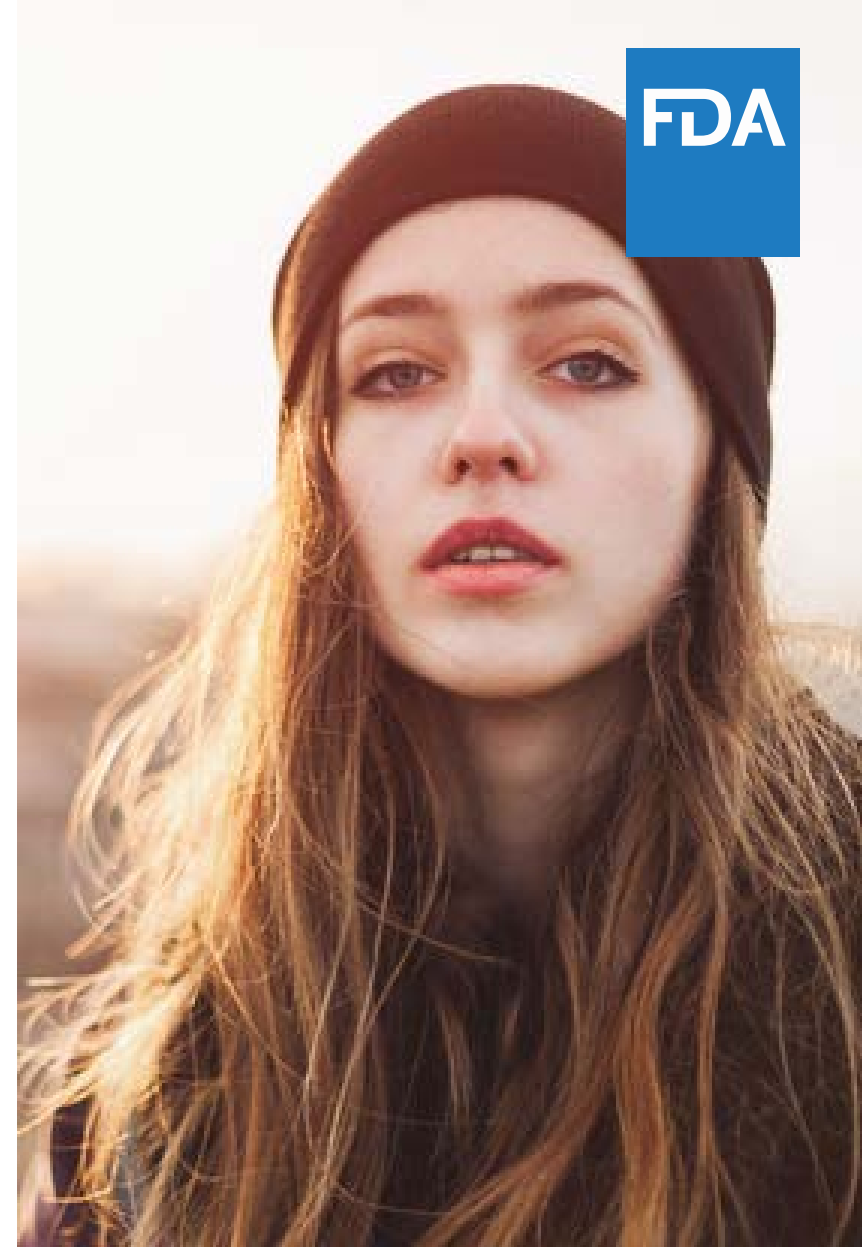


THE REAL COST: TACKLING TEEN VAPING

*Presented by
Kathleen Crosby
Director, Office of Health Communication & Education
FDA Center for Tobacco Products*

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

FDA

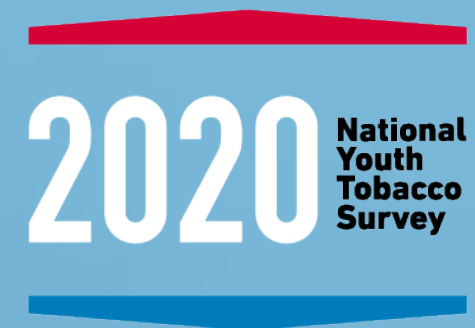


AGENDA

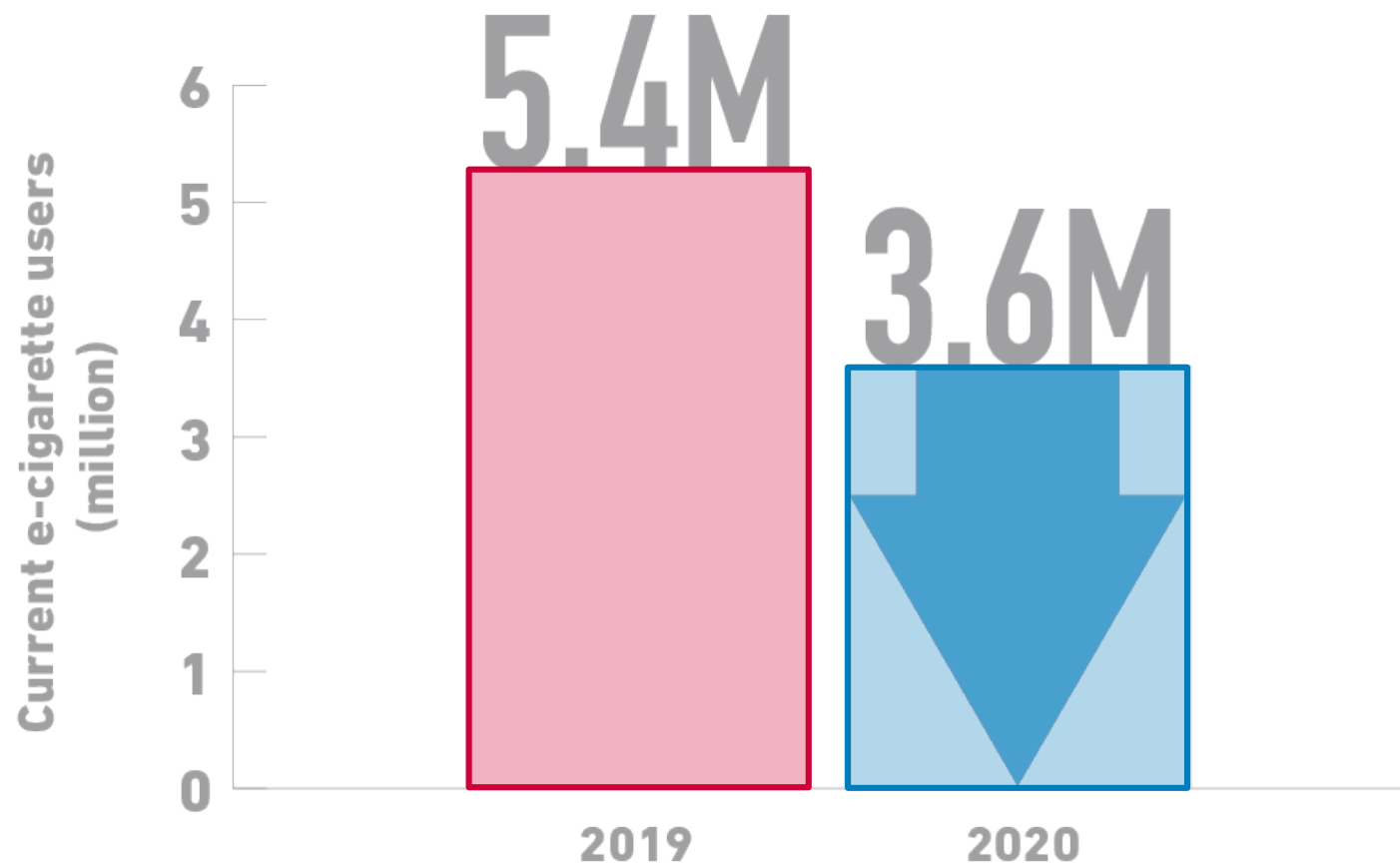
- Changing Youth Behaviors Toward Using ENDS
- Update on FDA's Policies in 2020
- How The Real Cost Campaign Is Helping
- Questions/Discussion



CHANGING BEHAVIORS TOWARD USING ENDS: 2020 NYTS DATA

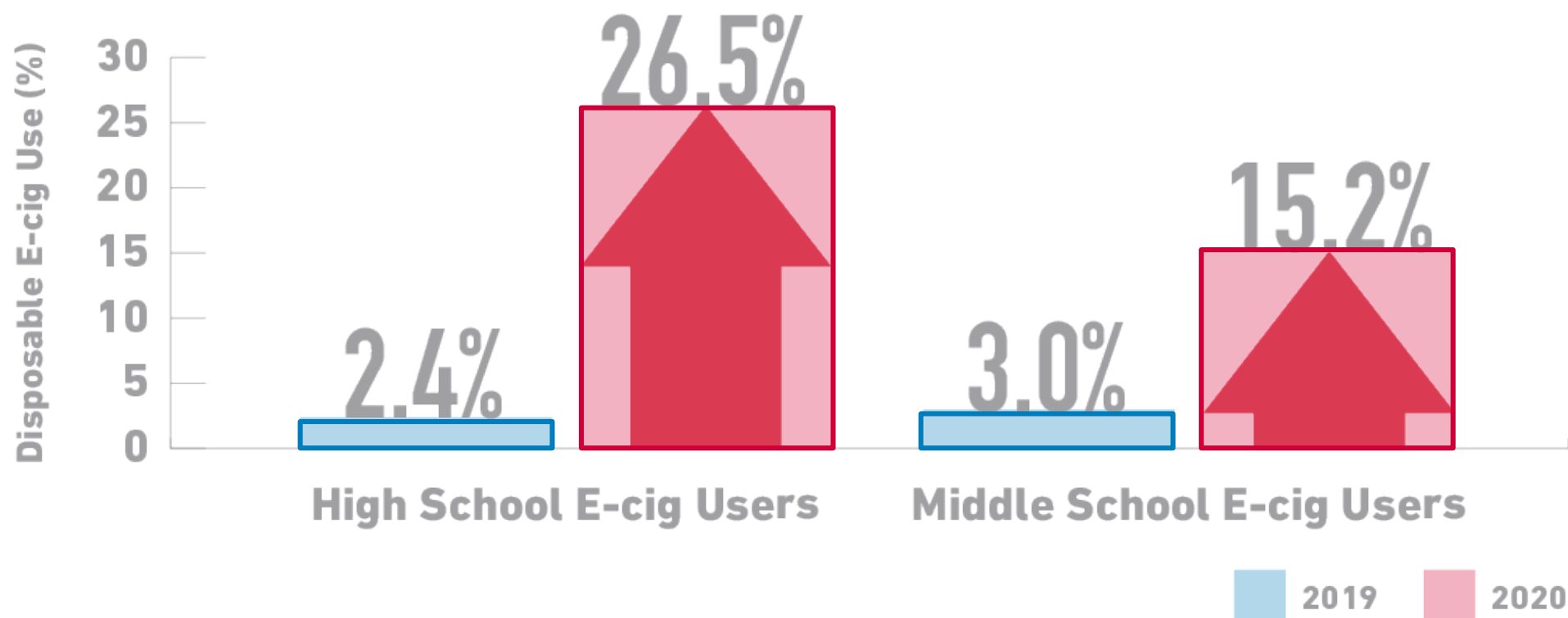


NYTS 2020: SIGNIFICANT DECLINE IN YOUTH E-CIG USE; BUT LEVELS REMAIN HIGH



Source: NYTS 2020

NYTS 2020: CONCERNING RISE IN THE USE OF DISPOSABLE E-CIGS

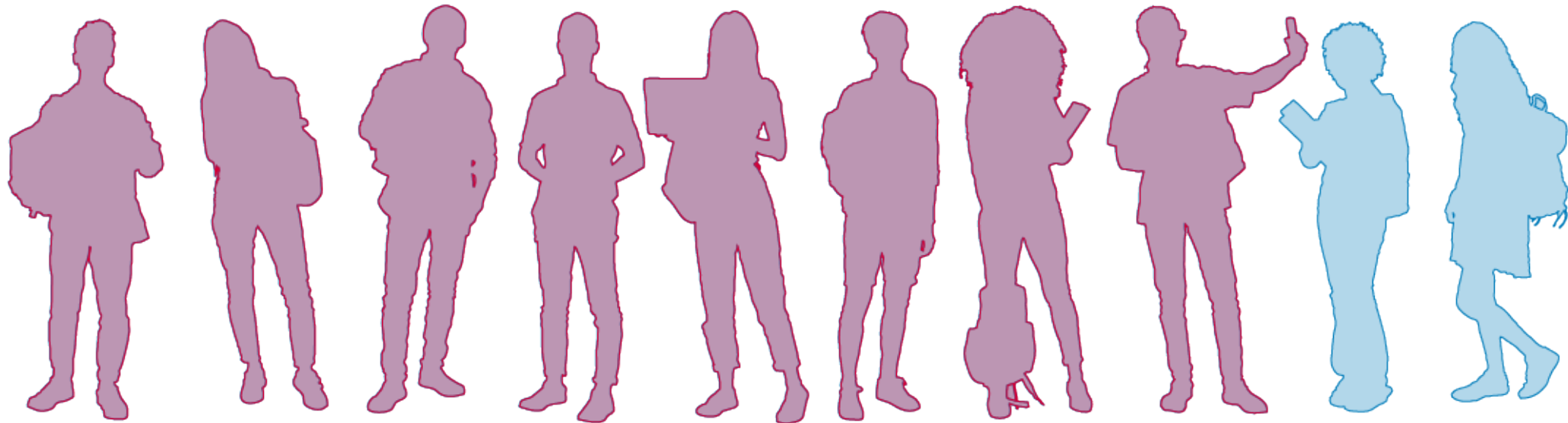


Source: NYTS 2020

NYTS 2020: HIGH LEVELS OF FLAVORS USE; FRUIT, MINT, CANDY & MENTHOL AMONG MOST COMMON

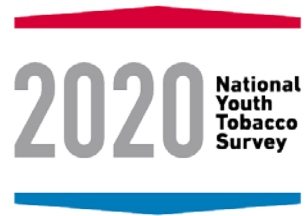


More than **8 out of 10** current
youth e-cig users use flavored e-cigs



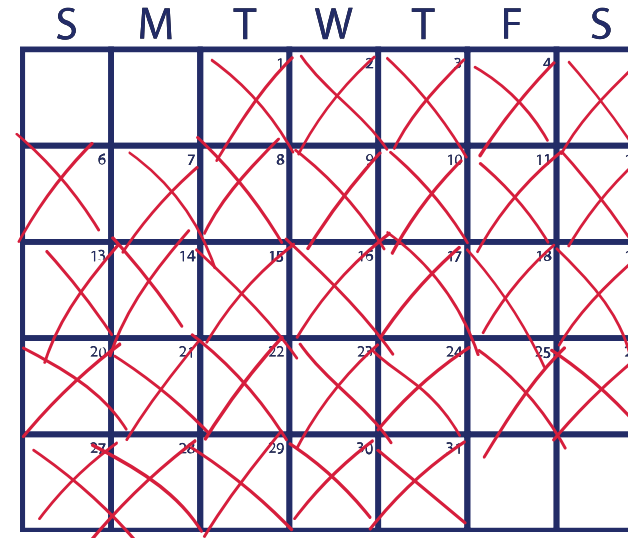
Source: NYTS 2020

SIGNS OF ENDS ADDICTION; FREQUENCY OF USE



22.5%

of high school current e-cig users
used e-cigs daily



Source: NYTS 2020



UPDATES ON FDA'S POLICIES IN 2020

ENFORCEMENT PRIORITIES GUIDANCE



- On Jan. 2, 2020, FDA announced a **policy prioritizing enforcement against certain unauthorized flavored e-cigarette products** that appeal to children
- On Feb. 6, 2020, FDA began prioritizing enforcement against certain illegally marketed ENDS products that do not have premarket authorization:
 - *Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS)*
 - *All other ENDS products for which the manufacturer has failed to take adequate measures to prevent minors' access*
 - *Any ENDS product that is targeted to minors or likely to promote use of ENDS by minors*
 - Took enforcement actions against Puff Bar and MYLE due to their youth marketing practices

ENFORCEMENT PRIORITIES



- After Sept. 9, 2020, FDA is also **prioritizing enforcement against any ENDS product** that continues to be sold and for which the agency has not received a product application
- New data, such as that from the 2020 NYTS, will inform the FDA's enforcement and other actions, and **flavored disposable ENDS will be an enforcement priority** for the agency

PREMARKET PRODUCT REVIEW SUBMISSION



- Applications for premarket review for certain deemed new tobacco products on the market as of Aug. 8, 2016—including e-cigarettes—were required to be submitted to FDA **by Sept. 9, 2020**
- For companies that submitted timely applications, FDA may continue to exercise **enforcement discretion until Sept. 9, 2021** – unless a negative action is taken by the FDA on an application during that time
- FDA plans to **post a list of the deemed new tobacco products** that were on the market in the U.S. as of Aug. 8, 2016, are still on the market now, and for which a premarket submission was made by Sept. 9, 2020
 - However, FDA must ensure that publishing complies with federal disclosure laws and regulations

PLANS FOR PREMARKET PRODUCT REVIEW

- FDA strives to review **as many applications as possible** during this one-year period and the agency will allocate reviewing resources to ensure we focus on products with **the greatest public health impact** while also **committing to fairness to all companies** regardless of size
- FDA plans to update the public and release information regularly as the agency refines plans for allocating product review resources and the process by which products would move into scientific review



CIGARETTE HEALTH WARNINGS FINAL RULE



- On March 17, 2020, FDA issued a **final rule to require 11 new health warnings** on cigarette packages and in cigarette advertisements to promote greater public understanding of the negative health consequences of cigarette smoking
 - The proposed rule was issued in August 2019
- Beginning Oct. 16, 2021***, the warnings will be required to appear prominently on cigarette packages and in advertisements, as shown in the below examples:



Occupying the top 50 percent of the area of the front and rear panels of cigarette packages



Occupying at least 20 percent of the area at the top of cigarette advertisements

**The effective date was recently postponed by 120 days from June 18, 2021 to Oct. 16, 2021 due to COVID-19 and its impacts*

NEW LEGISLATION: TOBACCO 21



- On Dec. 20, 2019, the President signed legislation amending the Federal Food, Drug, and Cosmetic Act, and **raising the federal minimum age of sale of tobacco products from 18 to 21 years**
- Effective immediately, **retailers must not sell any tobacco products** – including cigarettes, smokeless tobacco, hookah tobacco, cigars, pipe tobacco, electronic nicotine delivery systems including e-cigarettes and e-liquids – **to anyone under 21**
- FDA expects retailers to follow the law and take measures to ensure an individual purchasing a tobacco product is 21 or older, including manually checking IDs when needed
- FDA had begun utilizing individuals under the age of 21 in its nationwide compliance check inspection program to determine retailer compliance prior to the COVID-19 outbreak

HOW THE REAL COST IS HELPING

THE REAL COST

Campaign development and planning

Advertising and messages delivered to target audiences
(TV, radio, print, digital online, out-of-home)

A young person with light brown hair, wearing a maroon hoodie and large green and white headphones, is shown from the chest up. They have a serious, somewhat somber expression and are looking directly at the camera. The background is a blurred outdoor scene with a body of water and a distant shoreline under a bright sky. A semi-transparent blue horizontal band is overlaid across the middle of the image, containing white text.

CURRENT STATE OF YOUTH VAPING

HOW TEENS PERCEIVE AND SEE VAPING IN THEIR LIVES RIGHT NOW

VAPING CONTINUES TO BE A NORMALIZED PART OF THEIR LIVES



- School bathrooms are the *nerve center* of teen vaping – to the point that several respondents reported that their schools have gone on “bathroom lockdown” to discourage the practice
- As they see vaping spread throughout their social circles, they are wondering as much about the societal impact of vaping as its effect on individuals
- Some younger respondents reported not seeing a lot of vaping among their peers, but they were still very familiar with vaping and seemed to have a good understanding of it



*“It’s **kind of a given** at this point that anyone I meet at a party is going to vape.”*
—At Risk, Older, LA

SOCIAL MEDIA HAS THE POWER TO PROPAGATE THE HABIT/TREND BUT ALSO GIVE THEM PAUSE

- Social media can glamorize vaping, so many go on there to “showcase” their habit, whether it’s through tricks or just to do it
- It’s also where stories about negative consequences can spread more quickly and grab their attention

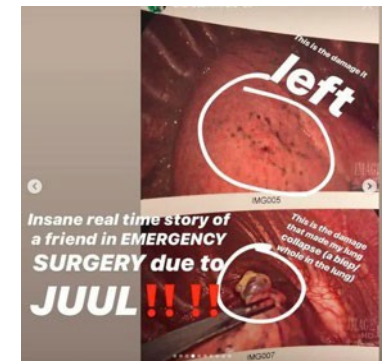


*“You definitely see a lot of celebrity influencers and Instagram famous people vaping on social media, and I do think that **some people start vaping because everyone wants to look like an Instagram star.**”*

– ENDS Experimenter, Older, NJ

“There’s this really popular post going around that has had a serious impact. People are actually choosing to stop JUULing now because there’s this guy whose lung popped. It caused deflation and he ended up in the hospital.”

– ENDS Experimenter, Older, LA



VAPING CONTINUES TO REMAIN “CLIQUE AGNOSTIC”

- From valedictorians to star basketball players, vaping doesn't seem to discriminate
- At risk and younger teens are likelier to make judgments about teens who vape

“Almost everyone vapes. It's not like, 'It's just the cool kids or it's just the jocks.' It's the church girls, it's everybody.”
– ENDS Experimenter, Older, ATL

“Valedictorians vape.”
– At Risk, Older, ATL

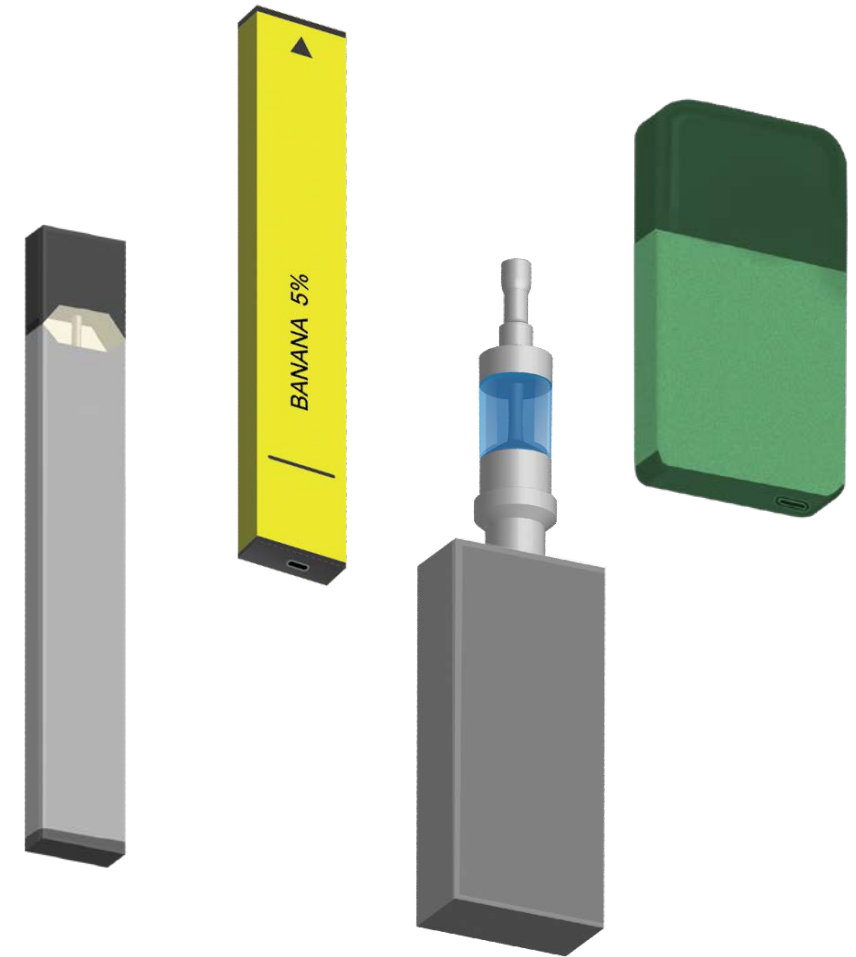
“I don't think there's a certain type of people that vape”
– HH ENDS Experimenter, Older, LA

*“It doesn't matter if you're going to a Brockhampton show or to see a local punk band, **everyone there** is going to be vaping.”*
– ENDS Experimenter, Older, LA



TEENS ARE EXPLORING VAPING OPTIONS

- Teens are becoming a bit more brand agnostic as they become familiar with more pod mod and disposable brands
- Availability, convenience and flavor selection are the key
- A “fiending” teen will not be picky when taking a hit from a friend’s vape
- Disposable vapes have gained popularity because they are cheaper, easier to find, and easier to sell
- Some also mentioned refillable options are becoming popular



TEENS OFTEN MENTIONED THE EMOTIONAL DEPENDENCE THAT CAN RESULT FROM VAPING, NOT JUST THE PHYSICAL

- Some teens were able to talk about peers or friends who just couldn't live without it and felt more secure when they had their vape
- When they can't access their vapes, teens start to "fiend" – acting angry, emotional, and irrational. Some teens suggest that vapers start to exhibit these emotional characteristics throughout their daily lives

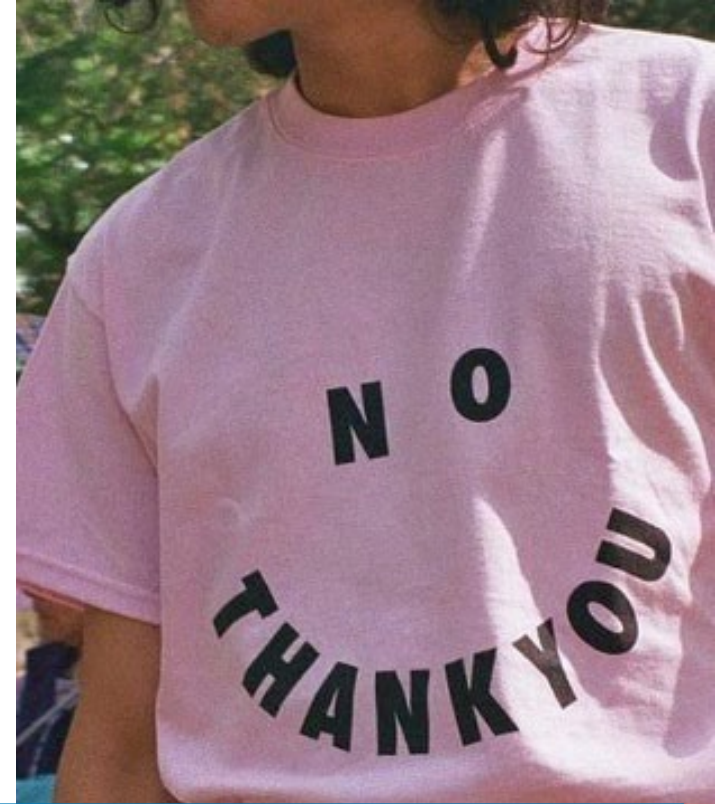


*"I remember one time before a cheer competition this girl **had a panic attack**, she was like 'I need my Suorin, I need my Suorin.' We all ran to the bathroom right before we went on so she could hit it."*

– ENDS Experimenter, Older, LA

ADDICTION IS NOW SOMETHING TEENS ARE STARTING TO PAY ATTENTION TO, BUT STILL WANT THE FULL STORY ON THE DANGER

- Previously, addiction wasn't something that teens took seriously – they would associate being addicted to vaping with being addicted to "chocolate" or "my phone"
- In this research, most teens agreed that vaping can be addictive, but they wanted a better understanding of the risks and ultimate consequences that could come from it – especially pertaining to harms to the lungs
- Not knowing the full story on addiction was now seen as more of a problem/question vs. something to ignore



"I think vapes might be equally as bad as cigarettes because a lot of people don't really see how dangerous vaping is and people suck down a whole pod in 20 minutes, which is like a whole pack of cigarettes." - At Risk, Older, NJ



RESEARCH FINDINGS LED TO NEW ADS FOR 2020

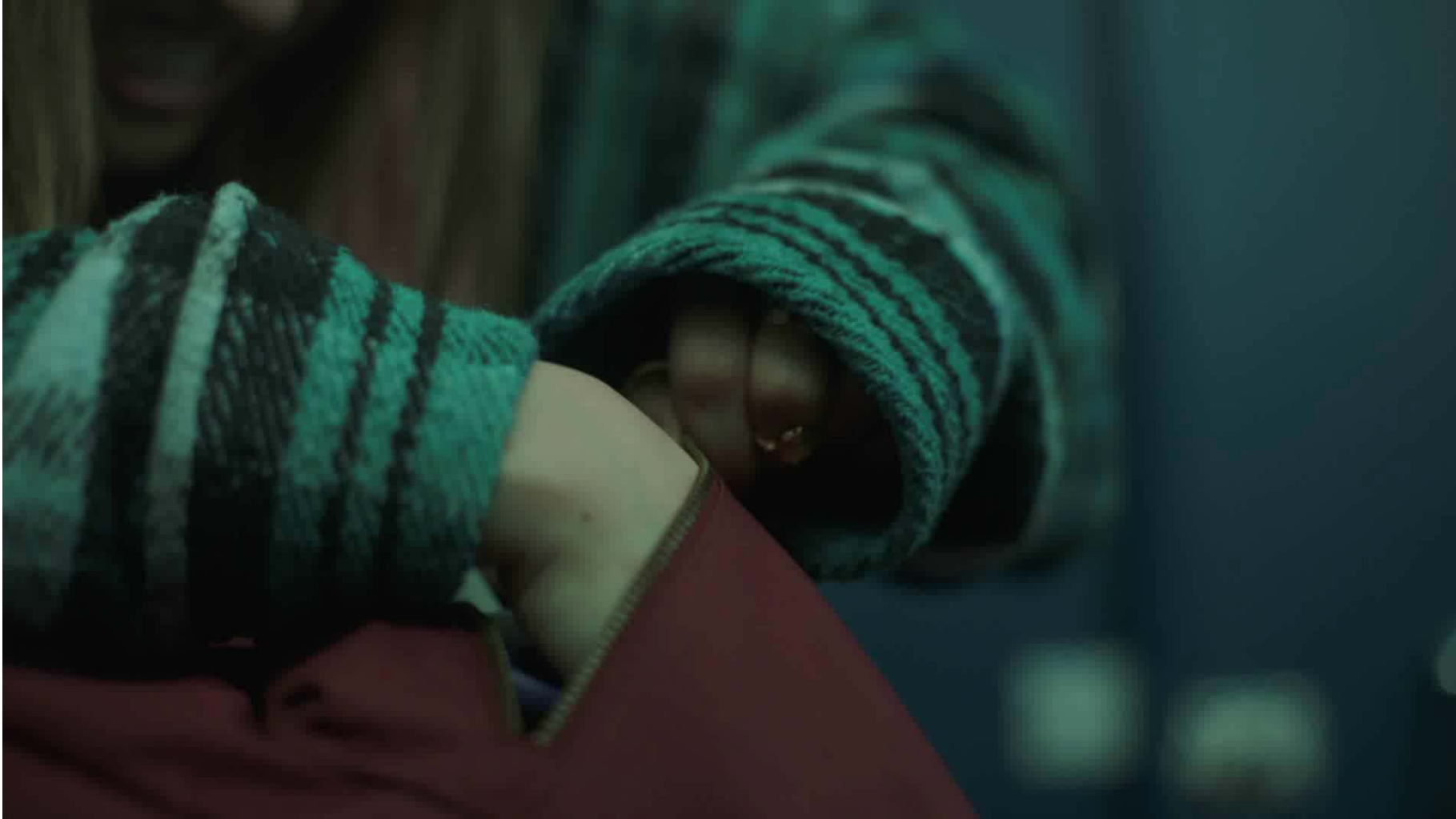
METALS – SCARY ENOUGH



ADDICTION – PURSE



ADDICTION - TOILET



ADDICTION - ATHLETE



A close-up, profile view of a person's face as they exhale a plume of white vapor from a mouthpiece. The person is holding a silver and black vape pen. The background is blurred, showing what appears to be a window with light coming through. A semi-transparent blue horizontal band is overlaid across the middle of the image, containing white text.

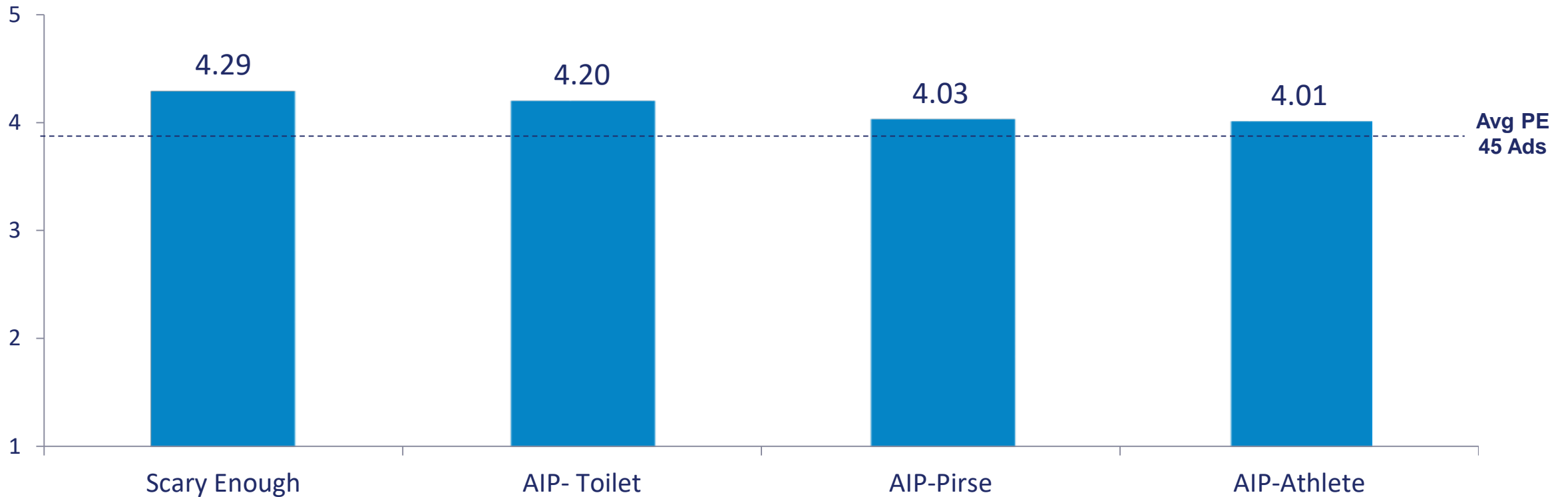
QUANTITATIVE COPY TESTING ENSURES ADS WILL HAVE AN IMPACT

BOTTOM LINE UP FRONT



- Excellent Perceived Ad Effectiveness scores – all above 4.0.
- No unintended consequences.
- All Knowledge, Attitude, and Belief (KAB) and behavioral intention measures saw statistically significant movement in the desired direction.
- The majority of youth understand the main message of the ads and the ads perform well on other measures.

PERCEIVED AD EFFECTIVENESS SCORE – COMPARISON



MAIN MESSAGE – UNAIDED RECALL

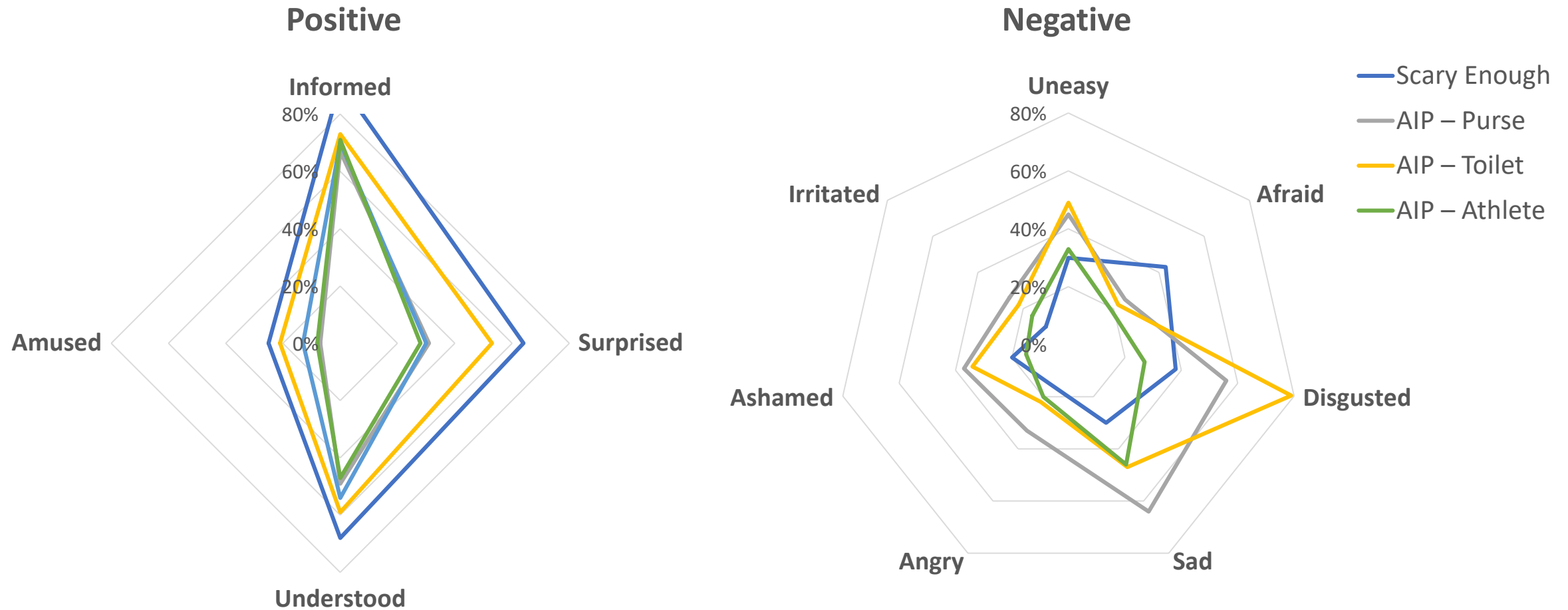


Out of 150 Respondents, the total that understood the main message:

- Scary Enough – 82%
- Addiction Isn't Pretty (Purse) – 74%
- Addiction Isn't Pretty (Toilet) – 80%
- Addiction Isn't Pretty (Athlete) – 83%

B1. Imagine you are talking to a friend; how would you describe the main message of the ad to them?

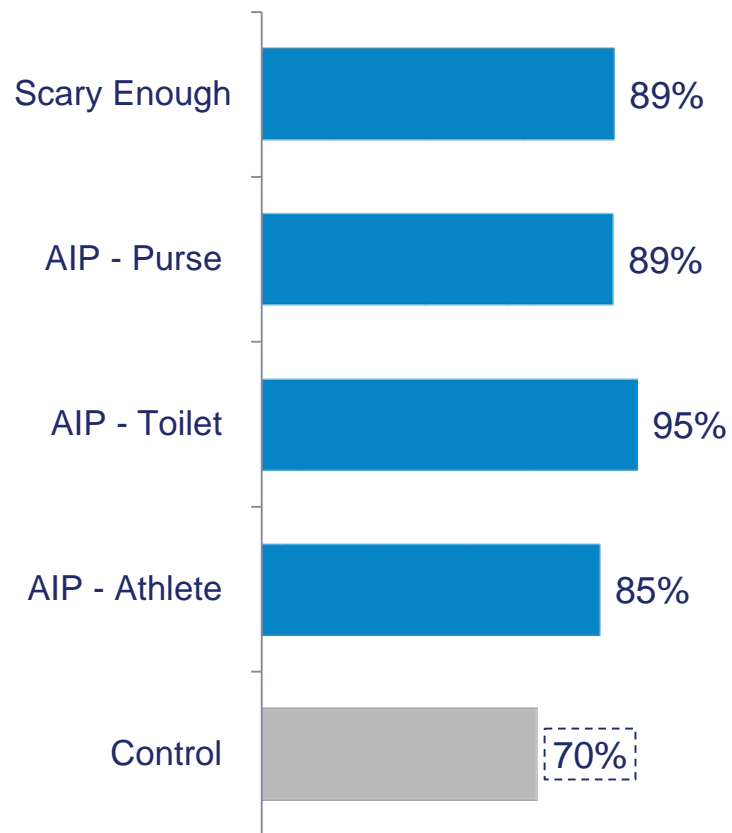
EMOTIONAL REACTION COMPARISON



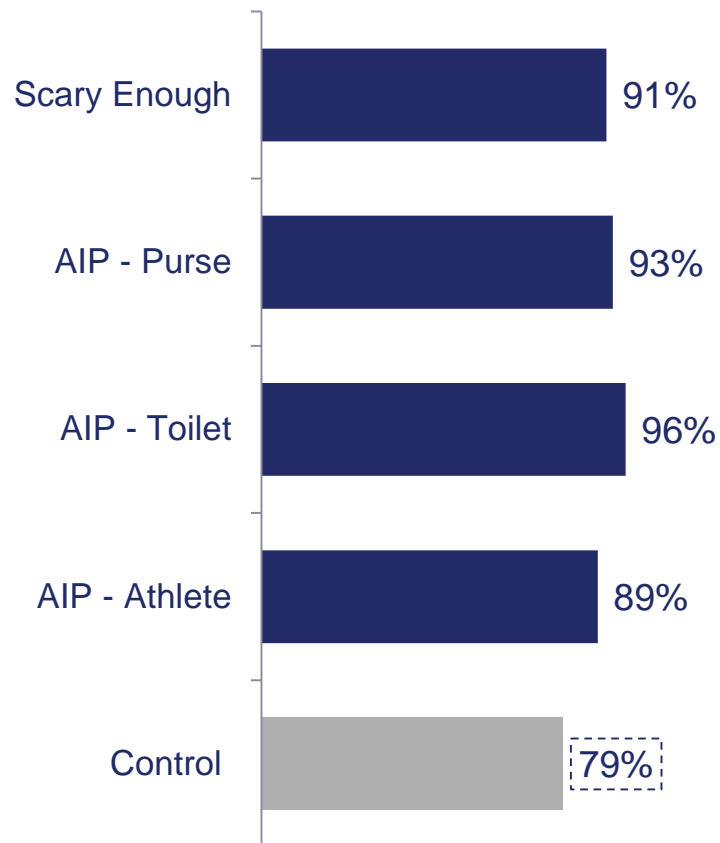
ALL HEALTH-RELATED KABs MOVED IN THE DESIRED DIRECTION



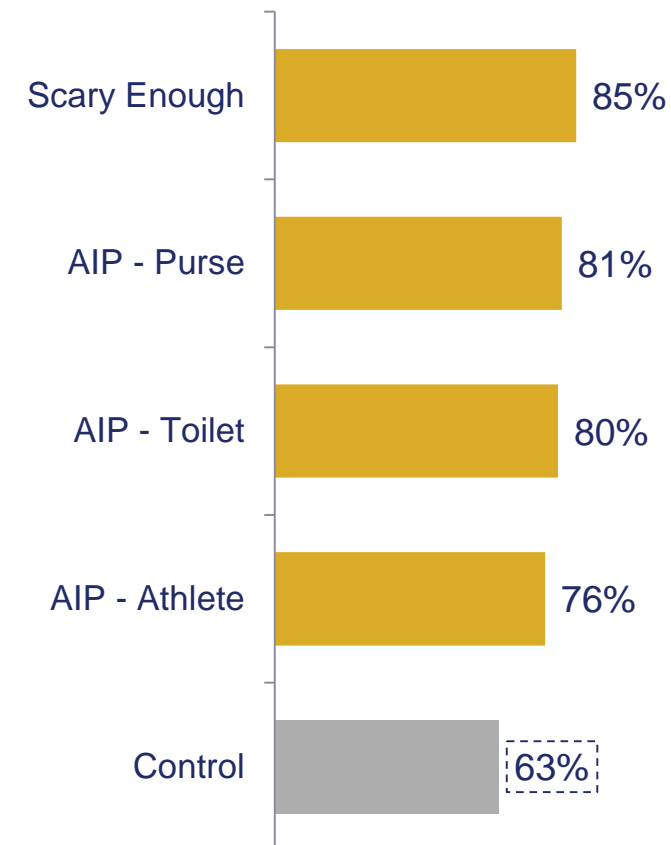
Damage My Body



Damage My Lungs



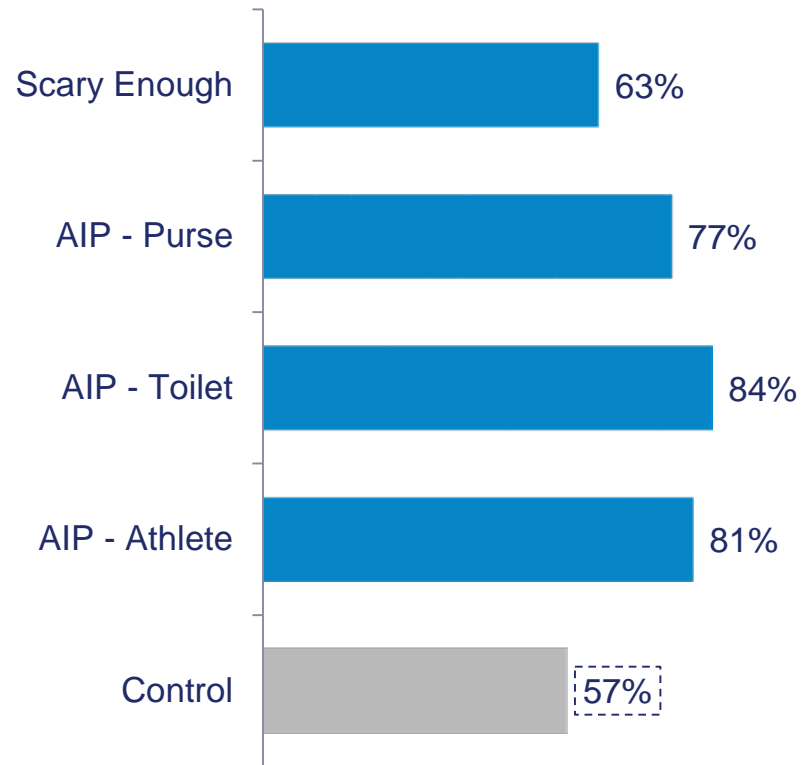
Develop Serious Health Problems



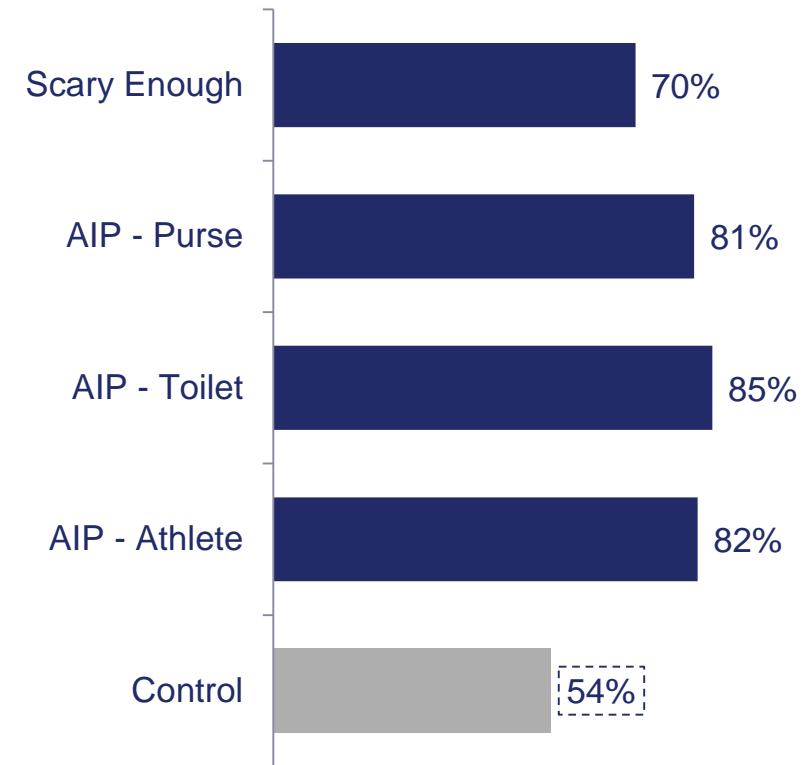
ALL ADDICTION-RELATED KABs MOVED IN THE DESIRED DIRECTION



Be Controlled by Addiction



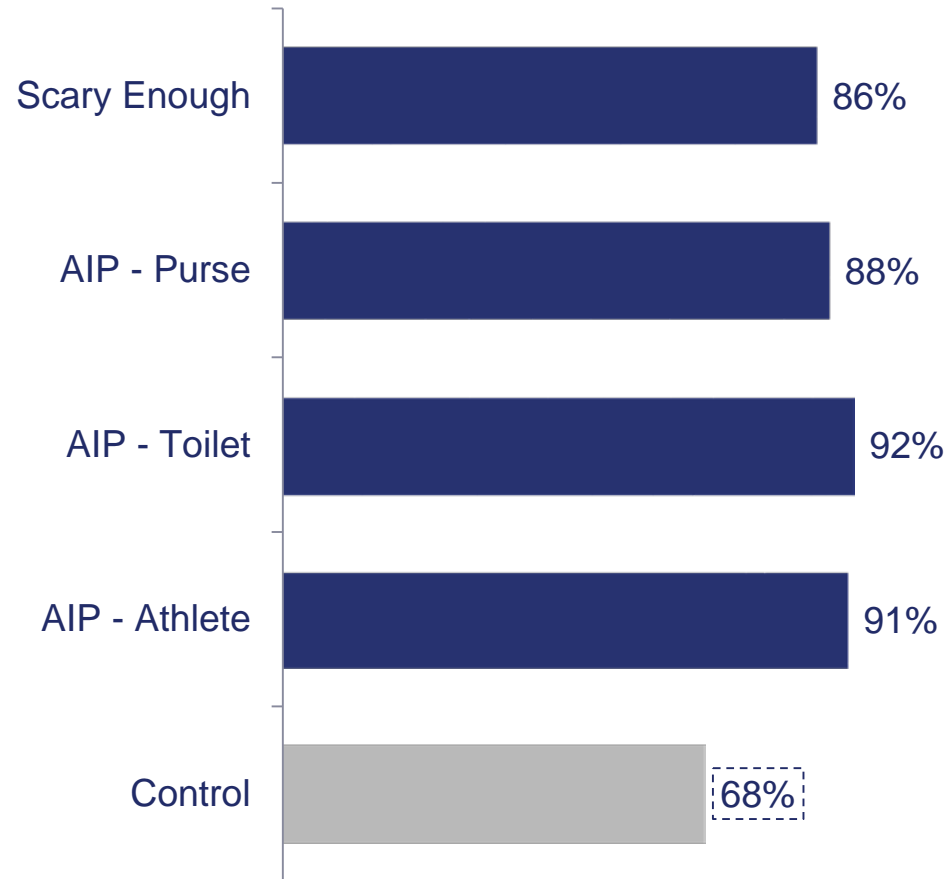
Become Addicted to Vaping



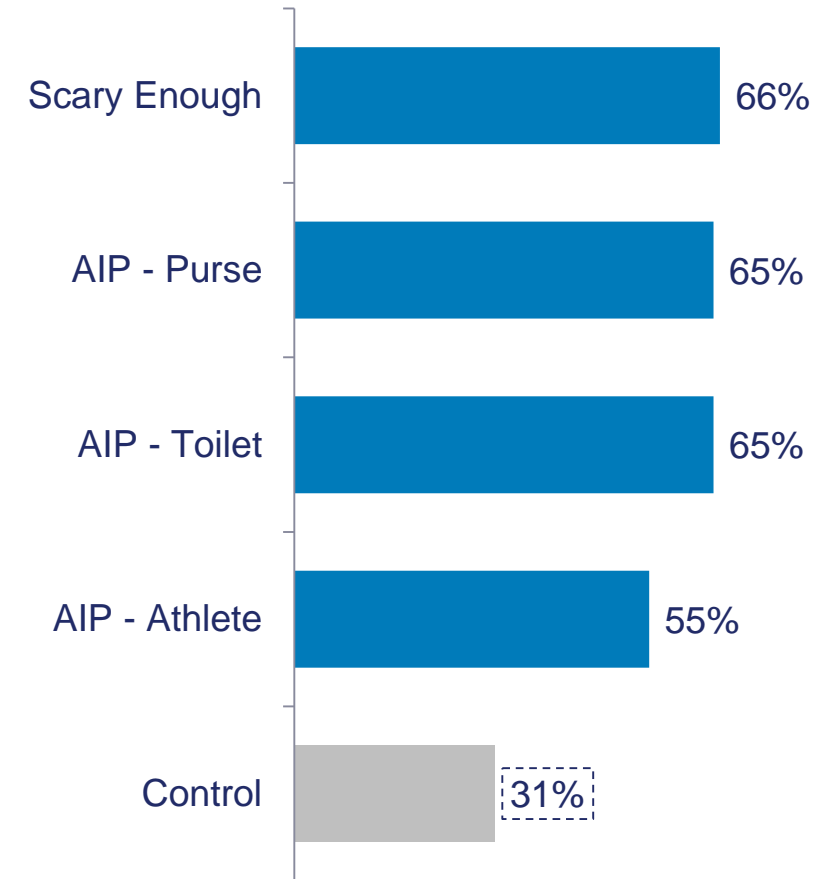
INTENTIONS TO USE ENDS BY TOBACCO USER TYPE



At-Risk Non-Triers



Youth Experimenters



SUMMARY



- All ads performed well in terms of perceived effectiveness and main message comprehension (excellent PE scores, high main message comprehension).
- No unintended consequences - all KAB and behavioral intention measures saw statistically significant movement in the desired direction.



PLACING ADS THAT REACH TEENS WHERE THEY ARE

REACHING TEENS WHERE THEY WANT TO BE

FDA

- ‘The Real Cost’ Youth E-Cigarette Prevention Campaign is laser-targeting the media to effectively *reach 12- to 17-year-olds* via their media passion points
- Nearly *10.5 Billion* teen impressions (eyes on messaging) since campaign launched

YouTube

THE CW

pandora®

teennick

SOUNDCLOUD

Spotify®

Music Choice

tubi tv

GAMES

[adult swim]

TEEN CHOICE 2019

f

Instagram

GAMELOFT

XBOX

PlayStation™

MTV

Discovery SHARK WEEK

REVOLT

ENGAGING WITH TEENS SINCE LAUNCH



Total Likes:
3,000,000+



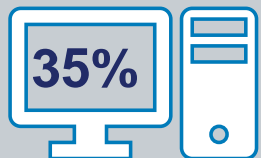
Total Shares:
326,000+



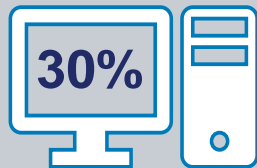
Total Comments:
76,000+



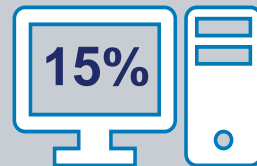
Teens think
vaping is safer
and proven for
cessation



Teens state
they plan to
continue using
tobacco



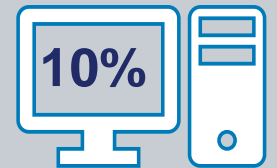
Teens ask for
sourced info on
health effects



Teens have
seen or felt
harmful effects



Teens ask
for help with
quitting



PARTNERING WITH NCI TO HELP WITH TEEN CESSATION CONTENT



NCI and CTP launched new e-cigarette cessation content on SmokeFree Teen, giving comprehensive behavioral techniques help teens deal with cravings, navigate peer pressure, prepare to quit, and make it through their quit day

Since July 2019, there have been over one million page views

The most time is spent on these pages:

- How to Quit Vaping – over 4 minutes
- Vaping Addiction and Nicotine Withdrawal – over 5 minutes



YOUTH E-CIGARETTE PREVENTION IN SCHOOLS



- Collaboration with Scholastic to bring lesson plans, infographics, and scientific facts to more than a million middle and high school teachers nationally
- New resources in English and Spanish released in 2020, including two new lessons and worksheets, five short videos focused on content areas that align with e-cigarette prevention lesson plans

www.scholastic.com/youthvapingrisks

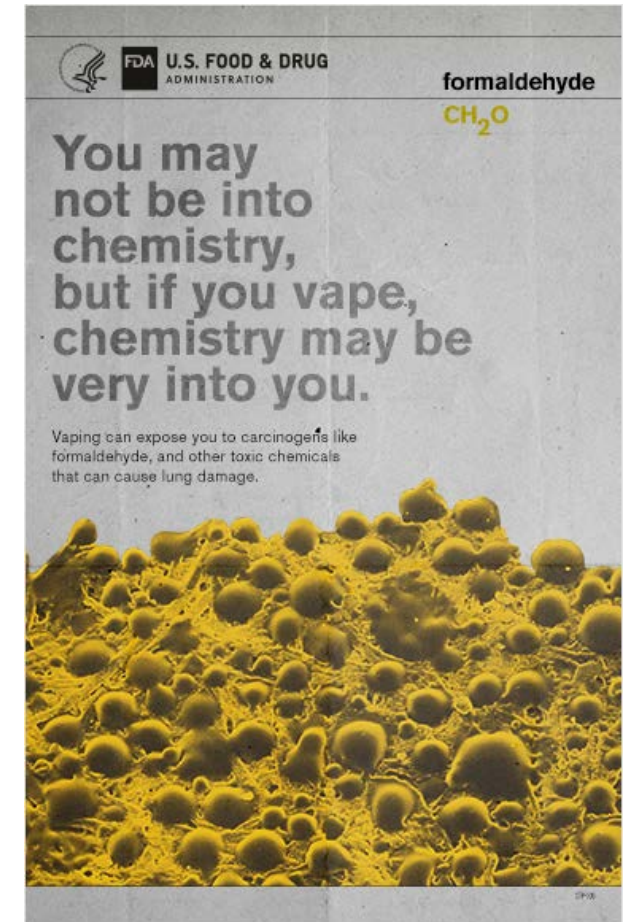
The screenshot displays the 'The Real Cost of Vaping' website, which is a collaborative effort between the U.S. Food and Drug Administration (FDA) and Scholastic. The website's main title is 'The Real Cost of Vaping', with a subtitle 'ELA • Math • Science/Technology/'. It features a navigation bar with 'LESSON & ACTIVITIES' and 'DIGITAL ACTIVITY'. The 'Lesson & Activities' section is currently selected, showing a grid of resources for 'Grades 6-8' and 'Grades 9-12'. Three lesson cards are visible: 'Lesson 1 • Activity: Teens and Vaping: The Real Health Consequences' (Grades 6-8), 'Lesson 2 • Activity: Vaping Research Project' (Grades 6-8), and 'Lesson 3 • Activity: Sizing Up E-Cigarette Marketing' (Grades 6-8). Each card includes a 'DOWNLOAD' button. To the right of the website is a Scholastic infographic titled 'How to Talk to Kids About Vaping Risks'. This infographic provides key facts about teen vaping, such as 'Most e-cigarettes, including the popular Juul brand, contain nicotine, the same highly addictive chemical in regular cigarettes' and 'Nearly 60% of current middle school e-cigarette users report using a flavored product'. It also highlights that 'Teens are more susceptible to nicotine addiction than adults because their brains are still developing' and that 'Kids who vape are more likely to start smoking cigarettes'. The infographic includes illustrations of e-cigarettes, a person vaping, and a person with a thought bubble.

ADDITIONAL MATERIALS AVAILABLE ON CTP'S EXCHANGE LAB



Free print materials, web content and social media content are available to download and order on CTP's Exchange Lab:

<https://digitalmedia.hhs.gov/tobacco/>

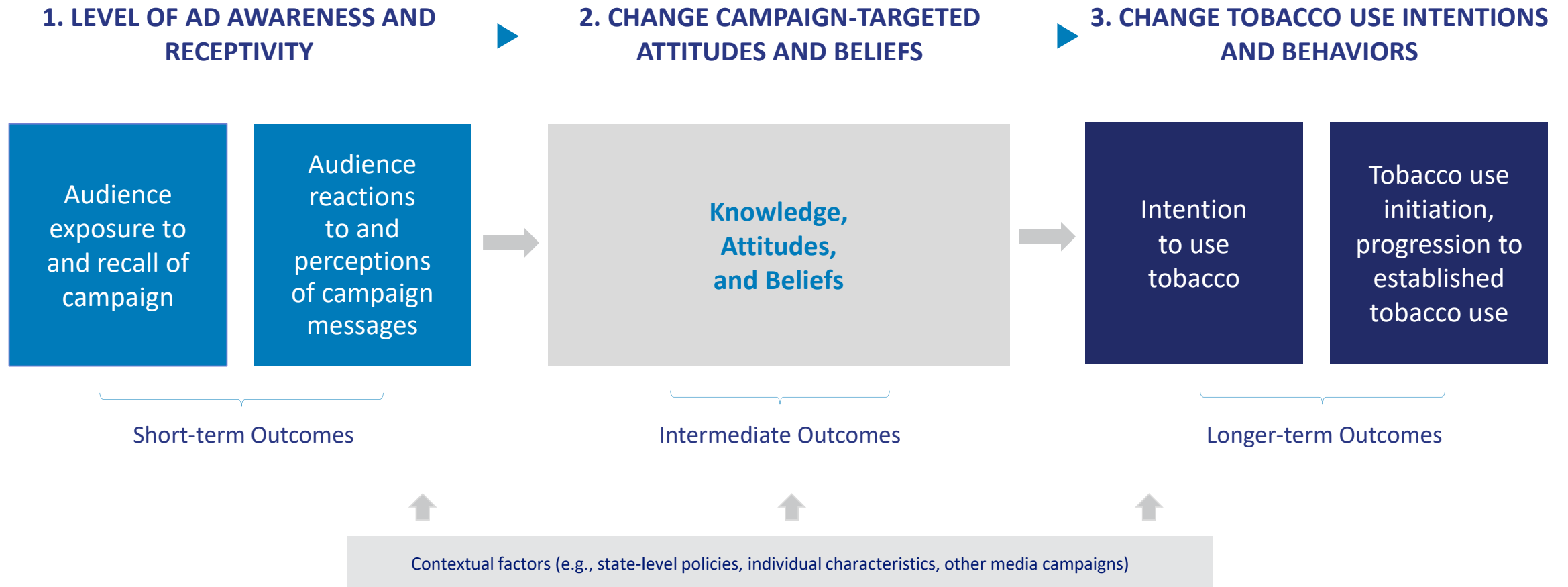


THANK YOU! QUESTIONS?

A young man and woman are standing in a library. The woman, on the left, is smiling and has her arm around the man's shoulder. The man, on the right, is looking directly at the camera. They are both wearing backpacks. The background shows bookshelves and other people in the library.

APPENDIX: EVALUATION RESULTS TO DATE

LOGIC MODEL: THREE SEQUENTIAL STEPS LEADING TO BEHAVIOR CHANGE

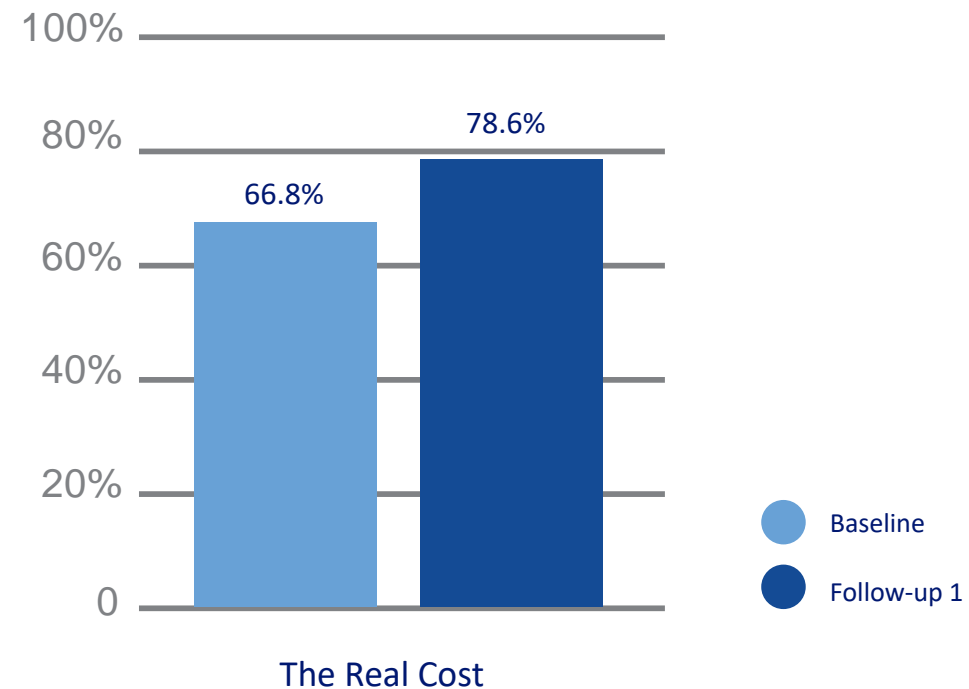


BRAND AWARENESS AND RECEPTIVITY REMAINS HIGH FOR THE VAPING PREVENTION CAMPAIGN



THE REAL COST

79% of youth recalled seeing The Real Cost brand logo



COLLECTIVELY, WE'RE MOVING IN THE RIGHT DIRECTION



Beliefs and risk perceptions about vaping are rapidly evolving

29 of 36 items assessing youth beliefs about vaping changed in the direction of increased perceptions of risk and improved knowledge of harm

For example, U.S. youth nationwide who believe*:

*“If I vape I will deliver nicotine to my brain” **increased 13%***

*“Vaping makes you more likely to smoke cigarettes” **increased 16.7%***

*“Vapes contain formaldehyde” **increased 20%***

**Relative Change*