



# A Comprehensive Discussion About Flavors in Tobacco and Nicotine Products

**Tony Abboud**, Executive Director, Vapor Technology Association

**Aruni Bhatnagar**, Chair, School of Medicine, University of Louisville and co-Director,  
American Heart Association Tobacco Center for Regulatory Science

*Moderated by* **Seth A. Mailhot**, Partner, Husch Blackwell LLP



**HUSCH BLACKWELL**

**A Comprehensive  
Discussion About Flavors  
in Tobacco and Nicotine  
Products:  
Background**

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Seth A. Mailhot, Partner  
Leader, FDA Group

October 24, 2019

# Overview



- Ban on Characterizing Flavors in Cigarettes
- Review of Menthol Cigarettes
- Tobacco Product Standard Considerations
- ENDS Flavor Policy and Enforcement

# Ban on Characterizing Flavors

- Sec. 907(a)(1)(A): “a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.”
- Prohibition limited to:
  - “a cigarette or any of its component parts” (i.e., no restriction on flavored cigars, little cigars, cigarillos, pipe tobacco, ENDS, etc.)
  - “characterizing flavor” (i.e., flavors introduced through casings to achieve a consistent tobacco flavor are not prohibited)

# FDA Review of Menthol

- Sec. 907(e): “Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee . . . the Secretary shall refer to the Committee for report and recommendation . . . the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.”
  - March 2011, TPSAC concludes “Removal of menthol cigarettes . . . would benefit public health. . .” Does not recommend any specific actions, like restricting or banning menthol.
  - July 24, 2013, FDA issues advance notice of proposed rulemaking (ANPRM) on the potential regulation of menthol in cigarettes and releases study “Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes.”
  - November 15, 2018, Commissioner Gottlieb announces FDA “will advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars.”

# Tobacco Product Standard Considerations

- **the risks and benefits to the population as a whole**, including users and nonusers of tobacco products, of the proposed standard;
- the increased or decreased **likelihood that existing users of tobacco products will stop using** such products; and
- the increased or decreased likelihood that **those who do not use tobacco products will start using** such products.
- the **technical achievability of compliance** with such standard.
- **all other information** submitted in connection with a proposed standard, including . . . the countervailing effects of the tobacco product standard on the *health of adolescent tobacco users, adult tobacco users, or nontobacco users*, such as the creation of a significant *demand for contraband* or other tobacco products . . . and the significance of such demand.

# Additional Policies and Enforcement

- May 2018, FDA issued 17 warning letters to manufacturers, distributors, and retailers for selling e-liquids with labeling and/or advertising that resemble kid-friendly food products, such as juice boxes, candy, or cookies.
- September 12, 2018, FDA issued letters to five ENDS product manufacturers and considers withdrawing enforcement discretion with respect to certain flavored tobacco products.
- March 2019, FDA issues draft guidance proposing “prioritize enforcement” over:
  - flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol-flavored ENDS products)
  - ENDS products that are targeted to minors or likely to promote use of ENDS by minors
  - flavored cigars (other than tobacco flavored)
- September 11, 2019, Trump administration announced that FDA is finalizing its guidance to remove all non-tobacco flavors of e-cigarettes, including mint and menthol, from the market within 30 days.

QUESTIONS?





# HUSCH BLACKWELL



## Seth A. Mailhot

750 17<sup>th</sup> Street, NW  
Washington, DC 20006

Phone: (202) 378-2306

Cell: (617) 842-0484

Fax: (202) 378-2319

[Seth.Mailhot@Huschblackwell.com](mailto:Seth.Mailhot@Huschblackwell.com)

Seth Mailhot is a Partner and lead of the FDA Regulatory Practice Group in Husch Blackwell's Washington D.C. office. His 14 years working in the U.S. Food and Drug Administration (FDA) has provided him a unique perspective when counseling clients on a broad range of matters involving the FDA.

Seth's practice includes representation of the medical device, pharmaceutical, dietary supplement, tobacco and food industries, and covers both premarket and post-market issues. His practice is focused on development of premarket submission strategies, and FDA enforcement of good manufacturing practices, both domestically and abroad.

## Admissions

- California
- District of Columbia
- Massachusetts
- U.S. Patent and Trademark Office

## Education

- New England School of Law, J.D., Valedictorian, *summa cum laude*
- University of Massachusetts, B.S., Chemical Engineering



# Flavors in Nicotine and Tobacco Products

Aruni Bhatnagar, PhD, FAHA

Director, American Heart Association Tobacco Regulation Center

Department of Medicine

University of Louisville, Louisville, KY



# Issues with flavored tobacco products

Appeal to Youth

Youth initiation

Help adults quit?

Variety in marketing

Difficulties in Regulation

Toxicity



# Youth Prefer more flavors than adults

## PATH STUDY

Adult Past 30-day ENDS User N = 1809		Youth Past 30-day ENDS User N = 226	
	% (LB, UB)		% (LB, UB)
Fruit	30.8 (28.1, 33.6)	Fruit	52.8 (45.4, 60.1)
Tobacco	24.5 (21.6, 27.6)	Candy/desserts/other sweets	24.4 (19.9, 29.7)
Candy/desserts/other sweets	18.2 (15.7, 21.1)	Menthol/Mint	10.8 (7.0, 16.2)
Menthol/Mint	17.9 (15.9, 20.1)	Tobacco	5.1 (3.0, 8.4)
Other flavor	3.1 (2.2, 4.3)	Chocolate	3.0 (1.1, 7.8)

# Use of Flavored E-cigarettes

Adolescents and Young Adults are more likely to use fruit flavored e-cigarettes than older adults

OR = 2.31

And concurrently use multiple flavor types

OR = 4.58

# Association of E-cigarette use with subsequent initiation of tobacco cigarettes in US youths

Prior e-cigarette users had 4.09 times the odds of ever combustible cigarette use compared with youth with no prior tobacco use

Odds of current cigarette use were higher among prior e-cigarette users – OR 2.75 and prior other product use OR 3.43 compared with youths with no prior tobacco use.

At the population level, about 180,000 new never smokers and 45,000 current smokers in the US may have started smoking combustible cigarettes after initiating e-cigarette use

# Role of flavors in e-cigarette initiation and addiction

Flavor was a reason some users initially tried and continued to use e-cigarettes.

- Most e-cigarette users typically used flavors other than tobacco flavor.
- Typical flavors included fruit, mint/menthol, sweet, candy, coffee and other.
- Satisfaction was greater among users of flavored versus non-flavored e-cigarettes.
- Perceived addiction was also greater among users of flavored e-cigarettes.

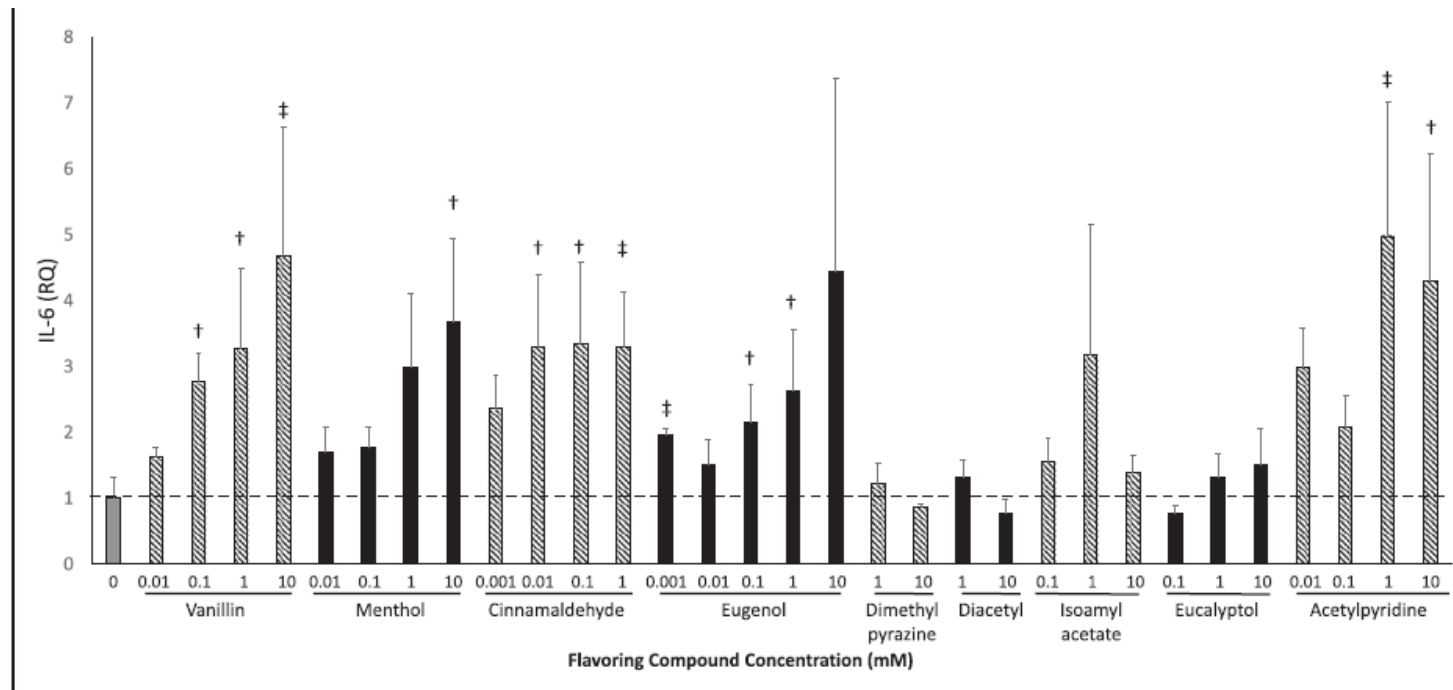
Survey of 1492 current e-cigarette users  
>18 years

Addict Behav 2019

# Flavor Toxicity

Although most flavors used are generally regarded as safe (GRAS) when ingested, their effects when inhaled remain unknown

Some flavors have been reported to induce oxidative stress and inflammation and display carcinogenic potential





# Flavor Toxicity

Flavors increase the generation of toxic chemicals (carbonyl) during vaping

Flavors such as strawberry significantly increase puff duration and the average number of puffs

Flavors such as green apples increase dopamine neuron firing frequency due to a decrease in inhibitory tone from GABA neurons – could facilitate addiction

Flavored e-cigarettes are easier to use than unflavored e-cigarettes

Sweet taste potentiates the reinforcing effects of nicotine in e-cigarettes resulting in heightened brain cue-reactivity

Flavors (strawberry) increase rate of nicotine absorption (through pH effects)



life is why™

es por la vida™

全為生命™



# A Comprehensive Discussion About Flavors

**Tony Abboud**

**Executive Director**

**Vapor Technology Association**

**October 25, 2019**



# What is VTA?

The national trade association advocating for rational, science-based laws and regulations to permit the continued growth of diverse vapor marketplace

- Open & Closed Device Manufacturers
- E-Liquid Manufacturers
- Vapor Wholesalers
- Vapor Distributors
- Retail Vape Shops
- Online Sellers
- Importers
- Suppliers

# Topics

- ✓ Youth Vaping – Apparently Not What It Seems
- ✓ Twin Goals:
  - ✓ Protecting Youth from Vaping and Smoking
  - ✓ Protecting Adults from Smoking
- ✓ Flavor Bans Don't Work
- ✓ Common Ground: Alternatives to Flavor Bans



# What Is the Youth Issue?

1% active vapers

88% of regular users =  
current/former smokers

Historic and unanticipated lows in  
smoking

# Real Science on Flavor *Initiation* Is Limited

NYTS is “Not  
Enough”:  
Zeller

*Multiple  
reasons* for  
potential  
initiation

- Flavors are not *the* reason
- Flavors are *a* reason at most
- Flavors often not in the top 3

At best mere  
correlation,  
not  
causation

# Still No Evidence of Gateway

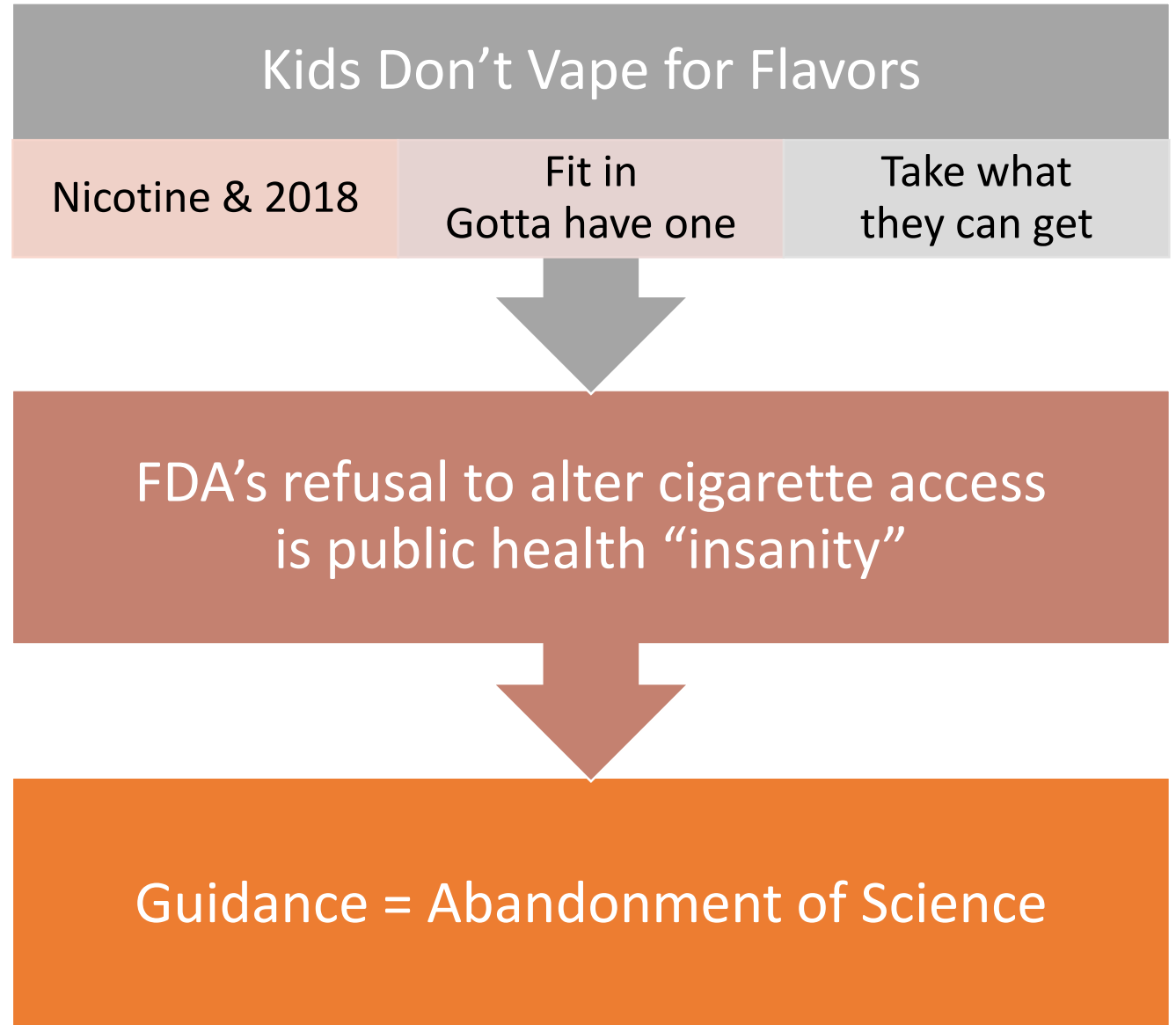
“So, what we [NASEM] are **not** actually saying here is that it leads to young youth smoking, something that has been sometimes lost in translation.”

Dr. Nancy Rigotti  
E-Cig Summit 2018

2018 crash of youth smoking rates con



Bans Don't  
Work; Never  
Have



# The Abandonment of the Adult Smoker

After years of corrective thinking about addiction as a disease, smokers are being ignored, denigrated, pushed to the fringes.

Scientific disregard: How much is FDA spending on evaluating ENDS' role in cessation?

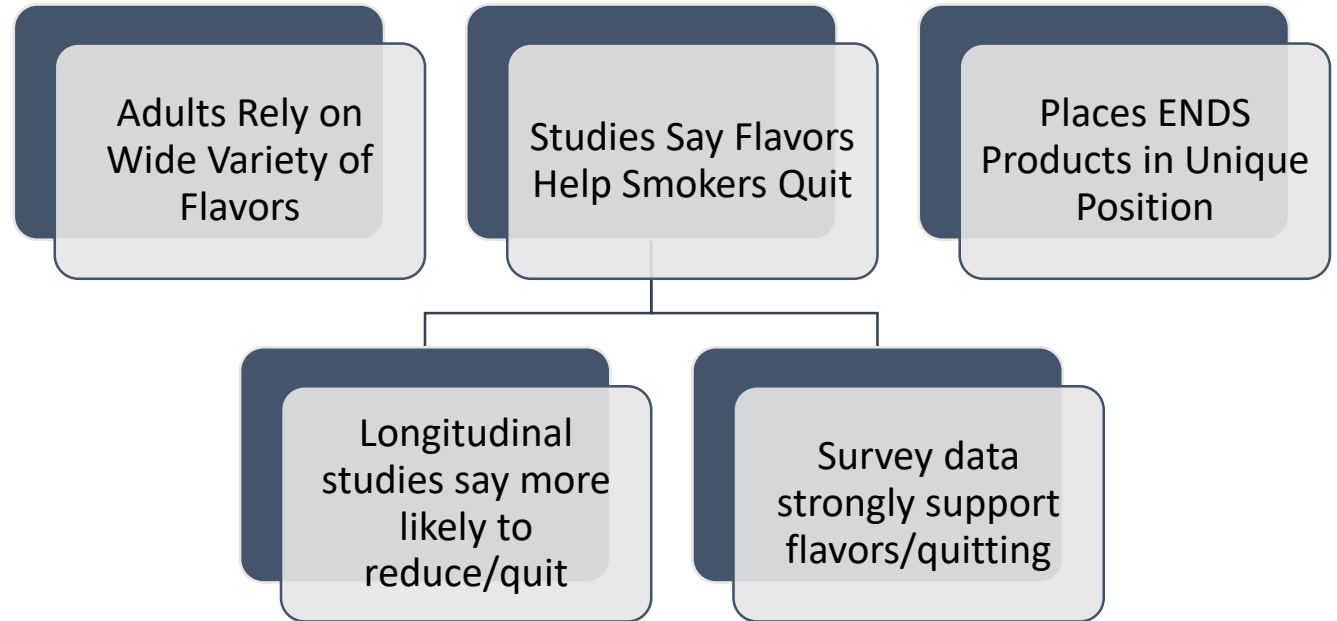
Yet, we have time for conferences on new youth "addiction" strategies?

We don't have the luxury of talking and thinking and advocating only for one segment of our vulnerable population and not the others.

Recent piling on flavors demagoguery at its worst.

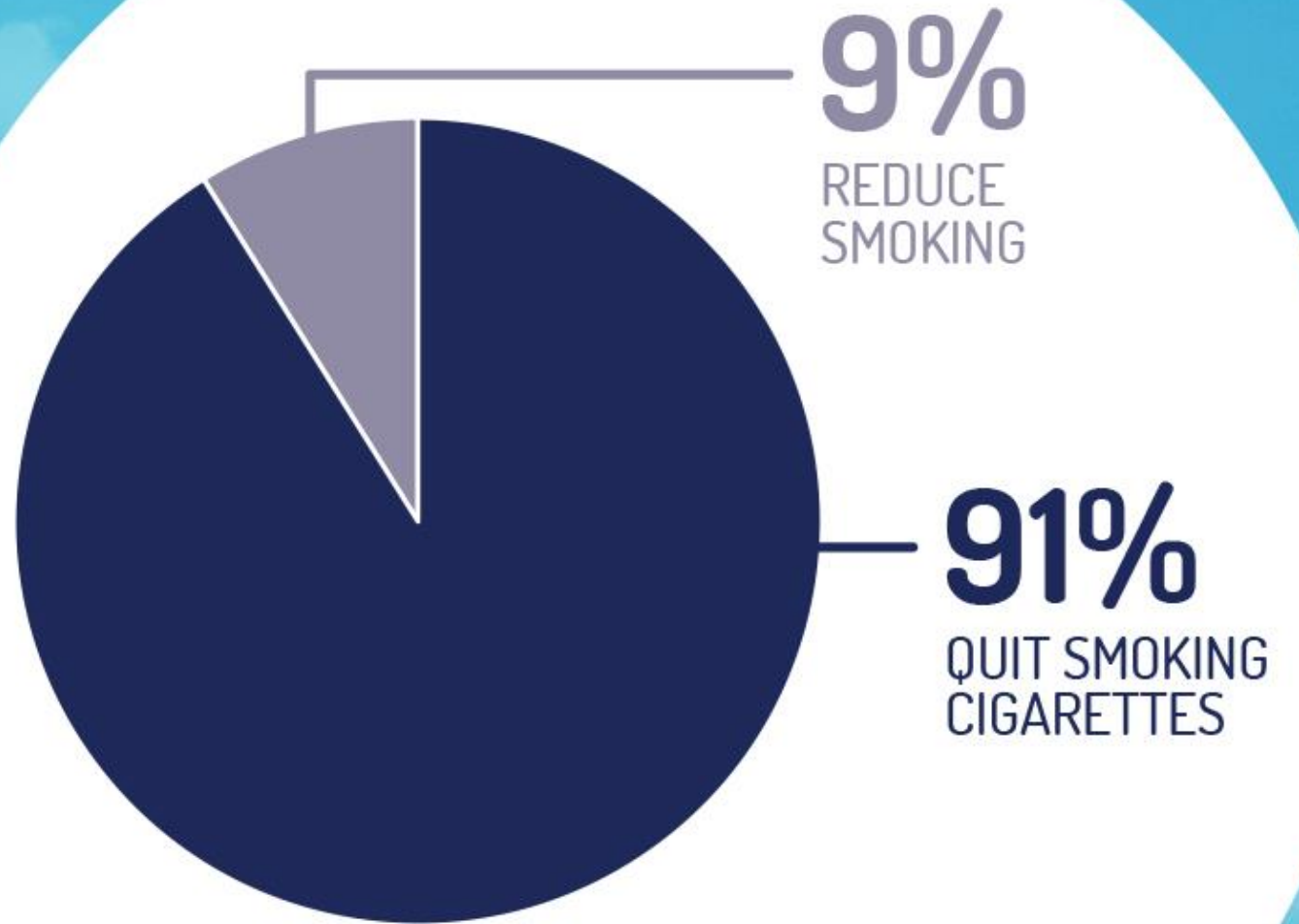


Flavor  
“Reset” =  
Unmitigated  
Disaster



# Quitters *with* Flavors

VAPING  
FLAVORED  
E-LIQUIDS  
HELPED  
ADULT  
SMOKERS



9,308 Sworn Declarations Submitted to FDA's ANPRM on Flavors

# These Were Long Time Smokers

VAPING FLAVORED  
E-LIQUIDS HELPED  
**ADULT  
SMOKERS  
QUIT**



**VTA**  
VAPOR TECHNOLOGY  
ASSOCIATION

NUMBER OF YEARS  
SMOKING CIGARETTES  
BEFORE SWITCHING  
TO VAPING

**490**

LESS THAN  
10 YEARS

**7932**

MORE THAN  
10 YEARS

9,308 Sworn Declarations Submitted to FDA's ANPRM on Flavors

# These Were Heavy Smokers

VAPING FLAVORED  
E-LIQUIDS HELPED  
**ADULT  
SMOKERS  
QUIT**

.....

**VTA**  
VAPOR TECHNOLOGY  
ASSOCIATION



9,308 Sworn Declarations Submitted to FDA's ANPRM on Flavors

# E-LIQUID FLAVORS USED MOST TO OFTEN QUIT SMOKING:



44.9%



34.1%



6.7%



4.7%



4.6%



2.9%



2.1%



FRUIT

DESSERTS

OTHER SWEETS

TOBACCO

MENTHOL / MINT

OTHER FLAVORS

BEVERAGES

Over 95% relied on non-tobacco flavors

# “Reset” Will Evaporate the New Industry

## TOTAL ECONOMIC IMPACT

THE GLOBAL E-CIGARETTE & VAPOR MARKET SIZE  
IS PROJECTED TO REACH \$47.1 BILLION BY 2025<sup>1</sup>



THE VAPOR INDUSTRY  
GENERATES  
**\$ 24,457,512,300**  
FOR THE UNITED STATES  
ECONOMY

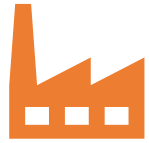
## TOTAL WAGES EARNED IN THE UNITED STATES



VAPOR BUSINESSES  
PAID OVER  
**\$ 7,897,889,500**  
IN WAGES AND BENEFITS TO  
THEIR EMPLOYEES



# TRADITIONAL TOBACCO DISTRIBUTION



Tobacco  
Manufacturing



Tobacco Wholesale



Tobacco  
Distribution



Retail

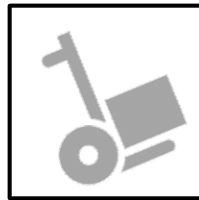
C-Stores  
Gas Stations  
Tobacco Outlets

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# NEW VAPOR DISTRIBUTION



E-Liquid  
Manufacturers



Vapor Wholesale



Vapor  
Distribution



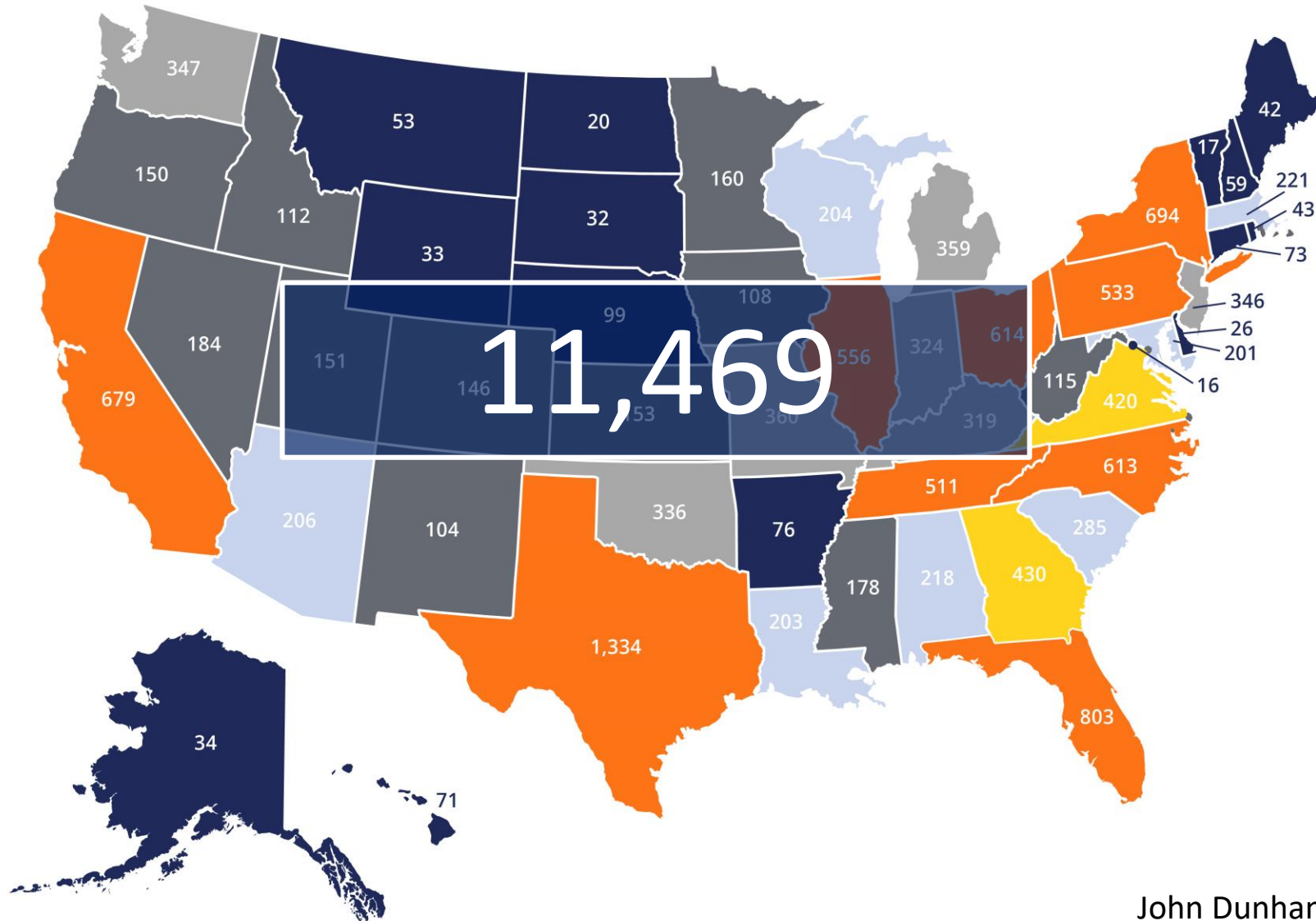
Retail

**VAPE SHOPS**

C-Stores  
Gas Stations

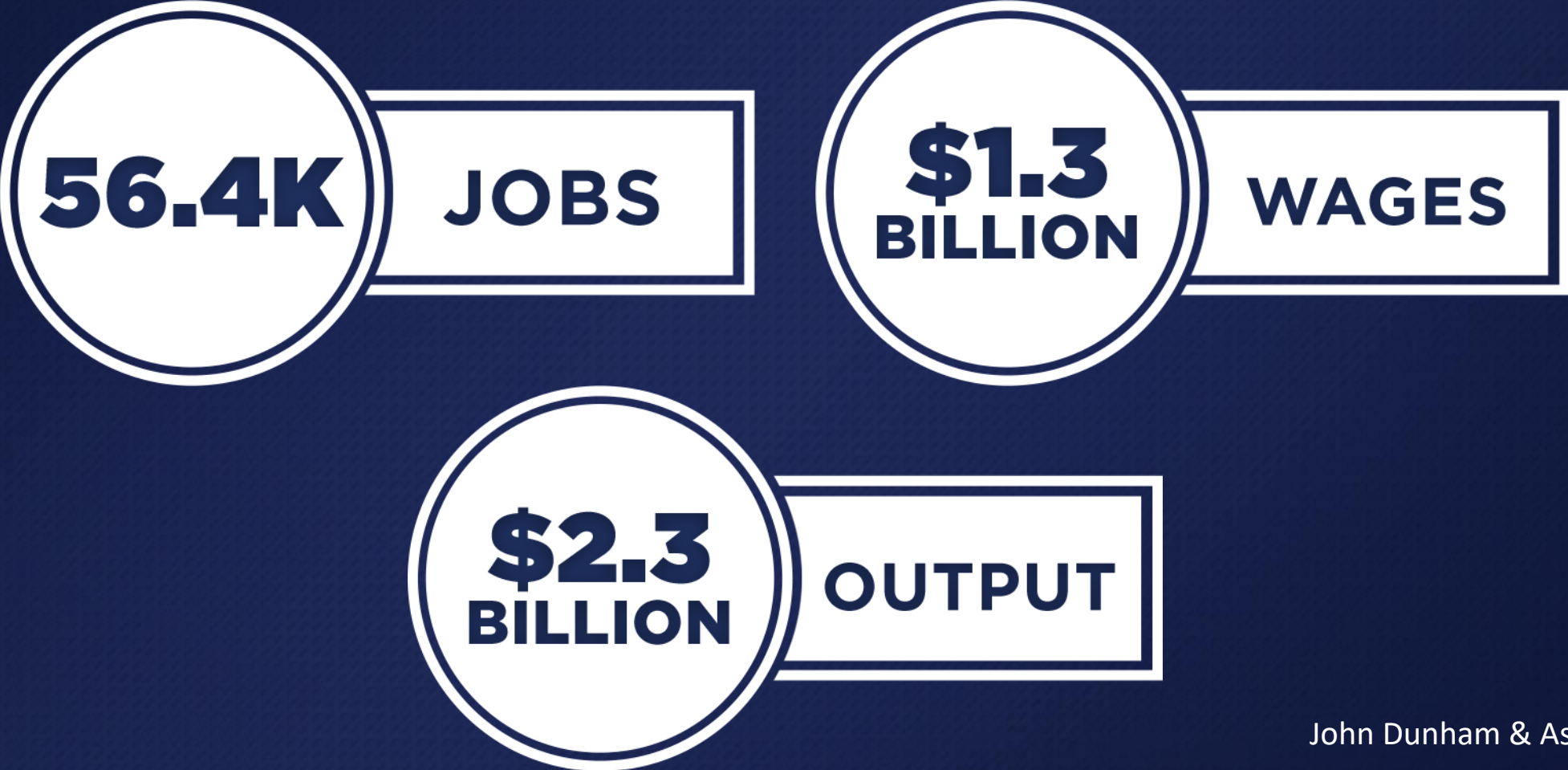
Vapor's Disruptive Distribution Chain

# VAPE SHOPS ACROSS THE COUNTRY



- 0-99
- 100-199
- 200-299
- 300-399
- 400-499
- 500+

# ECONOMIC IMPACT OF RETAIL VAPE SHOPS

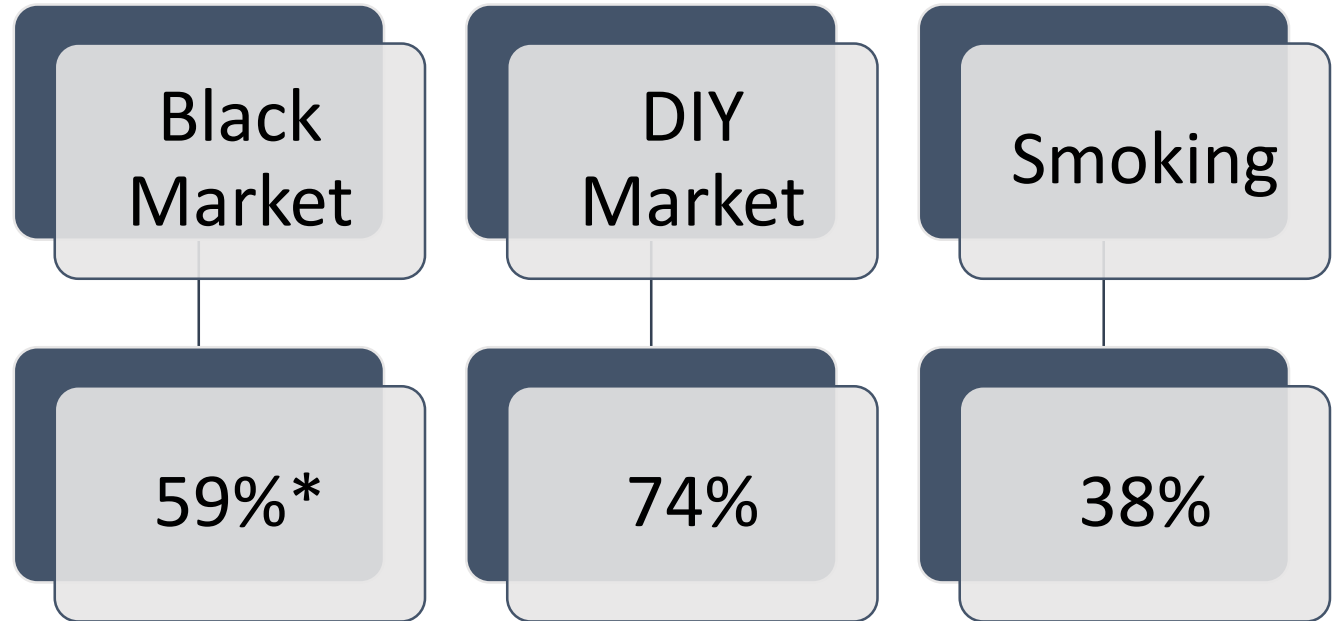




Why Vape Shops Are Important?

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Flavor Ban =  
Unmitigated  
Disaster for  
Current or  
Former  
Smokers



Based on 9,308 Sworn Declarations to FDA

Flavor  
“Reset” Will  
Be An  
Unmitigated  
Disaster

**“Dramatically and precipitously reducing availability of these products could 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, even if particular ENDS products ultimately receive marketing authorization and return to the market later.**

**“And, although there has been great recent progress in declining use of cigarettes for all age groups, I am concerned that these declines could be slowed or reversed in the case of very sudden and very dramatic reductions in availability.””**

CTP Director Mitch Zeller, June 11, 2019, USDC Maryland  
*AAP v. FDA*

**21 & DONE!**

**SEPTEMBER 25, 2019**

**VTA CALLS ON REGULATORS & LEGISLATORS TO IMPLEMENT:  
21 & DONE! A COMPREHENSIVE PLAN TO  
ADDRESS UNDERAGE USE OF E-CIGARETTES**

On September 25, 2019, the Vapor Technology Association (VTA) called on the Trump Administration, the Food & Drug Administration, the Federal Trade Commission and Congress to implement a comprehensive plan to ensure controlled distribution of all tobacco products, including e-cigarettes, and to impose real limits on access and appeal of all tobacco products to youth.

## 21 & DONE!

A REAL PLAN TO RAISE THE AGE &  
BE DONE WITH YOUTH ACCESS &  
BE DONE WITH YOUTH MARKETING

**TOBACCO 21**  
**RAISING THE AGE FROM 18 - 21**

- “The Tobacco to 21 Act takes bold and necessary action to reduce tobacco use among youth and young adults,” - ***Nancy Brown, CEO of the American Heart Association*** <https://bit.ly/2ZSnbR2>
- “As 95 percent of adult smokers start smoking before turning 21, this legislation will help prevent young people from using tobacco and save lives,” - ***Matthew L. Myers, President Campaign for Tobacco-Free Kids*** <https://bit.ly/2ZSnbR2>



## 21 & DONE!

**A REAL PLAN TO RAISE THE AGE &  
BE DONE WITH YOUTH ACCESS &  
BE DONE WITH YOUTH MARKETING**

## **IMPLEMENT 21 MARKETING RESTRICTIONS TO BAN....**

1. use of the terms “candy” or “candies,” “bubble gum,” “cotton candy,” “gummi bear,” “milkshake,” and “cake” or “cakes” or variants.
2. use of packaging, trade dress or trademarks that imitate those of food or other products primarily targeted to minors such as candy, cookies, juice boxes or soft drinks.
3. use of packaging that contains images of food products primarily targeted to minors such as juice boxes, soft drinks, soda pop, cereal, candy, or desserts.
4. print advertising except in adult-only publications or media (adults are >85% of audience).
5. advertising and/or sponsorship at stadiums, concerts, sporting or other public events that are not primarily targeted to adults (adults are >85% of audience)
6. offers of any school or college scholarships by any company selling tobacco products.
7. television advertising of any tobacco products, including any vapor products.

## 21 & DONE!

**A REAL PLAN TO RAISE THE AGE &  
BE DONE WITH YOUTH ACCESS &  
BE DONE WITH YOUTH MARKETING**

**IMPLEMENT 21  
MARKETING RESTRICTIONS TO  
BAN....**

8. packaging that imitates a product designed or intended primarily for minors.
9. use of cartoon characters.
10. use of superheroes.
11. use of any likeness to images, characters, or phrases that are known to appeal primarily to minors, such as “unicorn”.
12. references to video games, movies, videos, or animated television shows known to appeal primarily to minors.
13. advertising and marketing that makes any reference to the product as a smoking cessation device or as a product that may be used to quit smoking.
14. advertising and marketing that makes a claim of therapeutic value, as being safe or healthy for consumers, or as not producing secondhand health effects.

## 21 & DONE!

A REAL PLAN TO RAISE THE AGE &  
BE DONE WITH YOUTH ACCESS &  
BE DONE WITH YOUTH MARKETING

**IMPLEMENT 21  
MARKETING RESTRICTIONS TO  
BAN....**

15. advertising and marketing that makes uses modified risk descriptors or claims.
16. advertising that does not accurately represent ingredients.
- 17. use of health professionals** to market or otherwise endorse a tobacco product, directly or indirectly.
- 18. the use of contracted spokespeople** or individuals that do not appear to be **at least 25 years of age**.
19. advertising on **outdoor billboards near schools and playgrounds**.
20. sales of products without **warning labels** protecting youth such as “Sales to Minors Prohibited” or “Underage Sales Prohibited” and/or “Keep Out of Reach of Children”.
21. sales of products with advertising that is not accurate or is misleading.

## 21 & DONE!

A REAL PLAN TO RAISE THE AGE &  
BE DONE WITH YOUTH ACCESS &  
BE DONE WITH YOUTH MARKETING

## 9 DIRECT LIMITATIONS ON YOUTH ACCESS

1. **Ban Sales on Third-Party Marketplaces** like Alibaba, Amazon, eBay, et al.
2. **“Three Strikes and You’re Out”**: 3 violations in 3 years for selling to minors.
3. **Restrict Sale of “Super High Nicotine” Products** (>50 mg per ml) to Adult-Only Stores.
4. **Tax, Enforce & Educate.** Impose taxes and/or user fees to pay for education and enforcement by implementing a 3% *ad valorem* tax and/or user fees on vapor products instead of restricting flavors.
5. **Ban Self Service Displays.** Require all tobacco products, including vapor products, to be behind a counter or in a locked display and accessible only by an employee.
6. **Point of Sale Age Verification.** Third-party age verification software/technology for **all** sales.
7. **Brick & Mortar Warning Signs.** Tobacco product retailers must display signage indicating that (a) “Unaccompanied Minors Are Not Allowed on Premises” or (b) “Products are Not for Sale to Minors” or (c) “Underage Sale Prohibited.”
8. **End “Straw Man” Sellers.** Make it illegal for any person who is not a licensed tobacco product dealer to sell, barter for, or exchange any tobacco product.
9. **End Bulk Sales.** Prohibit the sale of >2 devices or >5 packages/bottles of e-liquids in one transaction.

# LOTS OF TOOLS TO KEEP VAPOR AWAY FROM YOUTH

- Marketing Restrictions
- Taxes
- Truthful Education Campaigns
- Stronger Enforcement
- Increasing Penalties on Retailers
- Penalizing Straw Purchasers
- Technology
- Major Companies Already Pulled Products
- Fed T21 – Biggest Hammer





38 Million Addicted  
U.S. Smokers

480,000 Deaths Per Year

SADLY, WE HAVE FEW TOOLS  
TO HELP ADULTS QUIT

- No Secret that FDA-Approved Products Fail Smokers
- Over Reaction on Flavors Will Harm Adults
  - Adults Need Diversity
  - Limiting Channel Access Unwise
- Flavors Can Be a Pathway Out
  - Adults & Youth
- Real Danger of Restricted Market Controlled by Large Companies Only

Thank You

**VTA**

VAPOR TECHNOLOGY  
ASSOCIATION



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