



Protecting Youth: Targeting Appropriate E-Cigarette Users

Kathleen Crosby, Director, Office of Health Communication and Education, FDA - CTP

Mark Greenwold, Senior Consultant, Campaign for Tobacco-Free Kids

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October 25, 2018

Panelists

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Discussion Topics

- FDA's Enforcement Actions/Tools
- Communication Efforts / Real Cost Campaign
- What to Expect
 - Future of CTP's "comprehensive" approach to harm reduction
 - Flavors / PMTA Submissions / Nicotine Standard

FDA Enforcement Efforts

- Retail Inspections / Warning Letters
- Untitled letters to Manufacturers
 - Plans to address youth access
 - Evidence of Aug. 8, 2016 Marketing
- Facility Inspections
- Change in Premarket Compliance Dates?

PREVENTING TEEN TOBACCO USE

Kathy Crosby
Director, Office of Health Communication & Education
FDA Center for Tobacco Products

October 25, 2018



AGENDA

- FDA's Youth Tobacco Prevention Plan
 - Actions To Restrict Youth Access
 - Actions To Curb Marketing of Products
 - Actions to Educate Teens





FDA'S YOUTH TOBACCO PREVENTION PLAN

YOUTH TOBACCO PREVENTION PLAN (YTPP)



In April, Commissioner Gottlieb announced a new segment of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation focused on reducing access to – and use of – tobacco products, particularly e-cigarettes

“But as we work to keep kids from making the deadly progression from experimentation to regular cigarette use, it’s imperative that we also make sure children and teenagers aren’t getting hooked on more novel nicotine-delivery products.”

– Commissioner Gottlieb, April 24, 2018

3

Strategies

Preventing
Youth
Access

Curbing
Marketing
Of Products

Educating
Teens on
Dangers

YTPP ACCESS & MARKETING: ACTIONS OVER THE LAST SIX MONTHS



- Conducted the largest coordinated enforcement blitz in FDA's history of retailers illegally selling e-cigarettes to teens
- Worked with eBay to remove listings for JUUL on its website
- Sent 904(b) document request letters to JUUL and others manufacturers
- Issued warning letters to manufacturers, distributors, and retailers for selling e-liquids that resembled kid-friendly food products like juice boxes, candy and cookies
- Sent letters to industry for potentially marketing e-cigarettes that were not on the market as of August 8, 2016, nor received premarket authorizations
- Issued letters concerning the five, top-selling brands, asking the companies to submit plans describing how they will address the widespread youth access and use of their products
- Signaled that all options are on the table when it comes to reconsidering, and potentially changing, the existing compliance policy for deemed tobacco products

YOUTH USE OF E-CIGARETTES: WHY WE MUST ALL ACT NOW

Preliminary data from the 2018 National Youth Tobacco Survey show a disturbingly sharp rise in the number of teens using e-cigarettes. From 2017 to 2018:

- The number of high-school-age children reporting use of e-cigarettes **rose by more than 75%**
- Use among middle-schoolers **increased nearly 50%**
 - Data will be made public soon, but FDA and Industry both have an obligation to act now



YOUTH USE OF E-CIGARETTES: WHY WE MUST ALL ACT NOW

FDA

The Washington Post

Opinions

We cannot let e-cigarettes become an on-ramp for teenage addiction

By **Alex M. Azar** and **Scott Gottlieb**

October 11 at 8:05 AM

Alex M. Azar is the secretary of health and human services. Scott Gottlieb is the commissioner of the Food and Drug Administration.



Secretary Alex Azar
@SecAzar

Following

The e-cig technology that might help adults end one addiction cannot pull a generation of kids into a new one. At @HHSGov, we're intent on combating tobacco use, the leading cause of preventable death in the US. Read my op-ed with @SGottliebFDA →



Opinion | We cannot let e-cigarettes become an on-ramp for teenage addiction
The technology that might help adults end one addiction cannot pull a generation of kids into a new one.
washingtonpost.com

11:14 AM · 11 Oct 2018

“At the Department of Health and Human Services, we are deeply concerned about the risks that e-cigarettes pose for children, given how quickly teenage use of these products has accelerated.”


“The surge in e-cigarette use by teenagers is alarming because nicotine is highly addictive and can harm brain development, which continues into young adulthood.”

TACKLING A THREAT TO TEENS WHILE LIMITING ADULT VIEWERS



**THE
REAL
COST™**

MORE TEENS ARE AT RISK NOW

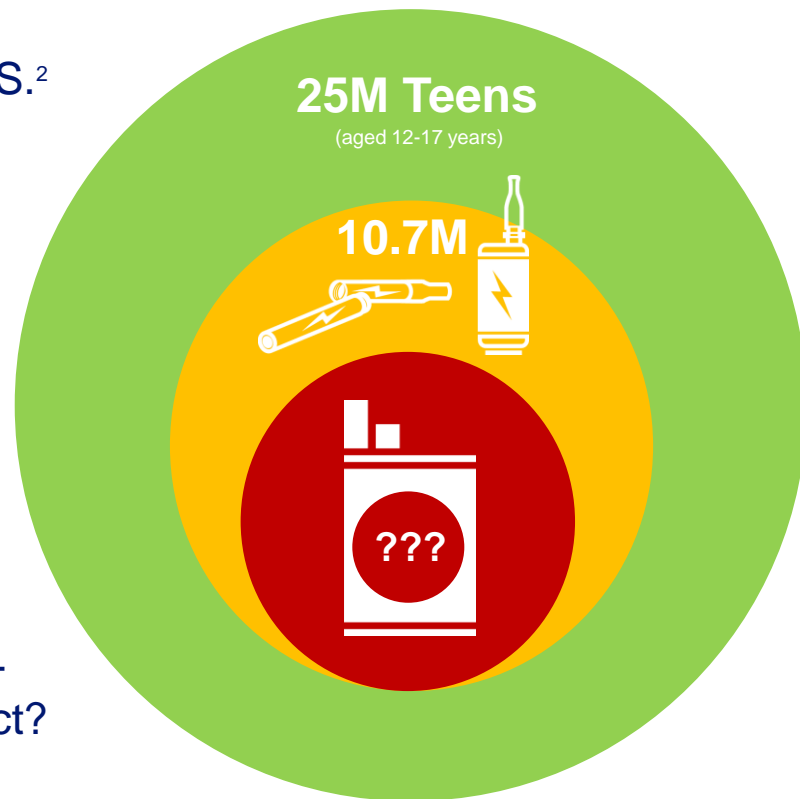
The background of the slide features a photograph of a person with long, curly brown hair, wearing a dark blue hoodie. They are exhaling a large, thick cloud of white vapor that completely obscures their face. The background of the photo is a clear, bright blue sky. The text is overlaid on this image.

With as many as 80% of teens¹ not perceiving great risk of harm from regular e-cigarette use, we are likely looking at a larger target than with combustibles alone

¹MTF 2017; average of responses of 8th, 10th, 12th graders

THE UNIVERSE OF AT-RISK TEENS TODAY

- There are approximately 25 million teens in the U.S.²
- In 2017, teens at risk for or already smoking cigarettes dropped to 8.7 million teens³
- However, FDA estimates nearly 10.7 million youth³ are at risk for or already experimenting with e-cigarettes
- Even if there's 100% overlap, there are millions more youth at risk for e-cigarettes than for cigarettes alone
- Science indicates that teens who vape are more likely to try smoking cigarettes⁴ – will formerly non-susceptible teens transition to the deadliest product?



²U.S. Census Bureau 2016; ³NYTS 2017; ⁴NASEM 2018

LEARNING FROM HUNDREDS OF TEENS AT RISK FOR E-CIGARETTES



They are
Aspirational



They are
Academically Driven

They are
**Popular
and Social**



They are
Athletic



TEENS UNDERSTAND RISKY BEHAVIORS, BUT DON'T SEE USING E-CIGARETTES AS RISKY



**They have limited knowledge about e-cigarettes
and need more information**

**They believe they are smart enough to make
good decisions based on a spectrum of risk**

**They compare e-cigarettes to other substances
with vaping seen as being among the lowest risk¹**

¹MTF 2017; average of responses of 8th, 10th, 12th graders

“THE REAL COST” YOUTH E-CIGARETTE PREVENTION

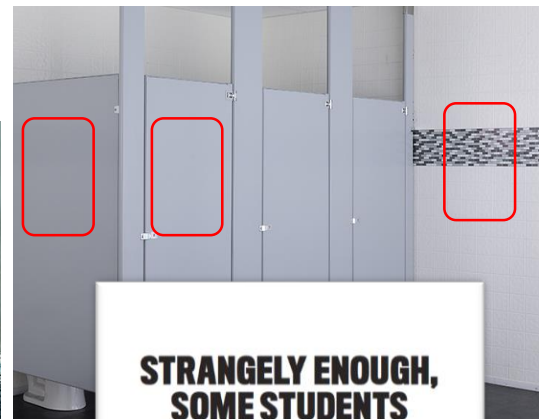
Snap teens out
of their “cost-free”
mentality by sharing
information about the
potential impact that
e-cigarette use
can have on
their health



FDA LAUNCHED “EPIDEMIC” ON SEPTEMBER 17, 2018



CREATIVE EXTENSIONS: WEB, SOCIAL, DIGITAL ADS & POSTERS



VAPING CAN PUT MICROSCOPIC METAL PARTICLES INTO YOUR LUNGS.

TRC-0809339

VAPING CAN PUT DANGEROUS CHEMICALS LIKE FORMALDEHYDE INTO YOUR BLOODSTREAM.

THE REAL COST

LEARN MORE

VAPING CAN CHANGE YOUR BRAIN.

TRC-0809339

THE REAL COST

LEARN MORE

THE SCIENTIFIC FACTS IN THE “EPIDEMIC” CAMPAIGN



- Vaping can expose your brain to nicotine, which can harm your brain and lead to addiction⁵⁻⁹
- Vaping can expose your lungs to acrolein, which can cause irreversible damage^{5,10-12}
- Vaping can expose your lungs to diacetyl, a chemical that has been linked to irreversible lung disease¹³
- Vaping can expose your lungs to toxic metal particles like chromium, nickel and lead^{14,15}
- Vaping can release dangerous chemicals into your bloodstream, like formaldehyde, which is known to cause cancer^{5,10,16}

¹Goniewicz et al. 2014; ¹Marynak et al. 2015; ¹HHS 2016; ¹England et al. 2017; ¹Dwyer et al. 2009; ⁶Cheng 2014; ⁷Bein & Leikauf 2011; ⁸Rubinstein 2018; ⁹Allen 2016; ¹⁰Williams et al. 2013; ¹¹Olmedo et al. 2018; ¹²OSHA

- Ad was copy tested **with 300 youth**
 - “Epidemic” had a Perceived Effectiveness (PE) score of 4.17 out of 5.0¹⁷
 - Youth clearly understood the main message of the ad and the ad performed well on other performance measures
 - Findings indicate a significant opportunity to increase teen’s knowledge about health effects
- Ads were copy tested **with 900 young adult and adult smokers** open to using e-cigarettes
 - Copy testing revealed potential unintended consequences among adults
 - Perception of risk shifted to think that e-cigarettes were equally or more harmful than cigarettes
 - Viewing the ad did not impact a smoker’s intention or motivation to quit smoking cigarettes
 - However, adults were less interested in using e-cigarettes to help them quit smoking
 - Based on these mixed findings, the campaign is being laser targeted to only reach youth

¹⁷FDA 2018, unpublished data

- ‘The Real Cost’ Youth E-Cigarette Prevention Campaign will be limited to **age-verified digital** media, **limiting adult “spill”** by hyper-targeting the media to **exclusively reach 12- to 17-year-olds** on digital and social channels
- **Limiting the buy** to digital and social media means this campaign **will reach 60% teens**, at least 28 times per quarter, instead of at least 75% of the target audience, the goal for all other FDA education campaigns




TEENS (AND ADULT) ENGAGEMENT IN THE LAST MONTH



Total Likes:

51,684 

Total Shares:

11,073 

Total Comments:

2,467 

Teens think
vaping is less
harmful than
smoking



Teens don't
think vaping is
an epidemic



Teens think
vaping is a
harm reduction
tool



Teens ask
for help with
quitting



TEENS (AND ADULTS) THINK VAPING IS LESS HARMFUL THAN SMOKING



E cigs are actually 95% less harmful than normal ones but facts don't matter i guess

Like · Reply · 3w



• Comment



Oh please. Vaping nicotine is better for you then smoking is



Reply



The Real Cost Couldn't we find some common ground and say vaping is a safer and better alternative than smoking





The Real Cost ✓ Hey [redacted] - Cigarettes are the most deadly tobacco product, so yes, e-cigarettes may expose users to fewer harmful chemicals. This doesn't mean they are safe to use. Vaping can expose you to chemicals like formaldehyde and acrolein, which are known to cause cancer and permanent lung damage. In addition, Some vapes can expose you to similar amounts of nicotine as cigarettes.

TEENS (AND ADULTS) DON'T THINK VAPING IS AN EPIDEMIC

How's it a epidemic why ban vaping when y'all don't want to do anything about smoking it's 95% safer then traditional smoking 😂

Lmao what, it's not an epidemic 😂, you can also, ya know, choose not to do nic

 **therealcost** There is no safe tobacco product, especially for teens. Both cigarettes and vapes can deliver cancer-causing chemicals into your lungs, and both can also expose you to nicotine, which can disrupt your brain development.

 **therealcost** Hey - you should know that even if your vape doesn't contain nicotine, you may still be exposing your lungs to harmful chemicals that come from the e-liquid itself, including formaldehyde and acrolein, which are known to cause cancer and lung damage.

TEENS (AND ADULTS) THINK VAPING IS A HARM REDUCTION TOOL



You guys are really wasting your time going after vaping. It would make a ton more sense to endorse it as a significantly less harmful smoking alternative rather than making it look just as bad as smoking.

Like · Reply · Message · 2w



The Real Cost ✓ Hey [redacted] - We're sorry to hear that you feel this way. Cigarettes are the most deadly tobacco product, so yes, e-cigarettes may expose users to fewer harmful chemicals. This doesn't mean they are safe to use. Vaping can expose you to chemicals like formaldehyde and acrolein, which are known to cause cancer and permanent lung damage.

Like · Reply · Commented on by Sprinkl[r] · 1w



TEENS ASK FOR HELP WITH QUITTING



I didnt know this, any recommendations to quit vape? 😞



My friend, [redacted] has been struggling with addictions for three years now, starting in 7th grade. It started with candy, and eventually escalated to something the youth call "The Juul". He can't seem to stop vaping and does it everywhere. I, his friend, have tried to convince him to stop but to no avail. He simply replies with, "Do it for the Juul" and "Juul life". He needs help desperately and his addiction has simply gone too far.

I'm addicted to my Juul help



Hey [redacted] - The best way to quit may be a combination of options and may be different for each person. Check out quitting resources on our website: http://bit.ly/TRC_QuitTools.



“To be clear, the FDA remains committed to the idea that e-cigarettes have the potential to help adult smokers transition away from combustible cigarettes. But we may have to narrow the off ramp for adults, to close the on ramp for kids.”

– Commissioner Gottlieb

THANK YOU

FDA

REFERENCES

1. Johnston LD, Miech RA, O'Malley PM, et al. Monitoring the Future national survey results on drug use: 1975–2017: Overview, key findings on adolescent drug use. Ann Arbor: Institute for Social Research, The University of Michigan. www.monitoringthefuture.org/pubs/monographs/mtf-overview2017.pdf. Updated January 2018.
2. U.S. Census Bureau. *Monthly Population Estimates by Age, Sex, Race, and Hispanic Origin for the United States: April 1, 2010 to July 1, 2015*. Washington, D.C.: U.S. Census Bureau, Population Division; 2016.
3. CDC, FDA. Total at-risk experimenters and susceptible non-trier estimates, e-cigarettes: 2017 NYTS dataset and codebook. Atlanta, GA: CDC. www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html. Updated May 9, 2018.
4. NASEM. Public Health Consequences of E-cigarettes. Washington, DC: The National Academies Press; 2018. <https://doi.org/10.17226/24952>.
5. Goniewicz ML, Hajek P, McRobbie H. Nicotine content of electronic cigarettes, its release in vapour and its consistency across batches: regulatory implications. *Addiction*. 2014; 109(3):500-7.
6. Marynak KL, Gammon DG, Rogers T, Coats EM, Singh T, King BA. Sales of nicotine-containing electronic cigarette products: United States, 2015. *American Journal of Public Health*. 2017; 107(5):702-705.
7. HHS. *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2016.
8. England LJ, Aagaard K, Bloch M, et al. Developmental toxicity of nicotine: A transdisciplinary synthesis and implications for emerging tobacco products. *Neuroscience & Biobehavioral Reviews*. 2017; 72:176-189.
9. Dwyer JB, McQuown SC, Leslie FM. The dynamic effects of nicotine on the developing brain. *Pharmacology & Therapeutics*. 2009; 122(2):125-39.
10. Cheng T. Chemical evaluation of electronic cigarettes. *Tobacco Control*. 2014; 23:ii11–ii17.
11. Bein K, Leikauf GD. Acrolein—a pulmonary hazard. *Molecular Nutrition & Food Research*. 2011;55(9):1342-1360.
12. Rubinstein M, Delucchi K, Benowitz N, Ramo D. Adolescent exposure to toxic volatile organic chemicals from e-cigarettes. *Pediatrics*. 2018; 141(4):e20173557.
13. Allen J, Flanigan SS, LeBlanc M, et al. Flavoring chemicals in e-cigarettes: Diacetyl, 2,3-pentanedione, and acetoin in a sample of 51 products, including fruit-, candy-, cocktail- flavored e-cigarettes. *Environ Health Perspect*. 2016;124. <https://ehp.niehs.nih.gov/15-10185/>.
14. Williams M, Villarreal A, Bozhilov K, Lin S, Talbot P. Metal and silicate particles including nanoparticles are present in electronic cigarette cartomizer fluid and aerosol. *PLoS One*. 2013; 8(3):e57987.
15. Olmedo P, Goessler W, Tanda S, et al. Metal concentrations in e-cigarette liquid and aerosol samples: the contribution of metallic coils. *Environmental Health Perspectives (Online)*. 2018; 126(2).
16. OSHA. *Occupational Safety and Health Standards. Medical surveillance – Formaldehyde*. Washington, DC: U.S. Department of Labor, Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10078.

FDA Enforcement Policies Designed to Address the Epidemic of Youth E-Cigarette Use

Mark E. Greenwold

Senior Consultant, Campaign for Tobacco-Free Kids

Food and Drug Law Institute Meeting

October 25, 2018

FDA is faced with an epidemic of youth usage of Juul and Juul look-alikes

- High school usage has increased by 77% between 2017 and 2018. (Preliminary NYTS data)
- “E-cigarette use increases risk of ever using combustible cigarettes among youth and young adults.” (Nat’l. Academy of Science, Engineering and Medicine—2018)
- High school usage of cigarettes increased from 7.5% to 8.1% between 2017 and 2018. (Preliminary NYTS data)

Reasons for the epidemic

- Current crisis is the result of FDA's failure to impose any regulation on e-cigarettes prior to 2016 and its failure to regulate the introduction and promotion of products effectively since then.

Other effects of the absence of effective regulation

Granting compliance period to all products and postponing PMTA application date reduces the incentive for manufacturers to identify the specific products that may promote harm reduction without increasing youth tobacco use.

Makes it harder to get the information to guide good policy.

Enables products that may produce no net public health benefit to dominate the market.

Denies smokers valuable information about which products may actually help cessation and how they must be used to facilitate quitting smoking.

Absence of regulation prior to 2016

- Between the D.C. Circuit's Sottera decision in 2010 and the issuance of the deeming rule in May 2016 there was no regulation at all of e-cigarettes.
- Manufacturers were free to introduce new products at will and advertise them in ways that appealed to kids.
- High school usage rose from 1.5% in 2011 to 16% in 2015.

Deeming Rule Submitted by FDA to OMB in 2016

- Assert jurisdiction over e-cigarette products effective 90 days after promulgation.
- 2-year compliance period for unflavored e-cigarettes.
- No compliance period for flavored e-cigarettes in the absence of a marketing order.
- Prohibition of new products introduced after effective date in absence of a marketing order.

Deeming Rule as Promulgated

- Jurisdiction over e-cigarettes asserted effective 90 days after promulgation (8/8/16). Detailed draft guidance for PMTA applications issued simultaneously.
- Compliance period of 2 years for all e-cigarettes, whether flavored or not.
- Prohibition of new products introduced after 8/8/16.
- No effective limitation on advertising and marketing.

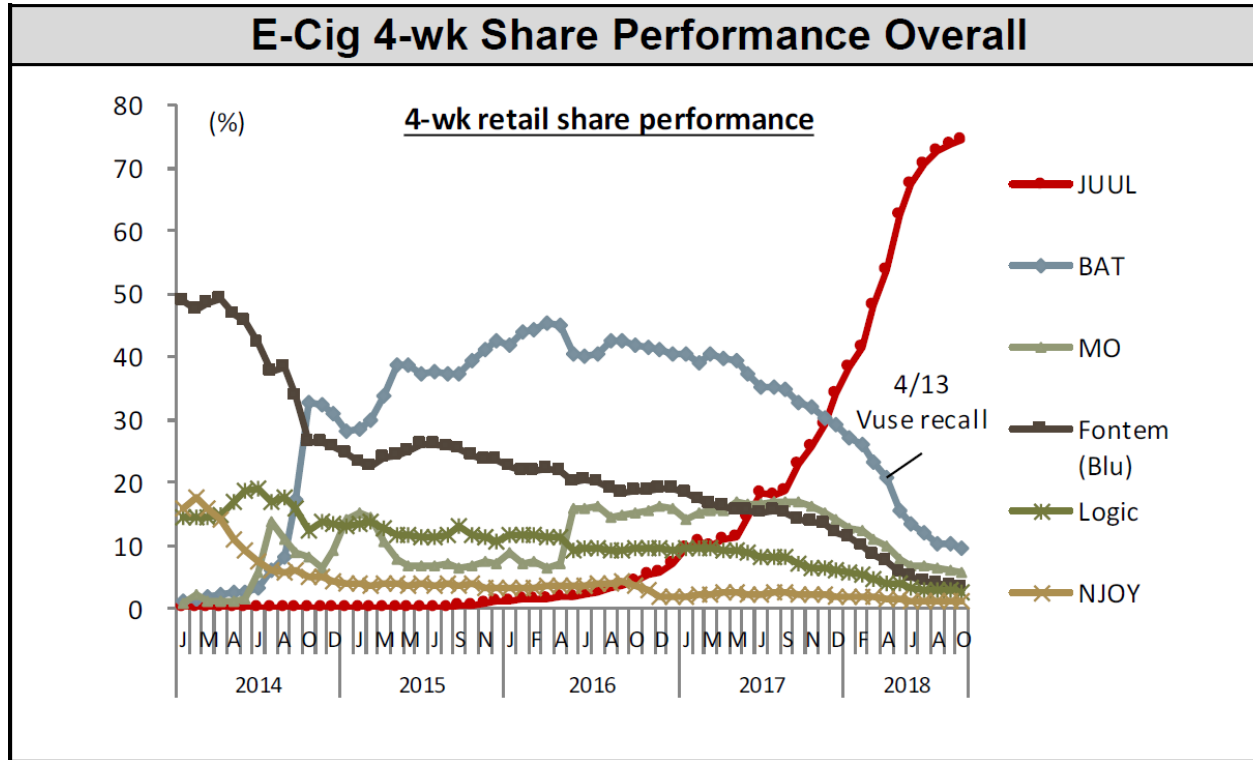
FDA's September, 2017 Amendment of the Deeming Rule

- Compliance deadline extended by at least four years, to August 8, 2022, plus whatever time needed to review application.
- Reassertion of prohibition on new products introduced after effective date of deeming rule (8/8/16) but no policy established to enable enforcement.
- No limitation on advertising and marketing.

Result of Policies Adopted

Radical changes in e-cigarette market. Juul market share (less than 4% on date of deeming rule) rises to 74.5% by September 2018.

JUUL Market Share: 74.5%



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

Incentives created by the absence of regulation

- Market receptive to products that
 - Have youth-friendly flavors
 - Deliver potent nicotine dose
 - Have sleek design
 - Are easily concealable
 - Are advertised and promoted as “cool”

Claims of Innocence Undermined By A Deliberate Marketing Effort

***Juul Executives claimed*,
“all of the things you see on social media, we have absolutely
nothing to do with. We actively try to take these things down”***

The Facts could not be more different

- Juul launched its product with a campaign using images that are similar to those long used by the cigarettes industry; and
- paid for a social media campaign using Twitter, Instagram and YouTube; and
- used sponsored “ambassadors” supplemented by social media promoted by other Juul vendors.

* Sharfstein, J., “How Do You Solve a Problem Like Juul”, Milbank Quarterly, 2018, pp 2,3



OPEN ACCESS

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2018-054382>).

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BMJ

Research paper

Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market

Jidong Huang,¹ Zongshuan Duan,¹ Julian Kwok,¹ Steven Binns,² Lisa E Vera,^{2,3} Yoonsang Kim,² Glen Szczypka,² Sherry L Emery²

ABSTRACT

Background While national surveys showed declines in e-cigarette use in the USA between 2015 and 2016, recent reports indicate that JUUL, a sleekly designed e-cigarette that looks like a USB drive, is increasingly being used by youth and young adults. However, the extent of JUUL's growth and its marketing strategy have not been systematically examined.

Methods A variety of data sources were used to examine JUUL retail sales in the USA and its marketing and promotion. Retail store scanner data were used to capture the retail sales of JUUL and other major e-cigarette brands for the period 2011–2017. A list of JUUL-related keywords was used to identify JUUL-related tweets on Twitter; to identify JUUL-related posts, hashtags and accounts on Instagram; and to identify JUUL-related videos on YouTube.

Results In the short 3-year period 2015–2017, JUUL has transformed from a little-known brand with minimum sales into the largest retail e-cigarette brand in the USA, lifting sales of the entire e-cigarette category. Its US\$150 million retail sales in the last quarter of 2017 accounted for about 40% of e-cigarette retail market share. While marketing expenditures for JUUL were moderate, the sales growth of JUUL was accompanied by a variety of innovative, engaging and wide-reaching campaigns on Twitter, Instagram and YouTube, conducted by JUUL and its affiliated marketers.

Conclusions The discrepancies between e-cigarette sales data and the prevalence of e-cigarette use from surveys highlight the challenges in tracking and understanding the use of new and emerging tobacco products. In a rapidly changing media environment, where successful and influential marketing campaigns can be conducted on social media at little cost, marketing expenditures alone may not fully capture the influence, reach and engagement of tobacco marketing.

INTRODUCTION

Use of electronic cigarettes has increased rapidly over the past decade in the USA, particularly among youth.^{1–4} A development that raised significant public health concerns about the creation of a new generation of nicotine dependency.^{1–4} E-cigarette devices that youth prefer have also evolved substantially over time: from early-generation cigalike e-cigarettes; to more advanced modifiable tank-style e-cigarettes;⁵ to the recent emergence of a sophisticated, sleekly designed, discreet high-tech device called JUUL⁶—a flat, rectangular portable e-cigarette device fashioned to look like a computer flash

drive and rechargeable at a USB port.⁷ A JUUL has two basic components: the device, which includes a battery and temperature regulation system, and the perfilled e-liquid cartridge, called a 'JUUL pod' which also serves as the mouthpiece. JUUL is manufactured to be a closed system, that is, non-modifiable.^{8–9} JUUL and its competitors, such as Suorin e-cigarettes, are colloquially known as 'pod vaporizers' or 'vape pods'. JUUL is made by the San Francisco-based JUUL Labs, which was founded in early 2017 by two former Stanford graduate students as a spinoff of the Pax Labs, manufacturers of the hybrid Pax brand vaporizers.⁸

Recent news is abuzz with the stories of JUUL's striking appeal to teens and the dramatic increase in JUUL use among the youth population since its mid-2015 market debut.^{8–14} A 2017 survey reported that 8% of American youth and young adults (aged 15–24 years) used JUUL in the 30 days prior to the survey.¹⁵ The reported popularity of JUUL among youth has prompted enforcement actions from FDA to stop youth use of, and access to, JUUL and other e-cigarettes.¹⁶ The characteristics that purportedly make JUUL more popular among youth than its predecessors include its trendy design (called the 'iPhone of e-cigarettes');¹⁷ youth-friendly flavours like Fruit Medley and Caramel Brulée; and JUUL's discreet profile—teens even report having vaped in class.^{18,19} JUUL is reported to contain high levels of nicotine (0.7 mL or 59 mg/mL per pod) and uses a proprietary e-liquid formula (JUUL salts) based on the nicotine salts found in leaf-based tobacco rather than free-based nicotine.²⁰ Consequently, JUUL is said to deliver a nicotine peak in about 5 min, and can create an experience more like combustible cigarette smoking than found with other e-cigarettes on the market,²¹ an attribute appealing to both young and adult smokers.

Previous research demonstrated that the rapid growth in e-cigarette use was accompanied by a marked increase in advertising and promotion.^{22–24} Similarly, several news articles have covered JUUL's marketing.^{25–27} Concerns have been voiced regarding the youth of the men and women portrayed in JUUL's advertising in combination with the product design, which critics believe 'misleads about risk' of addiction.²⁸ JUUL is also highly discussed on social media platforms such as Twitter, Instagram, YouTube and Reddit.²⁷ Because the audience of these platforms disproportionately represent youth and young adults,²⁹ JUUL's marketing and promotion on social media

Huang J, et al. *Tob Control* 2018;0:1–6. doi:10.1136/tobaccocontrol-2018-054382

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Tob Control: first published as 10.1136/tobaccocontrol-2018-054382 on 31 May 2018. Downloaded from <http://tobaccocontrol.bmj.com/> on 5 July 2018 by guest. Protected by copyright.

- JUUL spent at least \$1.6M on marketing its launch
- Strategy to supplement with social media
- Outside of “official” content, other JUUL related accounts even more popular
- Social media growth (tweets in particular) “highly correlated” with JUUL sales

The Masterful Use of Social Media

- Seven Juul related accounts amassed over **a QUARTER MILLION** followers
- 25% of people retweeting official JUUL tweets are under 18
- Juul related YouTube videos exceeded 100,000
- More than 15,000 members discussed Juul on Reddit
- Social media campaigns began in 2015 but continued at least through 2017. They were not short term and their popularity was well documented

Huang J et al. Tobacco Control 2018:

Billboards



2015 Times Square, New York City, <https://www.spencer-pederson.com/work-1/2017/2/23/juul-go-to-market>

Magazine



Vice Magazine 2015, <http://cultideas.com/case-study/juul> and
<http://gaia.adage.com/images/bin/image/jumbo/juulvicespreadFinalpage001.jpg>

Promotions – JUUL Vapor Lounge



September 6, 2015

<https://twitter.com/NocturnalWland/status/640418999856144384>

Events – Launch Party





2015, <http://ads.gawkerassets.com/creative/ads/live/Juul/Launch%20Party/carousel/carousel.html>

Failure to enforce the requirement that new products not on the market on 8/8/16 require a PMTA.

- Although FDA claimed that only new products on the market on 8/8/16 were eligible for the extended compliance period, scores of new products not marketed on that date have been introduced.

Stigpods blog May 2018: **“New revolutionary inventions seem to continually be released everyday in the vaping industry and that is why it is an honor to finally introduce the STIG to the vaping market.”**

1 The highly anticipated STIG Is available now!

May  May 01, 2018  Ejuices (<https://stigpods.com/blog/ejuices/>)



New revolutionary inventions seem to continually be released everyday in the vaping industry and that is why it is an honor to finally introduce the STIG to the vaping market! This disposable, all in one pod system does not fall short of incredible. The STIG is going to transform the vaping experience for everyone who uses it do to the fact that it provides an effortless, flavorful and satisfying salt nicotine experience! It is an on-draw device that is always ready when you are. It rivals the smoking experience with a smooth throat hit and higher nicotine absorption with less vape juice and vapor production. Best of all, your clothes won't smell, no stale smoke odor from cigarette butts or yellow teeth!

Accessed 7.3.18; dated 5.1.18: <https://stigpods.com/blog/the-highly-anticipates-STIG-is-available-now/>

Saltprn May 2018: “It feels like there is a new pod system released every day and we receive tons of them.”



Dated 5.27.18: <https://www.instagram.com/p/BjSkidRj5HS/?tagged=suorin>

Vape Deals Website February 2018: **“The pod systems just keep coming! I’m having a hard time keeping track of all the new devices that are hitting the market.”**

7 DAZE ZOOR CLOSED POD SYSTEM \$19.80

🕒 02/27/2018 📁 \$10 - \$25, Cigalike, Starter Kits, USA Vendor
💬 Comments Off on 7 Daze Zoor Closed Pod System \$19.80

👁 1,073 Views

The pod systems just keep coming! I'm having a hard time keeping track of all the new devices that are hitting the market. The **7 Daze Zoor** looks like another good one though. The cartridges have a 2mL **e-liquid** capacity, which is significantly better than your average closed pod system. If you want to check it out, head over to Ecig-City. They just did a big price drop on this one—it's now selling for only \$21.99. Plus, you can save an additional 10% with coupon code "VIPHDWR10" (\$19.80 total). Please note that the pods are sold separately, so you'll definitely want to pick up a pack of those as well (link below).

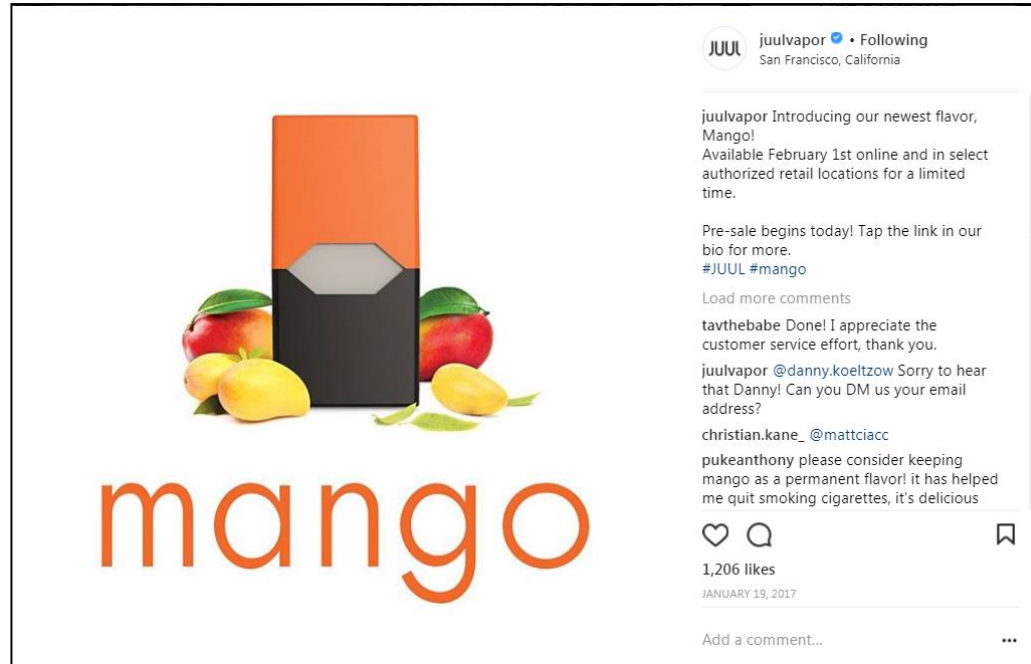
7 Daze Zoor Flavors

- MINT: A cool refreshing and sweet menthol
- APPLE: Apple juice flavor
- CAKE: Sweet and creamy dessert flavor
- MIXED: Multi-pack

Use Coupon Code: **VIPHDWR10**

Dated 2.27.18: <http://vape.deals/7-daze-zoor-closed-pod-system-19-80/>

Juul's most popular flavor appears to have been introduced after 8/8/16.



January 19, 2017 <https://www.instagram.com/p/BPdJVDjBlfG/?taken-by=juulvapor>

Many of the new e-
cigarettes closely resemble
the design features of
JUUL



Kandy
Pens'
Rubi



MLV's
PHIX



Myle



Altria's
Markten
Elite



Major tobacco companies
and independent
companies are producing
these types of e-cigarettes

Altria – MarkTen Elite

Altria Introducing Closed Vapor System

By Angel Abcede, Senior Editor/Tobacco, CSP Daily News



Convenience Store Daily News:

“With the recent explosion of the Juul closed-system vaping device in the convenience store channel, major tobacco manufacturer Altria Groups, Inc.....announced it will enter the closed-tank segment with a product called MarkTen Elite.”

With the recent explosion of the Juul closed-system vaping device in the convenience-store channel, major tobacco manufacturer Altria Group Inc., parent company of Altria Group Distribution Co., both based in Richmond, Va., announced it will enter the closed-tank segment with a product called MarkTen Elite. The product is described as “a pod-based product with a premium, sleek battery design” and having the “convenience of prefilled, magnetic click pods.”

February 28, 2018: <http://www.cspdailynews.com/category-news/tobacco/articles/altria-introducing-closed-vapor-system#page=0>

BAT/Reynolds – Vuse Alto

Reynolds Vapor prepares national launch of new e-cig rival to Juul

By Richard Craver Winston-Salem Journal Jul 17, 2018 🗨️ (0)

The goal is to have Vuse Alto in national distribution by November, Ricardo Oberlander said Tuesday. Oberlander is a longtime BAT executive who took over as chief executive of Reynolds American Inc. in January.

Accessed 8.3.18; article dated 7.17.18 https://www.journalnow.com/business/reynolds-vapor-prepares-national-launch-of-new-e-cig-rival/article_7ba10442-d438-575e-af23-794173089a8a.html

Joyetech Lists New Product Launch Dates on Its Website with Scores of Products Introduced After August 8, 2016

More news		
ESPION Silk with NotchCore Atomizer Kit Launching	Joyetech CuBox AIO Starter Kit Launching	2017-08-17
Joyetech RIFTCORE DUO Atomizer Launching		
Joyetech TEROS Launching	EKEE with ProCore Motor Launching	2017-08-02
eVic Primo Fit with EXCEED Air Plus Launching		
BATPACK with Joye ECO D16 Kit Launching	ATOPACK PENGUIN SE Launching	2017-07-25
ESPION Infinite with ProCore Conquer Launching		
Joyetech ProCore Air Plus Launching		
Joyetech EXCEED Edge Launching		
Joyetech EXCEED Air Atomizer Launching	CUBOID Pro with ProCore Aries Kit Launching	2017-07-18
ESPION Solo with ProCore Air Kit Launching		
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Joyetech eGo ECO Launching	eVic Primo SE with ProCore SE Kit Launching	2017-07-06
Introducing Joyetech Chief Designer – Jonathan Fairbanks		
Joyetech ESPION with ProCore X Kit Launching		
EXCEED Box Starter Kit Launching	ProCore Remix Atomizer Launching News	2017-06-20
Joyetech ATOPACK DOLPHIN Starter Kit Launching		
EXCEED D19 Starter Kit Launching		
Holiday Notice		
CUBOID Lite with EXCEED D22 Kit Launching		
Joyetech CuBox AIO Starter Kit Launching		
EKEE with ProCore Motor Launching		
ATOPACK PENGUIN SE Launching		
CUBOID Pro with ProCore Aries Kit Launching		
eVic Primo SE with ProCore SE Kit Launching		
ProCore Remix Atomizer Launching News		

Accessed 7.17.18: <http://www.joyetech.com/news/joyetech-teros-launching/>

Result of Policies Adopted

Explosion of youth e-cigarette usage—77% increase between 2017 and 2018. Attributed to youth-friendly flavors, potent nicotine delivery, sleek design, concealability, marketing programs appealing to kids.

Widespread introduction of new tobacco products after 8/8/16 with no effective enforcement.

Increase in youth cigarette usage from 7.5 to 8.1%

FDA's response to the crisis

April 24, 2018. “E-cigarettes have become wildly popular with kids. ..In some cases, our kids are trying these products and liking them without even knowing they contain nicotine [that can] rewire an adolescent’s brain, leading to years of addiction.”

40 retailers cited for illegal youth sales; information request to Juul to explain high youth usage; intent to pursue product standard and other regulations.

FDA Response to Crisis

- May 2018. Letters sent to four major e-cigarette companies requesting information to understand youth appeal and citing high nicotine concentration, concealability, and product design attractive to youth.

FDA Response to the Crisis

June 21, 2018 “E-cigarettes should never be marketed to, sold to, or used by kids... It’s critical [to] take a hard look at whether certain design features and product marketing practices are fueling youth use of such products.”

Announcement of possible “measures on flavors, designs that appeal to youth.”

FDA Response to the Crisis

- August 2, 2018 “No kids should be using any tobacco or nicotine-containing products, including e-cigarettes.”
- “We intend to expedite the review and analysis of comments [on the effects of flavors.]”
- “We need ...faster and more agile [ways to identify] illegal product marketing to youth.”
- “Products are being marketed both in violation of law and outside of FDA’s compliance policies.”
- “Real Cost” program expanded to communicate risk of e-cigarettes to youth.

FDA Response to the Crisis

September 12, 2018 “Youth use of electronic cigarettes has reached an epidemic proportion.”

- “We will revisit our compliance policy that extended the dates of certain flavored e-cigarettes to submit PMTA applications [and may require] removal. . .from the market.”
- “Address the entire category of cartridge-based e-cigarettes.”
- Five e-cigarette manufacturers given 60 days to submit plans to reduce youth usage.
- Investigating whether products not on the market on 8/8/16 are being sold.
- “Closely evaluating internet storefronts and distribution practices.”
- Warning letters to 1,300 companies

FDA's Response to the Crisis

- September 17, 2018 Commissioner Gottlieb: "I've been warning the electronic cigarette industry for more than a year that they needed to do much more to stem the youth trends. In my view, the [e-cigarette companies] treated these issues like a public relations challenge rather than seriously considering their legal obligations, the public health mandate, and the existential threat to these products."

FDA's Response to the Crisis

- September 18, 2018. “Based on our evidence, we believe the presence of flavors is one component making e-cigarettes especially attractive to kids... FDA won’t tolerate a whole generation of kids becoming addicted to nicotine...Trends are evidence of a significant swath of ... kids becoming regular users of nicotine. Kids who use e-cigarettes are more likely to try combustible cigarettes.”
- “Real cost” Youth E-cigarette Prevention Campaign launched.
- “Revisiting our compliance that extended compliance dates for certain e-cigarettes, including flavored e-cigarettes.”

FDA's Response to the Crisis

- October 2, 2018. FDA announces that it has seized “thousands of pages of documents” after an unannounced five-day visit to Juul’s headquarters.
- Commissioner Gottlieb: “I think people should interpret the fact that I and others have made such a dramatic shift from our prior position with respect to these products as representing the fact that we have seen information that is deeply disturbing and startling in terms of the rapid rise of youth use over a short period of time.”

FDA Response to the Crisis

- October 11, 2018 Washington Post Op-ed by Secretary Azar and Commissioner Gottlieb.
- “From 2017 to 2018, the number of high-school-age children reporting use of e-cigarettes rose by [more than 75 percent](#). Use among middle-schoolers also increased nearly 50 percent. That is an epidemic.”
- “The surge in e-cigarette use by teenagers is alarming because nicotine is highly addictive and can [harm brain development](#). Worse, kids who start on e-cigarettes are actually more likely than non-user peers to migrate to smoking tobacco.”
- “We know that the steps we have taken thus far are not enough. We are considering limits on the marketing and features of e-cigarettes to reverse their appeal and availability to minors. We are also actively reconsidering our policy under which certain e-cigarettes — particularly the products with flavors that might appeal to children — can remain on the market without submitting a premarket application to the FDA until 2022.”

FDA's Response to the Crisis

- October 12, 2018 “Given the explosive growth of e-cigarette use by kids, we’ll take forceful steps to stem youth use, even if our actions have the unwelcome effect of impeding some opportunities for adults.”
- “If products are . . .unlawfully marketed and outside FDA’s compliance policy, we’ll act to remove them.”
- 21 more letters re possibly illegal marketing.
- “This includes revisiting our compliance policy that has resulted in certain e-cigarettes, including flavored cigarettes remaining on the market until 2022.”

FDA's Response to the Crisis

- October 25, 2018. Commissioner Gottlieb:
- Some **WRONGLY** presume that kids who use e-cigs might have instead used cigarettes. So they'll say, "well at least they're not smoking". **THIS IS NOT TRUE**. Data shows most kids using e-cigs wouldn't have smoked instead. But now, having initiated to nicotine, they're more likely to.

-

Potential Regulatory Actions Mentioned by FDA

- Shorten compliance period and make it inapplicable to flavored products.
- Take products not marketed by 8/8/16 off the market unless they qualify for PMTA.
- Prohibit internet sales of e-cigarettes.
- Restrict sale of flavored e-liquids to vape shops.
- Restrict marketing that appeals to kids.
- Increased enforcement against retailers selling to kids.

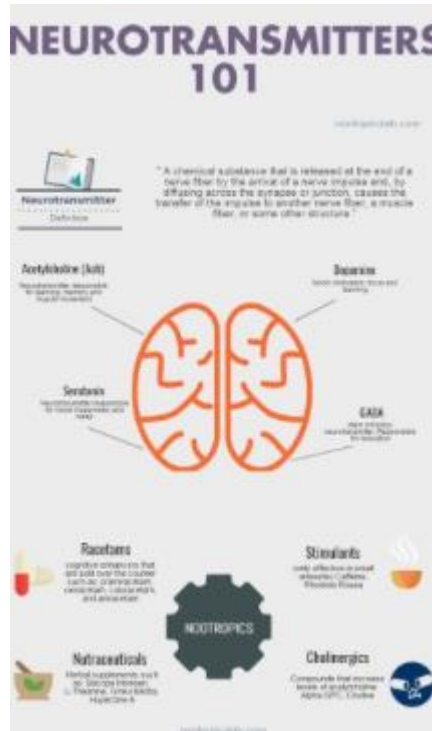
Protecting Youth: Targeting Appropriate E-Cigarette Users



Carrie L Wade
R Street Institute

Conflation of Nicotine Dangers

Nicotine = Smoking



Conflation of Nicotine Dangers

Nicotine = Smoking

Change is not always bad...

Until it is

- Violence
- Trauma
- Binge Drinking
- Concussion

Nicotine ≠ Smoking

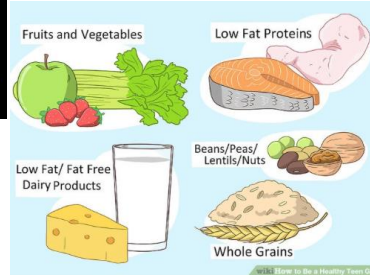
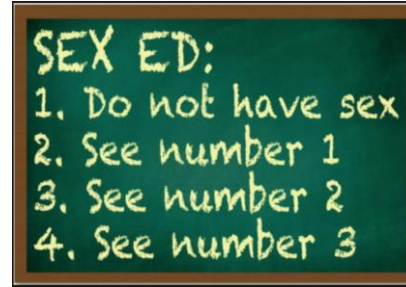
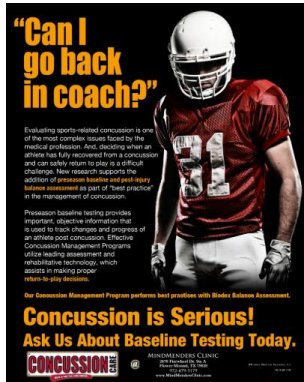
Media Plan Gone Wrong

Is messaging from FDA/Truth Initiative/CTFK discouraging vaping to the extent that it is encouraging smoking?

What are the implications for inconsistent messaging?

Media Plan Gone Wrong

Volume of warning, messages, “what-to-dos” are increasing and confusing.... Especially when inconsistent...



.... Tired Much???

Media Plan Gone Wrong



Leading to distrust in the message and of public health institutions

Tone Deaf

Who is *really* at risk for smoking?

Cigarette smoking is down, but almost
38 MILLION
American adults still smoke

Cigarette smoking remains high
among certain groups



Men



Adults 25-64
years old



Lower education



Below
poverty level



Midwest
and South



Uninsured
or Medicaid



Disabled



Serious
psychological
distress



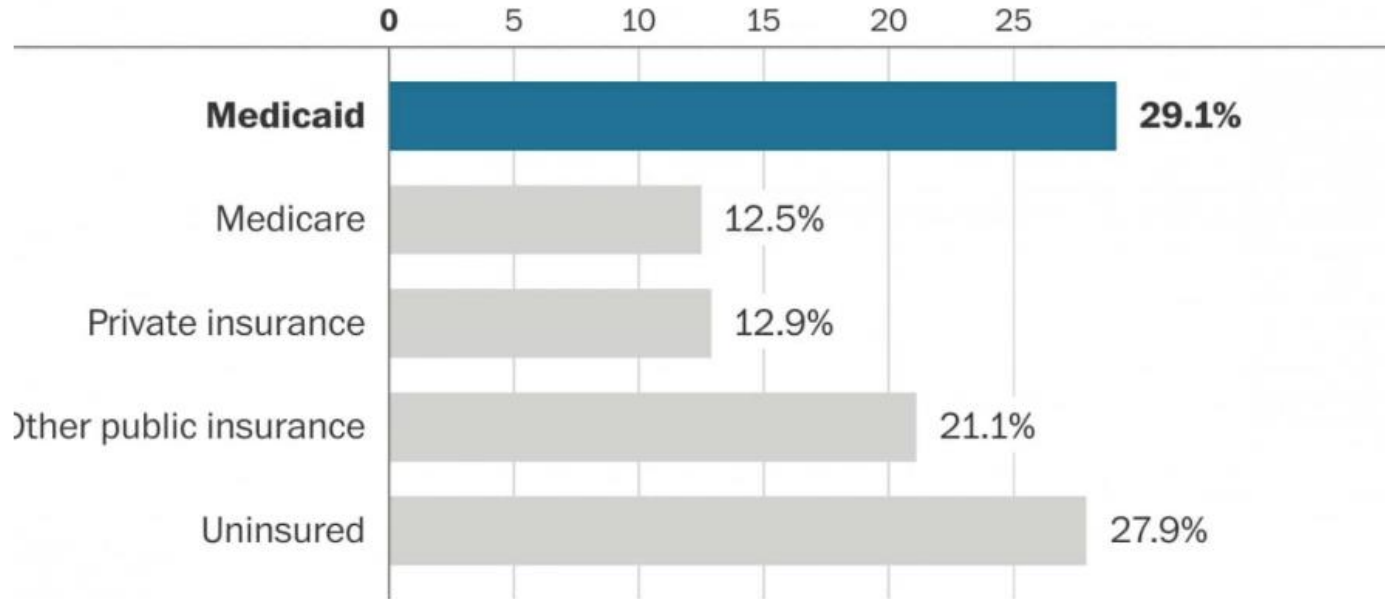
American Indians,
Alaska Natives and
Multiracial



Lesbians, gays,
and bisexuals

Tone Deaf

Smoking rates by insurance type

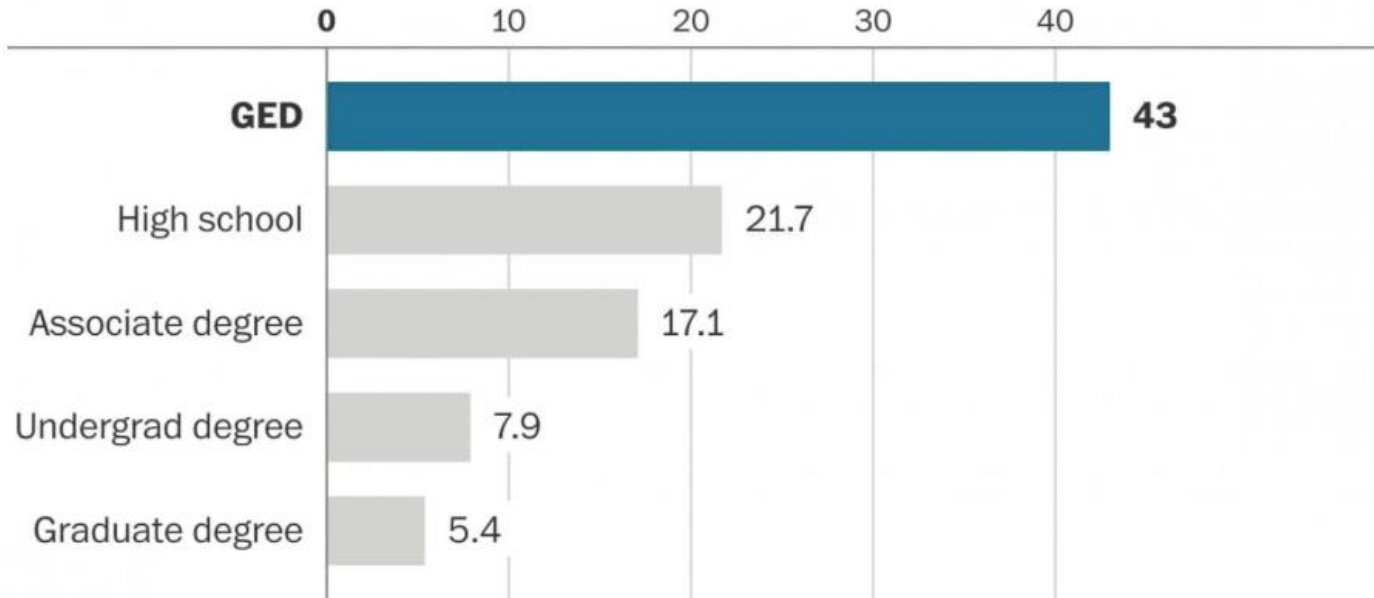


Source: CDC

THE WASHINGTON POST

Tone Deaf

Smoking percentage by education level

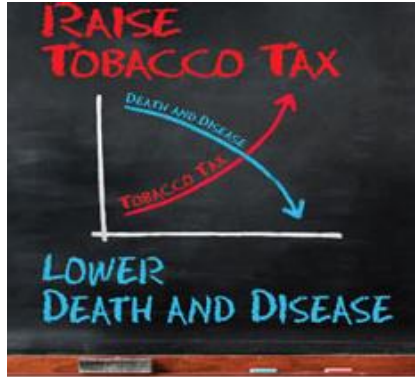


Source: CDC

THE WASHINGTON POST

Tobacco Control Policies

Taxation



Cessation

Quitters Win!

When you're ready to commit to quitting smoking - we're here to help.



Bans

**Tobacco-free
Campus**

For better health,
smoking and use of
tobacco products are
prohibited everywhere
on our property.



Warn

