Clive Bates, Director, Counterfactual Consulting Limited

Dennis Henigan, Vice President, Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids

Raymond Niaura, Professor, Department of Social and Behavioral Sciences, New York University

*Moderated by* Robyn Gougelet, Senior Associate, Pinney Associates, Inc.

Pinney Associates

Science. Strategy. Solutions.

**Robyn Gougelet, Senior Associate**

# Disclosure

- **Pinney**Associates consults for Reynolds American, Inc. (RAI), recently acquired by British American Tobacco (BAT), on noncombustible nicotine and tobacco products.
- Our work for RAI focuses on products, regulations, and policies related to tobacco harm minimization and smoking cessation; we do not work on combustible conventional cigarettes.

# FDA's Advance Notices of Proposed Rulemaking for Tobacco Products

Clive Bates

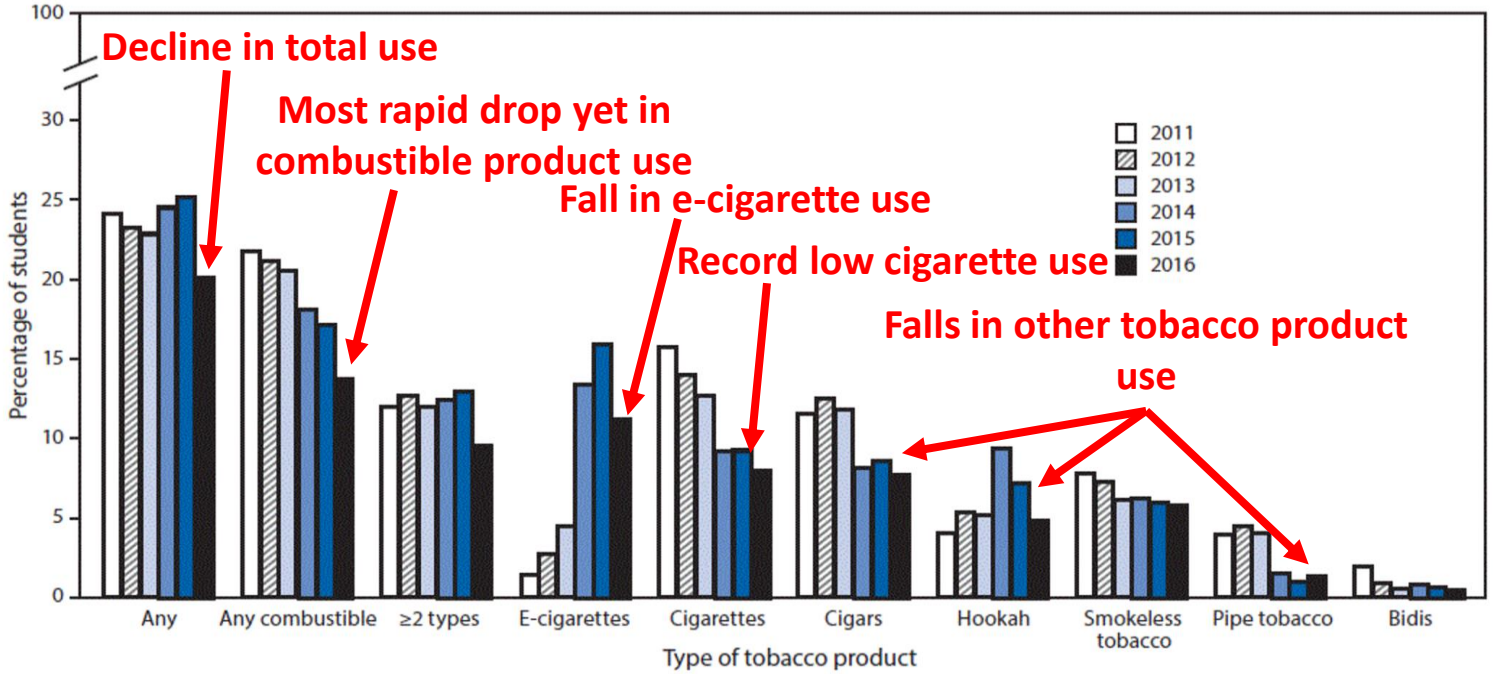
Counterfactual, London

# Cigars

# Flavors

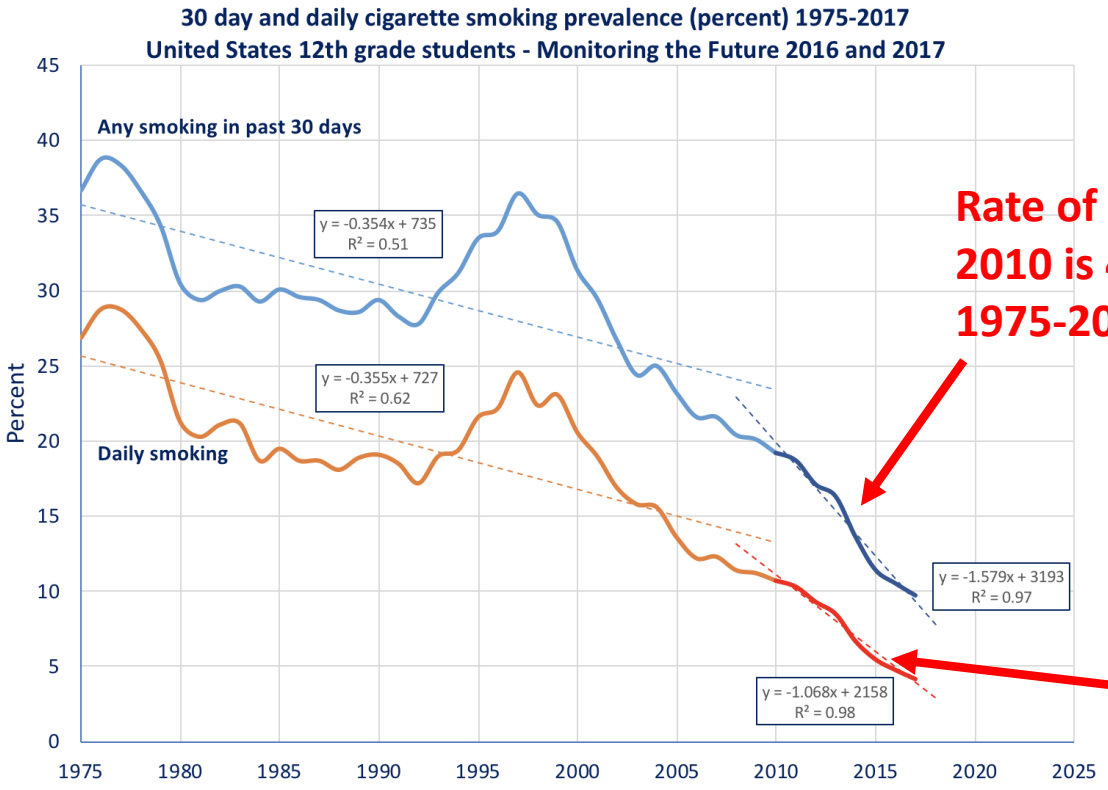
# Declining youth smoking

**FIGURE 1.** Estimated percentage of high school students who currently use any tobacco products,* any combustible tobacco products,† ≥2 tobacco products,§ and selected tobacco products — National Youth Tobacco Survey, United States, 2011–2016¶,**,††




* Any tobacco product use is defined as past 30-day use of electronic cigarettes, cigarettes, cigars, hookahs, smokeless tobacco, pipe tobacco and/or bidis.

# Declining youth smoking



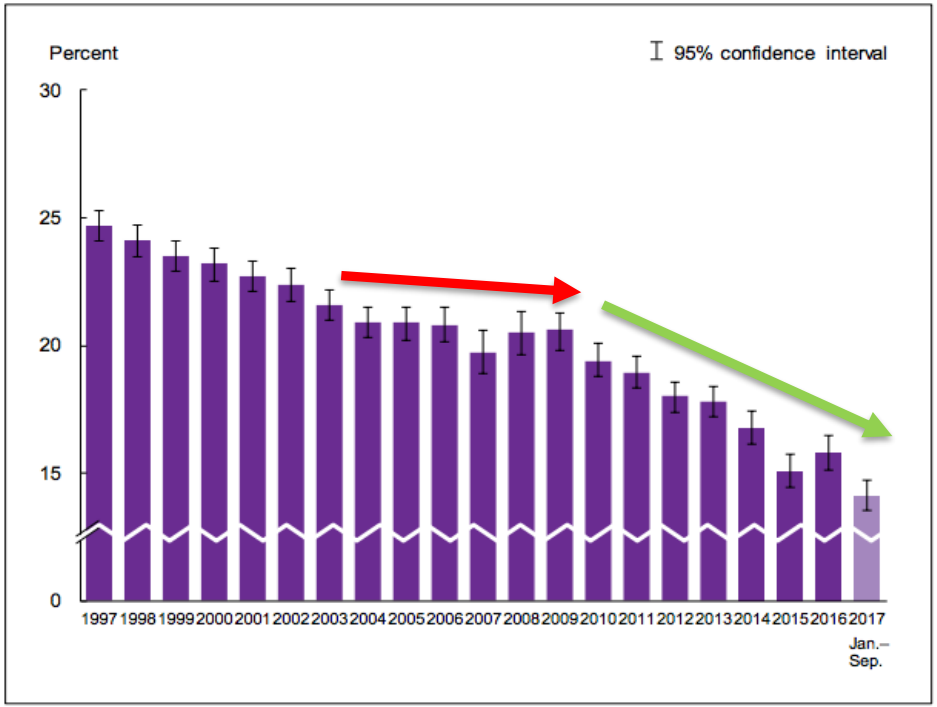

**Rate of decline post 2010 is 4 times 1975-2010**

**3 times**

# Declining adult smoking

**Current smoking**

**Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–September 2017**

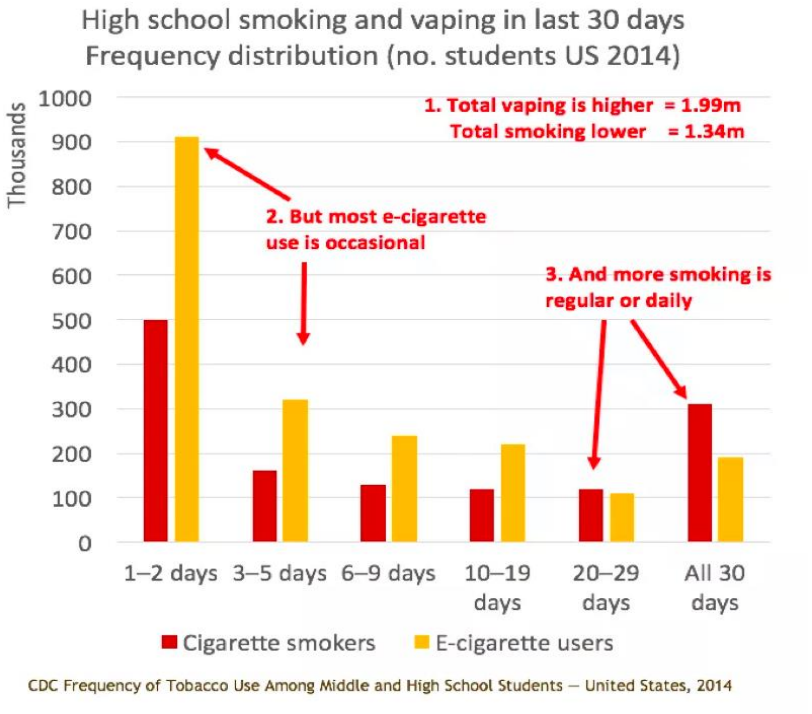


# Flavors – an interrogation

1. What are “Kiddie appealing” flavors?

2. What is the behavior of concern?

3. Do flavors change youth behavior?



# Flavors – an interrogation

1. What are “Kiddie appealing” flavors?
2. What is the behavior of concern?
3. Do flavors change youth behavior?
4. If so, is that change good or bad?

Ambrose et al, JAMA, 2015

| Reasons for Use | % (95% CI) e-Cigarettes (n = 418)[c] |
|---|---|
| I use [product] because they come in flavors I like | 81.5 (77.9-85.0) |
| I use [product] because they are affordable | 47.8 (42.9-52.6) |
| I use [product] because I can smoke/use them at times when or in places where smoking cigarettes isn’t allowed | 58.9 (54.1-63.7) |
| I use [product] because I like socializing while using them | 40.3 (34.9-45.8) |
| I use [product] because it doesn’t bother non-tobacco users | 53.9 (48.1-59.8) |
| I use [product] because they might be less harmful to me than cigarettes | 79.1 (75.2-83.0) |
| I use [product] because they might be less harmful to people around me than cigarettes | 78.1 (74.3-81.8) |
| I use [product] because they don’t smell | 58.7 (54.2-63.2) |
| I use [product] because they help people to quit smoking cigarettes | 59.5 (54.6-64.5) |
| I use [product] because people who are important to me use them | 34.9 (30.6-39.2) |
| I use [product] because people in the media or other public figures use them | 36.1 (31.5-40.7) |

# Flavors – an interrogation

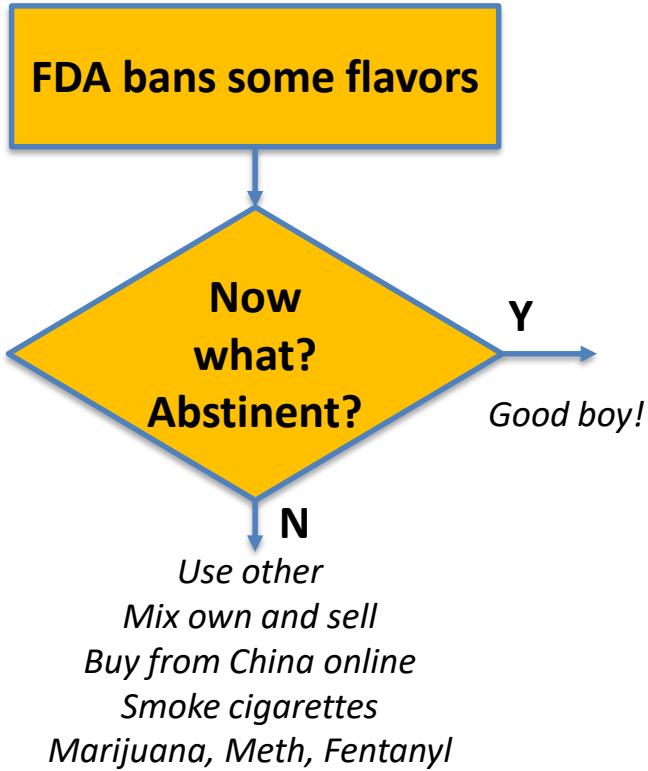
1. What are “Kiddie appealing” flavors?

2. What is the behavior of concern?

3. Do flavors change youth behavior?

4. If so, is that change good or bad?

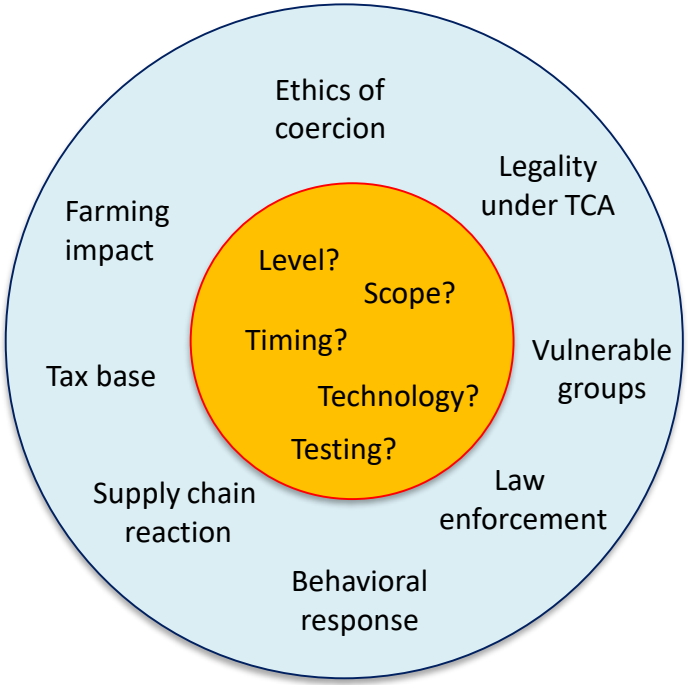
5. What effect does an FDA intervention have:
   - on adolescents?
   - on adults?



# Reduced nicotine: 3 concerns

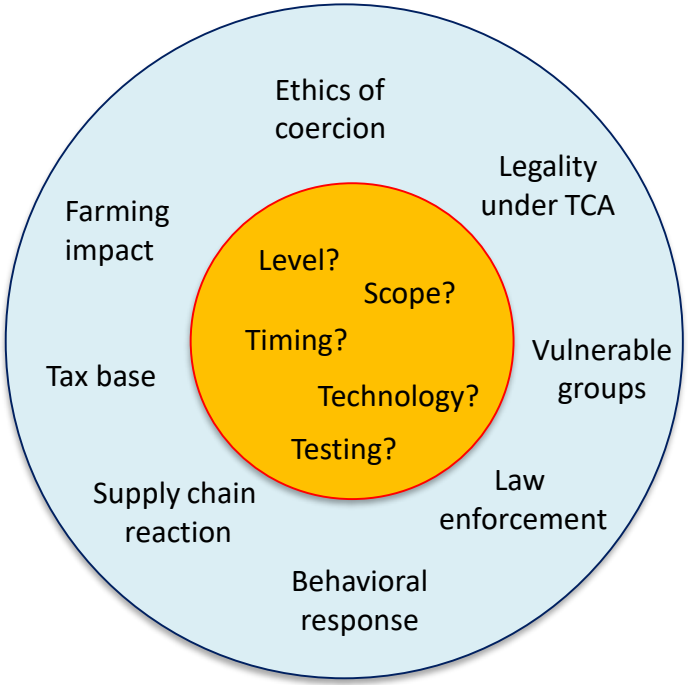
1. Breadth of analysis
2. Alternatives
3. Policy coherence

# Reduced nicotine: 1. breadth



# Reduced nicotine: 2. alternatives

**Alternative policies**

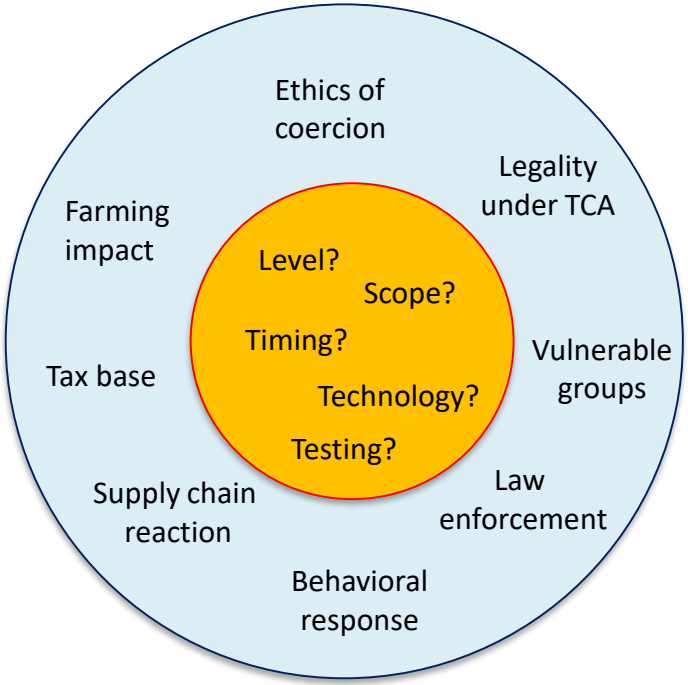
# Reduced nicotine: 3. policy coherence

## Alternative policies

Taxation

Toxin / additives regulation

Tobacco Control




## Flanking policies

ENDS

Innovation

Communication

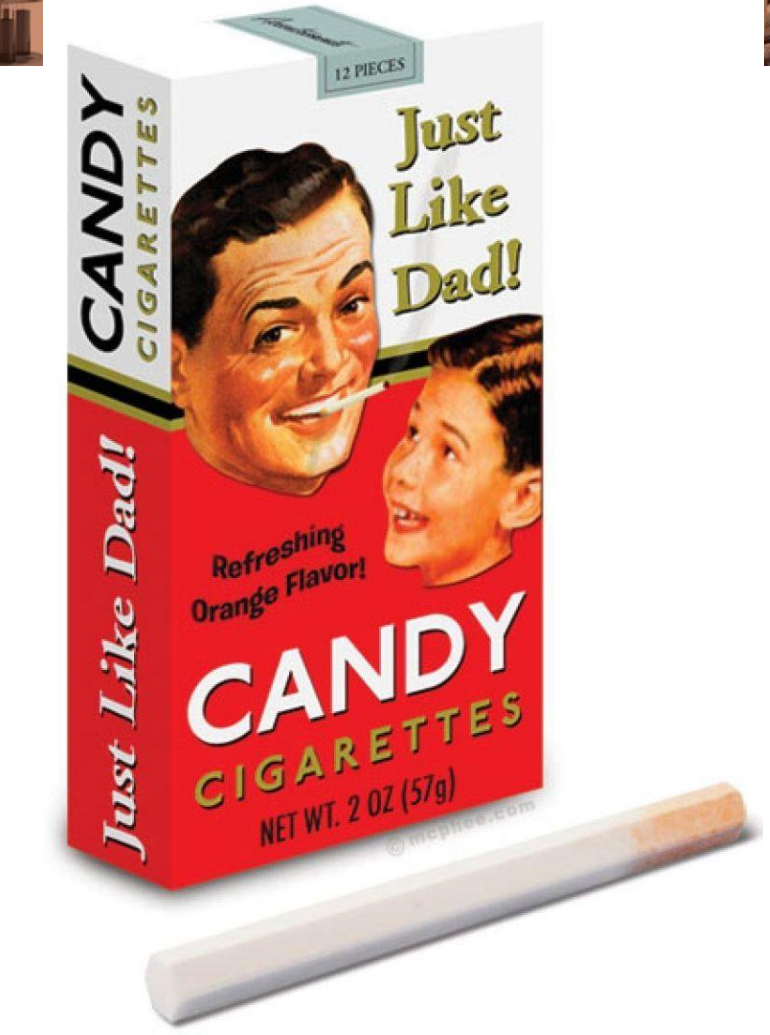
Taxation

# Thank you

www.clivebates.com

@clive_bates

clivedbates@gmail.com

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Preventive Medicine 45 (2007) 26–30

Preventive Medicine

www.elsevier.com/locate/ypmed

# History of childhood candy cigarette use is associated with tobacco smoking by adults

Jonathan D. Klein [a,*], Randall K. Thomas [b], Erika J. Sutter [a]

[a] *University of Rochester School of Medicine and Dentistry, Departments of Pediatrics and Community and Preventive Medicine, and the American Academy of Pediatrics Julius B. Richmond Center of Excellence, Rochester, NY, USA*
[b] *Harris Interactive, Rochester, NY, USA*

Available online 24 April 2007

**Abstract**

*Objective.* We examined whether childhood candy cigarette use was associated with adult tobacco smoking.

*Methods.* 25,887 U.S. adults from the Harris Poll Online (HPOL) were surveyed about current smoking status from November 2005 to May 2006. Respondents were randomly assigned to a yes/no item or a dose–response scale to assess candy cigarette use. Data were weighted to reflect the U.S. adult population.

*Results.* 26.4% of respondents reported current smoking and 29.4% reported former smoking. Candy cigarette use was reported by 88% of both current and former smokers and 78% of never smokers ($p \leq 0.001$). Logistic regression showed that the odds of smoking for those who used candy cigarettes was 1.98 (95% CI: 1.77, 2.21) for ever (current plus former) smokers and 1.83 (1.59, 2.10) for current smokers, compared to those who had not used candy cigarettes. Odds for current and ever smoking increased with increasing candy cigarette use.

*Conclusion.* History of candy cigarette use was associated with increased risk of ever and current smoking among this nationally representative online sample of adults. Odds of smoking increased as candy cigarette use increased; these relationships persisted when controlled for sociodemographics. Elimination of candy cigarettes may protect children from products that promote the social acceptability of smoking.

# Gummy Bear Flavors – The New Candy Cigarette Scare

## ELECTRONIC CIGARETTES AND YOUTH

### Flavored E-Cigarettes Attract Youth

The 2016 Surgeon General report stated that, "E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults."[15] Cigarettes with specific characterizing flavors were prohibited in the U.S. on September 22, 2009, as part of the Family Smoking Prevention and Tobacco Control Act. However, this prohibition did not apply to other tobacco products, including e-cigarettes, which come in flavors with obvious youth appeal such as gummy bear, cotton candy, and fruit punch.[16] As of January 2014, researchers had identified more than 7,700 unique e-cigarette flavors available online, with an average of more than 240 new flavors being added per month.[17] Among more than 400 available brands, 84 percent offered fruit flavors and 80 percent offered candy and dessert flavors.[18] In addition to the vast selection available online, thousands of "vape" shops have now opened throughout the country that allow consumers to sample and purchase refill liquids, including a combination of flavors chosen by the user.[19]

United States Senate
WASHINGTON, DC 20510

April 18, 2018

Kevin Burns
Chief Executive Officer
JUUL Labs, Inc.
560 20th Street
San Francisco, California 94107

Dear Mr. Burns:

However, much to our dismay, these gains are being threatened because of non-cigarette tobacco products, especially electronic cigarettes (e-cigarettes) like JUUL. While there has been a steep drop in youth use of traditional cigarettes, youth use of e-cigarettes is skyrocketing. Between 2011 and 2015, the use of e-cigarettes among high school students increased more than ten-fold—from 1.5 percent to 16 percent. While e-cigarette use by high school students declined to 11.3 percent in 2016, e-cigarettes remain the most popular form of tobacco use among youth. According to the U.S. Surgeon General's Report on E-Cigarette Use Among Youth and Young Adults, much of the popularity associated with youth use of e-cigarettes can be attributed to the appealing candy and fruit flavorings that accompany these devices—flavors such as gummy bear, cotton candy, peanut butter cup, and cookies 'n cream. No one with a straight-face could ever argue that these flavorings are not meant to appeal to children.

Sincerely,

Richard J. Durbin
United States Senator

Sherrod Brown
United States Senator

Richard Blumenthal
United States Senator

Charles E. Schumer
United States Senator

Patty Murray
United States Senator

Tom Udall
United States Senator

Chris Van Hollen
United States Senator

Jack Reed
United States Senator

Edward J. Markey
United States Senator

Elizabeth Warren
United States Senator

Tim Kaine
United States Senator

Pinney Associates

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**Robyn Gougelet, Senior Associate**

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**Robyn Gougelet, Senior Associate**

FOOD FOR THOUGHT

# Are Gummy Bear Flavors Just Fooling Our Brains?

January 8, 2018 · 10:59 AM ET

ASHLIE STEVENS

FROM 89.3 WFPL

Color really does impact our perception of taste — even if the ingredients are otherwise the same, scientists say. It's something candy companies use to their advantage.

*Justin Sullivan/Getty Images*


Jelly Belly
THE ORIGINAL GOURMET JELLY BEAN®
COCKTAIL CLASSICS™
NET WT 3.5 OZ (99g) Ⓤ


HARD LUCK CANDY
FLAVORED VODKA
LEMON DROP
LEMON FLAVORED VODKA
HARD LUCK CANDY
FLAVORED VODKA
RED FISH
BERRY FLAVORED VODKA
HARD LUCK CANDY
FLAVORED VODKA
ROOT BEER BARREL
ROOT BEER FLAVORED VODKA
HARD LUCK CANDY
FLAVORED VODKA
ORANGE DREAM
ORANGE & VANILLA FLAVORED VODKA


Strawberry
Cola
Mint
Chocolate
Vanilla
Banana
Grape

JAMA Pediatrics | Original Investigation

# Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015

Shannon Lea Watkins, PhD; Stanton A. Glantz, PhD; Benjamin W. Chaffee, DDS, PhD


Supplemental content

**IMPORTANCE** Approximately 90% of adult smokers first tried a cigarette by 18 years of age, and even infrequent smoking in adolescence is associated with established adult smoking. Noncigarette tobacco use is increasing and could stimulate subsequent conventional cigarette smoking in youths.

**OBJECTIVE** To estimate the longitudinal association between noncigarette tobacco use and subsequent cigarette smoking initiation among US youth.

**DESIGN, SETTING, AND PARTICIPANTS** In this prospective cohort study of the Population Assessment of Tobacco and Health (PATH) waves 1 (September 12, 2013, to December 14, 2014) and 2 (October 23, 2014, to October 30, 2015), a nationally representative sample of youths who never smoked a conventional cigarette at baseline and completed wave 2 follow-up (N = 10 384) was studied. PATH retention at follow-up was 87.9%.

**EXPOSURES** Ever use and past 30-day use of electronic cigarettes (e-cigarettes), hookah, noncigarette combustible tobacco, or smokeless tobacco at baseline.

**MAIN OUTCOMES AND MEASURES** Ever use and past 30-day use of cigarettes at follow-up.

**RESULTS** The present analysis was based on the 10 384 PATH youth respondents who reported never having smoked a cigarette in wave 1 and whose cigarette ever or past 30-day use was reported in wave 2 (mean [SD] age, 14.3 [1.7] years; age range, 12-17 years; 5087 [49.1%] female; 4829 [52.5%] white). At 1-year follow-up, 469 (4.6%) of all baseline never-smoking youths had tried a cigarette and 219 (2.1%) had smoked a cigarette within the past 30 days. Cigarette ever use at follow-up was higher among youths who had ever used e-cigarettes (78 [19.1%]), hookah (60 [18.3%]), noncigarette combustible tobacco (45 [19.2%]), or smokeless tobacco (29 [18.8%]) at baseline. After adjusting for sociodemographic, environmental, and behavioral smoking risk factors and for baseline ever use of other tobacco products, the odds of past 30-day cigarette use at follow-up were approximately twice as high among baseline ever users of e-cigarettes (odds ratio [OR], 1.87; 95% CI, 1.15-3.05), hookah (OR, 1.92; 95% CI, 1.17-3.17), noncigarette combustible tobacco (OR, 1.78; 95% CI, 1.00-3.19), and smokeless tobacco (OR, 2.07; 95% CI, 1.10-3.87). Youths who had tried more than 1 type of tobacco product at baseline had 3.81 (95% CI, 2.22-6.54) greater adjusted odds of past 30-day cigarette smoking at follow-up than did baseline never tobacco users.

**CONCLUSIONS AND RELEVANCE** Any use of e-cigarettes, hookah, noncigarette combustible tobacco, or smokeless tobacco was independently associated with cigarette smoking 1 year later. Use of more than 1 product increased the odds of progressing to cigarette use.


**CONCLUSIONS AND RELEVANCE** Any use of e-cigarettes, hookah, noncigarette combustible tobacco, or smokeless tobacco was independently associated with cigarette smoking 1 year later. Use of more than 1 product increased the odds of progressing to cigarette use.

**Author Affiliations:** Center for Tobacco Control Research and Education, Department of Medicine, University of California, San Francisco (Watkins); Center for Tobacco Control Research and Education, Department of Medicine, Philip R. Lee Institute for Health Policy Studies, University of California, San Francisco (Glantz); Center for Tobacco Control Research and Education, Department of Preventive and Restorative Dentistry, University of California, San Francisco (Chaffee).

**Corresponding Author:** Benjamin W. Chaffee, DDS, PhD, Center for Tobacco Control Research and Education, Department of Preventive and Restorative Dentistry, University of California, San Francisco, 3333 California St, Ste 495, San Francisco, CA 94118 (benjamin.chaffee@ucsf.edu).

*JAMA Pediatr*. 2018;172(2):181-187. doi:10.1001/jamapediatrics.2017.4173
Published online January 2, 2018.







FDLI

Table 2. Associations of Noncigarette Tobacco Ever Use With Subsequent Cigarette Use

| Wave 1 Use | No. of Observations Before Multiple Imputation | Wave 2 Cigarette Ever Use (n = 10 384)[a] | | | Wave 2 Cigarette Past 30-d Use (n = 10 380)[b] | | |
|---|---|---|---|---|---|---|---|
| | | Weighted, Unadjusted Cigarette Ever Use, % | OR (95% CI) | | Weighted, Unadjusted Cigarette Past 30-d Use, % | OR (95% CI) | |
| | | | Model 1[c] | Model 2[d] | | Model 3[c] | Model 4[d] |
| E-cigarettes | | | | | | | |
| Never | 9923 | 3.9 | 1 [Reference] | 1 [Reference] | 1.8 | 1 [Reference] | 1 [Reference] |
| Ever | 425 | 19.1 | 3.50 (2.48-4.94) | 2.53 (1.80-3.56) | 8.2 | 2.39 (1.42-4.00) | 1.87 (1.15-3.05) |
| Hookah | | | | | | | |
| Never | 10 026 | 4.1 | 1 [Reference] | 1 [Reference] | 1.9 | 1 [Reference] | 1 [Reference] |
| Ever | 339 | 18.3 | 2.67 (1.81-3.93) | 1.79 (1.23-2.62) | 9.4 | 2.85 (1.69-4.79) | 1.92 (1.17-3.17) |
| Noncigarette combustibles | | | | | | | |
| Never | 9818 | 4.2 | 1 [Reference] | 1 [Reference] | 1.9 | 1 [Reference] | 1 [Reference] |
| Ever | 226 | 19.2 | 2.23 (1.42-3.49) | 1.64 (1.06-2.54) | 10.8 | 2.47 (1.36-4.47) | 1.78 (1.00-3.19) |
| Smokeless | | | | | | | |
| Never | 10 101 | 4.4 | 1 [Reference] | 1 [Reference] | 1.9 | 1 [Reference] | 1 [Reference] |
| Ever | 155 | 18.8 | 2.64 (1.60-4.35) | 1.66 (1.00-2.76) | 12.5 | 3.78 (2.07-6.89) | 2.07 (1.10-3.87) |

Abbreviation: OR, odds ratio.

[a] For cigarette use ever, the *F* statistic was 56.1 in model 1 and 24.6 in model 2, and the largest fraction of missing information was 0.011 in model 1 and 0.0186 in model 2.

[b] For past 30-day cigarette use, the *F* statistic was 36.8 in model 1 and 19.7 in model 2, and the largest fraction of missing information was 0.028 in model 1 and 0.032 in model 2.

[c] Model includes all ever tobacco use categories.

[d] Model includes all ever tobacco use categories and the following wave 1 covariates: female, age, race/ethnicity, parental educational level, urban residence, sensation seeking, alcohol ever use, living with tobacco user, notice of cigarette warning labels, tobacco advertising receptivity, and summer season. Coefficient values for adjustment variables are given in eTable 8 in the Supplement.

There was little collinearity among baseline tobacco use variables (all variance inflation factors <1.4). Sensitivity analyses yielded similar findings to the main analyses (eTables 1-7 in the Supplement). Associations decreased in magnitude with adjustment for marijuana use (eTable 4 in the Supplement). The ORs not adjusted for other noncigarette tobacco products were consistently larger than the ORs with simultaneous control for other products (eTable 5 and eTable 6 in the Supplement).

**eTable 4.** Associations of Noncigarette Tobacco Single-Product Ever Use and Polyuse With Subsequent Cigarette Use: Sensitivity to Adjustment For Baseline Cigarette Susceptibility or Marijuana Ever Use

| | Outcome: Cigarette ever use | | | Outcome: Cigarette past 30-day use | | |
|---|---|---|---|---|---|---|
| **Predictors:** | OR (95% CI) | OR (95% CI) | OR (95% CI) | OR (95% CI) | OR (95% CI) | OR (95% CI) |
| e-cigarettes | 4.62 (3.10, 6.89) | 2.21 (1.42, 3.44) | 2.62 (1.65, 4.18) | 2.98 (1.55, 5.74) | 1.49 (0.75, 2.98) | 1.69 (0.79, 3.61) |
| hookah | 4.52 (2.90, 7.05) | 2.30 (1.39, 3.79) | 1.84 (1.06, 3.22) | 4.31 (2.31, 8.04) | 2.36 (1.19, 4.69) | 1.98 (0.93, 4.18) |
| other combustables | 3.52 (1.94, 6.40) | 1.95 (1.03, 3.69) | 2.45 (1.15, 5.21) | 5.25 (2.61, 10.58) | 2.90 (1.34, 6.25) | 3.33 (1.28, 8.64) |
| smokeless | 3.44 (1.74, 6.80) | 1.42 (0.65, 3.08) | 1.70 (0.75, 3.86) | 4.34 (1.74, 10.80) | 1.59 (0.59, 4.30) | 1.83 (0.63, 5.26) |
| polyuse | 8.55 (5.96, 12.26) | 3.67 (2.45, 5.51) | 3.41 (2.03, 5.75) | 9.03 (5.64, 14.45) | 3.65 (2.10, 6.34) | 2.80 (1.35, 5.78) |
| cigarette susceptibility | | 2.84 (2.22, 3.63) | | | 2.45 (1.73, 3.48) | |
| marijuana ever use | | | 2.61 (1.79, 3.81) | | | 2.54 (1.52, 4.24) |
| N | 9909 | 9189 | 8940 | 9907 | 9187 | 8938 |

Abbreviations: OR = odds ratio; CI = confidence interval

Notes: All models additionally adjusted for gender, age, race/ethnicity, parents' education, sensation-seeking score, ever use of alcohol, living with another tobacco user, noticing cigarette warnings score, having a favorite tobacco ad, and baseline interview conducted in the summer. Models are listwise deletion models with sample weights.

A proposed catalyst model comprehensively summarizes possible causal pathways from initial use of e-cigarettes to tobacco smoking among youths.[32] This model includes e-cigarette characteristics initially favored by youths (eg, flavors, social acceptability, and lower perceived harm) before transition to smoking through nicotine dependence, sensorimotor stimulation, increasing accessibility, and other pathways.[32] Similarly comprehensive models are lacking for other noncigarette tobacco products, but factors such as flavors and nicotine experiences may apply analogously.

Nicotine & Tobacco Research Advance Access published September 18, 2015

# Gateway Critiques

*Nicotine & Tobacco Research*, 2015, 1–8
doi:10.1093/ntr/ntv193
Review

Review

## Vaping as a Catalyst for Smoking? An Initial Model on the Initiation of Electronic Cigarette Use and the Transition to Tobacco Smoking Among Adolescents

Sven Schneider Dr. Phil., Katharina Diehl Dr. Phil.

**11 hypothesized mechanisms**

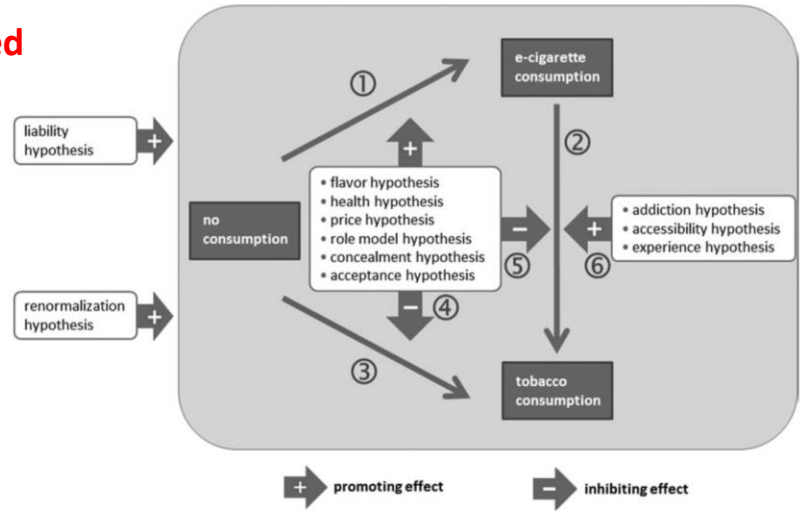


**Figure 2.** Schematic illustration of the possible catalyst function of electronic cigarettes, along with possible reasons for potential transitions.

# Policy Should Not Be Made Solely On The Basis Of Relative Risk

| | Disease | No Disease |
|---|---|---|
| Exposed | 232 | 768 |
| Not Exposed | 72 | 928 |

Confidence Level = 95

SOLVE

**Solution:**

*Calculation of the Odds Ratio (OR)*

The odds ratio is computed as follows:

$$OR = \frac{a/b}{c/d} = \frac{232/768}{72/928} = 3.894$$

| | Disease | No Disease |
|---|---|---|
| Exposed | 232 | 7680000 |
| Not Exposed | 72 | 9280000 |

Confidence Level = 95

SOLVE

**Solution:**

*Calculation of the Odds Ratio (OR)*

The odds ratio is computed as follows:

$$OR = \frac{a/b}{c/d} = \frac{232/7680000}{72/9280000} = 3.894$$

OMG!

# Electronic Cigarettes and Future Marijuana Use: A Longitudinal Study

Hongying Dai, PhD,[a,b,c] Delwyn Catley, PhD,[a,c] Kimber P. Richter, PhD,[d] Kathy Goggin, PhD,[a,c,e] Edward F. Ellerbeck, MD[d]

abstract

**BACKGROUND:** Cigarettes have been strongly associated with subsequent marijuana use among adolescents, but electronic cigarettes (e-cigarettes) are now rapidly replacing traditional cigarettes among youth. This study examines associations between youth e-cigarette use and subsequent marijuana use in a national sample.

**METHODS:** Youth (aged 12–17 years) never marijuana users at wave 1 ($n$ = 10 364; 2013–2014) from the Population Assessment of Tobacco and Health study were followed-up in 1 year (wave 2, 2014–2015). Multivariable logistic regressions were performed to evaluate associations between e-cigarette use at wave 1 and ever/heavy marijuana use in the past 12 months (P12M) and at wave 2.

**RESULTS:** Among never marijuana users, e-cigarette ever use (versus never use) at wave 1 was associated with increased likelihood of marijuana P12M use (adjusted odds ratio [aOR] = 1.9; 95% confidence interval [CI]: 1.4–2.5) at wave 2. There was a significant interaction between e-cigarette use and age ($P$ < .05) with aOR = 2.7 (95% CI: 1.7–4.3) for adolescents aged 12 to 14 and aOR = 1.6 (95% CI: 1.2–2.3) for adolescents aged 15 to 17. The association with heavy marijuana use was significant among younger adolescents (aOR = 2.5; 95% CI: 1.2–5.3) but was not among older adolescents. Heavier e-cigarette use at wave 1 yielded higher odds of P12M and heavy marijuana use at wave 2 for younger adolescents.

**CONCLUSIONS:** E-cigarette use predicts subsequent marijuana use among youth, with a stronger associations among young adolescents. Reducing youth access to e-cigarettes may decrease downstream marijuana use.



FDLI

# E-cigarettes: The new marijuana?