• Updates from the Center - Mitch Zeller
  - COVID-19
  - Regulations and Guidances
  - Compliance and Enforcement
  - Youth Tobacco Use
  - Premarket Applications and Plans for Review
• Updates from the Office of Science - Todd Cecil
• Updates from the Office of Health Communication and Education - Kathy Crosby
• Live Q&A Session
IMPACT OF COVID-19 ON CTP’S WORK

• The COVID-19 pandemic has presented a new and significant challenge for all of us, affecting many aspects of our work

• To prioritize the health and well-being of staff, in early 2020, 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 on many things including COVID data for each state and locality, and CDC, state and local guidelines
IMPACT OF COVID-19 ON CTP’S WORK

• To help with the challenges posed by COVID-19 on both the tobacco industry and FDA, we requested extensions for key regulatory actions:
  – Premarket application deadline for deemed tobacco products was moved to Sept. 9, 2020
  – Effective date of the cigarette health warnings rule was extended to Oct. 16, 2021 (recently further extended to Jan. 14, 2022 per court order)

• Despite the challenges, CTP continues to work vigorously to protect public health
COVID-19 AND TOBACCO USE

- Data shows that when compared to never smokers, cigarette smoking increases the risk of more severe illness from COVID-19, which could result in hospitalization, the need for intensive care, or even death.

- Smoking cigarettes can cause inflammation and cell damage throughout the body, and can weaken your immune system, making it less able to fight off disease.

- E-cigarette use can expose the lungs to toxic chemicals, but whether those exposures increase the risk of COVID-19 or the severity of COVID-19 outcomes is not known.
These factors further highlight the importance of quitting smoking, especially during the present time.

There are several FDA-approved smoking cessation products:
- Nicotine Replacement Therapy (NRT): Prescription NRT products (nicotine nasal spray, nicotine inhaler), and over-the-counter nicotine products (gum, transdermal patch, lozenge)
- Prescription Cessation Medicines without Nicotine: Chantix (varenicline tartrate), Zyban (bupropion hydrochloride)

FDA recently cleared the first device, “BrainsWay Deep Transcranial Magnetic Stimulation (Deep TMS),” to use as an aid for short-term smoking cessation in adults.
- Uses electromagnetic pulses to stimulate neurons in the brain reducing tobacco cravings and increasing cognitive control

**NOTE:** To date, no ENDS have been approved by FDA as a cessation aid.
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 Jan. 14, 2022*, 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 postponed by 120 days from June 18, 2021 to Oct. 16, 2021 due to COVID-19 and its impacts. In Dec. 2020, the date was further postponed by 90 days to Jan. 14, 2022.
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.
• On Oct. 27, 2020, FDA issued the draft guidance, “Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies”

• Describes the agency’s proposed recommendations on **designing and conducting tobacco product perception and intention (TPPI) studies** that may be submitted as part of a tobacco product application (MRTP, PMTA, SE)
  - TPPI studies are studies that can be used to assess, among other things, individuals’ perceptions of tobacco products, understanding of tobacco product information (e.g., labeling, modified risk information), and intentions to use tobacco products

• The public comment period closed on Dec. 28, 2020
On Jan. 19, 2021, the Premarket Tobacco Product Applications (PMTA) final rule and Substantial Equivalence (SE) final rule were displayed in the Federal Register, but did not publish.

These final rules provide information on the minimum requirements for the content, format and review of PMTAs and SE Reports.

On Jan. 20, 2021, per an Executive Order, these final rules were withdrawn; FDA will work closely with the new administration to advance appropriate regulations and policies that were withdrawn and are in line with the agency’s public health mission.
COMPLIANCE AND ENFORCEMENT
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)
- 209 No-Tobacco-Sale Order Complaints

*Data as of Nov. 2020*
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 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; 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
In the last year, FDA has issued:

- Over 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

- Smartwatch
- ENDS Product
- Portable Video Game System
- E-Liquid
- Food Product
- ENDS Product
- Cracker Jacks
- Popcorn
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.
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
• In Jan. 2021, FDA issued warning letters to **19 firms** that manufacture and operate websites selling ENDS which lack premarket authorization

• The firms did not submit a premarket application by the Sept. 9, 2020 deadline

• These were the first sets of warning letters issued to firms for products that do not have premarket authorization and for which the firms did not submit a premarket application by the Sept. 9 deadline
LATEST ON YOUTH TOBACCO USE
In Sept. 2020, FDA and CDC released findings from the 2020 National Youth Tobacco Survey on youth e-cigarette use; in Dec. 2020, findings released on use of all tobacco products.
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
PREMARKET APPLICATIONS & PLANS FOR REVIEW
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.
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
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.
• 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

• Authorized 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.”
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.
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
FDA CENTER FOR TOBACCO PRODUCTS: PROGRAMMATIC UPDATES AND ACTIVITIES

OFFICE OF SCIENCE

Todd L. Cecil, Ph.D.
Deputy Director for Regulatory Management
Office of Science, CTP

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

• Tobacco Product Application Review
• Tobacco Regulatory Science
• Using Science to Inform Regulatory Activities
TOBACCO PRODUCT APPLICATION REVIEW
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.

FDA is striving 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.
OFFICE OF SCIENCE NEEDS

• A complete application with adequate information for the subject product(s)

• A sound and consistent process with which to evaluate these applications

• A strong, diverse set of reviewers dedicated to protecting the public health

• Regulatory Science support
  – Published, peer-reviewed scientific literature
  – Define the standards of knowledge
  – Provide a basis for comparison
  – Provides the boundaries of public health
TOBACCO PRODUCT APPLICATION REVIEW

PHASE 1: Acceptance

PHASE 2: Notification or Filing

PHASE 3: Review

Action
ADVANCES IN APPLICATION REVIEW RESULTED IN MAJOR INCREASES IN EFFICIENCY & CONSISTENCY

- Streamlined & revamped PMTA, SE, and EX REQ programs
  - Increased number of TPLs
  - Removed redundancies in clearance
  - Role- & program-specific training
  - Developed or enhanced guidances, templates, & memos
  - Compressed PMTA review timelines
  - Decrease response to EX & SE Deficiency letters
  - Intend to issue only 1 Deficiency letter

- Completion of triage plan for all premarket programs
OFFICE OF SCIENCE NEEDS

- A complete application with adequate information for the subject product(s)
- A sound and consistent process with which to evaluate these applications
- A strong, diverse set of reviewers dedicated to protecting the public health
- Regulatory Science support
  - Published, peer-reviewed scientific literature
  - Define the standards of knowledge
  - Provide a basis for comparison
  - Provides the boundaries of public health
EXPANDING OUR TEAM - OFFICE OF SCIENCE

• Over 450 scientists and program staff

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

• Extensive knowledge & experience
  – Hire diverse staff with strong scientific background
OFFICE OF SCIENCE NEEDS

• A complete application with adequate information for the subject product(s)

• A sound and consistent process with which to evaluate these applications

• A strong, diverse set of reviewers dedicated to protecting the public health

• Regulatory Science support
  – Published, peer-reviewed scientific literature
  – Define the standards of knowledge
  – Provide a basis for comparison
  – Provides the boundaries of public health
TOBACCO REGULATORY SCIENCE
Publication growth statistically increased even while accounting for the dip in 2018 publications.

*52 projects/year since FY2011. FY2019 publications data remain preliminary, and the number is expected to increase as FY2019 publications are further identified and added to CTP’s publications database. ** p<0.05

Source: FDA contract HHSf223201510002B/HHSF22318008 (RTI)
CTP-FUNDED PUBLICATIONS ARE SHAPING THE TOBACCO REGULATORY SCIENCE FIELD

34 of the most highly cited CTP-funded publications were each cited >100 times

35% of CTP publications appeared in just 5 core journals

Median number of citations per CTP-funded article was 10

98% of cited publications were cited within 3-years of publication

CTP-funded publications have been cited in 10,240 publications

Source: FDA contract HHSF223201510002B/HHSF22318008 (RTI)
In Sept. 2020, FDA and CDC released findings from the 2020 National Youth Tobacco Survey on youth e-cigarette use; in Dec. 2020, findings released on use of all tobacco products.
NYTS 2020: DECREASE IN TOBACCO USE IN GROUPED CATEGORIES AMONG HIGH SCHOOL STUDENTS

*The 2019 estimates presented here do not include use of heated tobacco. Use of HTPs were added to the composite measures in 2020.

NOTES: Significant changes from 2019 for all three groups
SOURCE: National Youth Tobacco Survey (NYTS), 2019 – 2020
NYTS 2020: DECREASE IN TOBACCO USE AMONG INDIVIDUAL PRODUCTS AMONG HIGH SCHOOL STUDENTS

NOTES: Significant changes from 2019 for e-cigarettes, cigars and smokeless tobacco.
SOURCE: National Youth Tobacco Survey (NYTS), 2019 – 2020
NYTS 2020: CONCERNING RISE IN THE USE OF DISPOSABLE E-CIGS

NOTES: Arrows indicate significant changes from 2019.
SOURCE: National Youth Tobacco Survey (NYTS), 2019 – 2020
More than 8 out of 10 current youth e-cig users use flavored e-cigs

SOURCE: National Youth Tobacco Survey (NYTS), 2020
In 2020, **38.9%** of high school current e-cig users used e-cigarettes frequently (on 20 or more of the past 30 days)

**NOTE:** In 2019, 34.2% of high school current e-cig users reported using on 20 or more of the past 30 days.

**SOURCE:** National Youth Tobacco Survey (NYTS), 2020
In 2020, **22.5%** of high school current e-cig users used e-cigs daily.

NOTE: In 2019, 21.4% of high school current e-cig users used e-cigs daily.

SOURCE: National Youth Tobacco Survey (NYTS), 2020
POPULATION ASSESSMENT OF TOBACCO AND HEALTH (PATH) STUDY

- **Special Collection, Wave 5.5 – Adapting to COVID-19 Pandemic**
  - Nationally representative sample of youth and young adults ages 13 to 19 launched December 2019 with in-person data collection.

- **NEW: Special Collection, PATH Study Adult Telephone Survey (PATH-ATS)**
  - Examines adult tobacco use in the time of COVID-19 with focus on electronic nicotine devices (ENDS) and cigarettes. Includes questions on COVID-19.
  - Nationally representative sub-sample of adults aged 20 and older.
  - Conducted September 2020 - December 2020, telephone-only.
• When is the next data collection?
  – Wave 6 will launch in 2021

• What data is available now? When will the most recent data be available?
  – Data from Waves 1-4.5 available at https://doi.org/10.3886/Series606
  – Wave 5 (December 2018 – November 2019) available 2021
  – Wave 5.5 and PATH-ATS available 2022

• Where can I learn more about the PATH Study’s recent findings?
  – PATH Symposium 13
  – Live Q/A Session: Podium 50, 10:00 a.m. Saturday February 27, 2021
USING SCIENCE TO INFORM REGULATORY ACTIVITIES
All stakeholders have the opportunity to contribute to regulatory science. Important for broad stakeholder engagement. Coordination across stakeholders will maximize scientific advancement.

SCIENCE-BASED REVIEW OF TOBACCO PRODUCTS

- Policy decisions are complex and 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
CITED CTP-FUNDED PUBLICATIONS SUPPORTING FDA RULES AND GUIDANCES

40 CTP-funded publications were referenced out of 409 total references in the 2019 Rules and Guidances analyzed.

Of 376 researchers leading CTP-funded projects between FY2010-FY2019 – 4 researchers submitted comments with references to the FY2019 Rules and Guidances Dockets.

Of 100 TCORS trainees – 6 submitted comments with references to the FY2019 Rules and Guidances Docket.

Source: FDA contract HHSf2232015I0002B/HHSF22318008 (RTI)
Number of CTP-funded Projects by Research Domain (FY10 – FY19)

- Knowledge, Attitudes, & Behaviors: 227
- Toxicty & Carcinogenicity: 167
- Communication: 146
- Addiction: 117
- Chemistry & Engineering: 89
- Marketing: 77
- Health Consequences: 68
- Economics & Policy: 41

Number of CTP-funded Publications by Research Domain (FY10 – FY19)

- Knowledge, Attitudes, & Behaviors: 661
- Communication: 215
- Health Consequences: 204
- Toxicty & Carcinogenicity: 199
- Marketing: 170
- Addiction: 151
- Chemistry & Engineering: 131
- Economics & Policy: 130

Data represent 529 unique projects; projects could be classified as addressing multiple research domains.

Data represent 1,496 publications; publications could address multiple research domains; 47 publications classified as N/A are not displayed.
Number of CTP-funded Projects by Tobacco Product (FY10 – FY19)

- Cigarettes/Smoke: 234
- E-cigarettes: 203
- Cigars (all): 133
- Smokeless Tobacco & Snus: 117
- General Tobacco Products: 60
- Hookah/Waterpipe Tobacco: 58
- Research Cigarettes: 33
- Heated Tobacco Products: 7

Number of CTP-funded Publications by Tobacco Product (FY10 – FY19)

- Cigarettes/Smoke: 641
- E-cigarettes: 581
- Cigars (all): 254
- General Tobacco Product: 197
- Smokeless Tobacco & Snus: 166
- Hookah/Waterpipe Tobacco: 133
- Research Cigarettes: 53
- Heated Tobacco Products: 0

Data represent 529 unique projects; projects could be classified as addressing multiple research domains.

Data represent 1,496 publications; publications could address multiple research domains; 47 publications classified as N/A are not displayed.
FDA NEWS RELEASE

FDA permits sale of two new reduced nicotine cigarettes through premarket tobacco product application pathway
USING RESEARCH IN 22ND CENTURY PMTA REVIEW

- Premarket Tobacco Product Scientific Review
- Various discipline reviews
  - Product Composition, Design, and Manufacturing
  - Toxicological Risk Assessment
  - Individual Health Impact
  - Population Health
  - Product Labeling, Consumer Comprehension, and Marketing Plan
- CTP-funded research is cited throughout the PMTA Scientific Review.

https://www.fda.gov/media/133633/download
In December 2019, FDA authorized marketing of two combusted, filtered cigarettes manufactured by 22nd Century Group Inc.

Authorization of the marketing 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

Review time

- Reviews completed in 180 days
- Orders were issued in 1 year
EXAMPLE CITED CTP-FUNDED PUBLICATIONS

Response to varying the nicotine content of cigarettes in vulnerable populations: an initial experimental examination of acute effects


Randomized Trial of Reduced-Nicotine Standards for Cigarettes

Eric C. Donny, Ph.D., Rachel L. Denlinger, B.S., Jennifer W. Tidey, Ph.D., Joseph S. Koopmeiners, Ph.D., Neal L. Benowitz, M.D., Ryan G. Vandrey, Ph.D., Mustafa al-Absi, Ph.D., Steven G. Carmella, B.A., Paul M. Cinciripini, Ph.D., Sarah S. Dermody, M.S., David J. Drobes, Ph.D., Stephen S. Hecht, Ph.D., John Jensen, M.P.H., Tonya Lane, M.Ed., Chap T. Le, Ph.D., F. Joseph McClernon, Ph.D., Ivan D. Montoya, M.D., M.P.H., Sharon E. Murphy, Ph.D., Jason D. Robinson, Ph.D., Maxine L. Stitzer, Ph.D., Andrew A. Strasser, Ph.D., Hilary Tindle, M.D., M.P.H., and Dorothy K. Hatsukami, Ph.D.
FDA wants to know about unexpected health or quality problems with a particular tobacco product.

www.safetyreporting.hhs.gov
CONCLUSION: SCIENCE DRIVES DECISIONS

Data

- Compliance
- Rulemaking
- Application Review
- Communication & Education

February 24, 2021 | SRNT 2021: FDA Session
CONCLUSION

- **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
CAREER OPPORTUNITIES AT CTP

• CTP offers many exciting career opportunities for motivated individuals seeking meaningful, mission-driven employment in the field of public health.

• To learn more about this opportunity and other openings, please stop by the CTP virtual booth, and visit us at www.fda.gov/ctpjobs.
Current NIH TRSP Funding Opportunity Announcements

- Tobacco Regulatory Science, RFA-OD-19-028 (R01 Clinical Trial Optional)
- Maximizing the Scientific Value of Existing Biospecimen Collections, RFA-OD-19-021 (R21 Clinical Trial Not Allowed)
- Secondary Analyses of Existing Datasets of Tobacco Use and Health, RFA-OD-19-022 (R21 Clinical Trial Not Allowed)
- K01 Mentored Research Scientist in Tobacco Regulatory Science:
  - RFA-OD-20-008 (Independent Clinical Trial Not Allowed)
  - RFA-OD-20-011 (Independent Clinical Trial Required)
- K99/R00 Pathway to Independence in Tobacco Regulatory Science:
  - RFA-OD-20-009 (Independent Clinical Trial Not Allowed)
  - RFA-OD-20-010 (Independent Clinical Trial Required)
THANK YOU

- Report adverse experiences with tobacco products at: https://www.safetyreporting.hhs.gov
- CTP Tobacco Science and Research, https://www.fda.gov/tobacco-products/tobacco-science-research
- Call us: (877) CTP-1373
- Email us: AskCTP@fda.hhs.gov
- Follow us on Twitter: @FDATOBABCCO
FDA CENTER FOR TOBACCO PRODUCTS: PROGRAMMATIC UPDATES AND ACTIVITIES

OFFICE OF HEALTH COMMUNICATION AND EDUCATION

Kathleen Crosby
Director
Office of Health Communication and Education, CTP

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.
MAKING A SIGNIFICANT IMPACT BY PREVENTING VAPING

THE REAL COST

- Campaign Planning & Development
- Advertising Production & Delivery In Market
- Campaign Evaluation
MAKING A SIGNIFICANT IMPACT BY PREVENTING VAPING

THE REAL COST

Scary Enough

Macroscopic Metals

Toilet
ADDICTION - TOILET
PERCEIVED AD EFFECTIVENESS SCORES CONTINUE TO BE HIGH

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<thead>
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<th>Macroscopic Metals</th>
<th>Scary Enough</th>
<th>Science Experiment</th>
<th>Possessed by Nicotine</th>
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Avg PE 45 Ads
3 WAVES OF OUTCOME EVALUATION DATA COLLECTED TO DATE

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BRAND AWARENESS REMAINS HIGH

THE REAL COST

75.2% of youth recalled seeing *The Real Cost* brand logo
AD AWARENESS ALSO REMAINS HIGH

THE REAL COST

79% of youth recalled seeing one or more *The Real Cost* vape prevention ads.

Individual ad awareness was highest for Epidemic ad with 56.9% of youth reporting having seen the ad.
Agreement with 3 of 9 campaign-targeted beliefs increased with increased exposure.
SELF-REPORTED EXPOSURE ASSOCIATED WITH BELIEF CHANGE

Agreement with 3 of 8 campaign-targeted beliefs increased with increased exposure

The nicotine in vapes may hack your brain
The nicotine in vapes can reprogram your brain
The nicotine in vapes changes your brain

Re-hacked Ad
FDA’S EFFORTS SHOW PROMISE IN INCREASING ENDS RISK PERCEPTIONS

- Pre-market copy test results show high levels of ad receptivity with perceived ad effectiveness scores ranging from 3.91 - 4.29
- In-market awareness of The Real Cost brand and vape prevention ads remain high with 75.2% of teens recall seeing the brand and 79% of teens recall seeing one or more ads.
- Increasing levels of exposure to The Real Cost ads were associated with more positive changes in campaign-targeted beliefs. Models indicate that increased exposure to ads would have led to larger observed effects.
GOOD NEWS: OVERALL, ENDS BELIEFS AND RISK PERCEPTIONS CONTINUE TO EVOLVE

29 of 34 items assessing youth beliefs about vaping continue to change 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 inhale metal particles” increased 30%
- “Vapes contain formaldehyde” increased 20%
- “Vaping can permanently damage your lungs” increased 20%
- “If I vape I will deliver nicotine to my brain” increased 16.6%

{Relative change (FU2 – Baseline)/Baseline}
UPDATES ON OTHER PUBLIC EDUCATION EFFORTS
UPDATE ON PUBLIC EDUCATION CAMPAIGNS

Goals

- Reduce cigarette initiation and experimentation among at-risk multicultural youth ages 12-17
- Encourage teens to reach their goals by emphasizing that they can embody Hip Hop values and still be tobacco-free

Results

- The campaign had high reach and high brand equity scores, with messages that garnered positive receptivity to the ads among the hard-to-reach audience of Hip Hop youth
- The effort had a modest effect on changing tobacco-related attitudes and beliefs
Goals

- Reduce cigarette use among at-risk lesbian, gay, bisexual & transgender young adults ages 18-24
- First large-scale LGBT tobacco prevention campaign, sought to align positive aspects of living tobacco-free with shared LGBT values, experiences, and interests

Results

- Achieved high brand awareness and notably high brand receptivity across a diverse population
- The campaign influenced a small number of outcomes associated with social perceptions of smoking, thus had a modest effect on changing tobacco-related attitudes and beliefs
- The final sample of 12,344 LGBT young adults represents one of the largest and most diverse samples of this population ever collected
Goals

• Reduce smokeless tobacco initiation and experimentation among at-risk boys ages 12-17 in rural counties

• First large-scale smokeless prevention campaign, used creative messaging to influence attitudinal and normative beliefs that SLT doesn’t mean harmless

Results

• The campaign was successful in reaching almost 90% of the intended rural teen boy audience

• Several campaign-targeted beliefs and attitudes increased significantly from baseline to post-campaign launch among older boys, ages 14 to 16
FDA remains dedicated to educating the public, especially youth, about the dangers of tobacco use, in keeping with the evolving tobacco marketplace.

The agency has gained valuable real-time insight from these efforts and our ongoing evaluation studies to better understand the impact of advertising on changing behaviors.

FDA will utilize what we’ve learned to inform the next generation of our existing work and future public health education efforts.
FOR IN-DEPTH EVALUATION RESULTS

Evaluations of National Media Campaigns
Friday, February 26, at 1:30 PM

- Anna MacMonegle
  RTI International

- Erik Crankshaw
  RTI International

- Jamie Guillory
  RTI International
THANK YOU! QUESTIONS?