

Ideas. Experience. Practical answers.

**VAPING 2019: LEGAL AND REGULATORY FRAMEWORK** 

AND RESPONSES TO TWO EPIDEMICS

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# **Terminology and Products**

Electronic Smoking Device—ESD (Maryland statutes)

Electronic Nicotine Delivery System—ENDS (Federal regulations)

Electronic cigarette or e-cigarette (CDC)

Closed system v. Tank system

And JUUL . . .



# 2018 National Youth Tobacco Survey Data (released 2019)

20.8% of high school students reported ESD use (up from 11.7% in 2017)

4.5% of middle school students reported ESD use (up from 3.3% in 2017)

#### Of student users:

- » 28% used 20 or more days (up from 20%)
- » 68% used flavored ESD (up from 61%)

## 3.6 MILLION youth use ESD

Now the most commonly used tobacco product by youth.

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# Federal Tobacco Laws and Vape

- The Tobacco Control Act (2009) granted FDA authority over the manufacture, marketing and sale of tobacco products.
- The Act directly regulates cigarettes, cigarette tobacco, rollyour-own tobacco, and smokeless tobacco.
- FDA authorized to "deem" any "product made or derived from tobacco that is intended for human use" as a tobacco product and subject to all or part of the Act.
- On August 8, 2016 "deemed" anything meeting the statutory definition of a tobacco product, including e-cigarettes as subject to the Tobacco Control Act...



### "Deeming" Rule on Vape Products

### Retailers

Ban sale to minors

Must check ID (under age 27)

Ban on vending machine sales

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# "Deeming" Rule and Vape Products

### Vape Product Manufacturers

Register with FDA and provide product listings

Report ingredients and harmful/potentially harmful constituents

Place health warnings on packages and ads

Child resistant packaging

Not sell tobacco products that make modified risk or cessation claims (unless approved by FDA)

And...



### **Pre-Market Tobacco Product Applications**

Deeming Rule also imposed:

Pre-market review and market authorization of products entering market after February 15, 2007

Deadline has changed several times:

- $^{\circ}$  Deeming said August 8, 2018 and products could stay on the market for 12 months after application filed.
- $^{\circ}~$  2017 Agency changed to August 8, 2022 and products could stay on the market until application rejected or affirmative order issued.
- 2018 Agency changed to August 8, 2021.
- 2019 Court Ordered May 11, 2020 (12 months on market, or longer if Agency close to determination)—must address flavors!

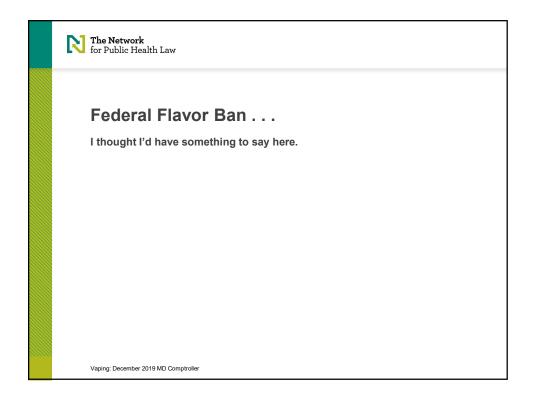
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#### **Public Health Standard for PMTA**

FDA must deny a PMTA where it finds "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health."







### **State Flavor Bans/Proposals**

Michigan, New York, Rhode Island, Washington, Oregon, Montana: Banned flavored vape products, by emergency declaration/executive order, temporary in nature

Massachusetts: ALL vapes (done as executive order but pending legislation now)

Several local jurisdictions around the country have banned flavors; SF bans all vape products (eff. 1/1/2020—just survived election challenge); lots under consideration now. . .

Why????

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Current Outbreak of Lung Illness or NYTS Data? According to the CDC as of 10/29/19 11/20/2019:

- \* 1888 2,290 confirmed or probable cases across 49 states, DC, PR, USVI (not AK)
- 37 47 deaths across 25 states
- Most patients reporting vaping nicotine and THC; some only nicotine.

Recall NYTS data came out late summer as well, showing massive spike in youth vaping.



### **CDC Recommendations**

https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html

Easier to link to this than to try to keep it current!

Recent focus clearly on the THC cartridges and Vitamin E Acetate.

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### Questions?

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