UPDATES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

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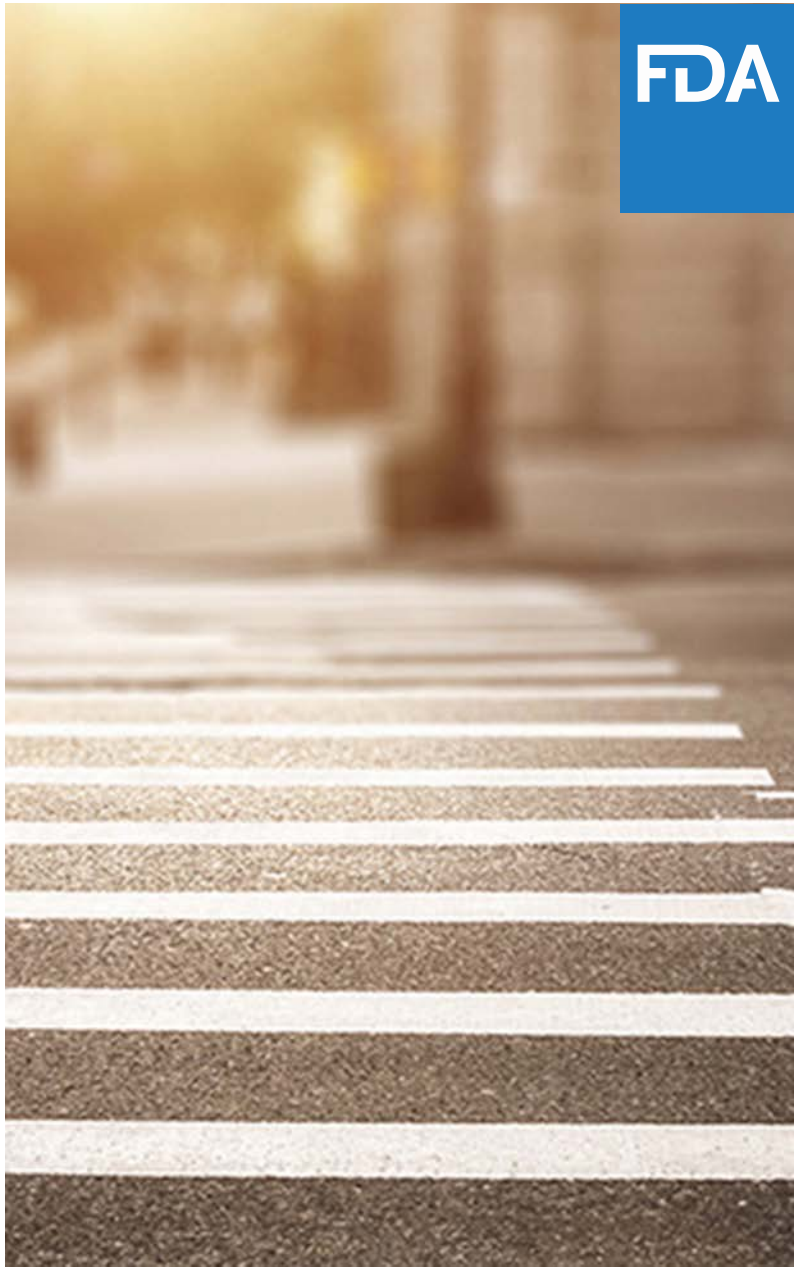
October 21, 2020

CENTER FOR TOBACCO PRODUCTS

AGENDA

- COVID-19
- Latest Findings on Youth E-Cigarette Use
- Compliance and Enforcement
- Product Review
- Regulations
- Health Communication and Education



IMPACT OF COVID-19 ON THE WORK AT CTP

- The COVID-19 pandemic has presented a new and significant challenge for all of us, affecting many aspects of our work
- Over the past year, CTP has made several adjustments due to the impact of COVID-19
- To help with the challenges posed by COVID-19 on both the tobacco industry and FDA, we requested extensions for certain key actions:
  - Premarket review submission deadline for deemed new products (since passed)
  - Effective date of the cigarette health warnings rule

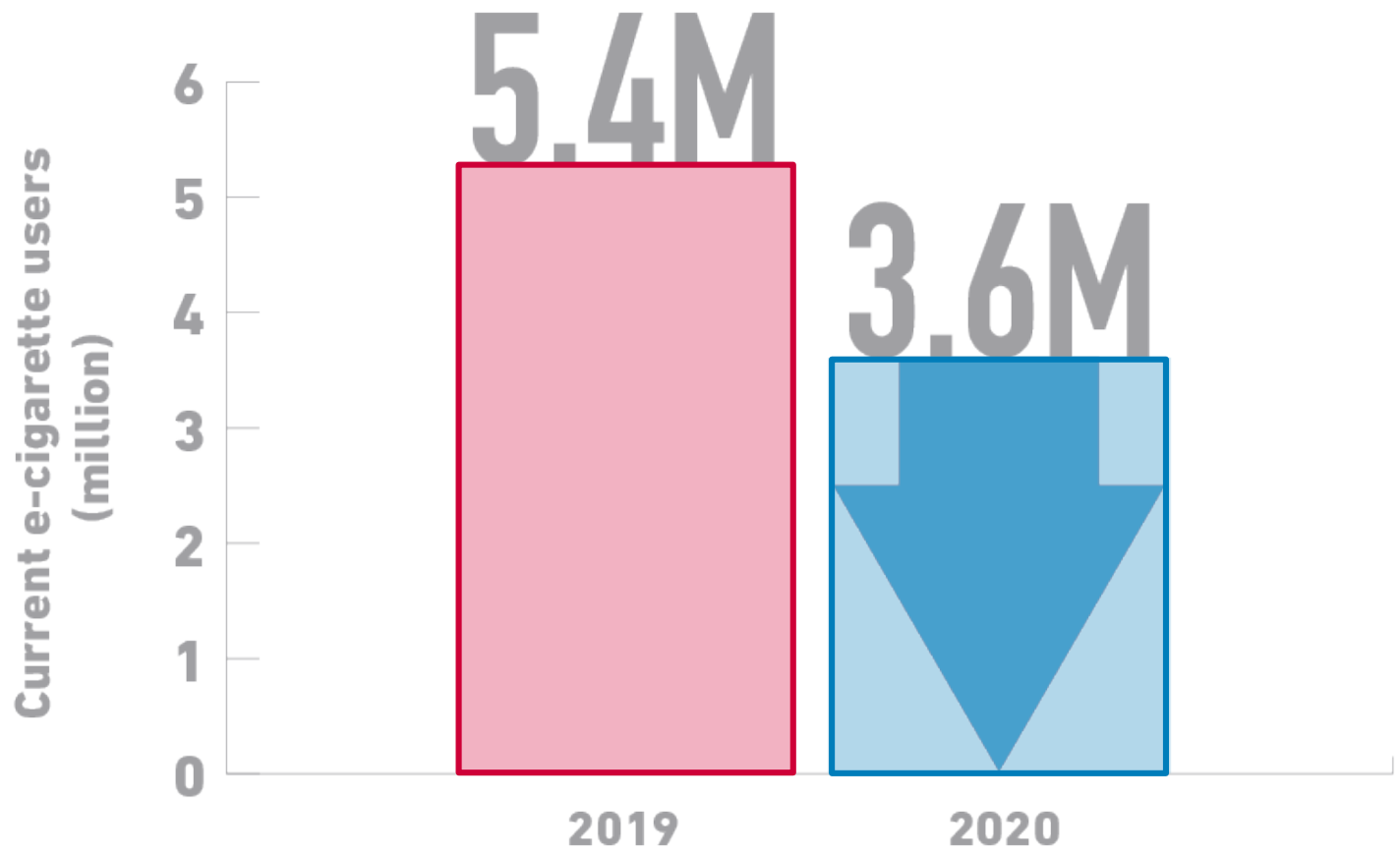
IMPACT OF COVID-19 ON THE WORK AT CTP

- To prioritize the health and well-being of staff, we issued a partial stop work order to the entities the agency contracts with at the state level for compliance checks and vape shop inspections
  - All in-person tobacco retail establishment inspections were temporarily suspended, however FDA's monitoring and surveillance of websites, publications, and social media continued
  - FDA is now working with states and contractors to begin resuming a limited number of these inspections; this will depend of many things including COVID data for each state and locality, and CDC, state and local guidelines

- Despite the challenges, CTP continues to work vigorously to protect public health

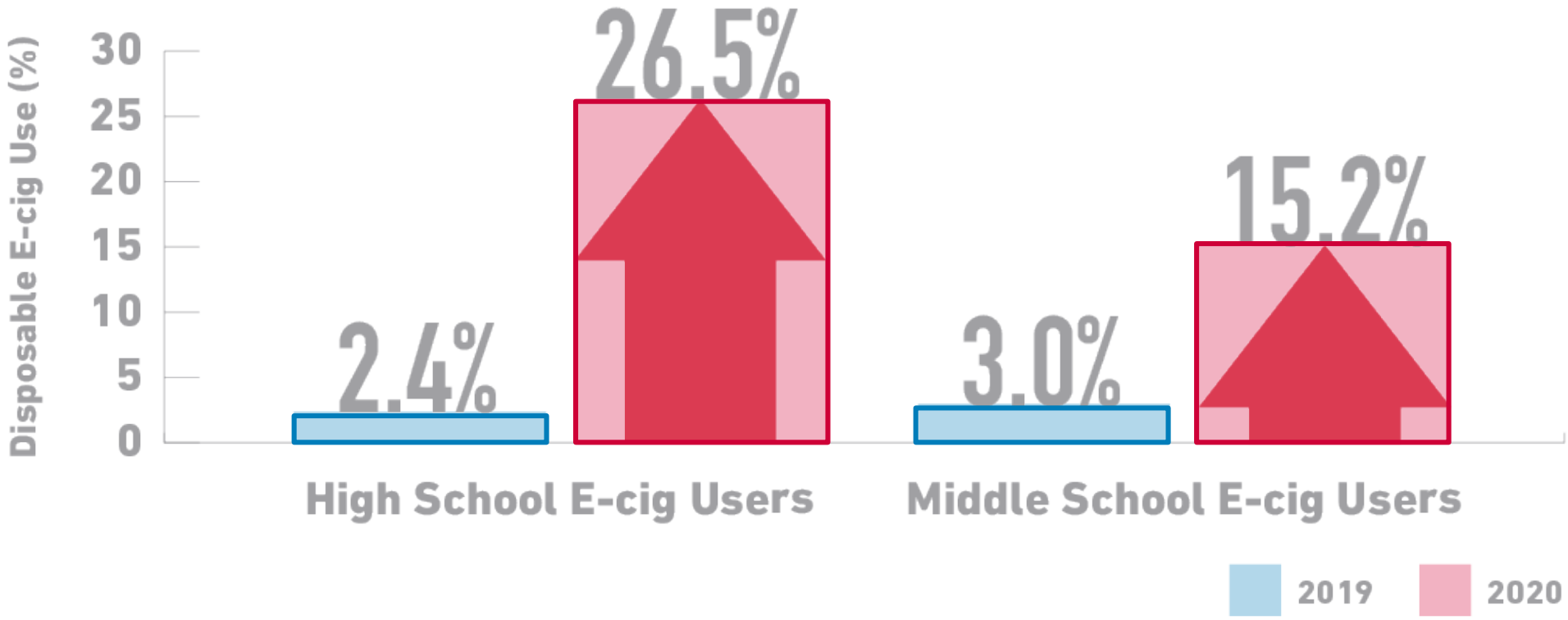
LATEST FINDINGS ON YOUTH E-CIGARETTE USE

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



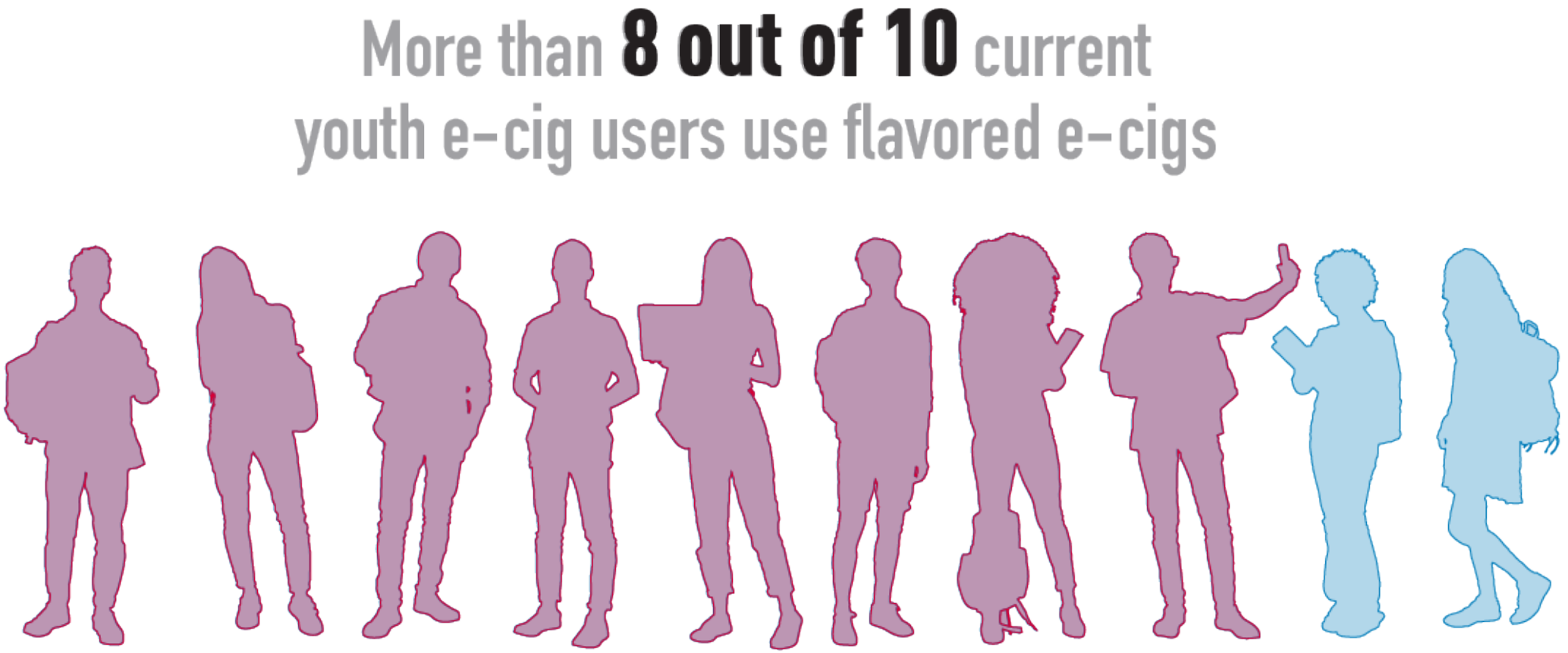
Source: NYTS 2020

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



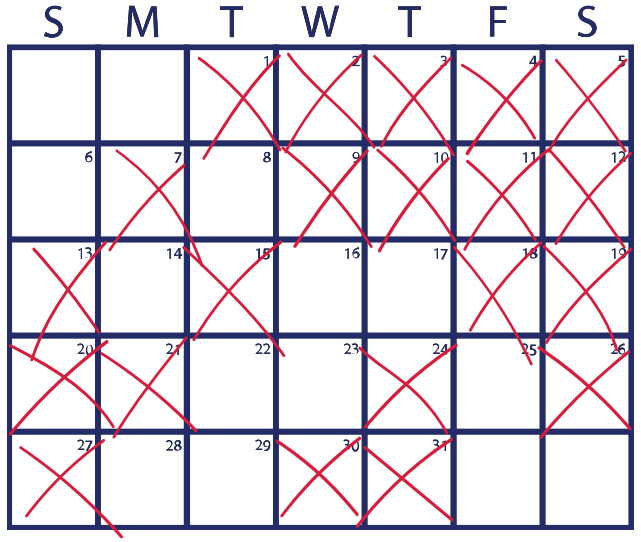
Source: NYTS 2020

NYTS 2020: SIGNS OF NICOTINE ADDICTION; FREQUENCY OF USE

In 2020, **38.9%**

of high school current e-cig users used e-cigarettes frequently (on 20 or more of the past 30 days)

Compared to 34.2% in 2019



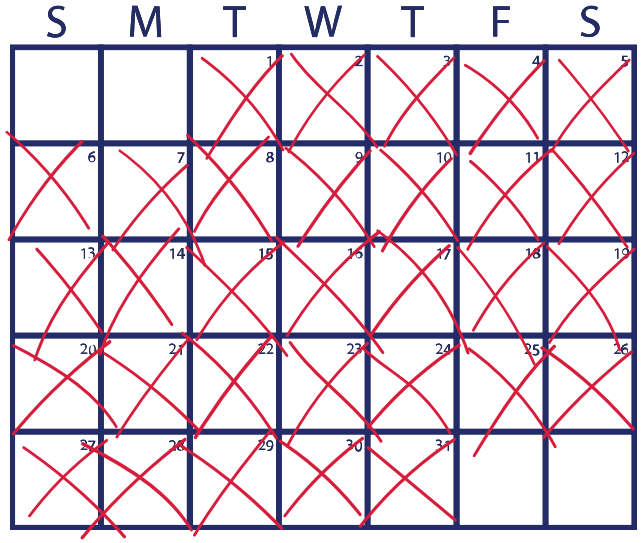
Source: NYTS 2020

NYTS 2020: SIGNS OF NICOTINE ADDICTION; FREQUENCY OF USE

In 2020, **22.5%**

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

Compared to 21.4% in 2019



Source: NYTS 2020

UPDATES ON COMPLIANCE AND ENFORCEMENT

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 product)*
  - *All other ENDS products for which the manufacturer has failed to take (or is failing 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*

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

- Additionally, based on several factors – including the likelihood of youth use or initiation – the FDA will **make the best use of agency resources to enforce against any other deemed new tobacco product** that does not have the required premarket authorization
  - As the result of a recent court decision, FDA will not be enforcing this requirement for "premium" cigars

- 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

**Extended from May 12, 2020 due to COVID-19 and its impacts*

UPDATE ON PREMIUM CIGARS

- Per a court ruling issued Aug. 19, 2020, FDA **will not enforce the premarket review requirement against manufacturers of premium cigars** that do not submit premarket applications for these products by the Sept. 9, 2020 deadline
- For purposes of the court's order, a premium cigar is defined as a cigar that meets all of the following eight criteria:
  - Is wrapped in whole tobacco leaf
  - Contains a 100 percent leaf tobacco binder
  - Contains at least 50 percent long filler tobacco
  - Is handmade or hand rolled
  - Has no filter, nontobacco tip, or nontobacco mouthpiece
  - Does not have a characterizing flavor other than tobacco
  - Contains only tobacco, water, and vegetable gum with no other ingredients or additives
  - Weighs more than 6 pounds per 1,000 units

LATEST ENDS ENFORCEMENT ACTIONS

- In September, FDA issued warning letters to three companies who sell or distribute unauthorized ENDS products:
  - **XL Vape LLC** (doing business as Stig Inc.), a popular disposable e-cigarette brand among youth
  - **Flavour Warehouse LTD** (doing business as Vampire Vape) and **Pretty Women UK LTD** (T/A Coil2oil and Mad Kingdom Liquids) for illegally marketing unauthorized menthol-flavored e-liquids

- The warning letters underscore FDA's concern with the rise in youth use of disposable e-cigarettes and the notable use of menthol-flavored e-cigarettes

- In July, three additional firms received warning letters for illegally marketing disposable e-cigarettes: **Puff Bar, HQD Tech USA LLC, Myle Vape Inc**.

UNAUTHORIZED YOUTH-APPEALING ENDS

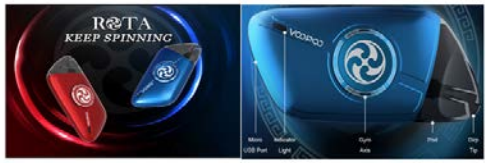
- Since March, FDA has issued over **260 warning letters to online and brick-and-mortar e-cigarette product retailers and manufacturers** across the country who sell unauthorized **flavored, cartridge-based ENDS** products
  - Including establishments such as 7-Eleven and Shell

- In April, FDA issued **6 warning letters to retailers and manufacturers** who sell, manufacture and/or import unauthorized ENDS products targeted to youth or likely to promote use by youth
  - The products for which companies received warning letters **appeal to youth in the way they are designed and labeled**

EXAMPLE OF PRODUCTS RECEIVING WARNING LETTERS

ENDS Product

Smartwatch



ENDS Product

Fidget Spinner

ENDS Product

Portable Video Game System

INSPECTIONS AND ENFORCEMENT ACTIONS

In FY 2020, prior to the issuance of the stop work order, FDA had already completed:

- More than 65,600 brick and mortar retail establishment inspections
- 396 vape shop inspections
- 125 manufacturer inspections

Since the enforcement program began in 2010, FDA has completed over **1.2 million inspections** of tobacco retailers resulting in the following enforcement actions:

- Over 98,000 Warning Letters (over 11,500 related to ENDS)
- Over 25,000 Civil Money Penalties (over 2,000 related to ENDS)
- 207 No-Tobacco-Sale Order Complaints

UPDATES ON PRODUCT REVIEW

PREMARKET 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, before making such a list available, FDA needs to ensure that publishing any such information complies with federal disclosure laws and regulations

ADDITIONAL EXTENSION REQUESTS

- FDA **received multiple requests for an additional extension** of the Sept. 9, 2020 deadline from individual manufacturers, importers and industry groups due to the COVID-19 pandemic, recent natural disasters, or other circumstances
  - Requests from individual manufacturers and importers ***were not granted***

- FDA intends to take the **firm's individual circumstances into account** in considering timely-submitted premarket applications

- FDA encouraged each firm to **provide information on any content missing** from their application, including how COVID-19 or any other unforeseen circumstances has prevented them from providing the information, and a timeframe for submission of the missing information

- FDA intends to **take into account relevant considerations in deciding whether to grant enforcement discretion** on a case-by-case basis for applications under review as the one-year review period ends Sept. 2021

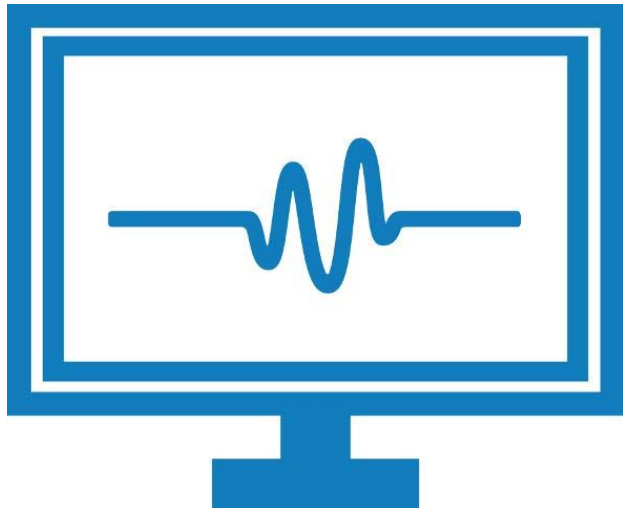
PLANS FOR REVIEW

- 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

DATA REPORTING

- FDA will be **posting data on the progress** the agency has made in the review process, including metrics such as:
  - Total number of applications received
  - Number of products for which applications were accepted
  - Number of products for which applications were filed
  - Number of products for which FDA has taken final actions, such as:
    - Refuse-to-Accept
    - Refuse-to-File
    - Positive marketing orders
    - Negative marketing orders



2019 PMTA DECISION – 22ND CENTURY

- In **December 2019**, FDA authorized marketing of two combusted, filtered cigarettes manufactured by 22nd Century Group Inc.
  - Cigarettes contain reduced amount of nicotine compared to other commercial cigarettes
  - **Authorized products include** Moonlight & Moonlight Menthol

- Authorization of these products is **appropriate for the protection of the public health** because
  - Potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure & cigarette consumption
  - Non-smokers, including youth, are also unlikely to start using the products
  - Non-smokers who experiment are less likely to become addicted than people who experiment with conventional cigarettes

2020 MRTP DECISION – IQOS

- In **July 2020**, FDA authorized the marketing of Philip Morris Products S.A.'s "IQOS Tobacco Heating System" as **modified risk tobacco products (MRTPs)**
  - The tobacco products received "exposure modification" orders, which permits the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of the population
  - The FDA previously authorized the marketing of these products without modified risk information in April 2019 via the premarket tobacco application (PMTA) pathway

- Authorizes the manufacturer to market the products with the following information:
  - "AVAILABLE EVIDENCE TO DATE:
    - The IQOS system heats tobacco but does not burn it.
    - This significantly reduces the production of harmful and potentially harmful chemicals.
    - Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

FOR MORE INFORMATION ON MRTPS

October 22, 2020, 12:00–1:00 PM

Modified Risk Tobacco Products (MRTPs): Recent Orders, Pending Applications, and Novel Products

Benjamin Apelberg, Division Director, Office of Science, CTP, FDA

UPDATES ON REGULATIONS

CIGARETTE HEALTH WARNINGS FINAL RULE

- On March 17, 2020, FDA issued a **final rule to require 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*

CIGARETTE HEALTH WARNINGS FINAL RULE

The final rule established **11 warnings featuring text statements accompanied by photo-realistic color images** depicting some of the lesser-known, but serious health risks of cigarette smoking, including impact to fetal growth, cardiac disease, and diabetes

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

UPDATES ON HEALTH COMMUNICATION AND EDUCATION

FDA'S PUBLIC EDUCATION CAMPAIGNS

- Public education campaigns are a proven strategy in preventing and reducing population-level tobacco use

- FDA has efforts targeting discrete audiences:
  - ✓ *The Real Cost:* General market teens at risk of smoking (February 2014)
  - ✓ *Fresh Empire:* Multicultural teens at risk of smoking (October 2015)
  - ✓ *The Real Cost Smokeless:* Rural male teens at risk of using smokeless (April 2016)
  - ✓ *This Free Life*: Lesbian, Gay, Bisexual, Transgender (LGBT) young adults at risk of becoming regular smokers (May 2016)
  - ✓ *Every Try Counts*: Smokers who have tried to quit in the last year but were unsuccessful (December 2017)
  - ✓ *The Real Cost Youth E-Cigarette Prevention*: General market teens on the dangers of e-cigarette use (Digital Ads launched September 2018; TV Ads launched July 2019)

- FDA also has a voluntary retailer education campaign, *This is Our Watch*, which educates retailers, clerks & the public on how to comply with federal tobacco laws (November 2017)

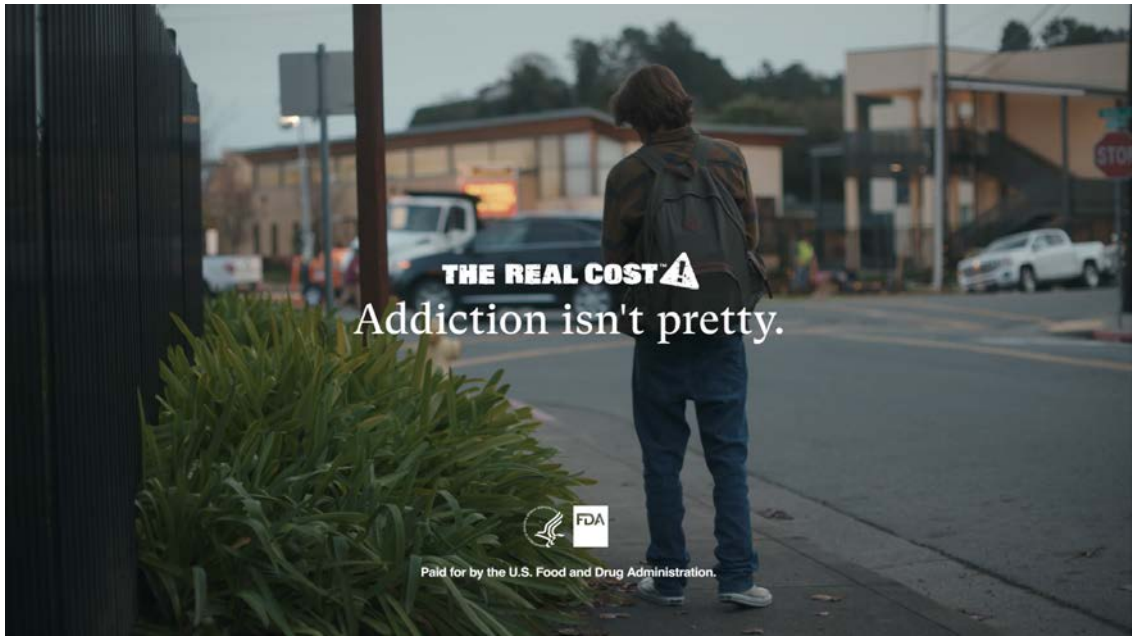
“THE REAL COST” YOUTH E-CIGARETTE USE PREVENTION CAMPAIGN

- “The Real Cost” Youth E-Cigarette Prevention Campaign is **targeted to youth aged 12-17** who have used e-cigarettes or are open to trying them; launched September 2018
- Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, **puts them at risk for addiction and other health consequences**
- Ads are running on television and online; include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms

THE REAL COST

- In August 2020, the Real Cost launched three executions under the concept **“Addiction Isn’t Pretty”** which shows how far some teens can go to get a hit of nicotine or show that addiction to e-cigarettes can turn you into someone you don’t want to be

- The ads leverage the fact that vapes can contain high levels of nicotine, and that many teens underestimate how easy it is to get addicted to nicotine



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

EXAMPLES OF FDA/SCHOLASTIC RESOURCES

Sponsored Educational Materials — SCHOLASTIC — Lesson Grades 6–8

Teens and Vaping: The Real Health Consequences

Help your students understand the health impacts associated with using e-cigarettes.

Objective
Students will gather, analyze, and select relevant evidence from multiple sources to understand the harmful health effects of vaping.

Standards
CCSS ELA
- RI.1 Cite textual evidence
- RI.7 Integrate information in different formats

NGSS
- Obtaining, Evaluating, and Communicating Information
- Cause and Effect

Time
50 minutes

Materials
- Get the Facts About Vaping activity sheet
- The Health Impacts of E-Cigarettes informational text
- What You Need to Know About Vaping interactive
- Optional: Video at whatsinavape.com
- 6 pieces of blank paper
- 6 sticky notes per student
- Family resource sheets

1 **Tell** students you are about to read them a statement, and they should prepare to anonymously write down their response to it on a slip of paper, using: *strongly agree, agree, disagree, strongly disagree,* and *don't know.* Read the statement aloud: *Electronic cigarettes are not harmful to your health.* Collect the slips (a pre-assessment of student perceptions; you'll repeat this at the end) while students work on step 2 below.

2 **Hand out** the Get the Facts About Vaping activity sheet and give students several minutes to complete the Predictions portion on the left. Have them set the sheets aside.

3 **Separate** the class into small groups. Distribute the informational text "The Health Impacts of E-Cigarettes" to the groups and direct them to take turns reading each paragraph aloud while other members record key facts. Tell the students they will use their notes for an activity coming up.

4 **Send** groups online to scholastic.com/vapingrisks to explore the interactive "What You Need to Know About Vaping," jotting down important details to add to their running notes. For older students, you also may want to share the video at whatsinavape.com. Note: If you have a limited number of computers in your classroom, direct half of the groups to complete Step 3 while the other half does Step 4; then have the groups switch.

5 **While** students are working, write the statements from the activity sheet on pieces of paper and hang them around the room. Instruct each group to choose one piece of evidence they think is most relevant to support or disprove each statement and write it on a sticky note. Have them press their sticky notes to the wall under each statement.
- **To support striving learners:** Point out that just because a fact is true does not mean it is re
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Online Resources
For students:
scholastic.com/vapingrisks

For additional teaching materials:
scholastic.com/youthvapingrisks

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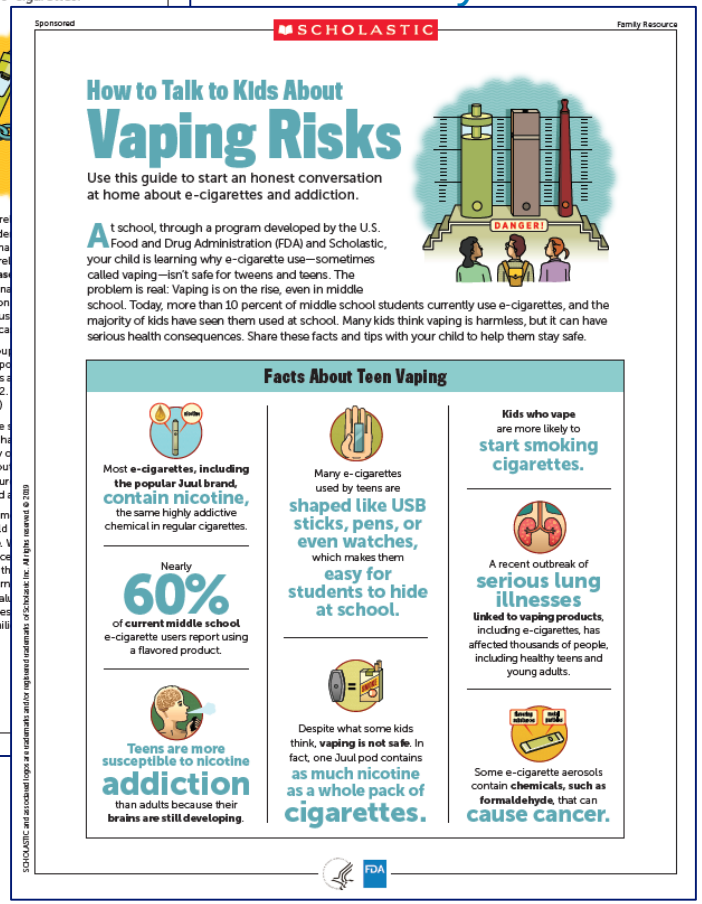
FDA

Lesson plan

Family Resource



Sponsored — SCHOLASTIC — Family Resource

How to Talk to Kids About Vaping Risks

Use this guide to start an honest conversation at home about e-cigarettes and addiction.

At school, through a program developed by the U.S. Food and Drug Administration (FDA) and Scholastic, your child is learning why e-cigarette use—sometimes called vaping—isn't safe for tweens and teens. The problem is real: Vaping is on the rise, even in middle school. Today, more than 10 percent of middle school students currently use e-cigarettes, and the majority of kids have seen them used at school. Many kids think vaping is harmless, but it can have serious health consequences. Share these facts and tips with your child to help them stay safe.

Facts About Teen Vaping

Most **e-cigarettes, including the popular Juul brand,** **contain nicotine,** the same highly addictive chemical in regular cigarettes.

Nearly **60%** of **current middle school** e-cigarette users report using a flavored product.

Teens are more susceptible to nicotine addiction than adults because their **brains are still developing.**

Many e-cigarettes used by teens are **shaped like USB sticks, pens, or even watches,** which makes them **easy for students to hide at school.**

Despite what some kids think, **vaping is not safe.** In fact, one Juul pod contains **as much nicotine as a whole pack of cigarettes.**

Kids who vape are more likely to **start smoking cigarettes.**

A recent outbreak of **serious lung illnesses** **linked to vaping products,** including e-cigarettes, has affected thousands of people, including healthy teens and young adults.

Some e-cigarette aerosols contain **chemicals, such as formaldehyde,** that can **cause cancer.**

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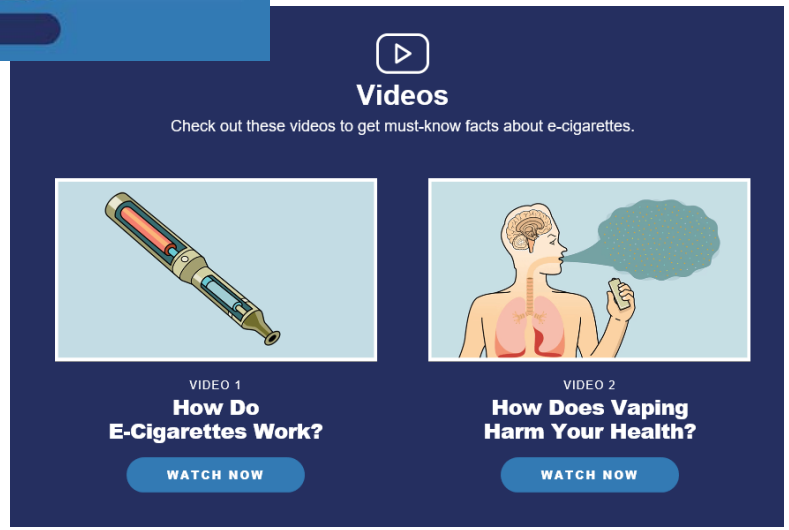
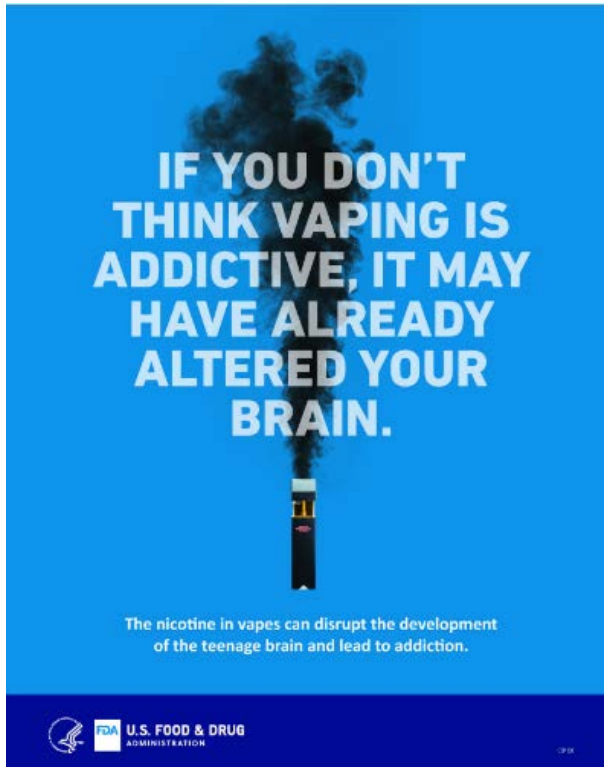
FDA

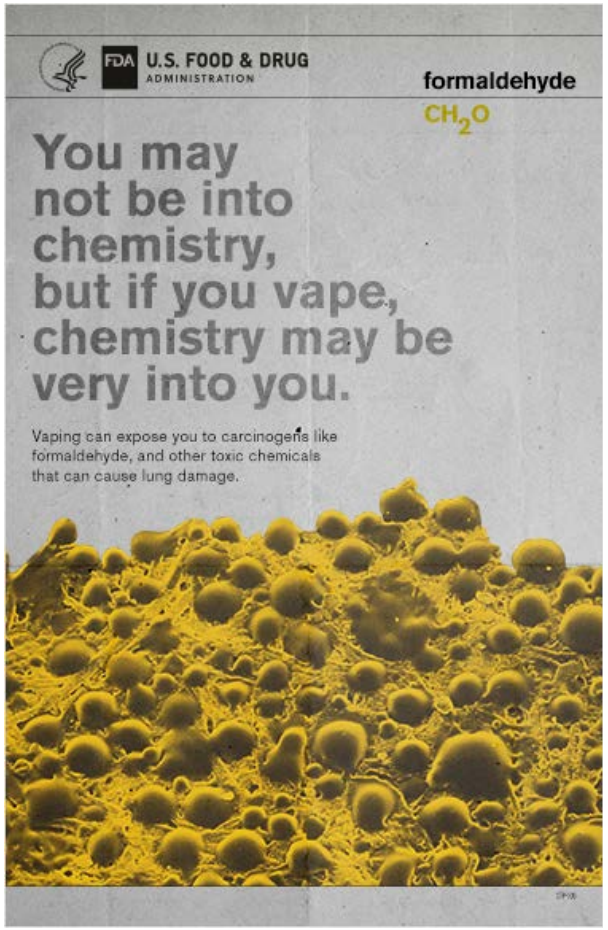


ADDITIONAL MATERIALS AVAILABLE ON CTP'S EXCHANGE LAB

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/





FOR MORE INFORMATION ON PUBLIC EDUCATION CAMPAIGNS

October 22, 2020,11:05–11:45 AM

Update on FDA Public Education Campaigns

Kathleen Crosby, Director, Office of Health Communications, CTP, FDA

CONTACTING/FOLLOWING CTP

- **Report adverse experiences with tobacco products at: https://www.safetyreporting.hhs.gov**
- Call us: (877) CTP-1373
- Email us: AskCTP@fda.hhs.gov
- Follow us on Twitter: @FDATOBACCO