Smoking Cessation Leadership Center

UCSF

University of California San Francisco

One Hour Power Break Webinar: FDA's Framework for Tobacco and Nicotine Regulation

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10/17/18

Moderator

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Disclosures

This UCSF CME activity was planned and developed to uphold academic standards to ensure balance, independence, objectivity, and scientific rigor; adhere to requirements to protect health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and include a mechanism to inform learners when unapproved or unlabeled uses of therapeutic products or agents are discussed or referenced.

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Mitchell R. Zeller, JD, Jon Jovi Bodestyne, Christine Cheng, Brian Clark, Jennifer Matekuare, Jessica Safier, Catherine Saucedo, and Steven A. Schroeder, MD

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National Behavioral Health Network
For Tobacco & Cancer Control

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- All participants will be in **listen only mode**.
- Please **make sure your speakers are on** and adjust the volume accordingly.
- If you do not have speakers, please request the dial-in via the chat box.
- **This webinar is being recorded** and will be available on SCLC's website, along with the slides.
- **Use the chat box to send questions** at any time for the presenters.

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- Licensed Professional Clinical Counselors (LPCCs)
- Licensed Educational Psychologists (LEPs)

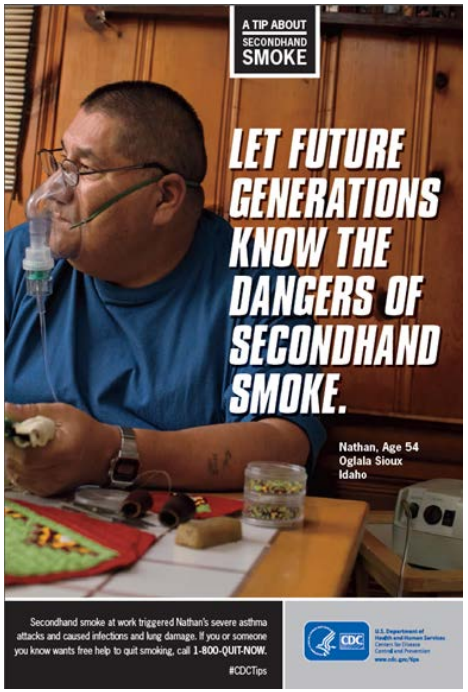
Instructions to claim credit for these CEU opportunities will be included in the post-webinar email and posted to our website.

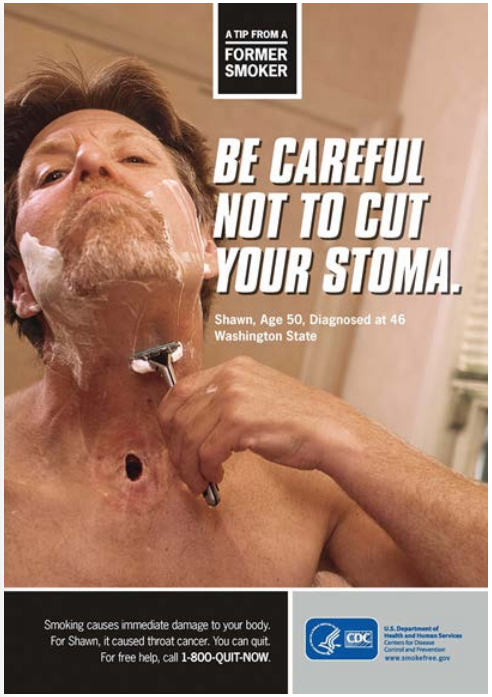
California Behavioral Health & Wellness Initiative

For our CA residents, we are starting a new venture in CA helping behavioral health organizations go tobacco free and integrating cessation services into existing services thanks to the support of the CTCP.

Free CME/CEUs will be available for all eligible California providers, who joined this live activity. You will receive a separate post-webinar email with instructions to claim credit.

Tips® Campaign Overview





1. CDC. Current Cigarette Smoking Among Adults—United States, 2005–2014.. MMWR 2015;64(44):1233–40
2. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: HHS,CDC, NCCDPHP, OSH, 2014

Presenter

Mitch R. Zeller, JD

Director, Center for Tobacco Products
FDA

FDA'S FRAMEWORK FOR THE REGULATION OF TOBACCO AND NICOTINE

Mitch Zeller, J.D.
Director, FDA Center for Tobacco Products

October 17, 2018

AGENDA

- Background and Regulatory Authorities
- E-Cigarettes & the Public Health Standard
- FDA's Comprehensive Plan for Tobacco and Nicotine Regulation
- Regulatory Policies on Addiction, Appeal & Cessation
- Youth Tobacco Prevention Plan
- Science-Based Review of Potential Modified Risk Tobacco Products
- Closing Thoughts
- Questions

BACKGROUND AND REGULATORY AUTHORITIES

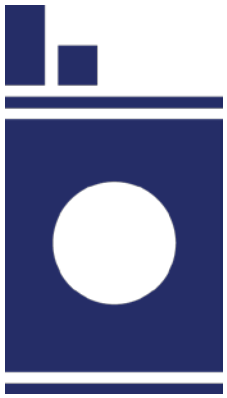
THE TOBACCO CONTROL ACT BECAME LAW ON JUNE 22, 2009

- To protect the public and create a healthier future for all Americans – particularly youth – a bipartisan Congress passed the Tobacco Control Act (TCA) with bipartisan support
- FDA's goal is to reduce the harm from all regulated tobacco products across the entire U.S. population:
  - Reducing the number of people who start using tobacco products
  - Encouraging more people to stop using these products
  - Reducing the adverse health impact for those who continue to use these products

THE TOBACCO CONTROL ACT BECAME LAW ON JUNE 22, 2009

Since 2009, FDA had authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Immediate authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- The law also permitted FDA to "deem" products meeting the statutory definition of tobacco product by issuing a regulation



FINAL DEEMING REGULATION

- On August 8, 2016, a final rule went into effect that “deems” all products meeting the statutory definition of tobacco product, including components or parts (but excluding accessories), to be subject to FDA’s tobacco product authorities, including:
  - ✓ ENDS (e-cigarettes, e-cigars, vape pens, etc)
  - ✓ All cigars
  - ✓ Pipe tobacco
  - ✓ Nicotine gels
  - ✓ Waterpipe (hookah)
  - ✓ Dissolvables not already under the FDA’s authority
  - ✓ Future tobacco products

E-CIGARETTES & THE PUBLIC HEALTH STANDARD

WHAT ARE E-CIGARETTES?

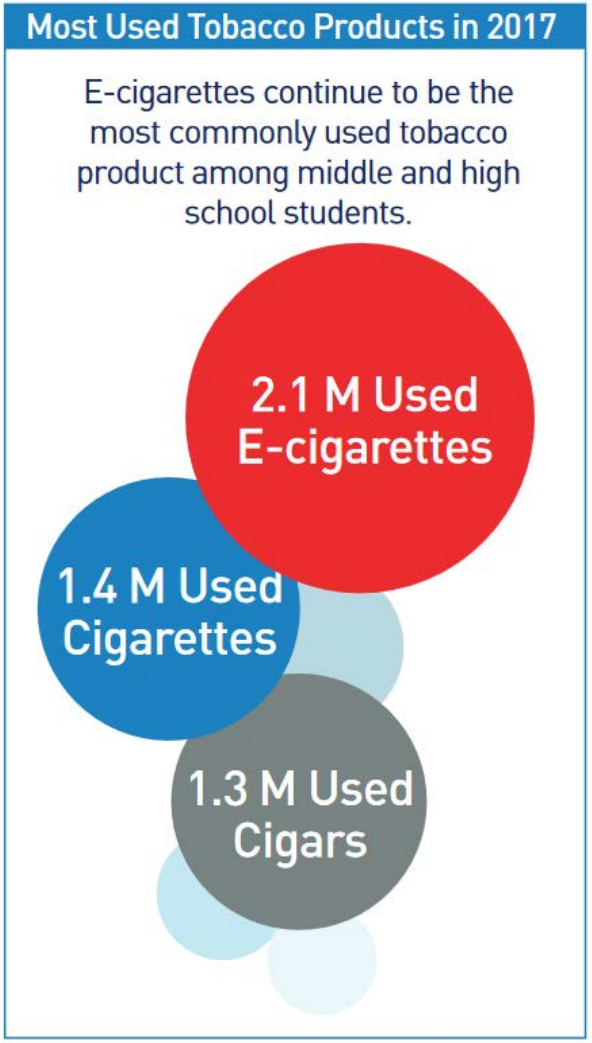
- Electronic Nicotine Delivery Systems (ENDS) are a heterogeneous group of products that include e-cigarettes, vapes, e-cigars and e-hookah
- In general these products heat an “e-liquid” that usually contains nicotine into an aerosol inhaled by the user
  - Include varying compositions of flavorings, propylene glycol, vegetable glycerin and other ingredients
- First introduced to the US in ~ 2007
- Come in a variety of shapes and designs (open tank vs closed system)
- For now, many on the market due to our compliance policy requiring them to submit marketing applications by August 2022 if they intend to stay on the market

FINDINGS FROM NASEM E-CIGARETTE REPORT

- National Academies of Sciences, Engineering, and Medicine (NASEM) published *Public Health Consequences of E-Cigarettes* in January
  - The report was commissioned by FDA at the direction of Congress
- Evaluates the available scientific evidence of the short- and long-term effects related to use of ENDS
- Key findings:
  - Substantial evidence that completely switching from regular cigarettes to e-cigarettes results in reduced short-term adverse health outcomes
  - Conclusive evidence that completely switching from combustible cigarettes to e-cigs reduces an individual user's exposure to numerous toxicants and carcinogens
  - Substantial evidence to suggest youth and young adults who use e-cigs are more likely to transition to combustible cigarettes

FINDINGS FROM THE 2017 NATIONAL YOUTH TOBACCO SURVEY (NYTS)

- NYTS is the only nationally representative survey of middle and high school students that focuses exclusively on tobacco use
- Over the past several years, e-cigarettes were the most commonly used tobacco product by youth
- More than 2 million middle and high school students were current users of e-cigarettes in 2017
- Recent rise in use of a particular brand (JUUL) and its eponymous verb ("JUULing")
- All of these factors are taken into consideration in the public health standard



EMPLOYING A PUBLIC HEALTH STANDARD

- Pursue a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard
- Take into account the effects on both users and non-users of tobacco products
- Assess the “net” population-level health impacts of tobacco products

FDA'S COMPREHENSIVE REGULATORY PLAN

HOW CAN WE MAKE THE GREATEST IMPACT?

"We truly find ourselves at a crossroads when it comes to efforts to reduce tobacco use. But if we're going to meaningfully improve the public health, we need to be willing to take a hard look at our entire approach."

FDA Commissioner Dr. Scott Gottlieb

July 28, 2017

ADDICTIVE NICOTINE IN COMBUSTIBLE CIGARETTES

"Nicotine, while highly addictive, is delivered through products on a continuum of risk...[and] the combustible cigarette is where nicotine's delivery vehicle leads to incredible amounts of disease and death."

FDA Commissioner Dr. Scott Gottlieb

October 19, 2017

FDA'S VISION FOR ADDRESSING NICOTINE

FDA envisions a world where **cigarettes would no longer create or sustain addiction**, and where **adults** who still seek nicotine could **get it** from alternative and **less harmful sources**

- Decrease the likelihood that future generations will become addicted to cigarettes
- Allow more addicted smokers to quit
- Encourage innovation of less harmful products for adults who need them
- Support innovations to medicinal nicotine and other therapeutic cessation products

LOOKING AT NICOTINE DIFFERENTLY

- Recognize that there is a continuum of nicotine-containing products
- Understand that people smoke for the nicotine but die from the tar
- Acknowledge public health opportunity

FDA'S COMPREHENSIVE REGULATORY PLAN

These efforts fall under several categories:

1) Regulatory Policies on Addiction, Appeal & Cessation

2) Youth Tobacco Prevention Plan
   - Access
   - Marketing
   - Education

3) Science-Based Review of Potential Modified Risk Tobacco Products

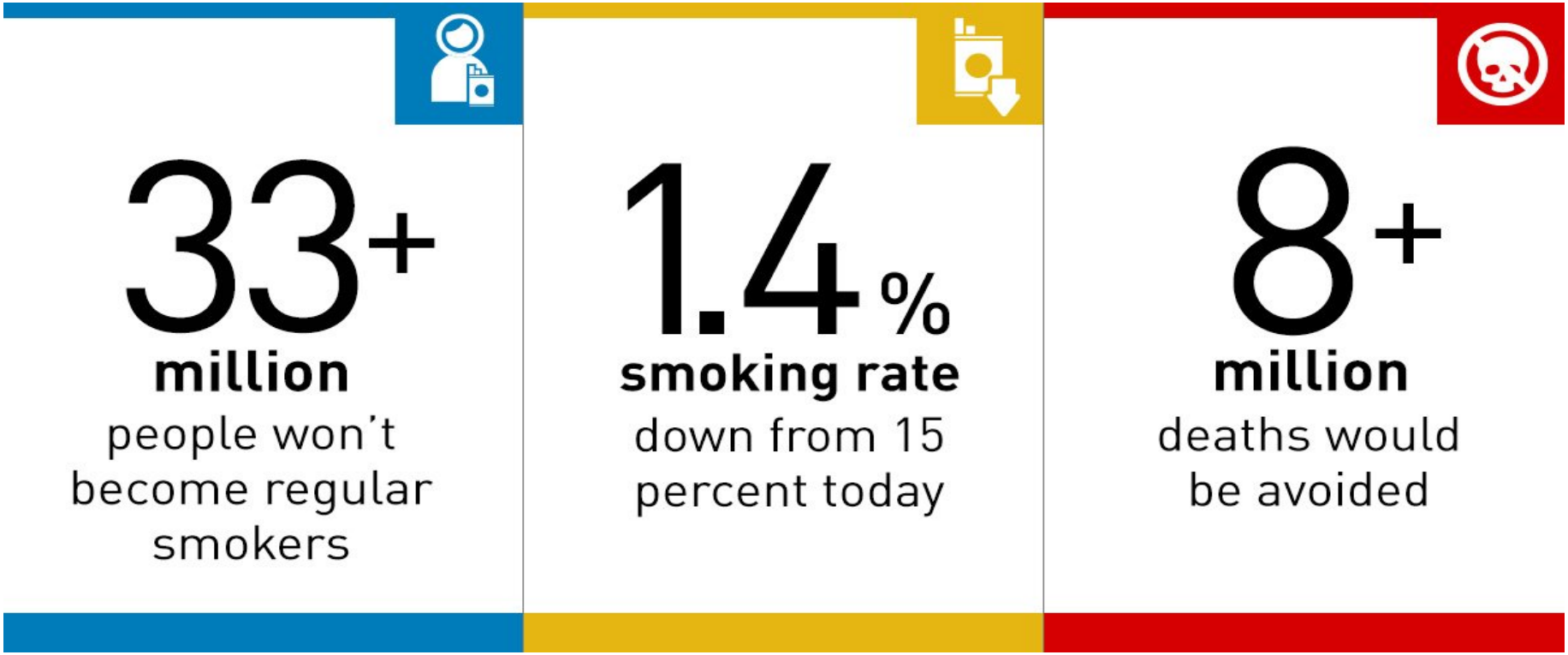

FDA
REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

NICOTINE PRODUCT STANDARD ANPRM

- On March 15, FDA issued the *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes,* an ANPRM
- Sought public comment for consideration in developing a potential product standard to lower nicotine to a minimally or non-addictive level in cigarettes
  - What potential maximum nicotine level would be appropriate for the protection of the public health;
  - How a maximum nicotine level should be measured;
  - Whether such a product standard should be implemented all at once or gradually;
  - Whether a nicotine product standard should also cover additional combustible tobacco products; and
  - What unintended consequences might occur as a result of such a standard
- Comment period closed on July 16, 2018

ESTIMATES FROM ONE POSSIBLE NICOTINE PRODUCT STANDARD POLICY

Included newly published estimates of one possible policy scenario to be realized by 2100:



ENCOURAGING A NATIONAL NICOTINE DIALOGUE

- Discuss core of the problem – but also the solution to addiction
- Engage public to educate and discuss:
  - **Correct common misperceptions**: Mistaken beliefs about nicotine and cancer
  - **Nicotine's role in continuum of risk**: Can be highly addictive; combustible cigarette is the delivery vehicle responsible for most disease and death; safe and effective in medicinal nicotine
  - **Nicotine and youth**: Potential for nicotine to rewire a teen's brain and create cravings leading to addiction; potential for future generations to not get addicted
  - **Adult smokers and nicotine**: How those who still seek nicotine can get satisfying levels from other and less harmful sources
  - **Vulnerable populations**: Consider the impact on adult smokers with mental health disorders

FLAVORS IN TOBACCO PRODUCTS ANPRM

- On March 20, FDA issued *Regulation of Flavors in Tobacco Products*, an ANPRM
- Sought comments, research and data on:
  - Role flavors play in initiation & patterns of tobacco use, particularly among youth & young adults;
  - Role flavors may play in helping some adult smokers reduce cigarette use and/or switch to potentially less harmful tobacco products;
  - Consumer perceptions of health risks and addictiveness of flavored products;
  - Whether certain flavors used in tobacco products present potential adverse health effects to users or others
- Comment period closed on July 19, 2018

YOUTH TOBACCO PREVENTION PLAN

YOUTH TOBACCO PREVENTION PLAN

In April, Commissioner Gottlieb announced a new focused segment of the Comprehensive Plan to reduce access to – and use of – tobacco products, particularly e-cigarettes

"But as we work to keep kids from making the deadly progression from experimentation to regular cigarette use, it's imperative that we also make sure children and teenagers aren't getting hooked on more novel nicotine-delivery products."

– Commissioner Gottlieb, April 24, 2018

YOUTH TOBACCO PREVENTION PLAN

- The Youth Tobacco Prevention plan has three main strategies:
  - *Preventing youth access*
  - *Curbing the marketing of products*
  - *Educating teens and their families*
- One major concern is the popularity of products that closely resemble a USB flash drive, have high levels of nicotine, and have emissions that are hard to see
  - These characteristics may facilitate youth use by making products more attractive to youth
  - Several of these products fall under the JUUL brand, but other brands with similar characteristics are emerging
  - Kids may be trying these products and liking them without knowing they contain nicotine

YTPP ACCESS & MARKETING: INITIAL ACTIONS

- Conducted a large-scale, undercover nationwide “blitz” of brick-and-mortar & online retailers for selling JUUL to underage youth
  - Issued 56 warning letters and filed 6 CMPs from March-June
- Worked with eBay to remove listings for JUUL on its website and voluntarily implement new measures to prevent new listings
- Sent 904(b) letters to JUUL and others requiring them to submit important documents on product marketing and research on health, toxicological, behavioral or physiological effects of the product, including:
  - Youth initiation and use
  - Whether certain design features, ingredients, or specifications appeal to different age groups
  - Youth-related adverse events and consumer complaints

YTPP ACCESS & MARKETING: INITIAL ACTIONS

- Issued 17 warning letters to manufacturers, distributors, and retailers for selling e-liquids used in e-cigarettes with labeling and/or advertising that cause them to resemble kid-friendly food products such as juice boxes, candy, cookies, and some included cartoon-like imagery

- FTC jointly-issued 13 of the letters because Section 5 of the Federal Trade Commission Act prohibits unfair or deceptive advertising

- All 17 companies have stopped selling these products
  - Several of the companies were also cited for illegally selling the products to minors

YOUTH USE OF E-CIGARETTES: NEW ACTIONS

Opinions

We cannot let e-cigarettes become an on-ramp for teenage addiction

By **Alex M. Azar** and **Scott Gottlieb**
October 11 at 8:05 AM

Alex M. Azar is the secretary of health and human services. Scott Gottlieb is the commissioner of the Food and Drug Administration.

YOUTH USE OF E-CIGARETTES: NEW STEPS

Preliminary data from the 2018 National Youth Tobacco Survey show a disturbingly sharp rise in the number of teens using e-cigarettes. From 2017 to 2018:

- The number of high-school-age children reporting use of e-cigarettes ***rose by more than 75%***
- Use among middle-schoolers ***increased nearly 50%***
  - Data will be made public soon, but FDA has an obligation to act now
- On Sept. 12, FDA announced a series of new steps in the three strategies of its Youth Tobacco Prevention Plan

YOUTH TOBACCO PREVENTION PLAN: NEW STEPS

- In the largest coordinated enforcement effort in FDA's history, issued more than 1,100 warning letters and 131 civil money penalty complaints to retailers who illegally sold e-cigarette to minors
- Issued 12 additional warning letters to online retailers for selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly products
- Issued warning letter to HelloCig Electronic Technology Co. Ltd for various violations, including selling two e-liquids that contain prescription drugs, leading the FDA to determine that the products are unapproved new drugs
- Sent letters to 21 companies as part of investigation of whether 40+ currently marketed e-cigarettes may be subject to enforcement actions because they were not on the market as of August 8, 2016 nor have they received premarket authorizations
- Indefinitely stepping up enforcement actions with a sustained campaign to monitor, penalize and prevent e-cigarette sales in retail locations including manufacturers' own internet storefronts

YOUTH TOBACCO PREVENTION PLAN: NEW STEPS

- Issued letters to JUUL, Vuse, MarkTen XL, blu e-cigs and Logic asking the companies to submit plans describing how they will address the widespread youth access and use of their products
  - These are the 5 top-selling brands and collectively make up over 97% of the U.S. market
  - Accounted for the vast majority of the 1,100+ warning letters issued
- FDA may revisit the current policy that provides manufacturers of certain deemed products more time to submit a premarket application (until 2022)
  - All options are on the table when it comes to reconsidering, and potentially changing, the existing compliance policy for deemed tobacco products
  - FDA could consider differences in patterns of use between youth and adult e-cigarette use, including the issue of characterizing flavors and cartridge-based products versus open-tank systems

PUBLIC EDUCATION: "THE REAL COST" YOUTH E-CIGARETTE 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 last month
- Ads are running online and include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms
- Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, puts them at risk for addiction and other health consequences
- To ensure these messages are reaching the intended youth audience, the ads will run on age-verified digital platforms

“THE REAL COST” YOUTH E-CIGARETTE PREVENTION CAMPAIGN: EPIDEMIC

CREATIVE EXTENSIONS: WEB, SOCIAL, DIGITAL ADS

YOUTH E-CIGARETTE PREVENTION IN SCHOOL

- "The Real Cost" will reach students with an e-cigarette prevention message in the exact moment and location that they are faced with the decision to use e-cigarettes
- Posters are currently being distributed to more than 10,000 high schools to place in bathrooms
- Snarky tone will catch their attention, but the facts will deliver a strong prevention message

SCIENCE-BASED REVIEW OF POTENTIAL MODIFIED RISK TOBACCO PRODUCTS

REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: MODIFIED RISK APPLICATIONS

- *iQOS*: In May 2017, FDA filed three MRTP applications for scientific review from PMI for its *iQOS* system and three *HeatStick* products
  - TPSAC meeting held Jan. 24-25, comment period is open-ended
- *Camel Snus*: In Dec. 2017, FDA filed MRTP applications for scientific review from R.J. Reynolds Tobacco Company for six *Camel Snus* smokeless tobacco products
  - TPSAC meeting held Sept. 13-14, comment period remains open
- *Copenhagen Snuff Fine Cut*: In Sept. 2018, FDA filed MRTP applications for scientific review from U.S. Smokeless Tobacco Company for one moist snuff tobacco product
- *General Snus*: In Dec. 2016, FDA denied one request in Swedish Match North America's MRTP applications for eight smokeless tobacco products and deferred on two other requests
  - In October 2018, FDA posted an amendment submitted by the company

CLOSING THOUGHTS

- Our responsibility is to assess the “net” impact on the population
- Concerns about teens and nicotine in any form remain
- FDA is committed to pursuing our comprehensive plan
  - A world where kids cannot become addicted to cigarettes, and addicted adults have access to less harmful forms of nicotine and improved medicinal products, is an achievable vision that will save countless lives
  - This is only possible in a regulated marketplace where public health considerations and the relevant science serve as the foundation for science-based oversight of the marketplace
- Are we ready, willing and able to ask tough questions about nicotine, e.g. long-term, permanent use for some?
- And as we figure out where and how e-cigarettes and non-combusted cigarettes fit in, how much weight should be placed on the negative impact of kids’ uptake as part of the population-level public health standard?

QUESTIONS?

THANK YOU

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Q&A

- Submit questions via the **chat box**

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- You will receive the webinar recording, presentation slides, information on certificates of attendance, and other resources, in our follow-up email. All of this information will be posted to our website.
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Upcoming SCLC Webinar

SCLC's next live webinar will be on **December 11, 2018 at 1:00pm ET** with Dr. Saul Shiffman, on the Non-Daily Smoker.

Registration is coming soon!

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Visit SCLC's website at: https://smokingcessationleadership.ucsf.edu/celebrating-15-years for more information.

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