


VAPE U
SIX PILLARS TO VAPE SPACE
SUCCESS



Welcome to VAPE U!



**Module V:
Dealing With the Law**



With Azim Chowdhury & Gregory Conley

Your Instructor: Azim Chowdhury, Esq.



- Specialist in food, drug, tobacco & e-vapor law.
- Spearheaded the FDA Tobacco and Electronic Cigarette practice at Keller and Heckman LLP.
- Represents e-cigarette and e-liquid manufacturers, suppliers and trade associations FDA regs & and corporate compliance.
- Speaker on “Deeming Regulation”

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**Your Instructor: Gregory Conley, Esq.
What You'll Learn Today**

- Governments -- Overview
- Threats Across the U.S.
- How to Fight Effectively
- Talking to Legislators
- Talking to the Media





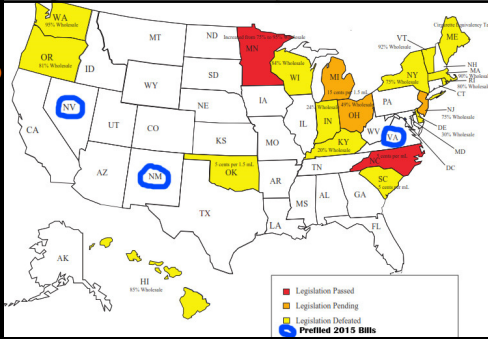
**Issues Facing The Sale & Use of Vapor
Products Today**

Gregory Conley, J.D., M.B.A.
President – American Vaping Association
Research Fellow – Heartland Institute
Twitter: @GregTHR / @AVABoard

State Legislation: Vapers & Retailers React



Attempts to Tax Vapor Products



Taxing Vapor Products – Why It’s a Bad Idea

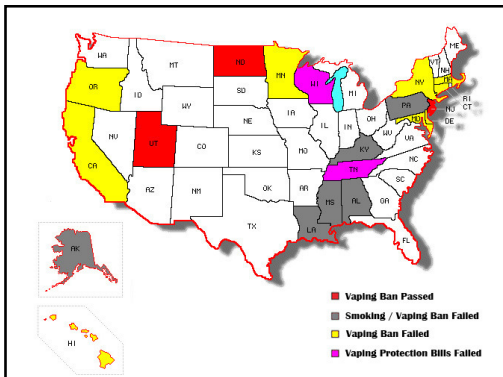
- Not science-based
- Discourages quitting
- Bad for businesses
- Cross-border sales
- Sends the wrong message
- Tobacco wholesaler system



“Taxes should be proportional to harms and should include ... no or minimal tax on e-cigarettes.”

- Dr. David Abrams, Schroeder Institute for Tobacco Research and Policy Studies at the Legacy Institute

State Attempts to Ban Usage



Active Consumer / Trade Organizations



Q and A



Twitter: @GregTHR / @AVABoard

What You'll Learn Today

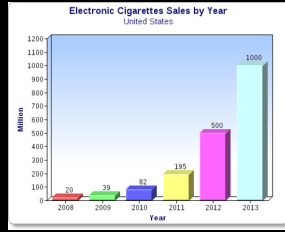
- History: The FDA then—and now
- Are e-cigarettes subject to FDA regulation?
- What are the “Deeming Regulations” and why you should care?



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The Growing E-Cig Market in the U.S.

- The last 5 years and future predictions
- Impacted of Federal and State regulations
- Without FDA guidance, states and local governments are imposing restricting.

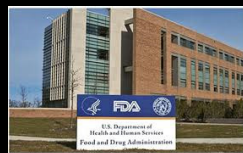


Proliferation of Vape Shops



U.S. Food and Drug Administration Overview

- Within U.S. Department of Health and Human Services
- FDA is responsible for the safety :
 - Human and animal drugs, Biological products, Medical devices
 - Food (including dietary supplements)
 - Cosmetics
 - **Tobacco**



Electronic Cigarettes: Are they subject to FDA Regulation?

- The Tobacco Control Act (2009) regulates **tobacco products** for public health.
- What is a “**tobacco product**”? Defined as “*anything made or derived from tobacco intended for human consumption, including any component, part or accessory of a tobacco product.*” **But...**



What Is “Tobacco?”

- The TCA gives FDA authority over:
 - Cigarettes
 - Cigarette tobacco
 - Smokeless tobacco
 - Roll-your-own tobacco
- **Not included:** other tobacco products, i.e., e-cigarettes, cigars, pipe tobacco, hookah, etc.



Deeming??



- FDA may “deem” other tobacco products to be *regulated* products subject to FDA’s authority under the Tobacco Control Act.
- Are they **drug delivery devices**?

A Quick History

- The 2008 Chinese imports
- *Drugs and medical devices* need FDA premarket approval, and products were seized
- E-cig companies sue and claimed that they were not drug delivery devices, but tobacco products



The Nicotine" Question

Remember the tobacco product definition



And the Judge Said...



Vs.



See *Sottera Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010)

The Aftermath

- 2011
- 2014
- Public comments (135,000)
- Office of Management and Budget approval
- Federal Register
- Process may take **1-2 years**; FDA may take "final action" shortly.



Possible Outcomes

- Subject to the **same requirements** that currently apply to tobacco products
- Unregulated tobacco products, (but not accessories) subject to FDA regulation
- **"Components and parts"** subject to regulation, but not accessories



What is Affected and What is Not?

- Nicotine-containing e-liquid?
- Hardware parts?
- Atomizer/cartomizers, tanks, cartridges, etc.



Likely "For Sure" Outcomes

- WARNING!
- Youth Sales
- Vending Machine Sales
- Free Samples
- Unauthorized Modified Risk Claims



The Feb 15, 2007 Question

- A "new" tobacco product is any product that was not marketed as of the "Grandfather Date."
- What are the premarket pathways?
- FDA said it does **not** believe it has the legal authority to change that date



Do Not Hold Your Breath

DELAYS
EXPECTED

Not in the Deeming Regulation?

- Flavors
- Internet sales
- Marketing and advertising toward youth



Q and A



This was an overview. More comprehensive presentation available on request)

Legal Packages Available

- Three programs, Bronze, Gold or Platinum
- Do you have your own e-liquids or wish to create them?
- Contact us for your VAPE U discount!
- <http://vapementors.com/programs/legal-packages>



Vape Shop of the Month

- Get profiled on Vape Radio
- Get profiled in Vape Magazine
- 12 month program to launch or grow you
- Contact us for your VAPE U discount!



Next Class: Social Media & PR

➤ Your instructor: Ray Yang