UPDATES FROM
FDA’S CENTER FOR TOBACCO PRODUCTS

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AGENDA

UPDATES

• Agency-wide Initiatives on Cessation
• Regulations and Guidances
• Compliance and Enforcement
• Science and Research
• Product Review
• Vaping Lung Injuries
• Health Communication and Education
Our goal is to **reduce the harm from tobacco products across the entire population**, including:

1. Reducing the number of people who start to use tobacco products
2. Encouraging more people to stop using these products
3. Reducing the adverse health impact for those who continue to use these products
THE COMPLEX TOBACCO LANDSCAPE

Source: IOM Report: Agent-based model for tobacco regulation report commissioned by CTP
For Adults:

- Over 480,000 Americans die each year from preventable tobacco related deaths
- 19.7% (49.1 million) currently use any tobacco product
- 13.7% (34.2 million) currently smoke cigarettes
- 3.2% (8.1 million) currently use e-cigarettes

For Teens:

- Each day approximately 1,600 youth aged 12-17 smoke their first cigarette in the United States
- 23.0% (6.2 million) middle and high school students currently use any tobacco product
- 20.0% (~5.4 million) currently use electronic cigarettes
- 4.3% (1.15 million) currently smoke cigarettes
A CONTINUUM OF RISK

- Approach: place nicotine – and issue of addiction – at center of regulatory efforts

- While highly addictive, nicotine delivered through products on continuum of risk and cigarettes are most harmful

- Strike appropriate balance between smart regulation and encouraging innovation of satisfying, less harmful products

- Continue to base all actions on regulatory and scientific foundation
UPDATES ON AGENCY-WIDE INITIATIVES ON CESSATION
• **September 2017:** Nicotine Steering Committee formed and charged with re-evaluating and modernizing FDA’s approach to the development and regulation of nicotine replacement therapy (NRT) products

• **January 2018:** Held public hearing to solicit comments on a variety of issues including new indications such as “Reduce to quit”

• **August 2018:** Issued “Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products”

• **February 2019:** Issued “Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products”
PUBLIC MEETINGS ON YOUTH CESSATION

• **January 2019:** FDA held a public hearing on “Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies”

• **May 2019:** FDA held a public scientific workshop entitled “Youth Tobacco Cessation: Science and Treatment Strategies”

*Links to the recorded webcast available on the “FDA Meetings, Conferences and Workshops” webpage*
UPDATE ON REGULATIONS AND GUIDANCES
RULES ISSUED OVER THE LAST YEAR

Proposed Rules

• April 2019: SE Reports

• August 2019: Cigarette Health Warnings

• September 2019: PMTAs

Upcoming Rule

• Tentative June 2020: Tobacco 21
SE PROPOSED RULE

• Proposes content & format requirements of SE Reports

• **When finalized, proposed rule would**
  – Provide information as to how FDA intends to evaluate SE Reports
  – Provide more clarity to applicants
  – Support efficient & predictable reviews of SE Reports

• Comments currently under review & analysis
• Proposes content & format requirements of PMTAs
• Provides information as to how FDA intends to evaluate PMTAs

• **When finalized, proposed rule would**
  – Help to ensure that PMTAs contain sufficient information for evaluation (e.g., details on physical aspects of a tobacco product, information on potential public health benefits and harms)
  – Codify the procedures by which FDA would review PMTAs
  – Require manufacturers to maintain records related to their PMTAs
NEW LEGISLATION: TOBACCO 21

• On Dec. 20, 2019, the President signed legislation amending the FD&C Act to raise the federal minimum age of sale of tobacco products from 18 to 21 years

• Effective immediately, retailers must not sell any tobacco products to anyone under 21

• FDA & retailers are updating practices to implement the new law

• FDA expects retailers to follow the law & take measures to ensure an individual purchasing a tobacco product is 21 or older, including manually checking IDs when needed

• FDA is updating our website and other materials, including our regulations, in the near future to reflect the change in law
GUIDANCES ISSUED OVER THE LAST YEAR

Revised Guidances

- **March 2019:** Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule
- **March 2019:** FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales & Distribution Restrictions, & Health Warning Requirements for Packages and Advertisements

Draft Guidances

- **March 2019:** Modifications to Compliance Policy for Certain Deemed Tobacco Products
- **December 2019:** Submission of Plans for Cigarette Packages & Cigarette Advertisements

Final Guidances

- **March 2019:** Interpretation of & Compliance Policy for Certain Label Requirements; Applicability of Certain FD&C Act Requirements to Vape Shops
- **June 2019:** Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)
- **November 2019:** Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products
- **January 2020:** Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) & Other Deemed Products on the Market Without Premarket Authorization
2019 NYTS RESULTS SHOWED THAT YOUTH E-CIGARETTE USE WAS AT ALARMING LEVELS

Source: NYTS 2019
MAJORITY OF YOUTH REPORT CARTRIDGE-BASED E-CIGARETTES AS THEIR USUAL PRODUCT

Source: NYTS 2019
Findings from the 2019 Monitoring the Future survey focusing on youth use of JUUL indicate that youth preference for menthol- and tobacco-flavored e-cigarettes is much lower than that for mint- and fruit-flavored e-cigarettes.

Menthol- and tobacco-flavored, cartridge-based ENDS products, are not among the current enforcement priorities.

### JAN. 2020 GUIDANCE: EXCLUSION OF MENTHOL AND TOBACCO FLAVORS

<table>
<thead>
<tr>
<th>Flavor</th>
<th>Use Among 12th Grade Past 30-Day JUUL Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco</td>
<td>&lt;2%</td>
</tr>
<tr>
<td>Menthol</td>
<td>&lt;6%</td>
</tr>
<tr>
<td>Fruit</td>
<td>8.6%</td>
</tr>
<tr>
<td>Mango</td>
<td>23.8%</td>
</tr>
<tr>
<td>Mint</td>
<td>47.1%</td>
</tr>
</tbody>
</table>

Source: Leventhal AM, Miech R, Barrington-Trimis J, Johnston LD, O’Malley PM, Patrick ME. Flavors of e-Cigarettes Used by Youths in the United States. JAMA. Published online November 05, 2019.
JAN. 2020 GUIDANCE: ENFORCEMENT POLICY

- Announces a **policy prioritizing enforcement against certain unauthorized flavored e-cigarette products**, including fruit & mint flavors, that appeal to children

- Policy attempts to balance **public health concerns** related to youth use of ENDS products with considerations regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products

- Enforcement priorities are **not a “ban”** on flavored or cartridge-based ENDS
  - If a company can demonstrate to the FDA that a product meets requirements in section 910 of the FD&C Act, FDA would authorize the product for sale
On Feb. 6, 2020, FDA began prioritizing enforcement against illegally marketed ENDS products that do not have premarket authorization:

- 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 targeted to minors or likely to promote use of ENDS by minors

After May 12, 2020, FDA intends to also prioritize enforcement against ENDS products that continue to be sold & for which the manufacturers have not submitted a premarket application.

Should FDA become aware of an increase in youth using any other flavored products, we will take additional steps to address youth use of those products.
UPDATES ON COMPLIANCE AND ENFORCEMENT
On Mar. 10, FDA issued 22 warning letters to retailers and manufacturers across the country.

These are the first of what will be a series of ongoing actions consistent with FDA’s recently issued policy of enforcement priorities for e-cigarettes and other deemed products on the market.

The warning letters were issued specifically to:
- 16 brick and mortar retailers, which include some well-known establishments such as 7-Eleven and Shell
- six online companies who make and sell cartridge-based ENDS products

The warning letters notify the retailers and manufacturers that selling or distributing ENDS products without a marketing authorization order to customers in the United States is prohibited under the FD&C Act.
Since our enforcement program began in 2010, FDA has completed over 1.1 million inspections of tobacco retailers resulting in the following enforcement actions:

• Over 96,000 Warning Letters (over 11,000 related to ENDS)
• Over 25,000 Civil Money Penalties (over 1,900 related to ENDS)
• 181 No-Tobacco-Sale Order Complaints

Any member of the public can also report potential tobacco product violations (Form FDA 3779):

• Online: www.fda.gov
• Email: CTPCompliance@FDA.hhs.gov
• Phone: (877) CTP-1373

Data through January 31, 2020
UPDATE ON SCIENCE AND RESEARCH
CTP: A WORLD LEADER IN TOBACCO SCIENCE

• Nearly 250 scientists

• Broad expertise
  – Epidemiology
  – Chemistry
  – Behavioral Pharmacology
  – Clinical Pharmacology
  – Toxicology
  – Social Science
  – Engineering
  – Microbiology
  – Statistics
  – Medical
  – Environmental

• Extensive knowledge & experience
  – 10 years of regulatory experience
  – Hire diverse staff with strong scientific background
237 OS Publications
In total, CTP has received submissions of:
- >3,100 regular SE Reports
- >3,600 provisional SE Reports
- >700 EX Requests

Of those, CTP has closed:
- 95% of all regular SE Reports
- 85% of all provisional SE Reports
- 83% of all EX Requests

In FY 2018, CTP exceeded goals for all established SE and EX performance measures

As of Dec. 31, 2019
In April 2019, FDA authorized marketing of Phillip Morris Products S.A.’s IQOS “Tobacco Heating System”

- Electronic device that heats tobacco-filled sticks wrapped in paper to generate a nicotine-containing aerosol; referred to as a “heat-not-burn” or “heated” tobacco product but meets the definition of a cigarette in the FD&C Act
- **Authorized products:** IQOS device, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, & Marlboro Fresh Menthol Heatsticks

Authorization of these products is appropriate for the protection of the public health because they produce fewer or lower levels of some toxins than combusted cigarettes

- Stringent marketing restrictions on the products to prevent youth access, use, & exposure
- Postmarket requirements include monitoring market dynamics such as potential youth uptake
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
• In **October 2019**, FDA authorized marketing of products through the MRTP pathway
  
  – **Authorized products include** 8 Swedish Match USA, Inc., snus smokeless tobacco products sold under the “General” brand name
  
  – **Modified risk claim:** “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis”

• FDA’s review determined that:
  
  – Claim is supported by scientific evidence
  
  – Consumers understand the claim & appropriately perceive the relative risk of these products as compared to cigarettes
  
  – Products, as actually used by consumers, will significantly reduce harm & the risk of tobacco-related disease to individual tobacco users & benefit the health of the population as a whole
## MRTPAS UNDER REVIEW

<table>
<thead>
<tr>
<th>Product</th>
<th>Applicant</th>
<th>TPSAC Meeting</th>
<th>Comment Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>VLN™ King VLN™ Menthol King</td>
<td>22\textsuperscript{nd} Century Group, Inc.</td>
<td>Feb. 2020</td>
<td>Open</td>
</tr>
<tr>
<td>IQOS system with Marlboro Heatsticks</td>
<td>Philip Morris Products S.A.</td>
<td>Jan. 2018</td>
<td>Closed Feb. 24, 2020</td>
</tr>
</tbody>
</table>
• Policy decisions are complex & involve data from a breadth of scientific disciplines

• Chemistry, engineering, behavioral pharmacology, epidemiology, social science, and toxicological research are examples of tobacco regulatory science disciplines that inform CTP regulatory activities
STAKEHOLDERS IN TOBACCO SCIENCE

• All stakeholders have the opportunity to contribute to regulatory science
• Important for broad stakeholder engagement
• Coordination across stakeholders will maximize scientific advancement

REGULATORY SCIENCE
• Scientific discipline with independent goals and measures not found in either the basic or applied sciences
• Ensures that scientifically valid techniques, tools, and models are available to evaluate products
• Informs regulatory actions that promote optimal public health outcomes

TOBACCO REGULATORY SCIENCE
• Informs FDA’s regulatory authority
• Recognizes that tobacco products cannot be regulated using FDA’s traditional “safe and effective” standard
• Enables FDA to best assess the “net” population-level health impacts
RESEARCH FOCUS

• **Research program is intentionally broad**
  – Broad scientific understanding is important
  – Public health challenges can be unpredictable

• **Some areas of current focus:**
  – E-Cig flavors
    ▪ Youth initiation
    ▪ Adult switching
  – E-Cig pulmonary illness
  – Low nicotine cigarettes
Tobacco marketplace is rapidly evolving

Research, surveillance, & evaluation mechanisms must be
- More frequent
- More agile
- More product-specific

Need diverse partnerships to meet shared needs
- Government, private, non-profit
- Federal, state, local, and international
PERIODIC REPORTING AND POSTMARKET SURVEILLANCE AND STUDIES (PMSS)

- Applicants receiving premarket authorization for new tobacco products (PMTAs) should submit periodic postmarket reports; frequency of reporting is detailed in the order letter.
- Each applicant who receives a modified risk granted order (MRGO) must conduct postmarket surveillance and studies (PMSS) (Section 911(g)(2)(C)(ii) and (i)(1)).
- Periodic Reports and PMSS allow for evaluation of the effect of issuance of an order and enables FDA to review the accuracy of determinations upon which the order was based. This may include:
  - Results from studies of the product(s) conducted for or by the applicant or in published literature.
  - Analysis of reported Adverse Experiences and Consumer Complaints for the product(s).
  - Longer-term assessment of exposure and health outcomes.
  - Any changes to the product manufacturing, facilities, or controls and copies of advertising and labeling.
  - Ongoing assessment of tobacco use behavior including data on real-world product use.
UPDATE ON VAPING LUNG INJURIES
• Work closely with federal, state, & local health officials to investigate cases of reported respiratory illness

• As of Feb. 18, 2020, 2,807 hospitalized e-cigarette, or vaping, product use-associated lung injury (EVALI) cases or deaths have been reported to CDC
  – 68 deaths have been confirmed in 29 states & DC

• No one substance has been identified in all of the samples tested
  – Patient reports & product sample testing suggest THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most EVALI cases
  – Vitamin E acetate is strongly linked to the EVALI outbreak- found in product samples tested by FDA & state laboratories & in patient lung fluid samples tested by CDC from geographically diverse states
On Feb. 14, 2020, FDA issued a request for information seeking information that can help identify and evaluate additional steps that could be taken by the Agency related to the use of vaping products that are associated with recent lung injuries

- **Docket number**: FDA-2020-N-0597 on regulations.gov
- **Comment period**: Open through April 20, 2020

FDA is interested in information on product design & how to prevent consumers from modifying or adding substances to these products that are not intended by the manufacturers
FDA wants to know about unexpected health or quality problems with a particular tobacco product

www.safetyreporting.hhs.gov
UPDATES ON HEALTH COMMUNICATION AND EDUCATION
FDA published a final rule requiring color graphics depicting the negative health consequences of smoking.

Aug. 2011

June 2011

Final rule was vacated after the U.S. Court of Appeals for the District of Columbia held that the rule violated the First Amendment.

Aug. 2012

The government announced its decision not to seek further review of the court’s ruling.

March 2013

2013 onward

FDA has been conducting comprehensive research and development activities in support of a new cigarette health warning rule to satisfy the requirements of TCA based on – and within the limits of – both science and the law.


Lawsuit filed by several public health groups challenging the time it was taking FDA to issue a new rule; order issued March 2019.

Aug. 2019

FDA announced a proposed rule to require new health warnings on cigarette packages and in advertisements. When finalized, this rule would fulfill the Agency’s statutory mandate under the TCA.

March 2020

FDA plans to publish final rule.
**Warning Statements**

Experimental study with 2,505 participants to assess which, if any, revised textual warning statements promote greater public understanding of the risks associated with cigarette smoking when compared to the TCA statements.

**Images**

Focus groups with 170 participants in 20 groups to examine what factual information the images conveyed to participants about the negative health consequences of cigarette smoking in the absence of a paired textual warning statement, as well as how concordant participants considered the images to be when paired with potential textual warning statements.

**Cigarette Health Warnings**

Experimental study with 9,760 participants to assess the extent to which any of the cigarette health warnings increase understanding of the negative health consequences of cigarette smoking.

*Warning statement combined with image*
The proposed rule includes **13 cigarette health warnings** accompanied by photorealistic images.

The warnings would be required to appear on cigarette packages and in advertisements **15 months after a final rule is issued**.

The warnings would appear prominently on cigarette packages and in advertisements, as shown in the below examples:

- Occupying at least 20 percent of the area at the top of cigarette advertisements
- Occupying the top 50 percent of the area of the front and rear panels of cigarette packages
CIGARETTE HEALTH WARNINGS INCLUDED IN THE 2019 PROPOSED RULE

1. **WARNING:** Tobacco smoke can harm your children.
2. **WARNING:** Tobacco smoke causes fatal lung disease in nonsmokers.
3. **WARNING:** Smoking during pregnancy stunts fetal growth.
4. **WARNING:** Smoking causes head and neck cancer.
5. **WARNING:** Smoking causes bladder cancer, which can lead to bloody urine.
6. **WARNING:** Smoking causes COPD, a lung disease that can be fatal.
7. **WARNING:** Smoking causes COPD, a lung disease that can be fatal.
8. **WARNING:** Smoking can cause heart disease and strokes by clogging arteries.
9. **WARNING:** Smoking causes type 2 diabetes, which raises blood sugar.
10. **WARNING:** Smoking reduces blood flow to the limbs, which can require amputation.
11. **WARNING:** Smoking reduces blood flow, which can cause erectile dysfunction.
12. **WARNING:** Smoking causes age-related macular degeneration, which can lead to blindness.
13. **WARNING:** Smoking causes cataracts, which can lead to blindness.
CHANGING BEHAVIORS TOWARD SMOKING
Reducing youth ENDS use and susceptibility is a top priority.
THE REAL COST

Look past the smoke and mirrors of vaping.

THE REAL COST

THERE’S AN EPIDEMIC SPREADING.

DON’T GET HACKED BY VAPING.
WE’VE HAD TREMENDOUS SUCCESS, AND NOW WE ARE MET WITH NEW CHALLENGES

4.1M
High School Vapers

890K
High School Smokers
THE REAL COST HAS HAD A SIGNIFICANT PUBLIC HEALTH IMPACT

Campaign Implementation

THE REAL COST

Campaign development and planning

Advertising and messages delivered to target audiences (TV, radio, print, digital online, out-of-home)
CIGARETTE PREVENTION CAMPAIGN FOLLOWED A LOGIC MODEL WITH THREE SEQUENTIAL STEPS LEADING TO BEHAVIOR CHANGE

1. LEVEL OF AD AWARENESS AND RECEPTIVITY
   - Audience exposure to and recall of campaign
   - Audience reactions to and perceptions of campaign messages

2. CHANGE CAMPAIGN-TARGETED ATTITUDES AND BELIEFS
   - Ads found to positively influence risk perceptions and beliefs specific to campaign messages

3. CHANGE TOBACCO USE INTENTIONS AND BEHAVIORS
   - The campaign prevented up to 587,000 youth from initiating smoking, will save more than $53 billion in smoking-related costs

Contextual factors (e.g., state-level policies, individual characteristics, other media campaigns)

Short-term Outcomes

Intermediate Outcomes

Longer-term Outcomes
CIGARETTE PREVENTION CAMPAIGN FOLLOWED A LOGIC MODEL WITH THREE SEQUENTIAL STEPS LEADING TO BEHAVIOR CHANGE

1. LEVEL OF AD AWARENESS AND RECEPTIVITY

Overall, 89.0% of U.S. youth were aware of at least one advertisement.

Audience exposure to and recall of campaign

Audience reactions to and perceptions of campaign messages

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The campaign prevents up to 587,000 youth from initiating smoking, will save more than $53 billion in smoking-related costs.

 Longer-term Outcomes

Overall, 89.0% of U.S. youth were aware of at least one advertisement.

Audience exposure to and recall of campaign
ENDS PREVENTION CAMPAIGN IS BUILDING ON WHAT WE KNOW AS THE PRECURSORS TO BEHAVIOR CHANGE

1. LEVEL OF AD AWARENESS AND RECEPTIVITY

- Audience exposure to and recall of campaign

2. CHANGE CAMPAIGN-TARGETED ATTITUDES AND BELIEFS

- Audience reactions to and perceptions of campaign messages

3. CHANGE TOBACCO USE INTENTIONS AND BEHAVIORS

- Knowledge, attitudes, and beliefs

The Real Cost of Vaping follows a similar logic model to combat the youth ENDS epidemic. We know the strategies that work and are building on 50+ years of tobacco control knowledge.

Intention to use tobacco

Tobacco use initiation, progression to established tobacco use

Contextual factors (e.g., state-level policies, individual characteristics, other media campaigns)
BRAND AWARENESS REMAINS HIGH

THE REAL COST

79% of youth recalled seeing The Real Cost brand logo
WE’RE ACHIEVING ADEQUATE LEVELS OF AD AWARENESS

73.4% of youth reported awareness of Re-Hacked

39.4% of youth reported awareness of Epidemic (digital only ad)
Most youth report that The Real Cost video ads on vaping were effective, with mean PE scores of 3.8 on a scale from 1 to 5.

Ads compare favorably to The Real Cost cigarette ads:

- Mean PE for cigarette ads were: 3.8 (Baseline) and 3.8 (First Follow-up).
WHILE OUR FOCUS IS STILL ON PREVENTION, MORE TEENS ARE EXPERIENCING SIGNS OF ENDS ADDICTION
IN 2019

NEARLY 1.6 MILLION

youth used e-cigarettes frequently
(on 20 or more days per month)

Source: NYTS 2019
SIGNS OF ADDICTION: TEEN STORIES

• **Teens are starting to see that addiction is a bad thing.** In previous research, teens were more dismissive of addiction, saying they are also addicted to their phones or chocolate or even “breathing.” Teens are now starting to believe that addiction to vaping is a possible consequence and are even starting to see some negative emotional consequences from vaping. However, they still want to hear about stronger, harmful health consequences.

• **Teens acknowledged that addiction can be emotional, not just physical.** For some teens, vaping is a consistent part of their daily ritual and don’t like when it’s disrupted or suddenly limited.

• **Teens mentioned friends or peers who would “fiend” for a vape or a hit.** They acknowledge they’ve seen negative behavior like irritability and irrational anxiety about losing access to vaping during time away – e.g., a weekend trip with parents.
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 launch in July 2019, there have been over half a million page views

The most time is spent on these pages:
- How to Quit Vaping – over 4 minutes spent
- Vaping Addiction and Nicotine Withdrawal – over 5 minutes spent
Don’t Get Hacked by Vaping is available for stakeholder use through CDC’s Media Campaign Resource Center.

- Co-branding is permitted
- There are no fees to use the ad, but interested parties have to pay talent rights
- If ad is used, FDA asks that you share TRP data so we can account for additional exposure in our outcome evaluation study

In the future, other ads may be made available after they are taken out of rotation in our national media buy.
Free print materials, web content and social media content are available to download and order on CTP’s Exchange

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

Content includes messages on:

- Harms of vaping
- Harms of cigarette use
- Federal rules and regulations
- Tobacco control research
FDA and Scholastic developed an educational program to help students understand the dangers of e-cigarette use. This co-branded effort provides high school teachers and school administrators resources to inform students on the health risks of vaping.


- Online microsite: [www.scholastic.com/youthvapingrisks](http://www.scholastic.com/youthvapingrisks)
- Educational infographics
- 3 Lesson plans and accompanying activity sheets for in-class learning
- Addiction and cessation resources
- Teacher resource guide
EDUCATIONAL RESOURCES
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
This environment provides unique opportunities for the public health community to influence the narrative surrounding vaping among youth most at risk.
CONCLUSION: SCIENCE DRIVES DECISIONS

- Data
- Rulemaking
- Compliance
- Application Review
- Communication & Education
• **Science-based approach** is crucial to CTP’s regulatory programs & mission

• **Regulatory science research** is critical to understanding the impact of manufacturing, marketing, & distribution of tobacco products on public health

• CTP continues to **strengthen** its research program

• **Broad stakeholder involvement** in tobacco research is important
CTP offers many exciting career opportunities for motivated individuals seeking meaningful, mission-driven employment in the field of public health. Currently, we are recruiting for an experienced Senior Science Advisor.

To learn more about this opportunity and other openings, please stop by our booth #6 & #7, and visit us at www.fda.gov/ctpjobs.
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