

UPDATES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

Mitch Zeller, J.D.

Director, FDA Center for Tobacco Products



AGENDA

- Current Data on Youth Tobacco Use
- Programmatic Updates
 - Regulations and Guidances
 - Premarket Applications and Plans for Review
 - Compliance and Enforcement
 - Health Communication & Education
- Live Q&A Session

The FDA logo is located in the top right corner of the slide. It consists of the letters "FDA" in white, bold, sans-serif font, set against a blue square background.



CURRENT DATA ON YOUTH TOBACCO USE

RELEASE OF NYTS 2020 FINDINGS



In Sept. 2020, FDA and CDC released findings from the 2020 National Youth Tobacco Survey on youth e-cigarette use; in Dec. 2020, findings on use of all tobacco products were released

Morbidity and Mortality Weekly Report

E-cigarette Use Among Middle and High School Students — United States, 2020

Teresa W. Wang, PhD¹; Linda J. Neff, PhD¹; Eunice Park-Lee, PhD²; Chunfeng Ren, PhD²; Karen A. Cullen, PhD²; Brian A. King, PhD¹

MMWR / September 18, 2020 / Vol. 69 / No. 37

US Department of Health and Human Services/Centers for Disease Control and Prevention

Centers for Disease Control and Prevention

MMWR

Weekly / Vol. 69 / No. 50

Morbidity and Mortality Weekly Report

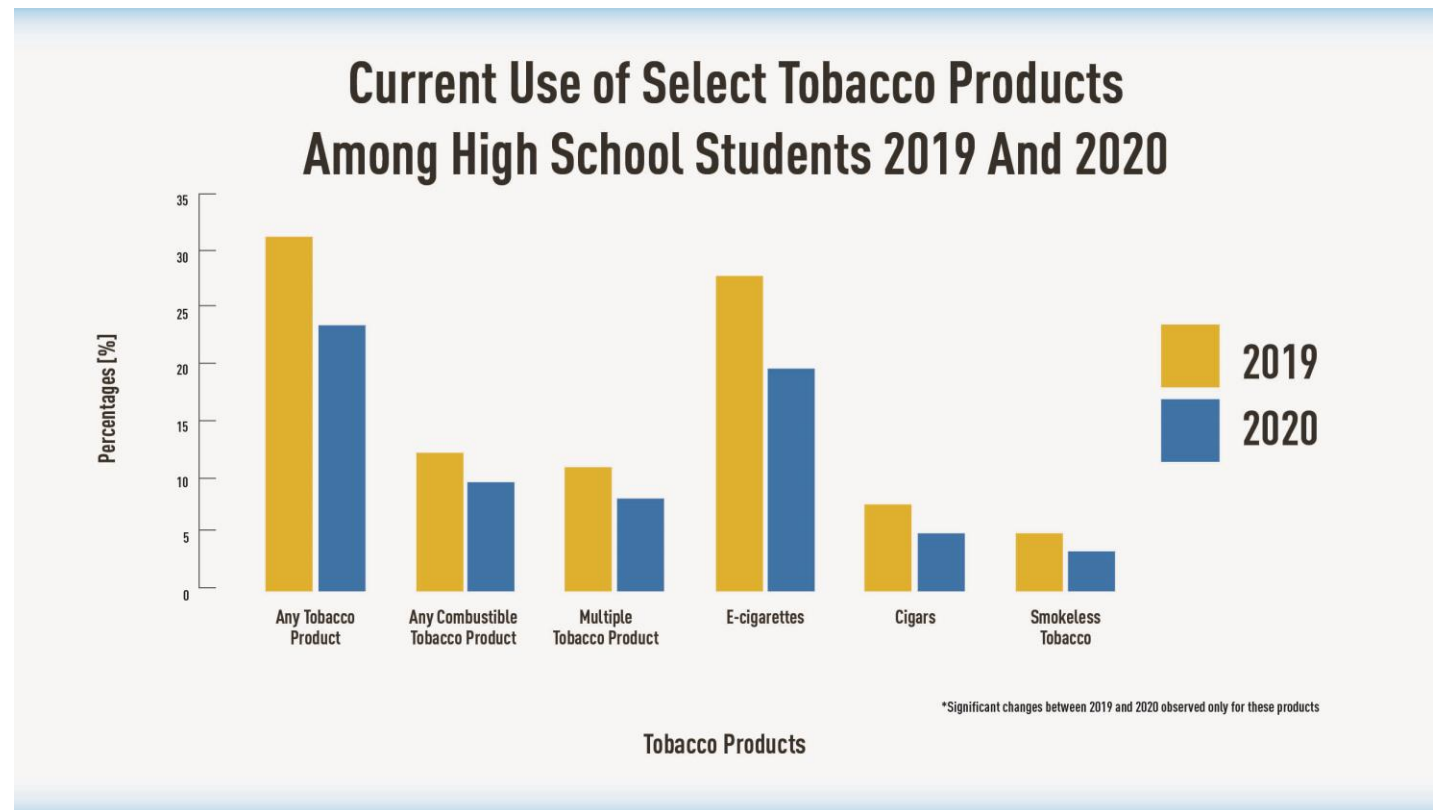
December 18, 2020

Tobacco Product Use Among Middle and High School Students — United States, 2020

Andrea S. Gentzke, PhD¹; Teresa W. Wang, PhD¹; Ahmed Jamal, MBBS¹; Eunice Park-Lee, PhD²; Chunfeng Ren, PhD²; Karen A. Cullen, PhD²; Linda Neff, PhD¹

KEY NYTS 2020 FINDINGS

FDA is encouraged by **declines in overall tobacco product** use from 2019 to 2020 but remains very concerned about the **24 percent of high schoolers and 7 percent of middle schoolers** who currently use tobacco products.



KEY NYTS 2020 FINDINGS



In 2020, about 1.8 million fewer U.S. youth are current e-cigarette users compared to 2019.

However

3.6M

U.S. youth still currently
use e-cigs

There is a notable uptick in use of

DISPOSABLE

e-cigs by youth

More than

8 out of 10

current youth e-cig users
use flavored e-cigs

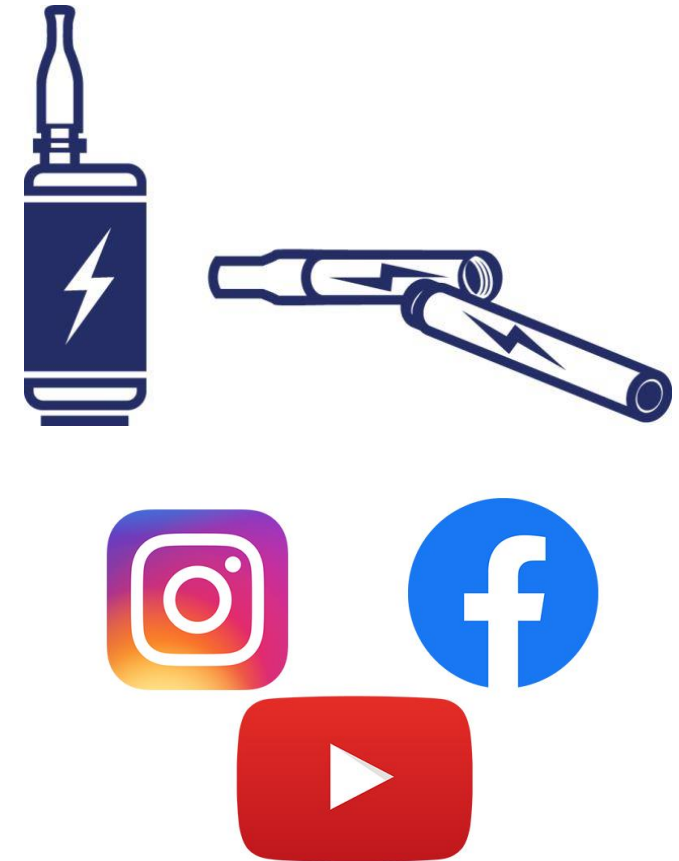
FLAVORED ENDS PRODUCTS AND YOUTH USE



- Our commitment to addressing youth use of e-cigarettes – especially those the data show are **most appealing to, and used by, youth** – is unwavering
 - This includes considering factors, such as appeal of flavors and product design type, in our enforcement priorities
- We continue to address youth use of e-cigarettes through:
 - Premarket review of tobacco product applications, which ensures that each new product introduced to the U.S. market is, for example, appropriate for the protection of public health
 - Compliance and enforcement efforts
 - Public education campaigns

904(B) LETTERS TO E-CIG FIRMS

- On Mar. 17, FDA requested information about the social media marketing of four companies' e-cigarette products, as well as their use of social media influencers, specifically as it relates to targeting youth
 - The companies that received the official requests for information market the following brands: **Aspire, Joyetech, Vaporesso, and Voopoo**
- FDA selected these companies through a systematic process, which included evaluating each company's presence, reach and activity on Facebook, Instagram and YouTube, and whether it uses age restriction tools for these platforms



904(B) LETTERS TO E-CIG FIRMS



- The information the FDA is requesting includes, but is not limited to:
 - Documents related to social media advertising and marketing plans, including planned content, cost of plans, plans to target specific audiences, and plans to restrict youth exposure and/or access to ads;
 - Use of partners, promoters, affiliates, influencers, bloggers, and/or brand ambassadors; and
 - The number of followers and/or viewers broken out by age group, how the ages of followers and viewers are tracked and managed, and any actions taken to restrict youth-access and/or limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion in social media channels and a summary of the effectiveness of such actions.
- The companies have 60 days to respond to the agency. Failure to provide the information is a violation of the law and subject to regulatory and enforcement action by the FDA.

The background of the slide is a low-angle photograph of several tall, fluted classical columns with Corinthian capitals. The columns are made of light-colored stone and are set against a blue sky. A semi-transparent blue horizontal band is overlaid across the middle of the image, containing the text "REGULATIONS AND GUIDANCES".

REGULATIONS AND GUIDANCES

TOBACCO PRODUCT STANDARDS

On Apr. 29, FDA announced plans to issue proposed product standards within the next year to:

- Ban menthol as a characterizing flavor in cigarettes
- Ban all characterizing flavors in cigars



“With these actions, the FDA will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities...Armed with strong scientific evidence, and with full support from the Administration, we believe these actions will launch us on a trajectory toward ending tobacco-related disease and death in the U.S.”

– Acting FDA Commissioner Janet Woodcock, M.D.

MENTHOL PRODUCT STANDARD



- There are nearly 18.6 million current smokers of menthol cigarettes in the United States
 - Nearly **85% of Black smokers** use menthol cigarettes, compared to 30% of White smokers
 - From 2011 to 2018, declines in menthol cigarette use were observed among non-Hispanic White youth but not among non-Hispanic Black or Hispanic youth
- We believe that the proposed menthol product standard would help address the disproportionate impact of menthol cigarette use on **racial and ethnic minority communities and other groups**
 - Researchers have estimated that hundreds of thousands of lives could be saved by **eliminating menthol** in cigarettes
 - FDA also granted a **citizen petition** requesting that the agency pursue rulemaking to prohibit menthol in cigarettes, affirming its commitment to proposing such a product standard

CIGAR FLAVORS PRODUCT STANDARD



- After the 2009 statutory ban on characterizing flavors in cigarettes other than menthol, use of flavored cigars **increased dramatically**, suggesting that the public health goals of the flavored cigarette ban may have been undermined by continued availability of these flavored cigars
- Flavored mass-produced cigars and cigarillos are combusted tobacco products that can closely resemble cigarettes, pose many of the same public health problems, and are disproportionately popular among youth and other populations
 - In 2020, non-Hispanic Black high school students reported past 30-day cigar smoking at levels **twice as high** as their White counterparts
 - Nearly 74% of youth aged 12-17 who use cigars say they smoke cigars because they come in **flavors they enjoy**. Among youth who have ever tried a cigar, 68% of cigarillo users and 56% of filtered cigar users report that their first cigar was a flavored product.
 - Moreover, in 2020, **more young people first tried a cigar** every day than tried a cigarette

ENFORCING TOBACCO PRODUCT STANDARDS



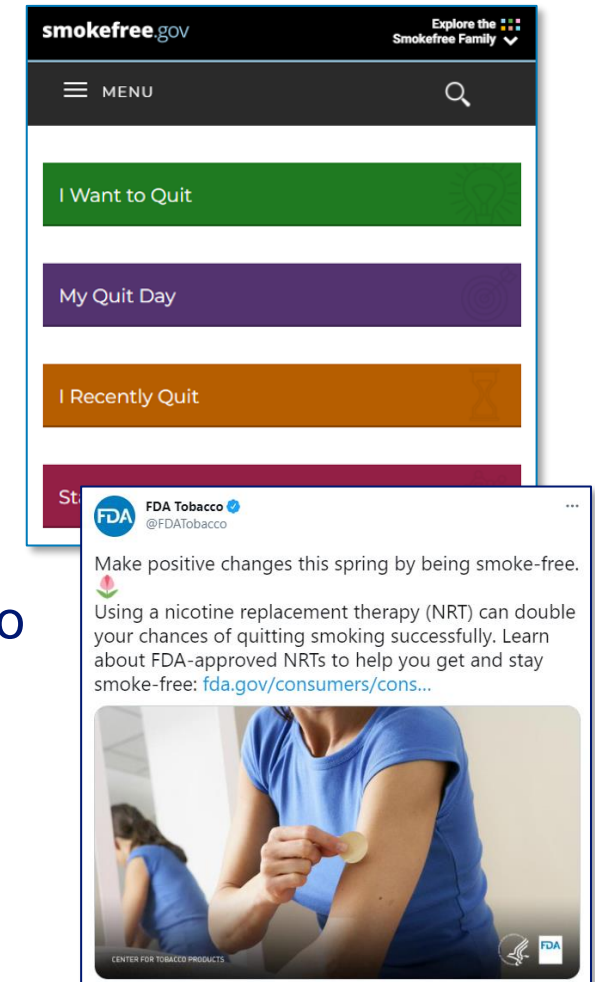
- We take very seriously the concerns that have been raised about discriminatory policing
- If finalized, FDA's enforcement of any ban on menthol cigarettes and all flavored cigars will be against **manufacturers, distributors, wholesalers, importers, and retailers**
- FDA **cannot and will not enforce against individual consumer possession or use** of menthol cigarettes or any tobacco product
- State and local law enforcement do not enforce the Food, Drug, and Cosmetic Act and so could not enforce a federal ban on menthol cigarettes or flavored cigars

“Banning menthol in cigarettes and flavors in cigars will decrease the appeal of these tobacco products and strengthen health equity. Together, these actions represent powerful, science-based approaches that over time will help end the cycle of children becoming the next generation of smokers and eliminate long-perpetuated health disparities.”

– HHS Secretary Xavier Becerra

TOBACCO PRODUCT STANDARDS

- The agency also recognizes the importance of ensuring broad and equitable access to all the tools and resources that can help currently addicted smokers seeking to quit
- The FDA will work with partners in other federal agencies to make sure the support is there for those who are trying to quit
 - We have developed a range of cessation messaging to educate smokers on the benefits of quitting and to increase motivation to quit
 - We have worked collaboratively with the National Cancer Institute (NCI) to develop a cessation website that features quitting tips, text message programs, and online cessation counseling
 - We also continue to work with stakeholders and public health partners to further amplify and disseminate cessation messaging through FDA's Exchange Lab and CDC's Media Campaign Resource Center



CIGARETTE HEALTH WARNINGS FINAL RULE

- Beginning Jan. 14, 2022, new health warnings will be required to appear prominently on cigarette packages and in advertisements to promote greater public understanding of the negative health consequences of cigarette smoking



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 postponed from June 18, 2021, to Oct. 16, 2021, due to COVID-19 and its impacts
- In Dec. 2020, the U.S. District Court for the Eastern District of Texas granted a motion by the plaintiffs in the case of *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration* to postpone by an additional 90 days to Jan. 14, 2022



PREMARKET APPLICATIONS & PLANS FOR REVIEW



PREMARKET APPLICATIONS




- Applications for premarket review for certain deemed new tobacco products on the market as of Aug. 8, 2016, were required to be submitted to FDA **by Sept. 9, 2020**
 - 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 companies that submitted timely applications, FDA may, and generally intends to, **defer enforcement until Sept. 9, 2021** – unless a negative action is taken by the FDA on an application during that time
- FDA **posted a list of the deemed products** for which a Substantial Equivalence (SE) Report or Exemption from SE Request was made by Sept. 9, 2020

- FDA continues to work on **processing submissions & requesting marketing information** of products received through the **PMTA pathway**
 - To date, we have requested this information for **~86,000 products**
- Due to the size, volume, variable quality, format & presentation of these PMTA submissions, processing & verifying this information is taking more time
- FDA will post information on products submitted through the PMTA pathway as soon as possible

PROGRESS ON PROCESSING



	Substantial Equivalence	Exemption Request	Premarket Tobacco Product Application
	100% Processing Complete	100% Processing Complete	Processing Still Underway
	FDA received applications for 6,800 products from 100 companies	FDA received applications for 350 products from 15 companies	FDA has processed applications for more than 6.0 million products from more than 500 companies

All numbers are estimates

EXPANDED REVIEW PROCESS METRICS



- FDA has started **posting expanded data** on new Tobacco Product Application Metrics
 - Provide more detailed updates on progress than previously available
 - For example, FDA is posting all metrics **both by pathway** (SE, EX REQ, and PMTA) & **by product category type** (e.g., cigarette, ENDS, cigars, smokeless)

FY 21 Products Accepted for Review

ENDS	318,146
Cigarette	111
Cigar	2,003
Waterpipe	560
Pipe	507
Roll-Your-Own	25
Smokeless	16
Other	35

Data as of Apr. 1, 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



OFFICE OF SCIENCE LIVE VIRTUAL MEETING



- Please join us for a live, virtual meeting with CTP's Office of Science Director, Matt Holman, discussing the scientific review of applications received by Sept. 9, 2020.

WHEN: Friday, June 11 from 1:00 to 3:30 p.m. EDT

REGISTER by June 10 at

https://iqsolutions.qualtrics.com/jfe/form/SV_9XdCOYsMGvwUX0W

- The meeting will focus on the application intake process, review progress, and allocation of review resources, and include time for audience questions
- More information is posted on the [CTP website](#)

KEY MARKETING DECISIONS FROM 2020: IQOS 3 – SUPPLEMENTAL PMTA



- In **December 2020**, FDA issued a marketing order to Philip Morris Products S.A. authorizing the sale of the IQOS 3 System Holder and Charger.
 - This is the first “supplemental” PMTA received by FDA
- Compared to the previous version of IQOS authorized in April 2019, the newly authorized version has minor design differences, including how the holder inserts into the charger, changes to the charging connectors and LED indicator lights, a new touch feedback feature, and an option to reduce the perceived heat from the tobacco aerosol inhaled by users
- Following FDA’s scientific review of the application, the agency found, among other things, that the modifications to the device do not raise new concerns related to safety, health effects, product quality, or product misuse

IQOS 3 – SUPPLEMENTAL MRTP APPLICATION



- In **May 2021**, FDA issued a Filing Letter for the IQOS 3 System Holder and Charger **modified risk tobacco product (MRTP)** application
 - Application materials will continue to be posted to the CTP website after they are redacted
 - Public comments may be submitted to [regulations.gov](https://www.regulations.gov); there is currently no deadline
- The company proposes to use the **same reduced exposure claims** FDA authorized for a previous version of the device, which states:
 - “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.”

A close-up, artistic photograph of a compass rose. The compass is centered, with its needle pointing towards the upper right. The background is a light blue gradient. A semi-transparent blue horizontal band is overlaid across the middle of the image, containing the text "COMPLIANCE AND ENFORCEMENT".

COMPLIANCE AND ENFORCEMENT

ENFORCEMENT AGAINST ENDS MANUFACTURERS THAT DID NOT SUBMIT PREMARKET APPLICATION BY 9/9

- In Jan. 2021, FDA issued warning letters to **19 firms** that **manufacture and operate websites selling ENDS** which lack premarket authorization
- These were the first sets of warning letters issued to firms that did not submit a premarket application by the Sept. 9 deadline and for products that do not have premarket authorization
- FDA continues to regularly issue warning letters for this violation and, to date, has issued **103 letters** to firms, which collectively have listed a combined total of more than **904,000 products** with the FDA



INSPECTIONS AND ENFORCEMENT ACTIONS

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)
- 221 No-Tobacco-Sale Order Complaints



Data as of Apr. 2021

ENFORCEMENT PRIORITIES GUIDANCE



- Since Feb. 6, 2020, FDA has been 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*
- After Sept. 9, 2020*, FDA has also **prioritized 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; since Sept. 2020, **flavored disposable ENDS have been an enforcement priority** for the agency

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

ENFORCEMENT AGAINST UNAUTHORIZED YOUTH-APPEALING ENDS



- In the last year, FDA has issued:
 - More than 260 warning letters to online and brick-and-mortar manufacturers and retailers across the country that **sell unauthorized flavored, cartridge-based ENDS products** (including establishments such as 7-Eleven and Shell)
 - Six warning letters to firms that **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**
 - Eleven warning letters to firms that **sell, manufacture and/or import unauthorized e-liquids that imitate packaging for food products** that often are marketed and appeal to youth such as candy, popcorn, cookies, cereal or feature cartoon characters

EXAMPLE OF PRODUCTS RECEIVING WARNING LETTERS

Backpack and sweatshirt designed with stealth pockets to hold and conceal an e-cigarette



E-liquids that imitate packaging for food products that often are marketed and appeal to youth

ENDS products that resemble smartwatches or devices appearing as children's toys



ENFORCEMENT AGAINST DISPOSABLE AND MENTHOL FLAVORED ENDS

- In Sept. 2020, 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.**

Illegally Marketed ENDS Products



SEIZURE OF PUFF BAR-LIKE ENDS PRODUCTS

- In Jan. 2021, U.S. Customs and Border Protection officers at the Dallas Fort Worth International Airport, working in conjunction with agents from FDA, announced that they **seized 33,681 units of e-cigarettes**
- The shipments included individual disposable flavored e-cigarette cartridges resembling the Puff Bar brand, including Puff XXL and Puff Flow



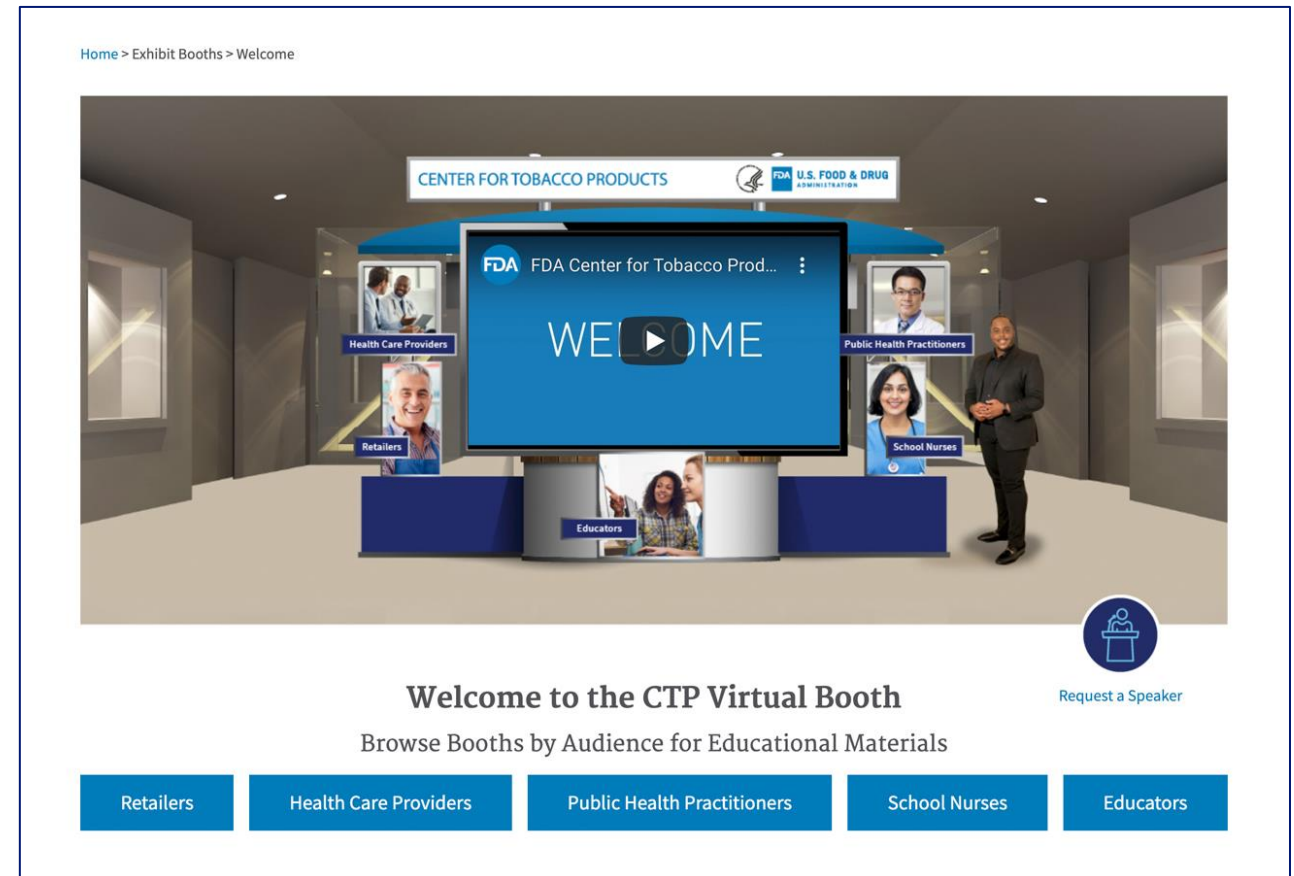


HEALTH COMMUNICATION & EDUCATION

VIRTUAL EXHIBIT BOOTH



- FDA recently launched a [virtual exhibit booth](#), which provides visitors an opportunity to explore CTP resources on the Exchange Lab
- This virtual platform provides a “site within a site” of carefully curated and tailored landing pages designed for several of CTP’s targeted stakeholder audiences - public health practitioners, health care providers, school nurses, educators, and tobacco retailers.



COLLABORATION WITH SCHOLASTIC



- FDA continues to collaborate with Scholastic to develop and distribute youth e-cigarette prevention educational resources for middle and high schools.
- In Dec. 2020, FDA and Scholastic launched supplementary program materials, including a student magazine with an accompanying teacher guide, a student contest, and a blog post.
- The “Vaping’s Not My Thing” Student Challenge asked students in grades 6-12 to submit posters or illustrations that aim to convince teens not to vape. Prizes for the contest are funded by Scholastic and will be awarded in spring 2021.

Teacher Guide

Lesson Grades 6-12

The Real Cost of Vaping

More than 3.6 million middle and high school students use e-cigarettes today. Many youths think vaping is harmless, but it can have serious health consequences.

Objective
Students will analyze informational texts to gather evidence about the risks of vaping, then create a persuasive anti-vaping infographic/poster for a teen audience.

Standards, Gr. 6-12
CCSS.ELA
• R.6-12.1 Cite evidence to support text analysis
• R.7-9 Analyze how two texts present information
• SL.6-12.1 Engage in collaborative discussions
• W.6-12.1 Write arguments to support claims
• W.6-12.2 Use domain-specific vocabulary
NGSS
• Practice: Obtaining, Evaluating, and Communicating Information
• Crosscutting Concept: Cause and Effect: Mechanism and Prediction
• Core Idea: MS-LS-4.1.8 Growth and Development of Organisms
National Health Education Standards
• #7 Avoid or reduce health risks
• #8 Advocate for personal, family, or community health

Time
60-180 minutes

Materials
• The *Risks of Vaping* student magazine
• Teens and Vaping reading passage
• Vaping's Not My Thing poster planner
• Rubric at [scholastic.com/youthvapingrisks](https://www.scholastic.com/youthvapingrisks)

NONFICTION TEXT ANALYSIS
1 Share the student magazine with your students (also available digitally at [scholastic.com/youthvapingrisks](https://www.scholastic.com/youthvapingrisks)) and discuss key facts about how vaping can affect their health. Use the questions.

CREATE POSTER/INFOGRAPHIC
1 Challenge your students to help keep their fellow teens safe by creating a persuasive poster to hang up around school. They'll synthesize what they have learned to create a poster or infographic.

Sponsored Educational Materials

SCHOLASTIC

THE RISKS OF VAPING

STORIES FROM **REAL TEENS**

DANGERS OF NICOTINE ADDICTION

SUPPORT FOR QUITTING

POSTER PROJECT

Student Magazine

FDA/AAP VIDEOS



- FDA and the American Academy of Pediatrics (AAP) collaborated to develop a video series featuring pediatricians answering common questions about youth e-cigarette use
- FDA also created a [new webpage](#) that includes tobacco education resources for parents and educators



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