The Latest on Product Standards and Other Potential Regulatory Action

Tony Abboud, Executive Director, Vapor Technology Association
Mitchell A. Neuhauser, Vice President and Assistant General Counsel, RAI Services Company (RAISC)
James Vail, Director of Communications, 22nd Century Group, Inc.
Moderated by **Dean R. Cirotta**, President & COO, EAS Consulting Group, LLC

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Foundational Rules Are Coming!?

Mitch Neuhauser

VP & Assistant General Counsel – Regulatory

RAI Services Company

October 25, 2018

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Agenda

- Substantial Equivalence
- TPMP

Substantial Equivalence

In General. In this section and section 905(j), the term 'substantially equivalent' or 'substantial equivalence' means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product

(A) has the same characteristics as the predicate tobacco product; or

(B) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

What Does “Same” Mean?

- FDA Guidance/SCSE Phase
  - “Same” = Identical
  - “Different” covered any physical change between new product and predicate

What Does “Same” Mean?

- Guidance/SCSE Phase
- *Philip Morris USA, et al v. FDA* (2016)
  - Same ≠ Identical
    - Absence of the term “label” under Sec. 905
    - SE Exemption Pathway

What Does “Same” Mean?

- Guidance/SCSE Phase
- *Philip Morris USA, et al v. FDA* (2016)
- SE Exemption in Practice

SE Rule– Format and Content

“This proposed rule would establish the format and content of reports intended to demonstrate substantial equivalence (SE) in tobacco products and would provide information as to how the Agency will review and act on these submissions.”

So What Must an SE Rule Address – Format and Content

- Format and Content: Only Part of What's Needed
- Must Define Same and Different Characteristic Buckets
- When Does a Difference Exist?
  - Spell out variability tolerances
  - Whole product v. components
- Appellate Treatment of Provisional SE

TPMP

e. Good Manufacturing Practice Requirements

1. Methods, Facilities, and Controls to Conform

A. In General. In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter.

3. Compliance. Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

TPMP History

- Jan 2012 - 13 tobacco companies filed recommendation for GMP and preamble
- May, 2 2012 – FDA holds listening session
- FDA establishes docket for comments
- June 7, 2017 – industry files supplement to proposed TPMP to account for deemed product

TPMP – A Long Road Still

B. Requirements. The Secretary shall

1. before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

2. before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

3. provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A);

4. in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices; and

5. not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

A New Flavor Paradigm for ENDS

Tony Abboud

Executive Director

Vapor Technology Association

October 25, 2018

VTA VAPOR TECHNOLOGY ASSOCIATION FDLI

Topics

- Framing the Issue
- Flavors Essential to Cessation
- Dual Use
- Flavors Are Not Initiators
  - ENDS Not A Gateway
- Adult Perspective and Need
- ENDS Are Unique

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Focus. Continuum Is Relevant

- 95% Safer than Cigarettes
- Risk Continuum - Opposite END
  - ACS / RCP / PHE / FDA
- Uniqueness Demands Differential
  - No Tobacco, Combustion
  - Tobacco v. Flavor Dialectic False
  - Role in Cessation Too Important

Tobacco products are designed and intended to deliver nicotine to the user, but the toxicity associated with these products varies widely. **At one end is the conventional cigarette, which, when burned and inhaled, delivers more than 7000 chemicals to the user, including at least 70 carcinogens, and is designed to cause and sustain addiction to nicotine while killing one-half of all long-term users**. At the other end are medicinal nicotine products, which pose minimal risk and have been approved by FDA as safe and effective for tobacco cessation. Along the spectrum— and **closer to nicotine-replacement therapies than to combustible tobacco products—are current-generation ENDS, which are likely to be much less harmful than combustible tobacco products.**

(Douglas, et al., 2018)

Although many ENDS deliver nicotine, flavor additives, and other chemicals, they do not burn tobacco, a process that yields an estimated 7000 chemicals, including at least 70 carcinogens. Thus, public misunderstanding underscores the urgent need for consumer education about the absolute and relative risks posed by different tobacco products and to reinvigorate smokers' understanding of the importance of quitting combustible tobacco.

Whereas complete information on all the potential risks and benefits of ENDS is not yet available, there is sufficient information to allow ACS to act now with a clear focus on the primary goal of ending deadly combustible tobacco use, which is responsible for approximately a one-half million deaths per year and 30% of all cancer deaths in the United States.

(Douglas, et al., 2018)

Flavored ENDS & Cessation

- Adults Rely on Wide Variety of Flavors
- Science Says Flavors Help Smokers Quit
  - Longitudinal studies say more likely to reduce/quit
  - Survey data strongly support flavors/quitting
- Only ENDS can claim flavors aid quitting

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Is Dual-Use A Concern?

- FDA: Replacing all cigs with e-cigs is good.
- FDA already has endorsed dual use for NRTs.
- Pre-2013 NRT Label Changed:

"**Do not use** if you continue to smoke, chew tobacco, use snuff, or use [a different NRT product] or other nicotine containing products."

"**Stop smoking completely** when you begin using the [NRT product]."

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FDA Changed Position on Dual-Use

- Dual Use Warning Converted to Instructions:
  - Removes the “Stop Use” warning
  - Removes the “Quit” first warning
  - Encourages continued use even if relapse
  - Encourages use beyond recommended period

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Taking Youth Marketing Seriously

- VTA Marketing Standards
- Presented to FDA in January 2018
- Applauded FDA's May 2018 Letters
- Reiterated Guidance to Industry
- Established Marketing Hotline
- Advocated for Marketing Restrictions in Congress
- Dug In to Science in Our ANPRM

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Flavor Initiation Science Is Limited

- NYTS is “Not Enough”
- Multiple reasons for potential initiation
  - Flavors are NOT the top reason
  - Flavors just one reason; not in the top 3
- Primary focus is correlation / causation
- Must have access to data

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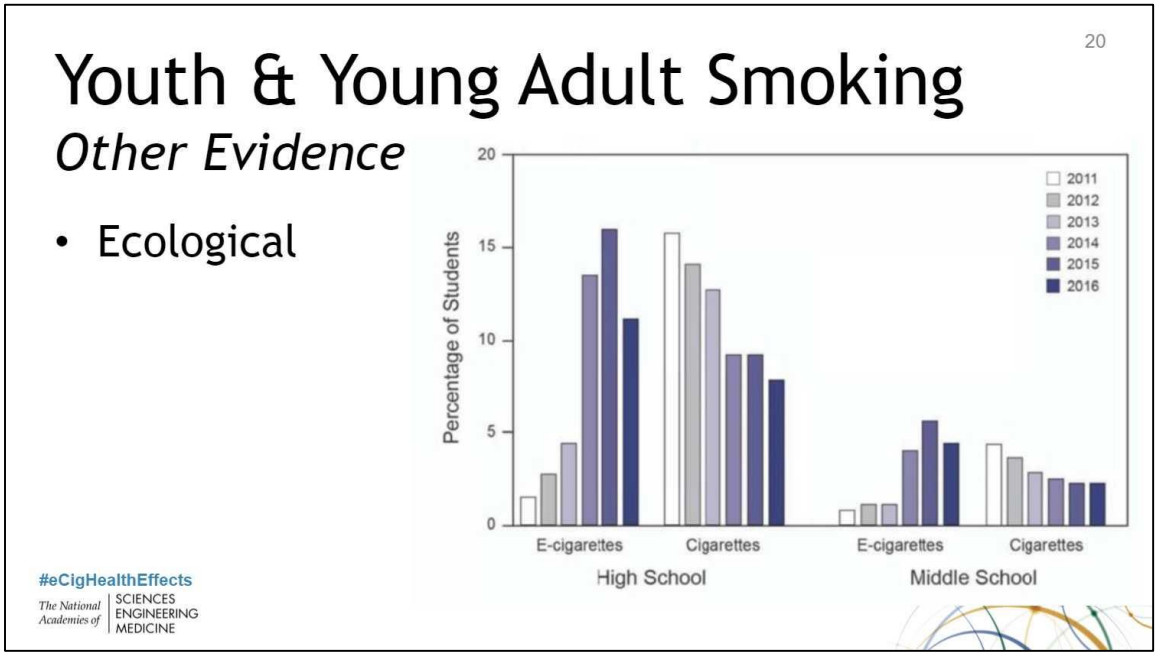
Core Issue: Gateway to Smoking?

- **Smoking** Rate Continues Decline…Despite Flavors
- Focus of most studies is on intent, not act



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“Hard to Argue There’s a Gateway”

“However, against that is **the enormous amount of ecological data that shows** – this is just an example that many of you are familiar with, you’ve probably seen it already today – **that at the same time that e-cigarette use went up very rapidly among adolescents in the U.S. that cigarette use was falling. Hard to argue that there is a gateway there.**”

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

Dr. Nancy Rigotti, Harvard University
Summarizing NASEM Findings
eCig Summit

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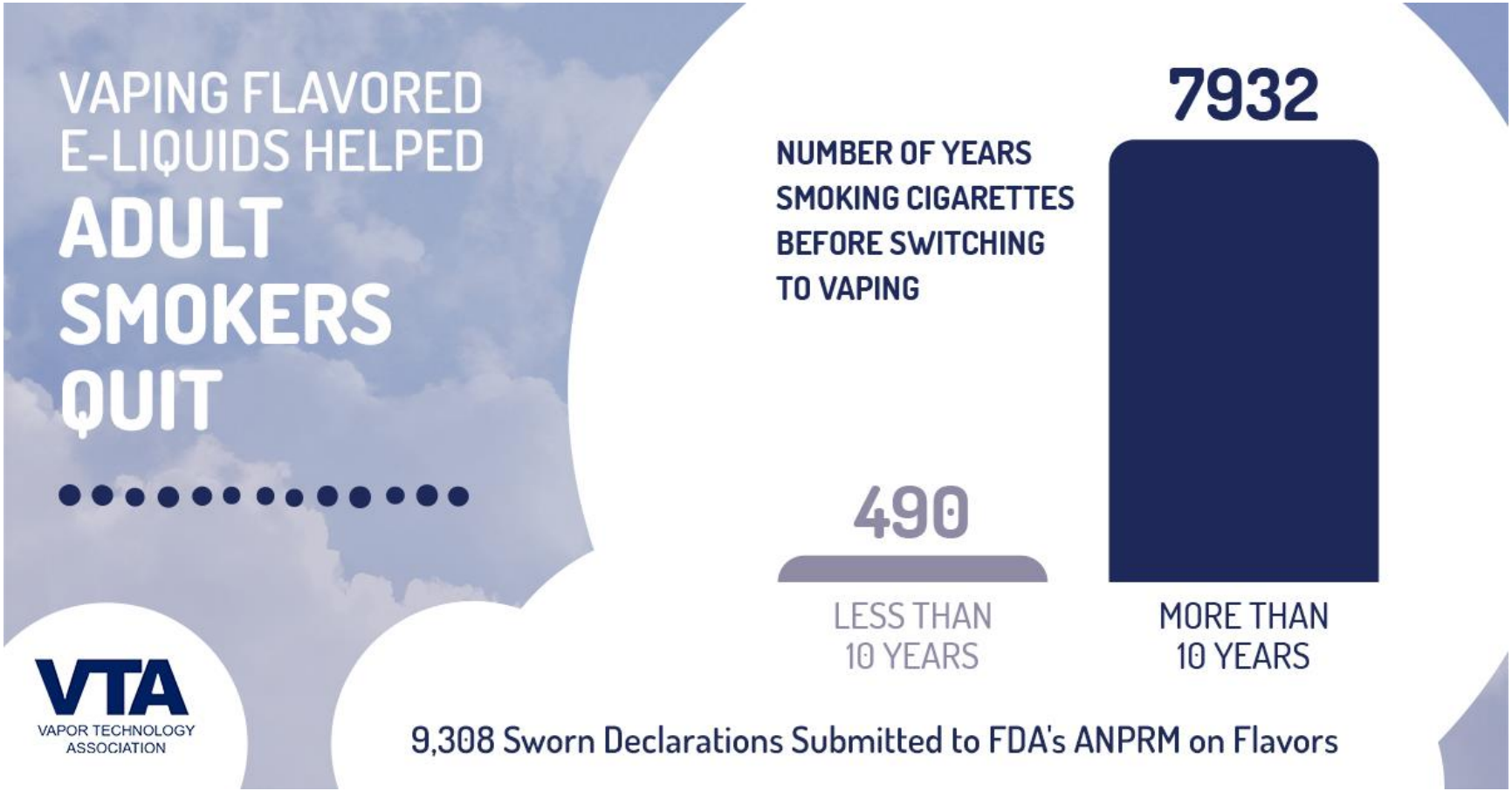
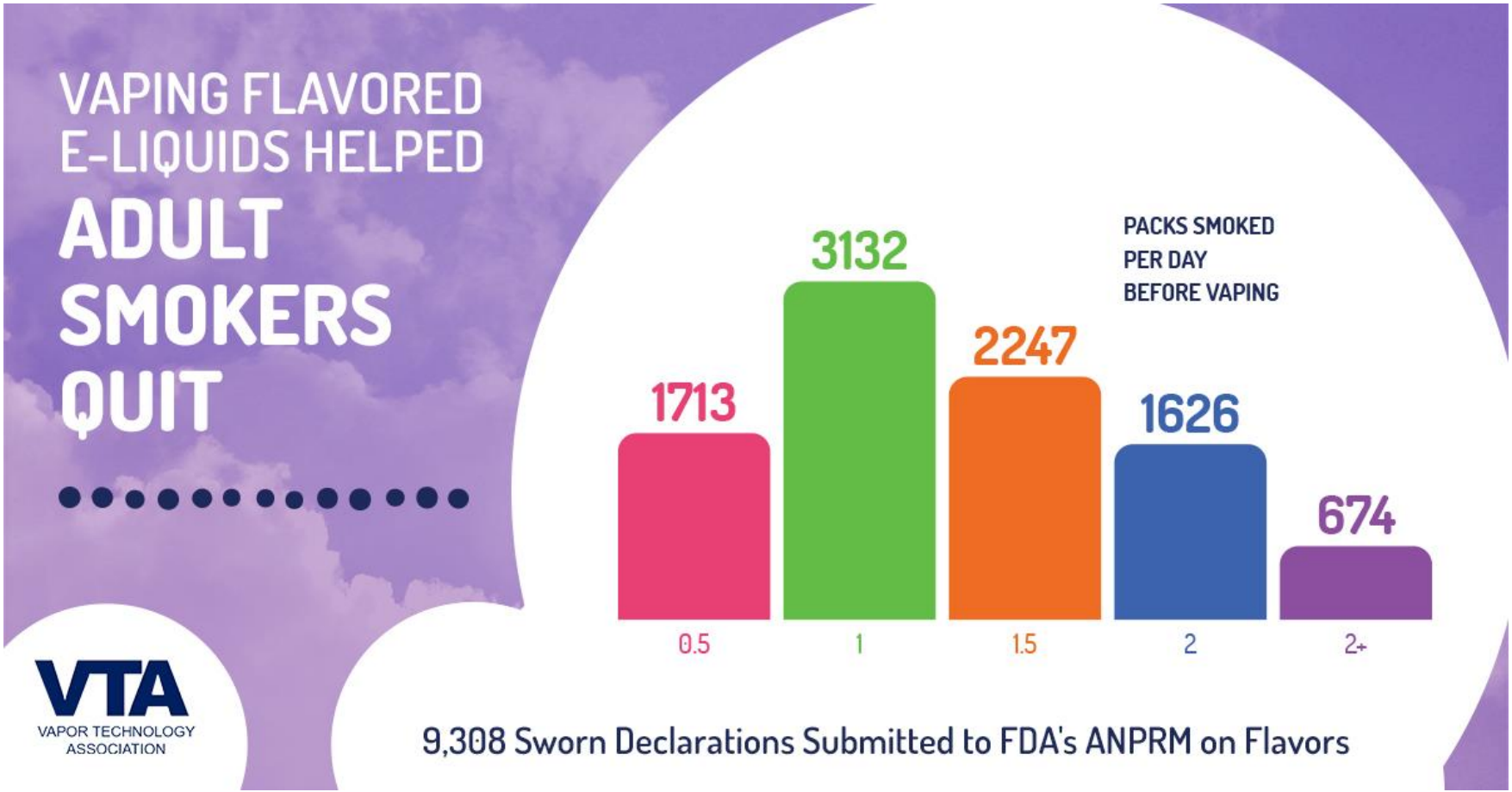
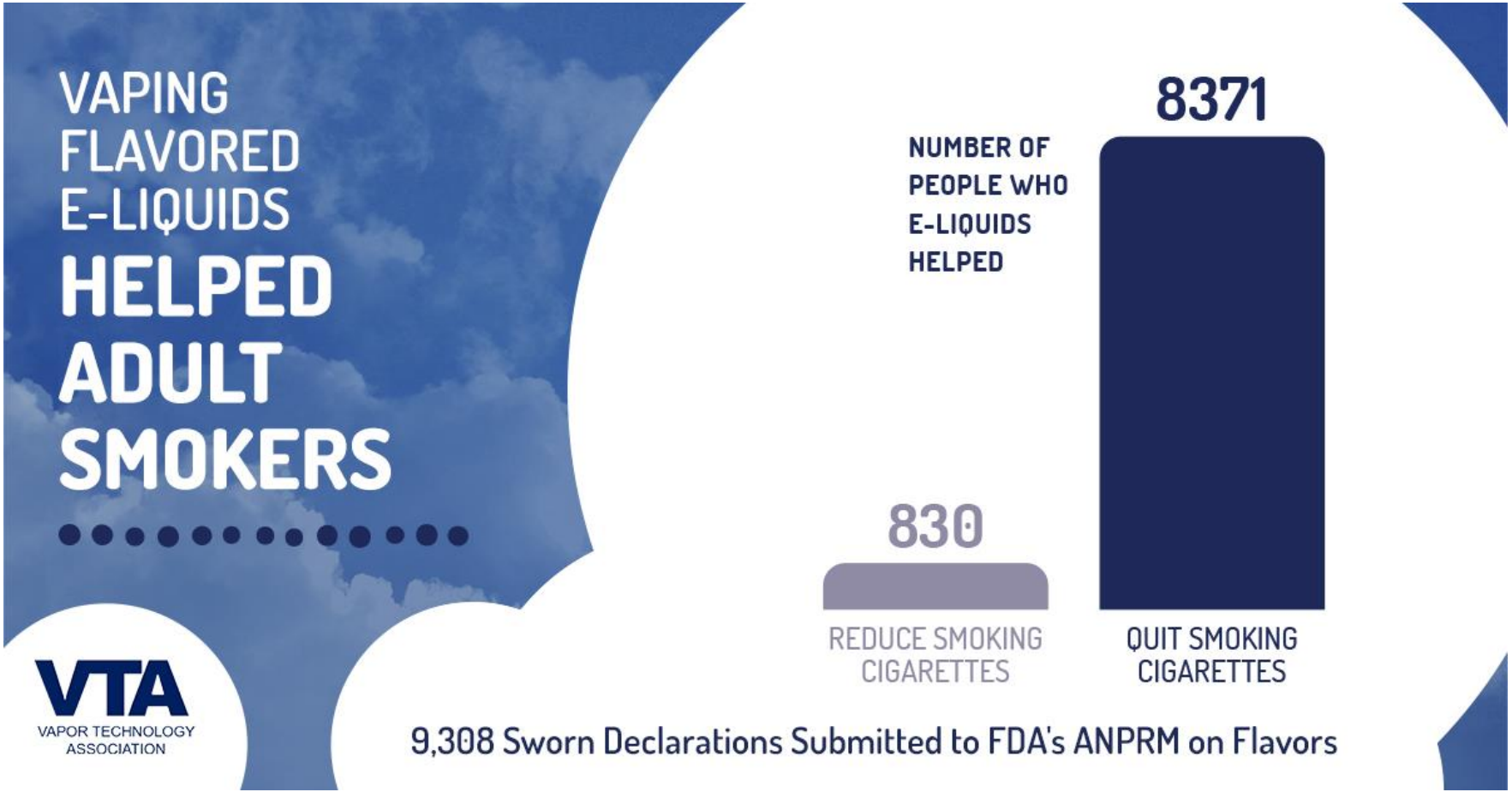
Entrenched Smokers - 1



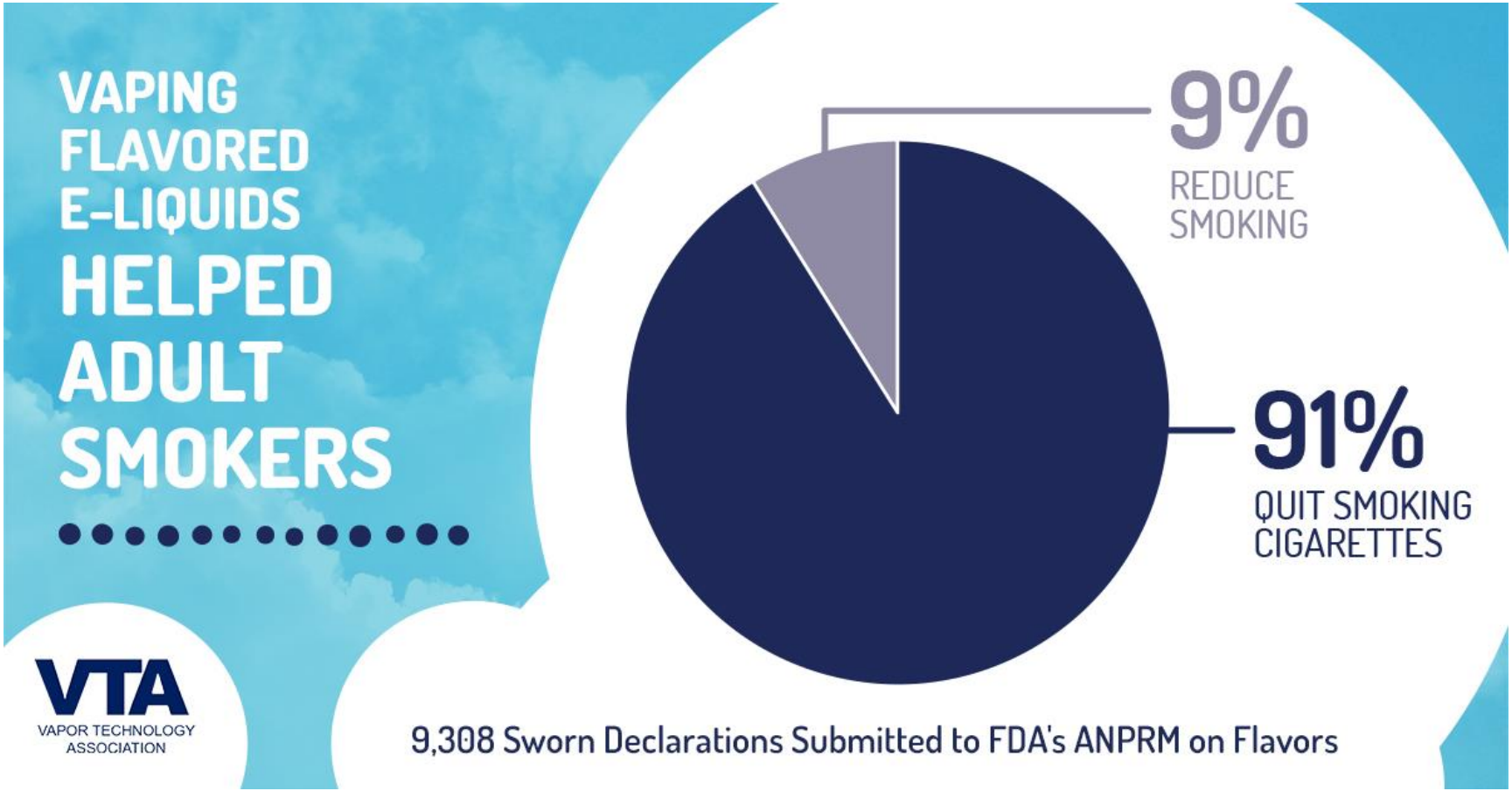
Entrenched Smokers - 2



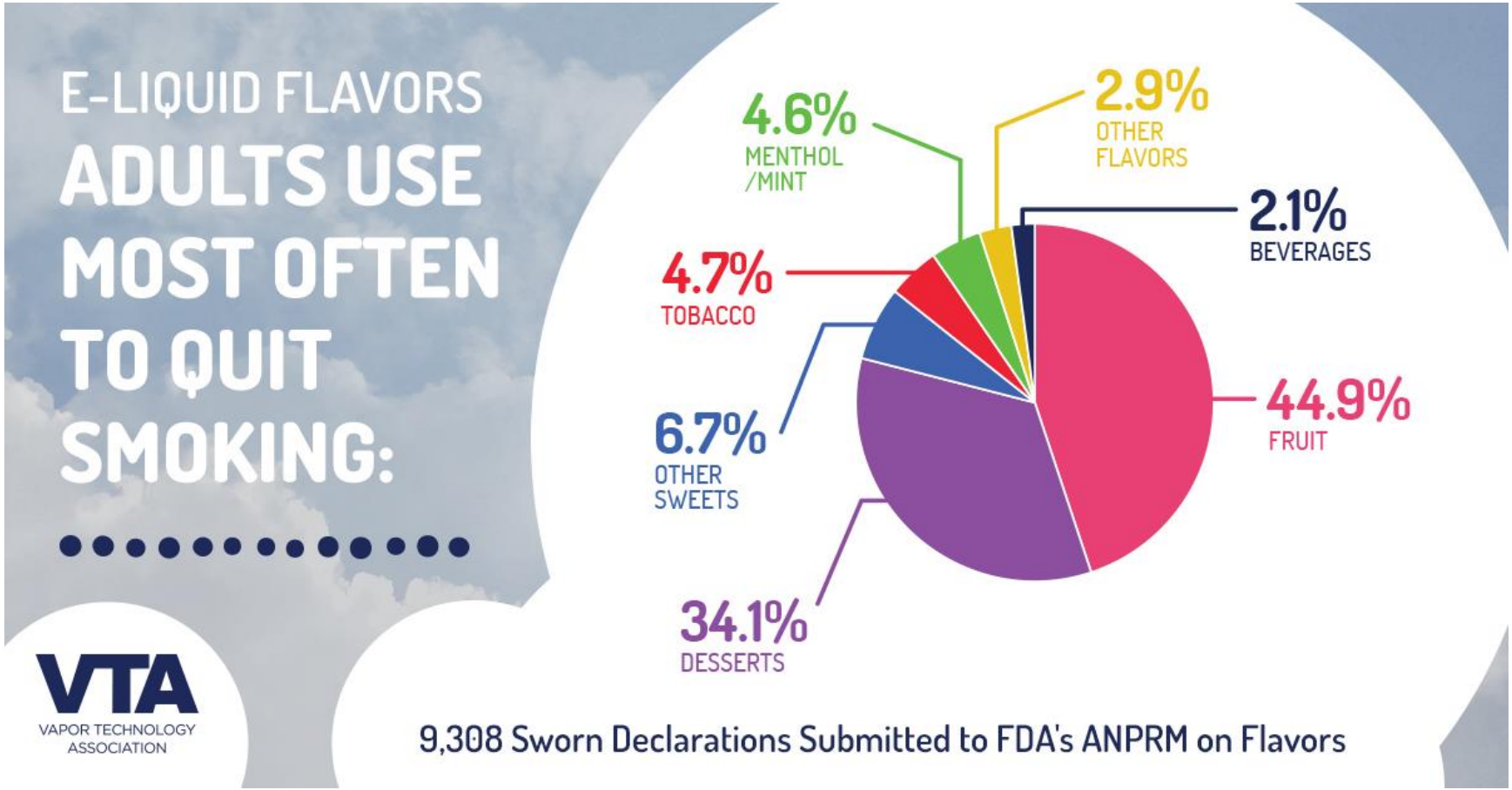
Reducers v. Quitters



Quitters with Flavors



Flavors Used Most Often to Quit



ENDS' Uniqueness

- Must Remember ENDS Place on Continuum
- The Tobacco v. Flavor Dialectic is False
  - ALL ENDS E-Liquids Are Flavored
- Danger: Putting Tobacco Flavor on a Pedestal
- Myriad Flavors Too Important
- Many Tools to Keep Products From Youth
- NO Effective Tools to Help Adults Quit

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VTA Response to Flavor ANPRM

Detailed Science, Analysis & Appendices

VTA Marketing Standards

www.vaportechnology.org

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The Latest on Product Standards and Other Potential Regulatory Action

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22nd Century Group, Inc.

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