



King Reactor Panel: CTP Needs to Reverse Course

FDLI Tobacco & Nicotine Conference

Washington, D.C.
October 26, 2023

Tony Abboud
Executive Director
Vapor Technology Association



Reactions & Perspectives

Youth

Education

PMTA

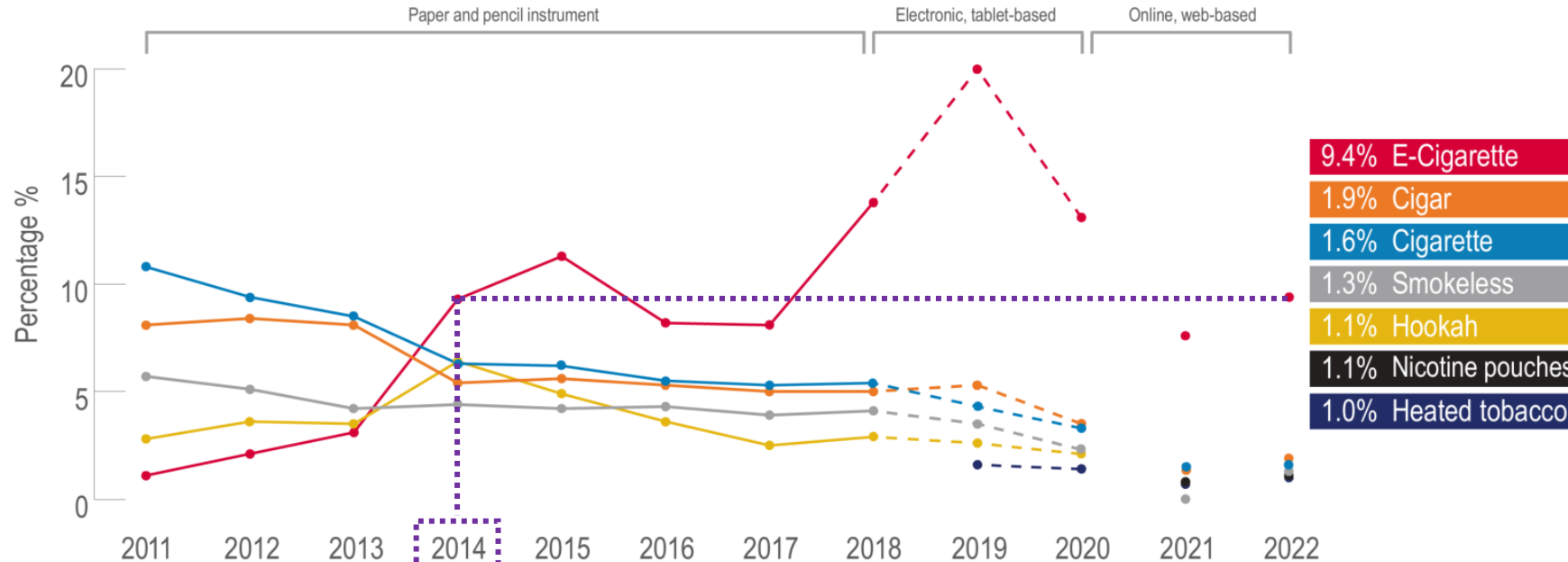
Enforcement

Health Equity

Perspective: CTP Must Reset Youth Narrative

CURRENT TOBACCO PRODUCT USE AMONG MIDDLE AND HIGH SCHOOL STUDENTS (2022)

FDA



Dashed lines represent electronic data collection and solid lines represent data collection via paper and pencil instrument. The ability to compare results between 2022 and previous survey waves is limited because of methodological changes.
NOTE: Smokeless tobacco use is defined as use of chewing tobacco, snuff, dip, snus, or dissolvable tobacco product on ≥1 day during the past 30 days.
SOURCE: National Youth Tobacco Survey (NYTS), 2011-2022

E-Cigarette = 9.4%

- *Pre-epidemic*
- *Pre-JUUL*
- *Pre-mass market*
- *Pre-disposables*
- *Pre-flavor ban*
- *Pre-T-21*

Combustible = 4.6%



CTP Must Reverse Course:

Focus on Adults



CTP must decide “**how to weigh the public health benefits of the percentage of adults who use ENDS that will completely quit smoking combustible tobacco products against the *potential* public health harms [for] youth.**”

- Acknowledge the dramatically reduced youth rate.
- Abandon youth presumption hurdle & fatal flaw approach.
- Develop an objective balancing test to protect adults.



Harm Reduction Must Be Foundation of CTP's Strategic Plan

- CTP must **immediately, loudly and repeatedly**:
 - State that tobacco harm reduction is its north star.
 - State that vaping is dramatically safer than smoking.
 - State that vaping and MON products are critical tools for THR & cessation.
 - Encourage smokers to use/try e-cigarettes if they can't quit.
 - Authorize a wide-variety of vaping products, including flavors.
- If this is not the **foundation** of CTP's Strategic Plan and announced as such, then we are all engaging in a futile exercise.
- The cacophony of misinformation regarding less harmful nicotine alternatives will undermine whatever Strategic Plan CTP puts in place.



glimmer of hope...

Glimmer of Hope?

FDLI, 2022

“While nicotine is not what makes smoking cigarettes so toxic, it’s the ingredient that makes it very hard to quit.” – FDA

But 80% of physicians apparently think it causes cancer!

“I’m fully aware of the misperceptions that are out there and aren’t consistent with the known science. We do know that e-cigarettes — as a general class — have markedly less risk than a combustible cigarette product.” - CTP Director Brian King

...has faded.



Director King's Commentary: Fixed in Past

- “No tobacco product is safe.”
- Emphasizes complete youth abstinence.
- “The *first line approach* for smoking cessation among adult smokers should be products scientifically shown to be **safe and effective**, including FDA-approved medications and devices.”

CONTINUUM OF RISK

ADDICTION

SSA SOCIETY FOR THE
STUDY OF
ADDICTION

COMMENTARY |  Free Access

Commentary on Wackowski *et al.*: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers


Brian A. King  Benjamin A. Toll

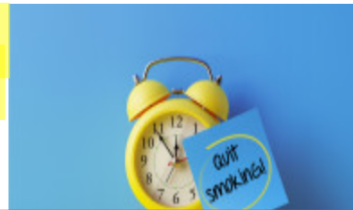
First published: 15 August 2023 | <https://doi.org/10.1111/add.16296>

Director King's Commentary: Reluctance to Fully Embrace Science

- Cites Cochrane: “A growing body of research *suggests certain* e-cigarettes *can* facilitate smoking cessation among adults” but more evidence is needed.

Latest Cochrane Review finds high certainty evidence that nicotine e-cigarettes are more effective than traditional nicotine-replacement therapy (NRT) in helping people quit smoking

A Cochrane review  has found the strongest evidence yet that e-cigarettes, also known as ‘vapes’, help people to quit smoking better than traditional nicotine replacement therapies, such as patches and chewing gums.



CONTINUUM OF RISK

ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

COMMENTARY |  Free Access

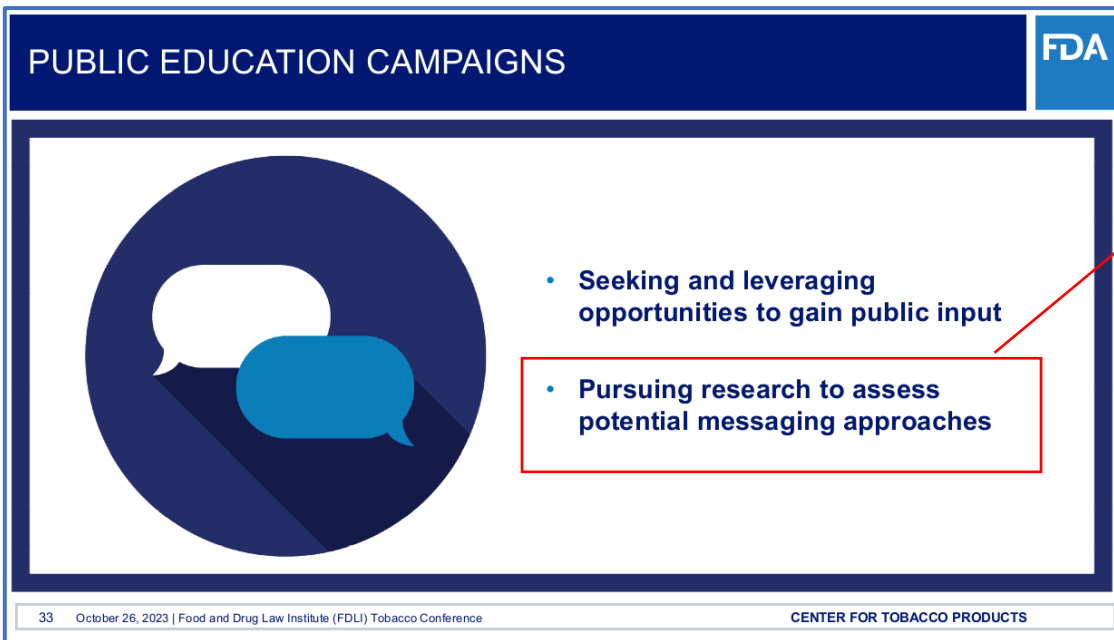
Commentary on Wackowski *et al.*: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers

Brian A. King  Benjamin A. Toll

First published: 15 August 2023 | <https://doi.org/10.1111/add.16296>

26 October 26, 2023 | Food and Drug Law Institute (FDLI) Tobacco Conference

CTP: No Commitment to Adult THR Education



- Education emphasis remains on “youth” and “dangers”
- And adults?
“*Pursue research to assess potential messaging approaches*”
- We are years away from knowing if CTP will educate adults, much less what it might say about harm reduction.

CTP Must
Reverse
Course:

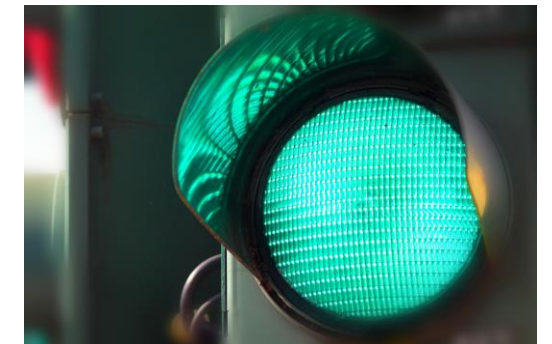
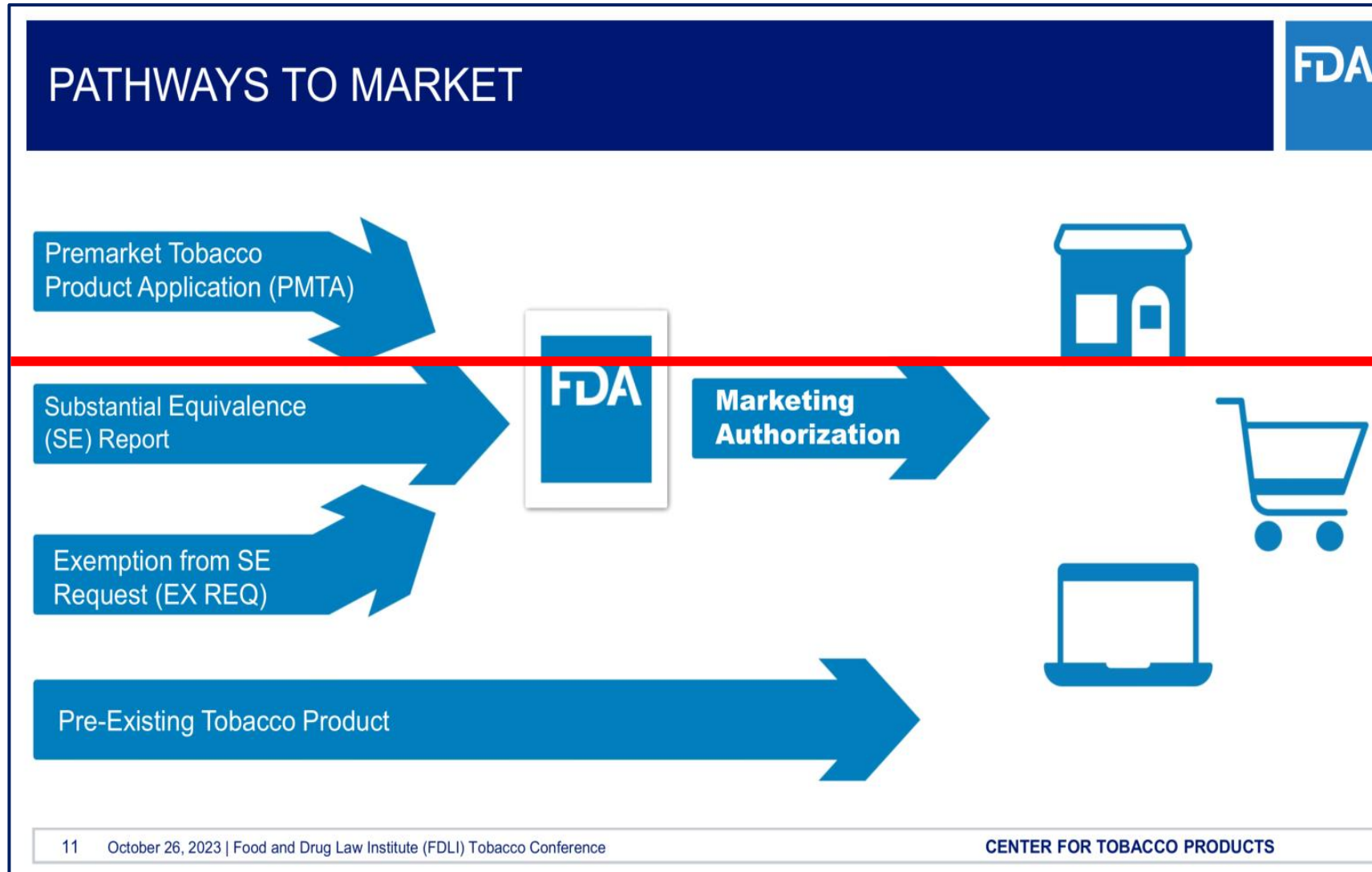
Embrace
Harm
Reduction



CTP Can – But Chooses Not to – Act

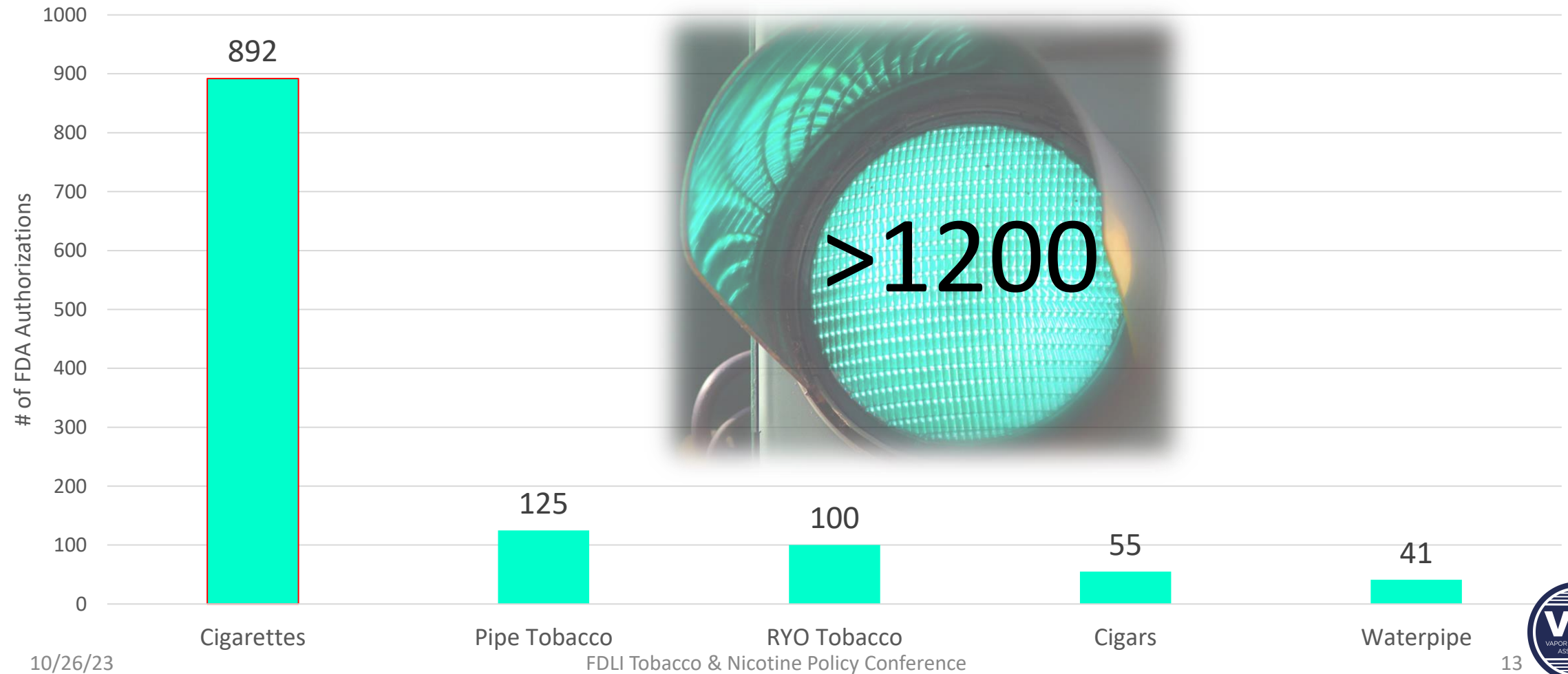
- Confronted with the COVID pandemic, FDA acted.
 - Relied on short-term and incomplete science.
 - Authorized new products at record speed.
 - Rapidly set its public messaging.
 - Spoke ***immediately, loudly, and repeatedly*** to Americans **about harm reduction**.
- One year will have passed between RUF Report and CTP's Strategic Plan announcement.
- Bold leadership on THR is needed *now*.
- Bureaucratic hand-wringing will only condemn Americans to a COVID-level death toll every two years.

What Harm Reduction Options Will Smokers Have?



FDA's Authorization of New Combustible Tobacco Products

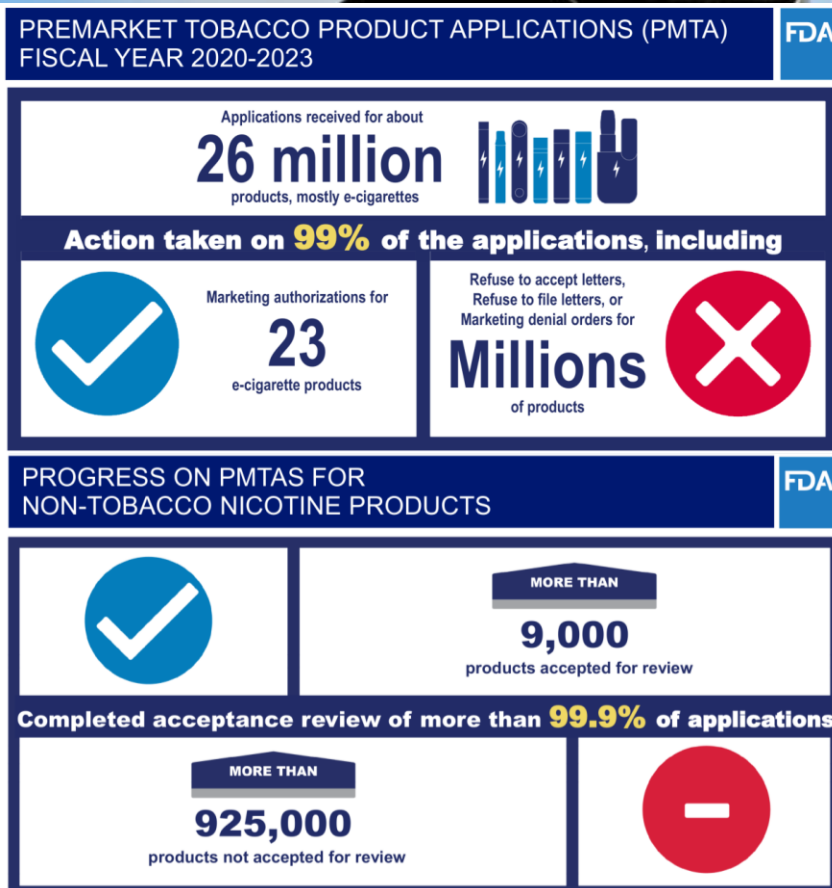
2018-2022 – VTA Report on FDA SE and SE-Ex Database





Perspective: Pathways to Market?

- 23 = 8* device options for smokers
 - Tobacco flavor only
- 23 = 0.00000008% ENDS authorized
 - “eight ten millionths of a percent”
- Zero open system devices
- Zero open system e-liquids
- Zero flavored products (inc menthol)
- Zero nicotine pouches
- Only in government is this “progress”



Concern: New Leadership Just Says No

[June 23, 2022](#): Marketing Denial Orders JUUL Labs Inc (JUUL System)

July – October 2022

[October 26, 2022](#): Marketing Denial Orders Logic, LLC (Logic Pro Menthol e-Liquid Package and Logic Power Menthol e-Liquid Package)

[October 6, 2022](#): Marketing Denial Orders Magellan Technology Inc. (Hyde)

December 2022

[October 12, 2023](#): Marketing Denial Order R.J. Reynolds Vapor Company (Vuse Alto menthol-flavored and mixed berry-flavored products)

[July 10, 2023](#): Marketing Denial Order Fontem, US, LLC (myblu Menthol 2.4%)

[May 18, 2023](#): Marketing Denial Orders Mothers Milk WTA (Mothers Milk)

[May 12, 2023](#): Marketing Denial Orders for 10 Companies

[March 17, 2023](#): Marketing Denial Orders R.J. Reynolds Vapor Company (Vuse Solo Menthol Products)

[January 24, 2023](#): Marketing Denial Orders R.J. Reynolds Vapor Company (Vuse Vibe Tank Menthol 3.0% and Vuse Ciro Cartridge Menthol 1.5%)

Director King takes over at CTP

Commissioner Califf calls for external review of CTP

Reagan-Udall Commences Review of CTP

CTP continued denials *during* pendency of RUF

RUF issues critical report

- No clear APPH standard (requirements / review)
- No clear policy / science decision making process
- “CTP struggles to function as a regulator”

Denials continue *after* RUF report and *before* CTP addresses core criticisms of RUF.

Denials based on same flawed APPH approach

CTP Must Reverse Course:

Speed Products to Market



“Applicants ... will struggle...to meet the APPH standard unless FDA clearly articulates its expectations. CTP has a responsibility to clearly identify application requirements.” ***That has not happened.***

- CTP must say YES; use regs to authorize wide variety.
- CTP must set specific list of scientific requirements.
- CTP must implement a streamlined PMTA process.



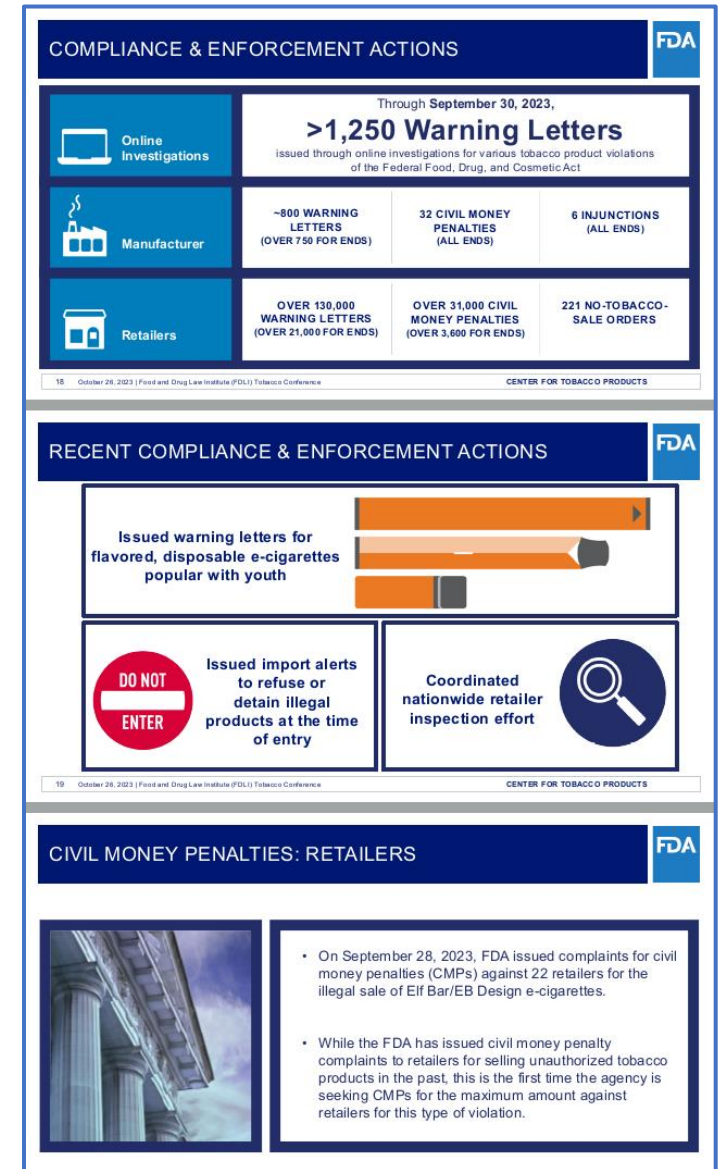
Enforcement:

Can't forget
why we are in
this situation?

- FDA leadership broke the PMTA process in 2021.
 - Overrode Office of Science and CTP Director
 - Rejected millions of products without review.
 - Plunged the agency into litigation.
- CTP refused to publish a list of pending PMTAs.
- CTP declared *all* vapes (w/o MGO) as illegal.
- CTP publicly retreated from (but still uses) discretion.

Perspective: Enforcement

- Who does FDA's new-found enforcement posture serve?
 - CTP uses enforcement announcements to perpetuate "youth epidemic" and "dangers" to youth (i.e., "poison control calls").
 - Politicians & vaping/nicotine prohibitionists pick winners/losers.
 - Handful of companies with authorized products.
- We've never wanted an unregulated market.
 - CTP's declaration of illegality = *de facto* ban.
 - Government can't enforce a ban.
- Mass market removal will not serve smokers' interests.
 - Should FDA's failings deprive adults of their preferred vapes?
 - Forced to the black market, DIY, back to smoking.



A Stark Warning to Remember

“Mass market exit of [vaping] products present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products”



“I am concerned that these declines [in cigarette smoking] could be slowed or reversed in the case of very sudden and very dramatic reductions in availability.”



“Mass market exit” is “a public health outcome that should be avoided if at all possible.”

Declaration of Mitch Zeller, Director, Center for Tobacco Products, *AAP v. FDA*, March 20, 2020

CTP Actions Fail Marginalized Communities



“African Americans suffer disproportionately from smoking-related deaths, a disparity that, a new clinical trial shows, vaping could reduce.”

“Today’s smokers come disproportionately from lower education and income groups, the LGBTQ (lesbian, gay, bisexual, transgender, and queer or questioning) community, and populations suffering from mental health conditions and from other drug addictions.”

Balfour et al., American Journal of Public Health, 2021



CENTER FOR BLACK EQUITY

“Broad access to e-cigarettes and vaping products is critical to advancing harm reduction and health equity among Black and LGBTQ+ communities.”

Because marginalized communities smoke at higher rates, the benefits of shifting from smoking to vaping will be felt most acutely among the communities most at-risk – Black and LGBTQ+ populations. This is the definition of health equity, and Americans deserve regulatory policies that allow choice rooted in science, not politics.

The CBE is calling on the U.S. Food and Drug Administration, including the Center for Tobacco Products, to reset its posture towards e-cigarette and vaping products by ensuring that adults have access to a variety of effective tobacco harm-reduction options, including flavored e-cigarette and vaping products. This is critical if the agency intends to effectively pursue both tobacco harm reduction and health equity, particularly for vulnerable populations.

EARL D. FOWLKES, JR.
President and CEO



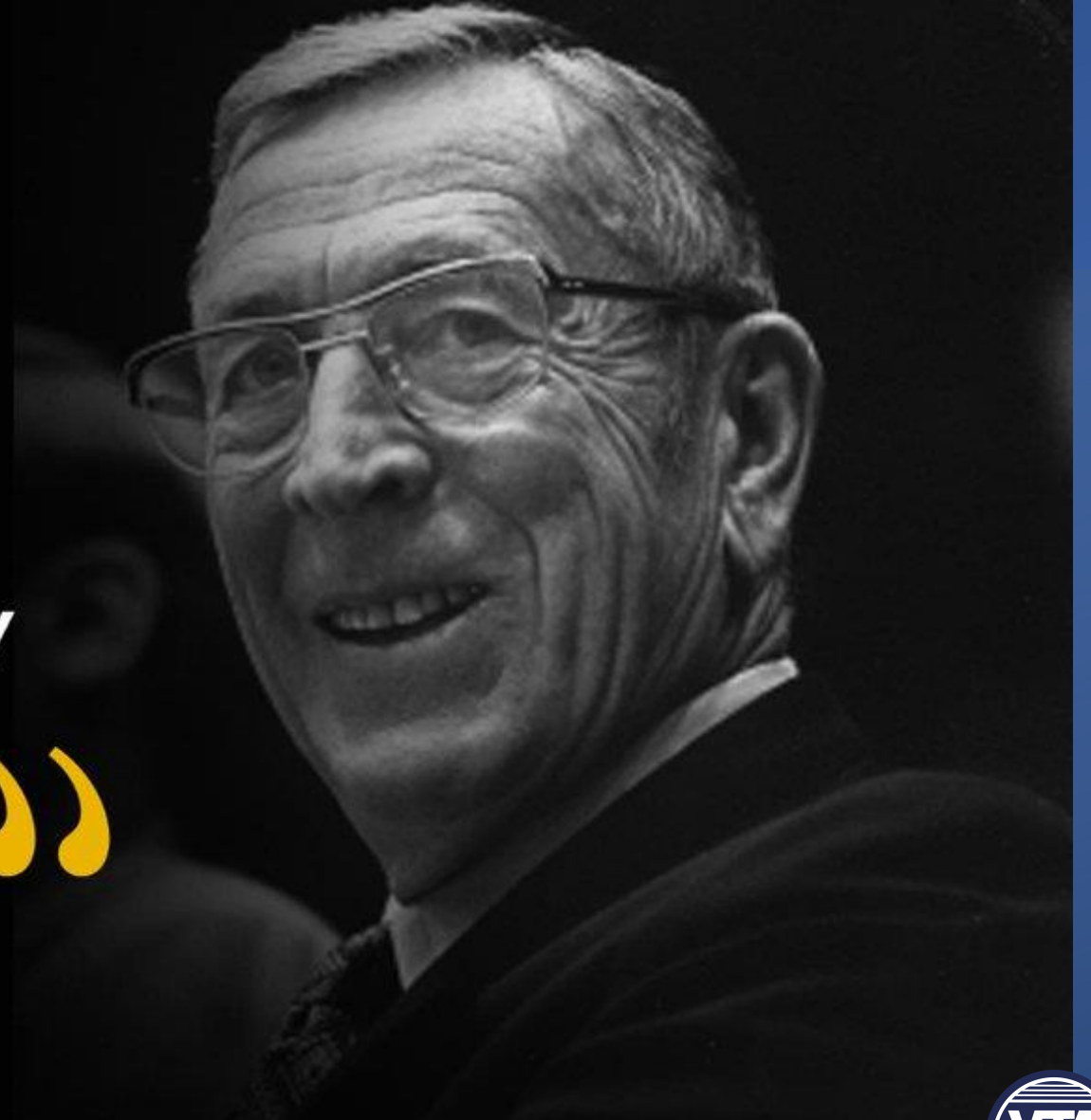
Concluding Warnings

**CTP
remains
focused on
youth; not on
adult and/or
marginalized
smokers**

**CTP
has no plans
to speak
accurately
about vaping
risks and
benefits**

**CTP
on path to
eliminate
vapes as a
THR or quit
option for
smokers**

**“DON'T MISTAKE ACTIVITY
FOR ACHIEVEMENT”**
- JOHN WOODEN



Thank you.

