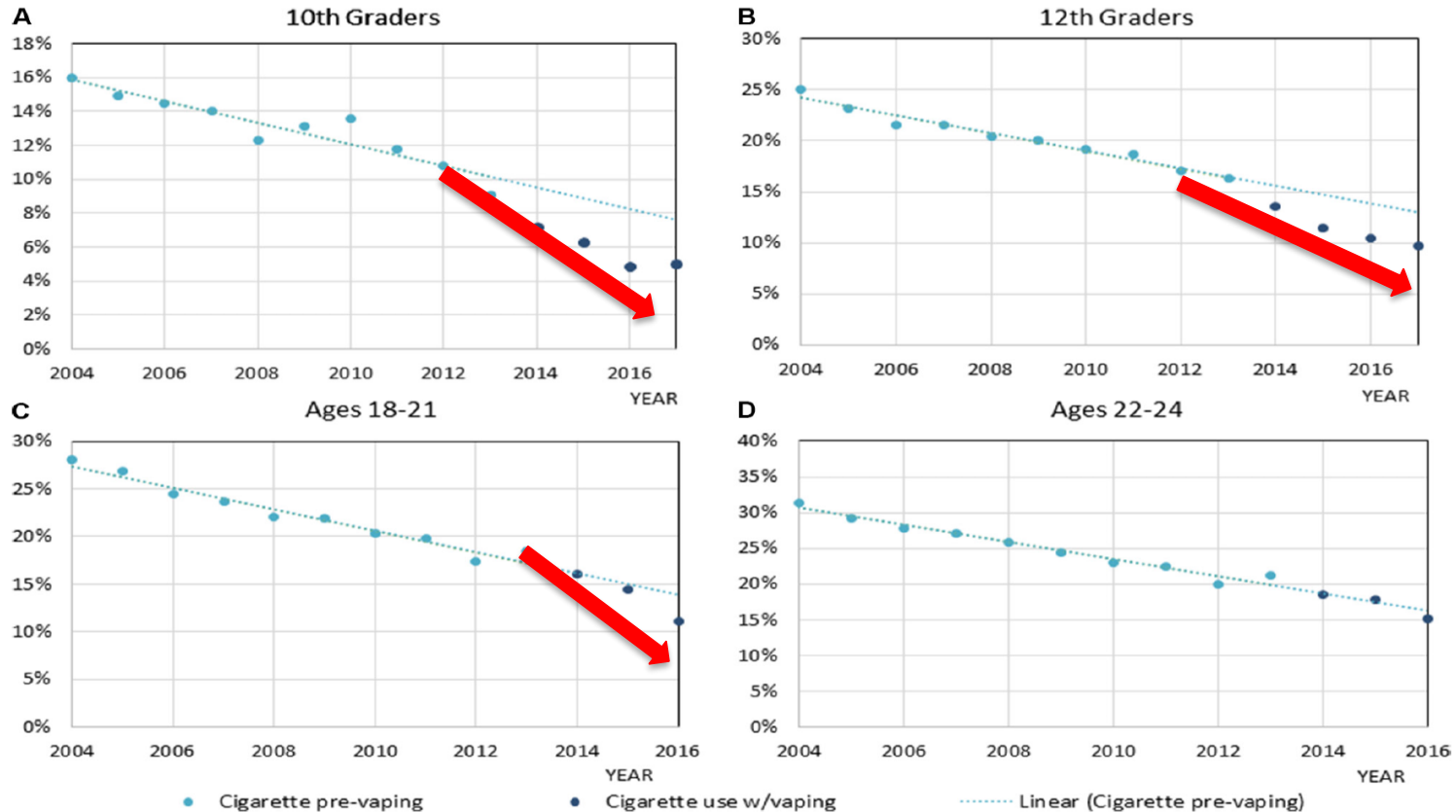
**Salary:** New York University, College of Global Public Health (Full Professor with tenure)

Extramural Funding in past 5 years:

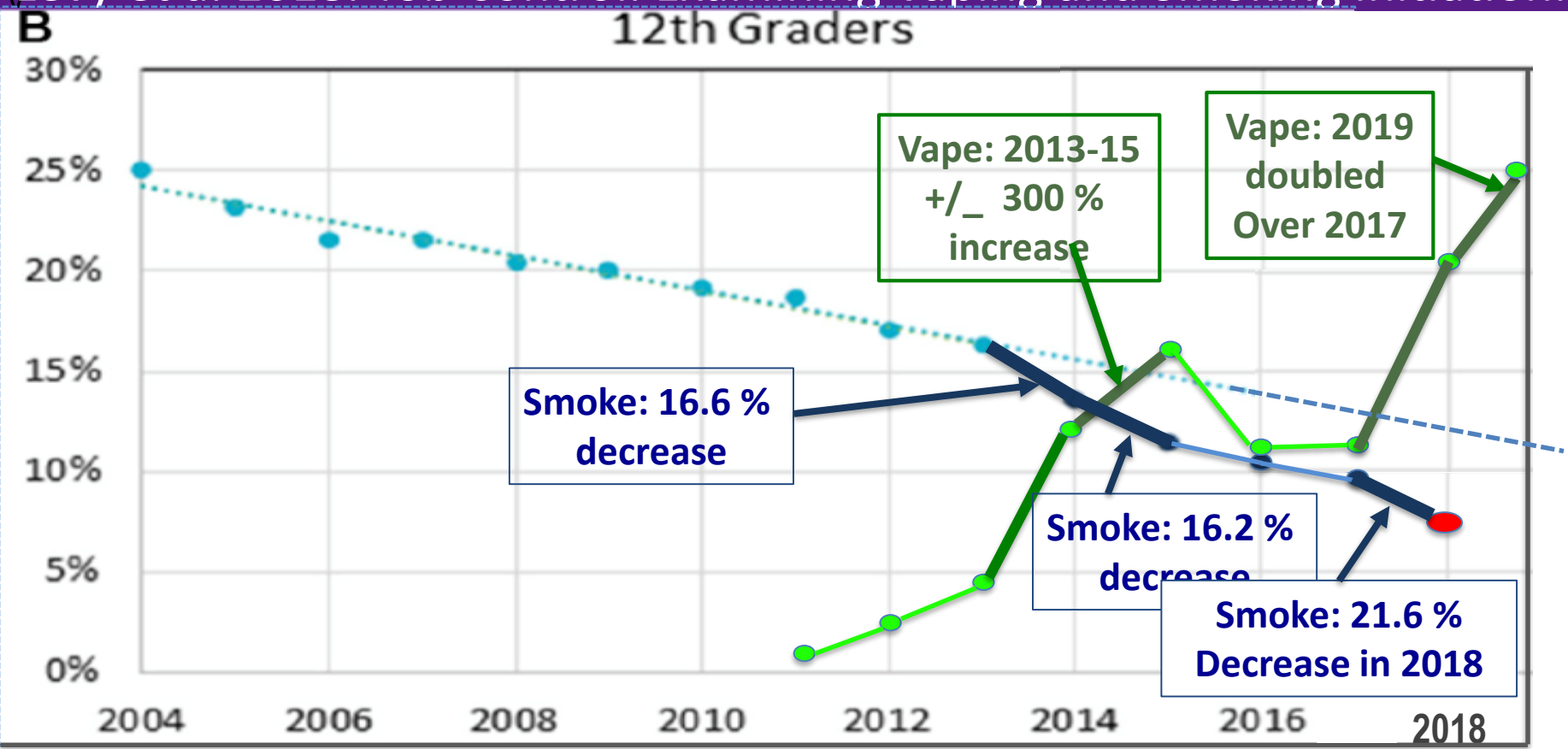
- NIH / FDA / Westat (subcontracts): **PATH (HHSN 27120110027C)**
- NIH / FDA / Westat (subcontracts): **CECTR (U54 CA189222)**
- **NIH-NIDA : R21 DA 036472; K01 DA 027903**
- **NIH-NCI: R01 CA 155369; R01 CA 155489**
- **Truth Initiative**
- **Georgetown University**

**No financial, consulting or other contracts from any tobacco, pharmaceutical or emerging nicotine product entities (e-cigarettes, Nicotine Replacement Therapy, Heat not Burn etc).**

# Levy et al. 2018 Tob Control. MTF : Examining Vaping and Smoking Initiation TRENDS 2018;0:1–7. A REALITY CHECK, MUCH LESS SMOKING



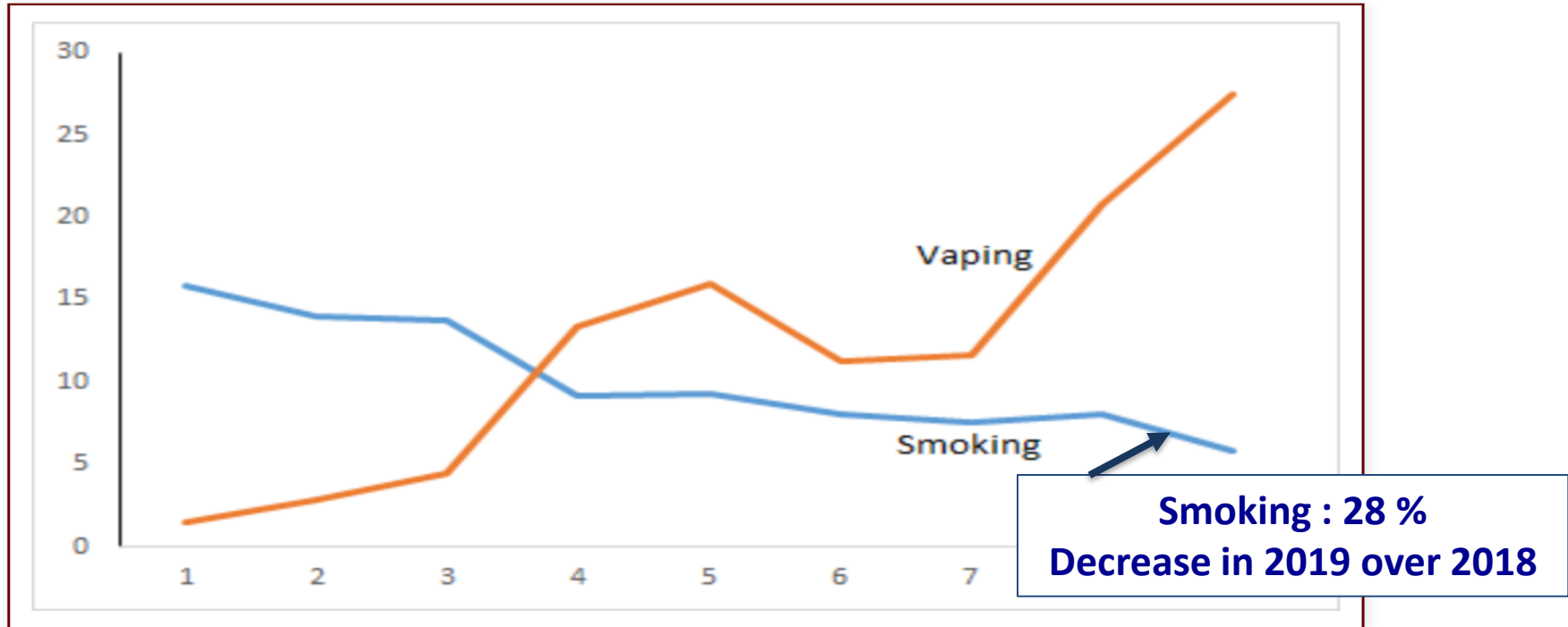
**Figure 2** Monitoring the Future survey, prevaping (2004–2013) and postvaping (2014–2017), and last 30 days cigarette prevalence with linear trend for prevaping period. (A) 10th graders, (B) 12th graders, (C) ages 18–21 and (D) ages 22–24.



Adapted from: Levy.. 2018 (added 2018 RED DOT) , & Any past 30 day NYTS Vaping Uptake  
Figure 2 Monitoring the Future survey, prevaping (2004–2013) and postvaping (2014–2017), and last 30 days cigarette prevalence



the National Youth Tobacco Survey indicate that while the rates of teen vaping continued to increase dramatically (from 21% in 2018 to 28% in 2019 and from 12% to 28% from 2017-2019), the rate of decline in youth smoking accelerated in 2019, dropping to its lowest level in recorded history.



# Monitoring the Future Survey: for 12th grade smoking – an unusually rapid decline as vaping rose

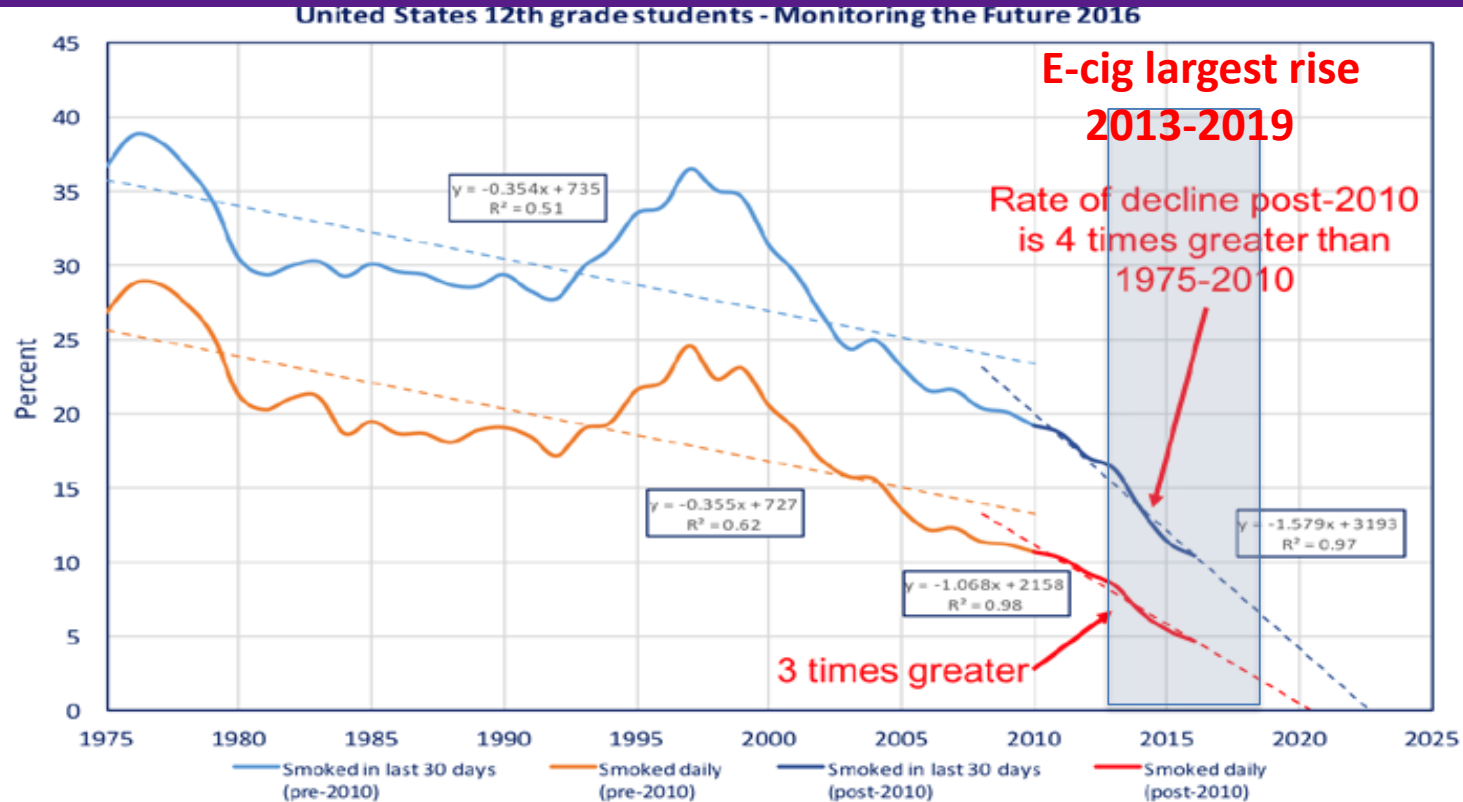
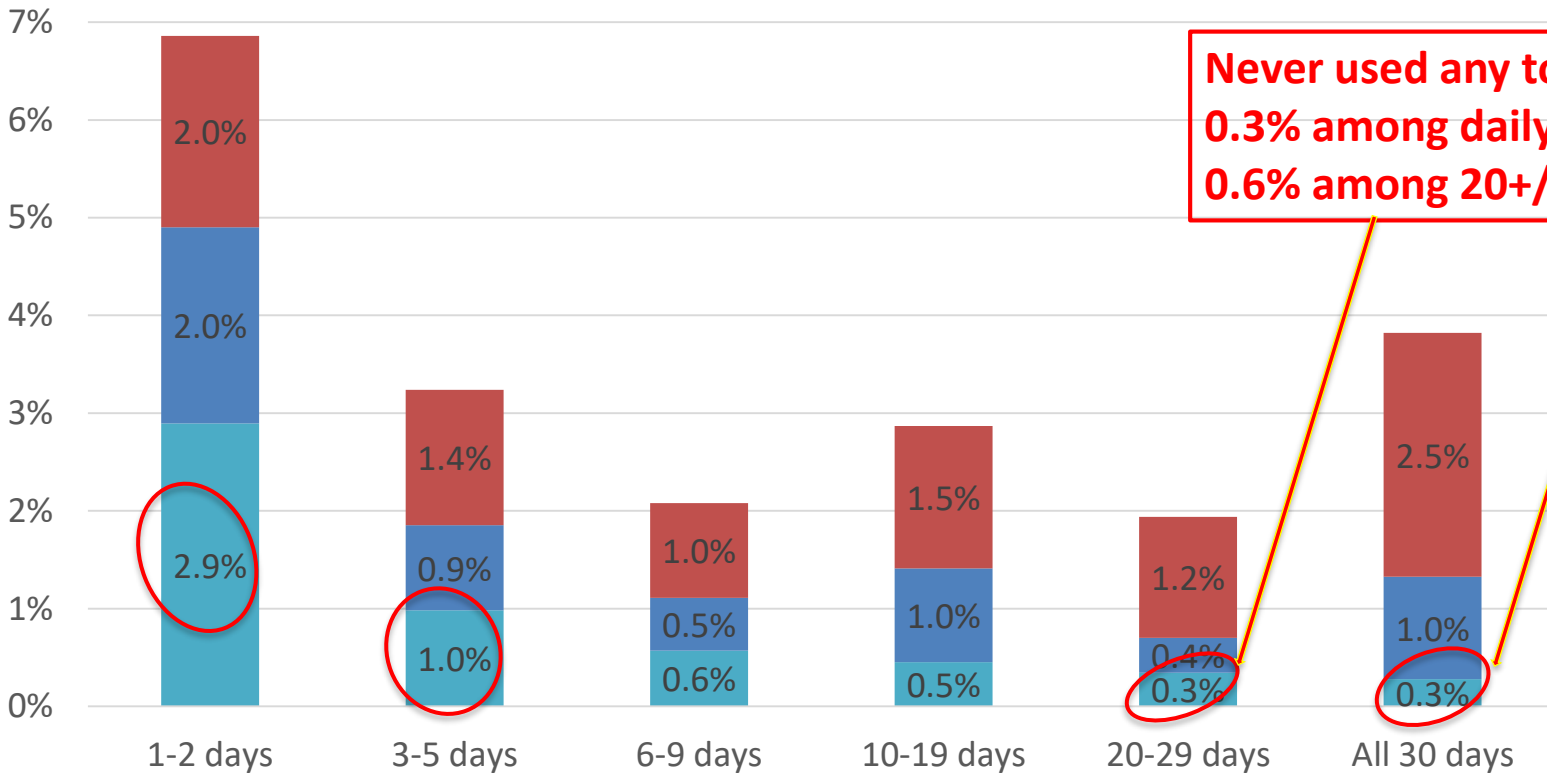


Figure X - Past 30-day e-cigarette frequency by non-e-cigarette tobacco use, 2018



**Never used any tobacco:  
0.3% among daily vapers  
0.6% among 20+/d vapers**



■ Never tobacco use    
 ■ Ever tobacco use, no P30D use    
 ■ P30D tobacco use

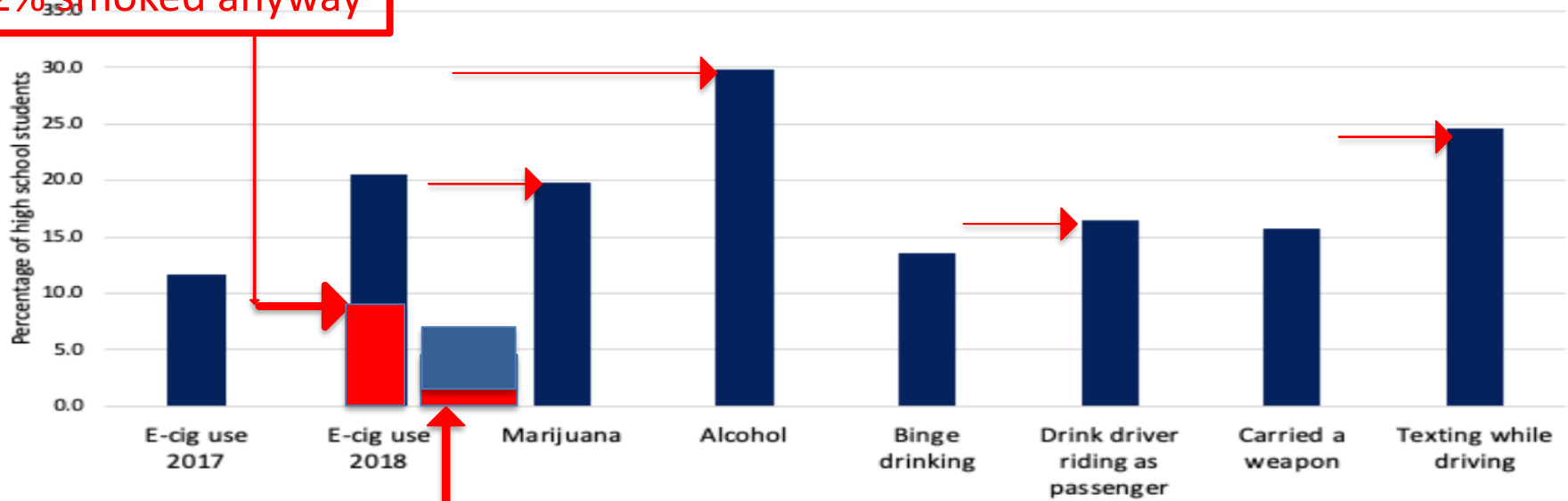
**5-/30d:  $3.9 / 10.3 = 38\%$  never used**    
 **20+/30d:  $0.6 / 5.8 = 10\%$  never used**

62% ever used or co-use with tobacco    
 89% ever used or co-use tobacco

# 2018 Youth Behavior Risk Factors: IN CONTEXT

1-5 /30d: and >  
62% smoked anyway

Past 30 day prevalence – high school students



Kann L, McManus T, Harris WA, et al. Youth Risk Behavior Surveillance-United States, 2017. *MMWR Surveill Summ* 2018;67(No. SS-8):1-114. [[link](#)]

20+ /30d:5.8%: but 89% have/smoke anyway; (and 41% ever used THC)



## Based on a deeper contextual Analysis of NYTS 2018: Following Recs by Villanti et al 2017

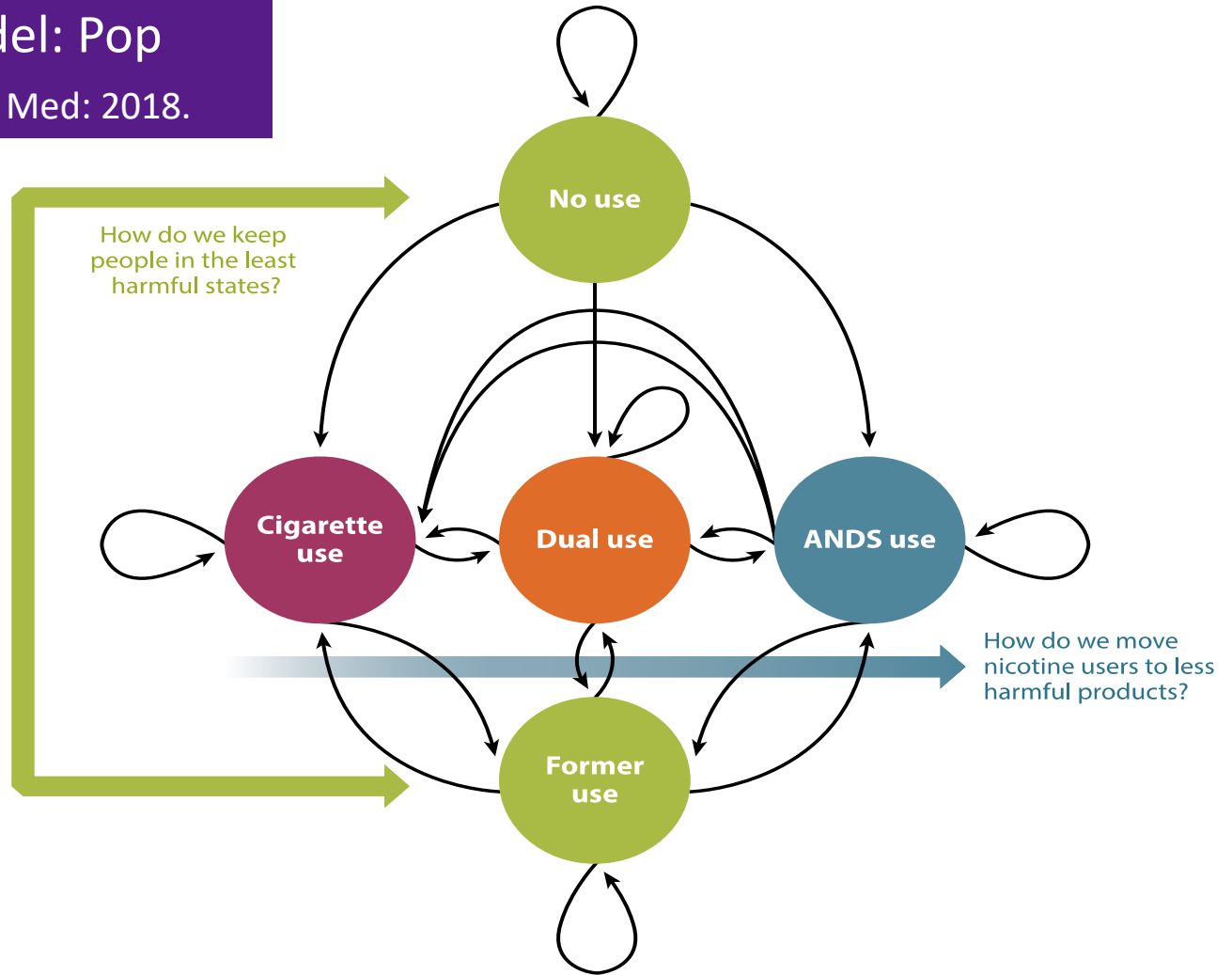
- Much youth vaping epidemic is *occasional use*: almost half (48.7%) is on 5 days or less – approximately weekly – rising to 58.7% vaping on 9 days or less in the last 30.
- It's hard to see how all this occasional use can amount to an **epidemic of nicotine addiction**.
- The area where most concern *should* arise is **tobacco-naive users** taking up vaping **and** becoming regular users – only 0.6% of high school students fall into this category. Even with this group, we cannot know whether some of these users would have gone on to smoke in the absence of vaping as an option -- and 41.8 % say they also Vape Cannabis.
- *Regular vaping* (at least 20+/30days ) is **dominated by people who had previously smoked or currently smoke (88%)** of regular vapers had previously smoked. ? a **gateway OUT or off ramp more than a gateway in or ON RAMP?**- Even for experimenters its **62 % out.....**
- For these users, there is a positive story: vaping is in the mix of their tobacco use and could provide longer-term protection against smoking, which is the actual risky behavior.
- **REFS: see also Jarvis et al just published for details and Glasser et al in press :**



*“I just feel fortunate to live in a world with so much disinformation at my fingertips.”*

# State Transition Model: Pop

Impact: Abrams et al Prev Med: 2018.



# COMPLEX Pathways of use: ON AND OFF RAMPS?



- Surveys from the UK and several US studies found that young people who have never smoked but have tried an e-cigarette at the beginning of the study are more likely to have gone on to try smoking several months or years later.
- This suggests there may be an association **but we cannot establish a cause based on these findings**
- ‘Common liability’ likely explains these findings (i.e. shared risk taking behavior)
- Some data to suggest the opposite trend – Vaping may be a route out of smoking
- WHAT IS THE RATIO OF VAPING BEING AN ON RAMP (GATEWAY IN) VERSUS AN OFF RAMP for TEENS (*about 2500/DAY start smoking anyway and 200 become daily smokers despite our best efforts at prohibition*). Est 5.6 million youth alive in 2014 will die from SMOKING
- See: Kozlowski and Warner 2017; Warner and Mendez, 2019; Warner 2018 /19) etc.

**HOW SURE ARE WE? BY FOCUSING ONLY ON VAPING HARMS WE ARE PROTECTING or NOT:  
SLOWING THE SMOKING OFF RAMP MORE THAN STOPPING THE SMOKING ON RAMP ?**



# HOW DO WE CURB SMOKING - PROTECT YOUTH AND SAVE SMOKERS LIVES TOO?

- It is not easy to achieve balance between abstinence and harm reduction
- Harm Reduction includes total abstinence as its first principle and thus **complements** traditional Tobacco Control and Nicotine management efforts
- **We are able to do it successfully but not perfectly with other risky products and behavior:** Society accepts alcohol, football, opioids, cars – BUT manages risk. E.g.
- Comprehensive sex education explains abstinence is the only way to prevent pregnancy, STDs. But provides explicit guidance on how to reduce risks for youth who chose to be sexually active - won't 'just say no' or be scared by adult threat.
- **Harm reduction embraces abstinence AND STILL gives practical advice to those who won't abstain to reduce their risks. It tells the truth honestly without exaggerating harm or omitting benefits**
- Does pragmatism, not perfection, point the way? Protecting youth while migrating smokers who can't quit to much less harmful e-cigs is possible and saves lives now

It is a capital mistake to theorize before one has data.  
Insensibly one begins to twist facts to suit theories, instead  
of theories to suit facts.

*Sherlock Holmes. Sir Arthur Conan Doyle (1891). A Scandal in Bohemia*

- We all fall short to some degree on occasions
- The aim is not to ascribe blame but to provide a framework for improving the quality of and interpreting of science

All are biased: how do best practices minimize bias for  consensus?

At stake: 38 million smokers and potential smokers lives.



THANK YOU

David B Abrams PhD.

Professor. New York University  
College of Global College Health

Email: [da94@nyu.edu](mailto:da94@nyu.edu)



# The Role of Government, Public Health, Industry, and Academia in Combatting Youth Vaping

Food and Drug Law Institute

October 24, 2019

James Baumberger, MPP

Senior Director, Federal Advocacy

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



# Conflicts

I have no conflicts to disclose.



## Opening Thought

*“At some point, regardless of your view on whether these products can help currently addicted adult smokers transition off cigarettes, the youth use is so widespread and rampant that whatever redeeming public health value these tools potentially have – and they haven't demonstrated that yet – is offset by youth use.”*

Scott Gottlieb, MD  
Former FDA Commissioner  
March 19, 2019

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



# Overview

Premarket  
review

Flavors

Addressing  
youth  
addiction



# Premarket Review

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
*Southern Division*

AMERICAN ACADEMY OF  
PEDIATRICS, *et al.*,

Plaintiffs,

v.

FOOD AND DRUG  
ADMINISTRATION, *et al.*

Defendants.

\*

\*

\*

\*

\*

\*

\*

Case No.: PWG-18-883

American Academy of Pediatrics

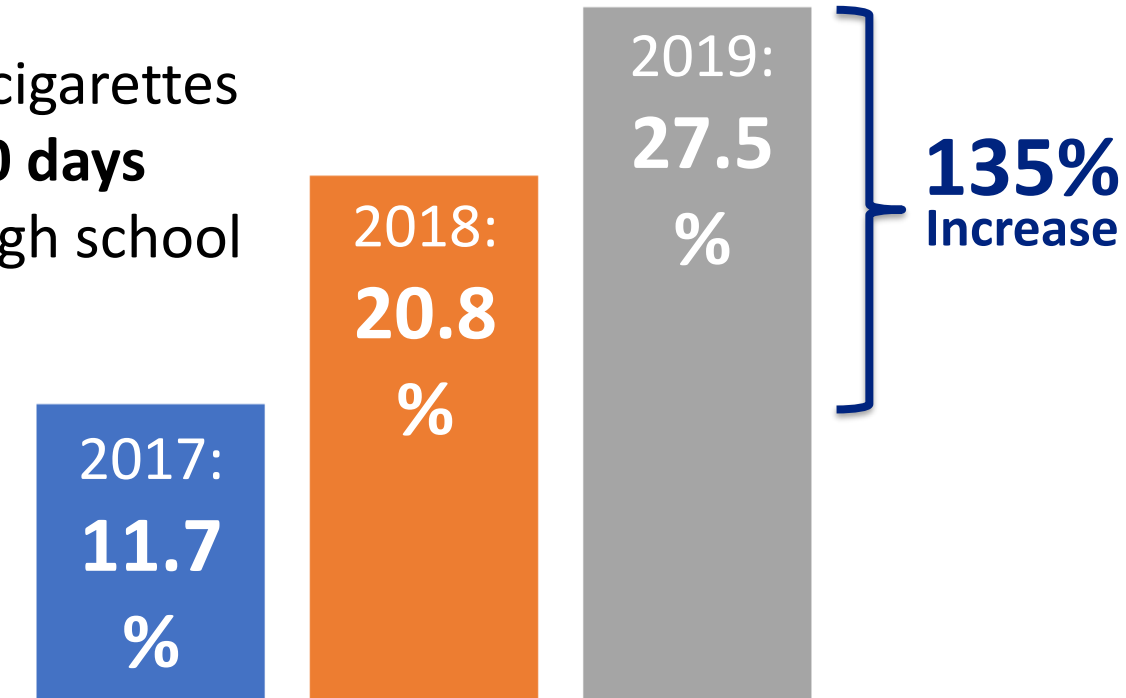
DEDICATED TO THE HEALTH OF ALL CHILDREN®





## Increasing Youth Use

Use of e-cigarettes  
in past 30 days  
among high school  
students



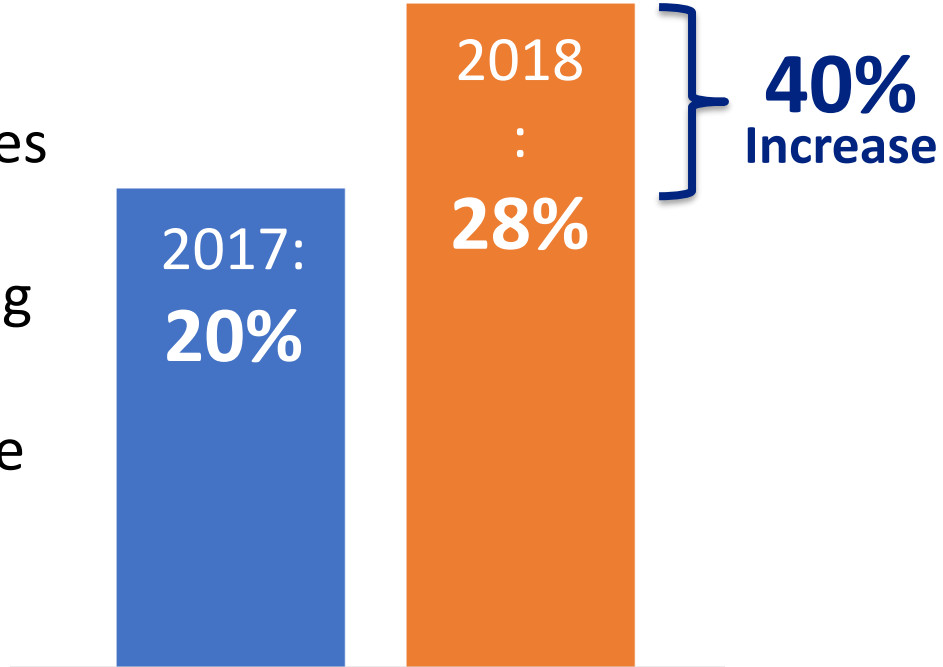
Source: National Youth Tobacco Survey

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



# Increasing Frequency of Use Among Youth

Use of e-cigarettes  
**20 days or more**  
per month among  
current high  
school e-cigarette  
users



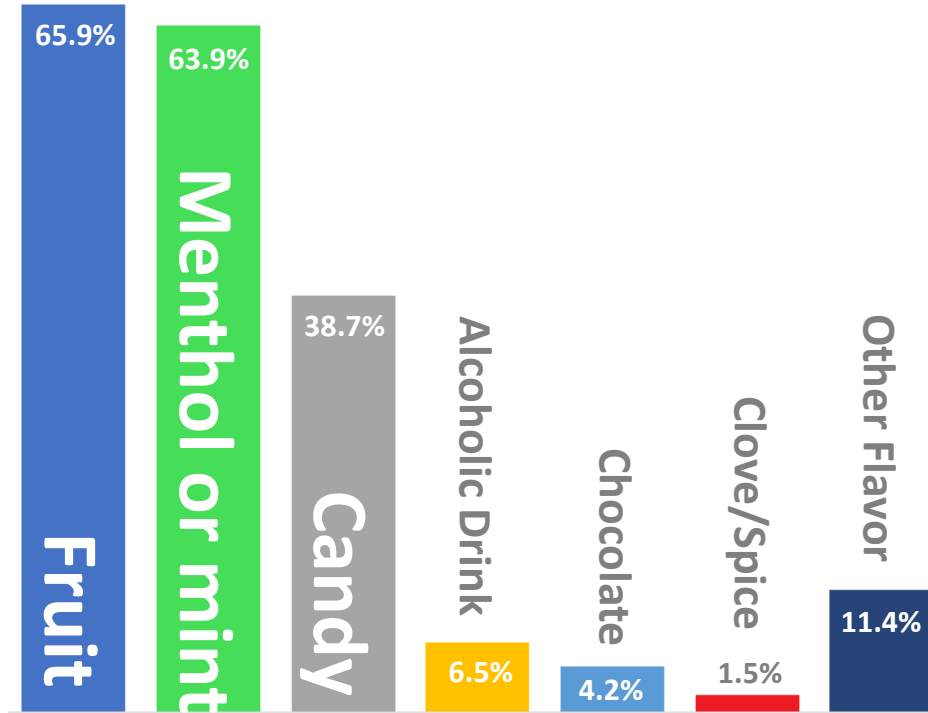
Source: National Youth Tobacco Survey

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



# Popular Flavors Among Youth

**Popular  
flavors**  
reported by  
high school  
e-cigarette  
users



Source: National Youth Tobacco Survey

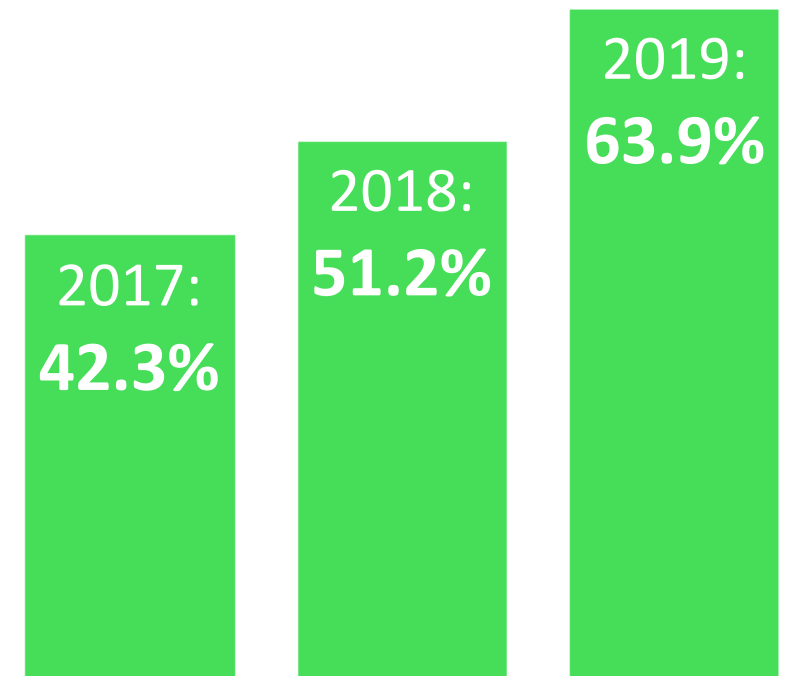
American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



## Youth Mint E-Cigarette Use on the Rise

Use of **mint** or **menthol** reported by high school e-cigarette users



Source: National Youth Tobacco Survey

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



# Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products

*FDA compliance policy would prioritize enforcement of premarket authorization requirements for non-tobacco-flavored e-cigarettes*

[f Share](#)

[t Tweet](#)

[in LinkedIn](#)

[✉ Email](#)

[🖨 Print](#)

**For Immediate Release:** September 11, 2019

Today, the Trump Administration announced that as part of its ongoing work to tackle the epidemic of youth e-cigarette use, the FDA intends to finalize a compliance policy in the

# Clinical Perspectives: Teen E-Cigarette Addiction

Teens don't understand addictiveness and health impacts

Experimentation to daily use happens quickly

Addiction is strong in many adolescents

Waking to vape

Pediatricians struggling to help addicted teens

Relapse rates high



# Addressing Teen E-Cigarette Addiction

Very limited data  
on helping teens  
quit smoking

No data on helping  
teens quit vaping

Nicotine  
replacement  
therapy cost and  
access

Prevention is  
paramount

Limiting youth  
access as an  
effective treatment

Research  
desperately needed



# Contact

**James Baumberger, MPP**

Senior Director, Federal Advocacy

American Academy of Pediatrics

**[jbaumberger@aap.org](mailto:jbaumberger@aap.org)**

**@jdbaumber**







## The Role of Government, Public Health, Industry, and Academia in Combatting Youth Vaping

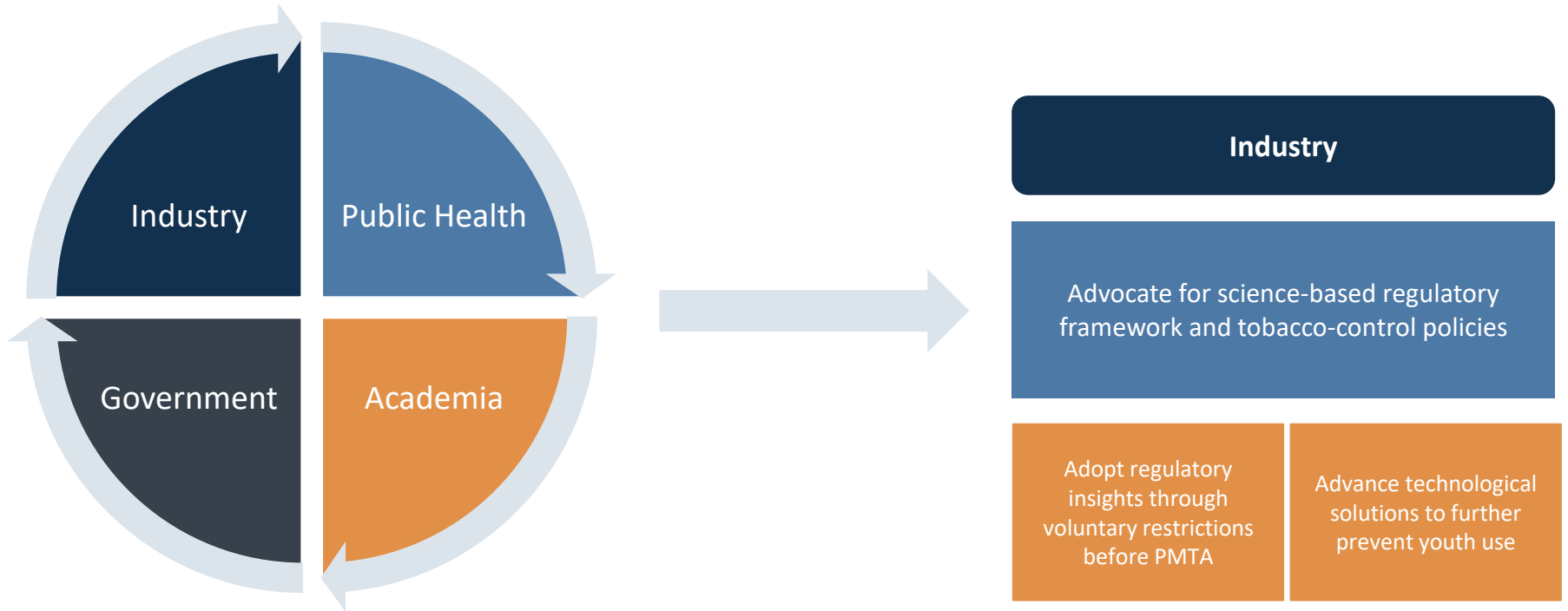
Parker D. Kasmer, Regulatory Counsel

FDLI Tobacco and Nicotine Products Regulation and Policy Conference | | October 24, 2019

# Roadmap

- 1 | Industry's Role Among Key Stakeholders
- 2 | Responsive and Voluntary Actions to Facilitate Marketing Authorization
- 3 | Sales and Distribution Controls to Restrict Youth Access –  
Retail Access Control Standards (RACS)

# Preserving opportunity for risk reduction, by preventing youth use



# Adopting regulatory insights today to support authorization “tomorrow”

## FDA Draft Guidance

- Sales and distribution controls at retail and online to limit youth access
- Flavor and labeling restrictions to limit youth appeal
- AdPromo restrictions to limit youth awareness

## IQOS Marketing Order

- Limited to traditional flavors
- Third-party age verification for online sales
- 30-day prior notification for AdPromo materials
- Data monitoring and verification for digital marketing
- Restrictions on third-party marketing (e.g., brand ambassadors, influencers)

## Responsive Industry Action

- Restrict access
- Limit appeal
- Reduce awareness

# Responding through voluntary restrictions

## Access

- Advocate for raising minimum-purchasing age to 21
- Restrict sale of non-traditional flavors, subject to PMTA authorization
- Partner with retailers to adopt enhanced access restrictions and expand secret-shopper program for bulk-purchasing limits

## Appeal

- Adopt simple packaging and labeling
- Limit flavor descriptors to basic naming conventions
- Avoid non-product imagery and references

## Awareness

- Exit social media
- Restrict use of brand ambassadors and influencers
- Utilize targeted marketing via 85%/21+ principle for paid media
- Limit above-the-line product marketing

# Advancing technological solutions to restrict youth access

## Social-sourcing remains main contributor to youth use

- **70-80%** of youth use occurs through third-party resale, shared use, or other non-commercial means<sup>1</sup>

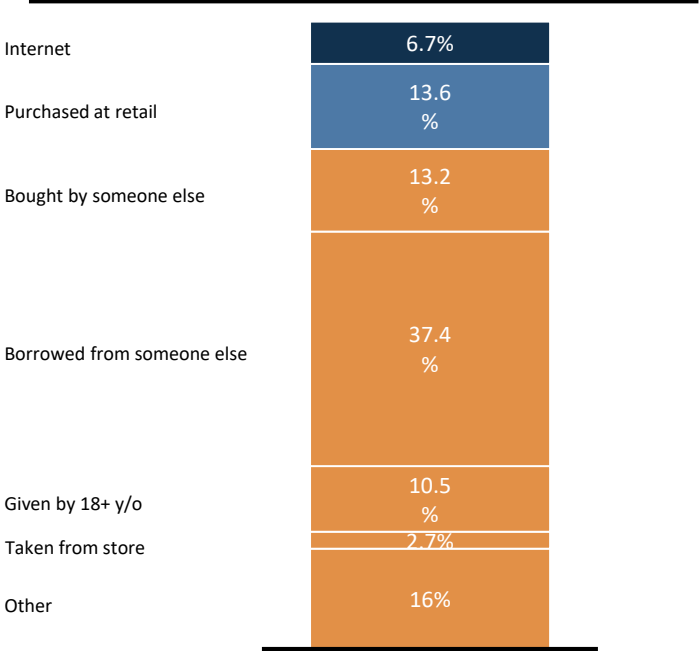
## Of illegal commercial sales, majority come from specialty tobacco and vape stores

- Based on 2018 NYTS data, **12.9%** of youth obtained vapor products from specialty vape shops; **6.6%** from gas and convenience stores
- Based on Wave 3, PATH data, **25.8%** of 15-17 year-olds accessed vapor products through specialty vape shops (in-person or social sourcing); **4.5%** through convenience stores

## Research of CA tobacco retailers found 1 of 2 specialty stores did not check ID

- **49.8%** of tobacco and vape shops, defined as retailers that “primarily sell tobacco products,” did not check ID
- Just over **20%** of convenience stores failed to check ID<sup>2</sup>

Source of vapor products in past 30 days

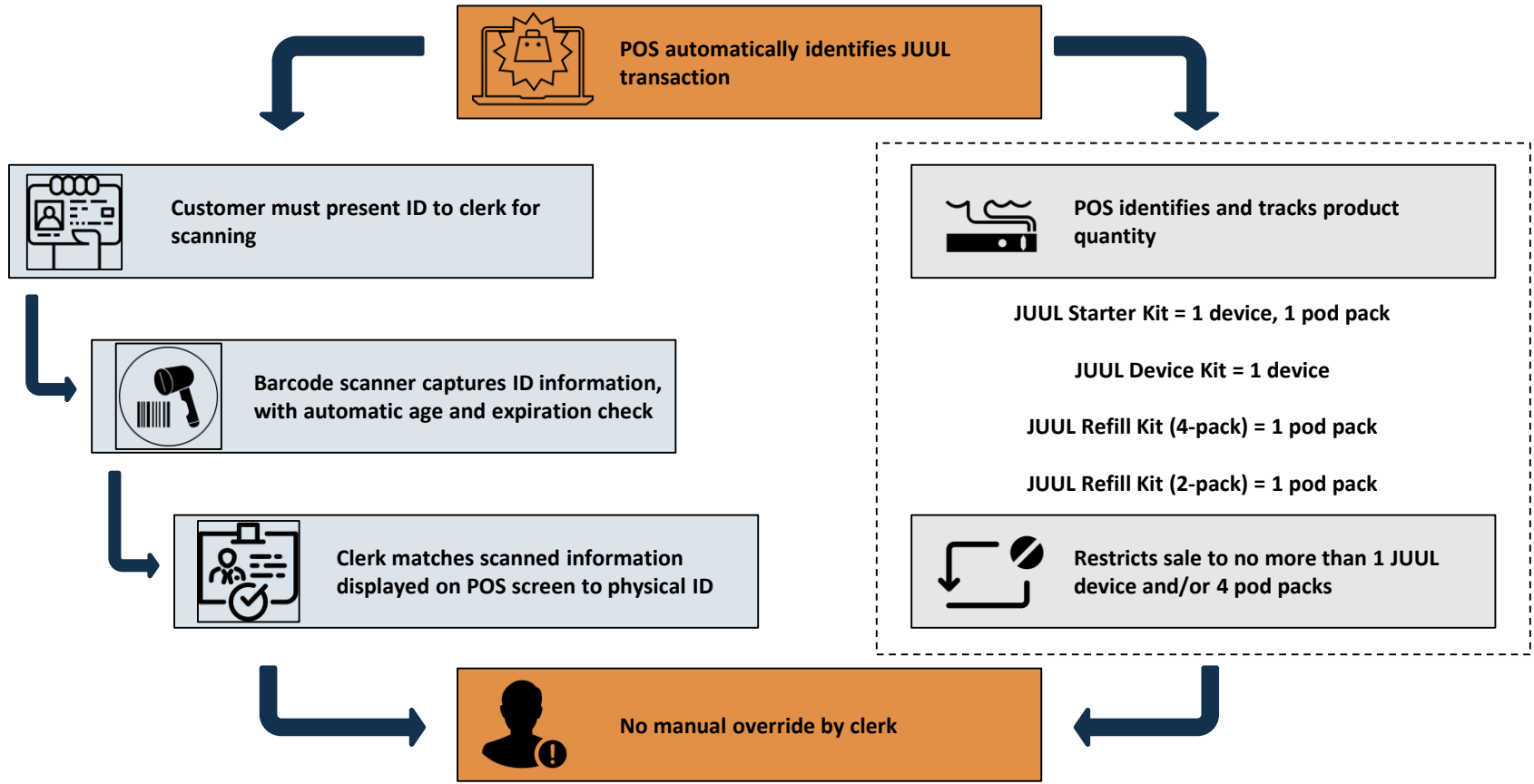


Source: 2018 National Youth Tobacco Survey

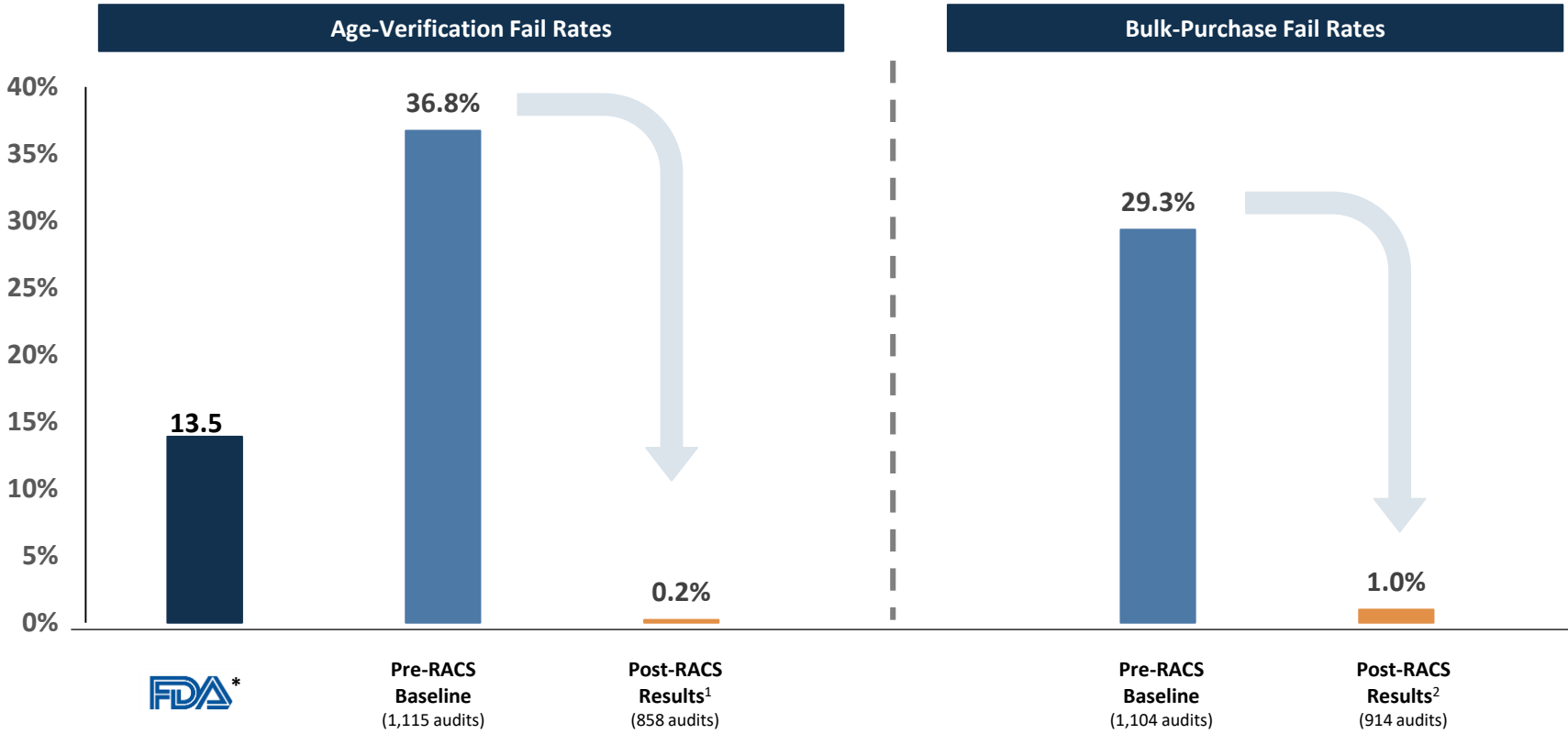
<sup>1</sup> See, e.g., CDC, 2018 NYTS; PATH, Wave 3; CDC, 2017 YRBS

<sup>2</sup> See A. Roeseler, et al., Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops, JAMA Pediatrics (2019)

# Using RACS as model for sales and distribution controls



# Realizing effectiveness of RACS across pilot retailers



<sup>1</sup> Data based on FDA compliance inspections of retailers for all tobacco products from 5.31.18 – 5.31.19  
<sup>2</sup> Data based on third-party compliance checks of pilot retail outlets for JUUL products following RACS adoption