Attorneys supporting tobacco control policy change.
Presenters

Kurt M. Ribisl, Ph.D.
*Gillings School of Global Public Health at the University of North Carolina at Chapel Hill*

Susan Morrison, M.Ed.
*New Hampshire Division of Public Health Services*

Desmond Jenson, J.D.
*Tobacco Control Legal Consortium of the Public Health Law Center*
Agenda

- Update on the published research related to vape shops
- Introduce a new standardized assessment tool for vape shops
- New Hampshire vape shop case study
- Options for regulating vape shops in light of FDA’s deeming regulation
- Q & A
Presenter: Kurt M. Ribisl, PhD

1. Overview of Vape Shop Systematic Review
2. vSTARS Assessment
Acknowledgements

Funding for this webinar was provided by SIP 14-029, CounterTobacco.org, Disseminating Point of Sale Resources from the CDC’s Office of Smoking and Health.

vSTARS

Funding for this study was provided by grant number U01 CA154281 from the National Cancer Institute's State and Community Tobacco Control Initiative. The funders had no involvement in the study design, collection, analysis, writing, or interpretation.
Systematic Review of Vape Shops

KURT M. RIBISL, PHD
JOSEPH G. L. LEE, PHD, MPH
ELIZABETH ORLAN
KERRY SEWELL, MSLS
Searches for vape shops
Research questions

What are the methods used to find, enumerate, or map vape shops?

What are the sales and marketing practices of vape shops (4 P’s)?

What are the attitudes and beliefs of vape shop owners and clerks relating to their products and marketing?
Systematic Review Criteria

Eligible:

- Studies of retailers selling ENDS, vaping devices, or e-liquids/juice as a primary tobacco product.

Not eligible:

- Studies about retailers who do not sell ENDS as a main product (e.g. convenience stores, grocery stores, and tobacco shops).

Purpose:

- Identification of ENDS retailers
- Sales and marketing practices of retailers
- Disparities by neighborhood characteristics in ENDS marketing at ENDS retailers.

Time:

- Search period --> January 2010-June 2016
- Studies about users of ENDS
- Studies before 2010
Records imported from searches (N=9284)
ECONLit (n=16)
EMBASE (n=2154)
Entrepreneurship (ProQuest) (n=266)
PsycINFO (n=462)
PubMed/MEDLINE (n=1651)
Scopus (n=3390)
ABI/INFORM (n=1345)

Duplicates removed (n=6407)

Records after de-duplication (n=2877)

Title/abstract screened (n=2877)

Records excluded as not relevant (n=2856)

Full text screened (n=21)

Records excluded (n=9)
No vape shop specific data (n=8)
Not empirical (n=1)

Records included (n=12)
Vape shop articles included in our study

- 10 articles - USA
- 1 article - Canada
- 1 article - South Korea
Studies included in systematic review

What are methods used to find, enumerate, or map vape shops?
- Dai, 2016
- Giovenco, 2016
- Kim, 2016
- Sussman, 2014

What are the sales and marketing practices of vape shops?
- Buettner-Schmidt, 2016
- Cheney, 2015
- Hammond, 2015
- Kim, 2015

What are the attitudes and beliefs of vape shop owners and clerks relating to their products and marketing?
- Allem, 2015
- Basch, 2016
- Cheney, 2016
- Nayak, 2016
Rise of vape shops

2013:
“There are more than 3,500 independent vape shops around the country, according to Aaron LoCascio, chief executive officer of Vape World, a distributor based in Boca Raton, Fla.”

(Klein, K. “Healthy Markups on E-Cigarettes Turn Vacant Storefronts Into ‘Vape Shops”. Bloomberg.)

2014:
“There are no reliable sales estimates for vape shops…the Smoke-Free Alternatives Trade Association, an industry group, estimates the number of vape shops has more than tripled to 35,000 in the past year.”

(Estrel M. “Big Tobacco’s E-Cigarette Push Gets a Reality Check”. The Wall Street Journal.)

2015:
“We identified 9,945 vape shops in the USA as of December 2015, a nearly threefold increase from 2013.”

(Dai & Hao. “Geographic density and proximity of vape shops to colleges in the USA”. Tobacco Control.)
Ways to identify vape shops for research

- Yelp
- Google Maps
- Whitepages
- Yellow Pages
- Ground-truthing
- Licensing lists
- VaporSearchUSA

The Vapor Girl
Mapping

Higher vape shop density in areas with high tobacco retailer density, fewer African Americans, Hispanics, & lower income (Giovenco, 2016)

66.5% of colleges had 1 vape shop within 3-mile radius (Dai, 2016)

Giovenco, 2016
Sales and Marketing Practices

Marketing

- Small budget → alternative strategies (Cheney, 2015)
  - Large signs
  - Wrapping vehicle
  - Giveaways
  - Fliers

- Punch cards for customer loyalty (Cheney, 2015)
Owners’ Beliefs and Attitudes

“24% believed e-cigarettes were completely safe” n=78 retailers in LA (Allem, 2015)

“Owner perceptions of health benefits and safety may also have been influenced by customers who reported that their physician sent them to the vapor store.” (Cheney, 2015)

“Multiple participants also described their products as ‘kosher’ and containing FDA approved ingredients. Owners reasoned that a safe food was a safe vape.” (Cheney, 2015)

“Most owners said their health had improved after substituting vaping for smoking.” (Nayak, 2015)
Products

51% of nicotine solutions (n=93) in ND had mislabeled nicotine concentrations ranging from -66% to +172% (Buettner-Schmidt, 2016)
- 34% contained less nicotine
- 17% contained more nicotine

In South Korea, a study showed labeling discrepancies ranging between -32.2% to +3.3% (Kim, 2015)
Researchers are using a wide variety of search strategies to find vape shops (Yelp*).

Vape shop owners use low cost options to market their stores and products, many of which parallel tobacco marketing.

Vape shop owners are largely users themselves and believe that e-cigs are a low-risk product.

The number of vape stores has been rising, but FDA regulation may affect future growth.
vSTARS Acknowledgments

**Scientific Collaborators**

Dianne Barker  
Todd Rogers  
Lisa Henriksen  
Kurt M. Ribisl  
Brett Loomis

**Pilot Sites**

**Chicago:** Lainie Sanker, Emily Zadikoff, & team  
**Minnesota:** Cassandra Stepan, Pa Khang, & team  
**New Hampshire:** Susan Morrison, Donna Asbury, Kristine Lindell, & team  
**NC & SC:** Jessica Eaddy, Susan Cavender & team  
**Oklahoma City:** Neil Molina & Leslie Driskill  
**Texas:** Ewald & Wasserman Research Consultants, LLC

Funded by grant number U01 CA154281 from the National Cancer Institute at the National Institutes of Health
STARS: Standardized Tobacco Assessment for Retail Settings

**Measures:** products, flavors, and placement; marketing; prices and promotions

**Inform policy:** not enforcement or compliance

**Target Audience:** state and local tobacco control practitioners

**User friendly:** completed by self-trained youth and adults; 10 minutes

**Purpose:** help advance policy change
97% of users want questions addressing vape shops and electronic smoking products
Store Policies: Age to enter
Store Policies: Age to enter

9. Exterior sign stating policy regarding minors entering the store?
   - [ ] Minimum age must be 18 or older to enter
   - [ ] Minimum age must be 19 or older to enter
   - [ ] Minimum age must be 21 or older to enter
   - [ ] No minimum age posted to enter
Psychoactive substances sold
10. Does the store sell...
   a. Alcoholic beverages?
      - Yes
      - No
   b. Cannabis / Marijuana?
      - Yes
      - No
   c. Whipped cream chargers or dispensers (used for whippets)?
      - Yes
      - No
   d. Other psychoactive substances (e.g., kratom, K2 “spice”, synthetic cannabinoids such as “herbal incense” or “Scooby Snax”, salvia)?
      - Yes
      - No
Vaping systems
Types of e-liquids
## Types of e-liquids

### 13. E-liquids/juices

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Are e-liquids/juices sold?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>b. Candy/fruit flavored?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>c. Flavor of alcoholic drinks?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>d. Menthol/mint flavored?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>e. Nicotine-free?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>f. Contains THC?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>g. Contains CBD?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>h. Contains caffeine?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>i. Displayed in self-service display?</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
</tbody>
</table>
Vaping claims: vaping > smoking

**Safer**

“If the health risk associated with tobacco smoking is equal to 100, vaping health risk is 4.
THE CHOICE IS YOURS”
- Prof. Polosa

**Cheaper**

**Cessation**

COST OF VAPING VS COST OF SMOKING
FOR AN AVERAGE VAPER AND AN AVERAGE SMOKER

- **AVERAGE VAPER**
  - $112.70 per month
- **AVERAGE SMOKER**
  - $291.01 per month

OLYMPIA VAPOR WORKS
Vaping claims: vaping > smoking

<table>
<thead>
<tr>
<th>Safer</th>
<th>Cheaper</th>
<th>Cessation</th>
</tr>
</thead>
</table>

**MESSAGING**

18. One or more sign(s) posted inside the store/kiosk that...

<table>
<thead>
<tr>
<th></th>
<th>a. Suggest vaping is safer than cigarettes (including customer testimonials)?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>b. Promote vaping as a way to quit smoking cigarettes (including customer testimonials)?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>c. Promote vaping as a cheaper alternative to conventional cigarettes?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Customer Loyalty Programs

e. Promote a customer loyalty program?  
   - Yes
   - No
Mixing e-liquids

23. Ask clerk at the end of the survey:
   a. “Can store staff make e-liquids (mix propylene glycol, and/or vegetable glycerin, flavors, and/or nicotine) on-site?”
      ☐ 1  Yes
      ☐ 0  No
      ☐ 9  Refused to answer

   b. “Does the store allow customers/staff to mix e-liquids on-site?”
      ☐ 1  Yes
      ☐ 0  No
      ☐ 9  Refused to answer
Presenter: Susan Morrison, M.Ed.

NH Tobacco Prevention and Cessation Program

Susan.Morrison@dhhs.nh.gov
603-271-6684
Case Study: New Hampshire

- Request: Tobacco Free NH Network
- Searched: current data, requirements, shop locations & survey tools
- Located: 80 vape shops statewide
- Set Plan: partner with UNC & CounterTobacco.org
  - Pilot new vSTARS tool statewide
  - Visited 75 shops
  - Completed 55 surveys
New Hampshire Vape Shop Locations

- = Vape Shop

Total = 80
as of February 2016

<table>
<thead>
<tr>
<th>Town</th>
<th>Store Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auburn</td>
<td>1</td>
</tr>
<tr>
<td>Berlin</td>
<td>1</td>
</tr>
<tr>
<td>Brookline</td>
<td>1</td>
</tr>
<tr>
<td>Concord</td>
<td>6</td>
</tr>
<tr>
<td>Conway</td>
<td>3</td>
</tr>
<tr>
<td>Derry</td>
<td>1</td>
</tr>
<tr>
<td>Dover</td>
<td>2</td>
</tr>
<tr>
<td>Durham</td>
<td>1</td>
</tr>
<tr>
<td>Epping</td>
<td>1</td>
</tr>
<tr>
<td>Epsom</td>
<td>1</td>
</tr>
<tr>
<td>Franklin</td>
<td>1</td>
</tr>
<tr>
<td>Hampton</td>
<td>1</td>
</tr>
<tr>
<td>Hillsborough</td>
<td>1</td>
</tr>
<tr>
<td>Hooksett</td>
<td>3</td>
</tr>
<tr>
<td>Hudson</td>
<td>1</td>
</tr>
<tr>
<td>Jaffrey</td>
<td>1</td>
</tr>
<tr>
<td>Keene</td>
<td>1</td>
</tr>
<tr>
<td>Laconia</td>
<td>3</td>
</tr>
<tr>
<td>Lebanon</td>
<td>3</td>
</tr>
<tr>
<td>Lincoln</td>
<td>1</td>
</tr>
<tr>
<td>Londonderry</td>
<td>1</td>
</tr>
<tr>
<td>Manchester</td>
<td>12</td>
</tr>
<tr>
<td>Merrimack</td>
<td>1</td>
</tr>
<tr>
<td>Milford</td>
<td>2</td>
</tr>
<tr>
<td>Nashua</td>
<td>5</td>
</tr>
<tr>
<td>New London</td>
<td>1</td>
</tr>
<tr>
<td>Newington</td>
<td>1</td>
</tr>
<tr>
<td>Ossipee</td>
<td>2</td>
</tr>
<tr>
<td>Plaistow</td>
<td>5</td>
</tr>
<tr>
<td>Plymouth</td>
<td>2</td>
</tr>
<tr>
<td>Portsmouth</td>
<td>3</td>
</tr>
<tr>
<td>Rochester</td>
<td>1</td>
</tr>
<tr>
<td>Salem</td>
<td>7</td>
</tr>
<tr>
<td>Seabrook</td>
<td>1</td>
</tr>
<tr>
<td>Somersworth</td>
<td>1</td>
</tr>
<tr>
<td>Tilton</td>
<td>1</td>
</tr>
</tbody>
</table>
## NH: Availability of E-Cigarettes

<table>
<thead>
<tr>
<th>E-cigarette Type</th>
<th>No. of stores</th>
<th>% of Stores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modifiable/rebuildable</td>
<td>50</td>
<td>92.6</td>
</tr>
<tr>
<td>Vape pens/eGo/Stick models (not modifiable)</td>
<td>48</td>
<td>88.9</td>
</tr>
<tr>
<td>Herbal/dry chamber</td>
<td>17</td>
<td>30.9</td>
</tr>
<tr>
<td>Cig-alikes</td>
<td>8</td>
<td>14.6</td>
</tr>
</tbody>
</table>
NH: Availability of e-liquids/cartridges

<table>
<thead>
<tr>
<th>Product</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available and visible (n = 53-55)</td>
<td>55</td>
<td>100.0</td>
</tr>
<tr>
<td>Candy/fruit</td>
<td>55</td>
<td>100.0</td>
</tr>
<tr>
<td>Menthol/mint</td>
<td>53</td>
<td>98.2</td>
</tr>
<tr>
<td>Nicotine-free</td>
<td>52</td>
<td>96.3</td>
</tr>
<tr>
<td>Alcoholic drinks</td>
<td>21</td>
<td>38.2</td>
</tr>
<tr>
<td>THC/CBD</td>
<td>11</td>
<td>20.0</td>
</tr>
<tr>
<td>Caffeine</td>
<td>4</td>
<td>7.3</td>
</tr>
</tbody>
</table>
## NH: Sampling inside stores

**Sampling permitted inside store** (n = 53-55)  

<table>
<thead>
<tr>
<th>Feature</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavored*</td>
<td>45</td>
<td>100.0</td>
</tr>
<tr>
<td>Nicotine-free</td>
<td>44</td>
<td>97.8</td>
</tr>
<tr>
<td>Disposable tips used</td>
<td>39</td>
<td>88.6</td>
</tr>
<tr>
<td>Contain nicotine</td>
<td>14a</td>
<td>31.1</td>
</tr>
<tr>
<td>Observed e-liquids/juices mixed on-site</td>
<td>3</td>
<td>5.5</td>
</tr>
<tr>
<td>Observed clerk using gloves</td>
<td>2</td>
<td>66.7</td>
</tr>
<tr>
<td>Contained in child-resistant packaging</td>
<td>54</td>
<td>98.2</td>
</tr>
<tr>
<td>Printed booklet, pamphlet, or menu board on wall/counter</td>
<td>46</td>
<td>83.6</td>
</tr>
</tbody>
</table>

*Includes candy/fruit, alcoholic drink, and menthol samples
NH: Lessons Learned

- Eye-opening experience
- Completing survey
- Language is important!
- Shop staff were very anti-tobacco
  - “Vaping safer than smoking”
- NH vape shops are moving targets
Vape Shop Regulation

Desmond Jenson

“The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .”
FDA Authority


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“The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .”
21 U.S.C. § 387a(b):
“...This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.”
FDA Authority

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Components, Parts & Accessories

“The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .”
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“The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .”
Components, Parts & Accessories

*Component or part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product.

Component or part excludes anything that is an accessory of a tobacco product.
Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

   (i) Solely controls moisture and/or temperature of a stored tobacco product; or

   (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.
## Components, Parts & Accessories

<table>
<thead>
<tr>
<th>Components and Parts</th>
<th>E-Cigarette</th>
<th>Hookah</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components and Parts</td>
<td>atomizers and cartomizers, flavors additives, liquid solvents, tanks and tank systems, batteries, coils, digital display/lights to adjust settings, clearomisers, a glass or plastic vial for liquid nicotine, and programmable software</td>
<td>flavor enhancers, hose cooling attachments, water filtration base additives, flavored hookah charcoals, bowls, valves, hoses, and heads</td>
<td>the wrapping or tube for a single cigar, a bag or tin for holding loose pipe tobacco</td>
</tr>
<tr>
<td>Accessories</td>
<td>screwdrivers for assembly, lanyards for carrying</td>
<td>hookah glow balls, foil pokers, shisha oyster forks, tongs and bags</td>
<td>ashtrays, spittoons, cigar clips, pipe pouches, cigar humidors</td>
</tr>
<tr>
<td>Statutory Framework</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulation of adulterated products</td>
<td>August 8, 2016</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prohibition on false or misleading advertising</td>
<td>August 8, 2016</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulation of modified risk claims</td>
<td>August 8, 2016</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration of manufacturers and disclosure of product lists</td>
<td>December 31, 2016</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disclosure of ingredients, substances, compounds, and additives</td>
<td>February 8, 2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disclosure of health-related documents</td>
<td>February 8, 2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prohibition on the use of “light,” “mild,” “low,” or similar descriptors</td>
<td>August 8, 2017 + 30 day sell-off period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premarket review</td>
<td>August 8, 2017 – August 8, 2019</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disclosure of harmful and potentially harmful constituents</td>
<td>August 8, 2019</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Regulatory Framework

<table>
<thead>
<tr>
<th>Policy</th>
<th>Cigarettes</th>
<th>Smokeless Tobacco</th>
<th>Cigars</th>
<th>E-cigarettes and other products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum sales age of 18 and age verification under 27</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Prohibition on vending sales</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
</tr>
<tr>
<td>Prohibition on free samples</td>
<td>✓</td>
<td>Allowed in adult-only facilities</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mandatory warning labels on packages and advertisements</td>
<td>9 Rotating warnings*</td>
<td>4 Rotating warnings</td>
<td>6 Rotating warnings*</td>
<td>1 Static warning</td>
</tr>
</tbody>
</table>
Nicotine vs. Non-nicotine

“Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.”
## Statutory Framework

<table>
<thead>
<tr>
<th>Regulation of adulterated products</th>
<th>August 8, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prohibition on false or misleading advertising</td>
<td>August 8, 2016</td>
</tr>
<tr>
<td>Regulation of modified risk claims</td>
<td>August 8, 2016</td>
</tr>
<tr>
<td>Registration of manufacturers and disclosure of product lists</td>
<td>December 31, 2016</td>
</tr>
<tr>
<td>Disclosure of ingredients, substances, compounds, and additives</td>
<td>February 8, 2017</td>
</tr>
<tr>
<td>Disclosure of health-related documents</td>
<td>February 8, 2017</td>
</tr>
<tr>
<td>Prohibition on the use of “light,” “mild,” “low,” or similar descriptors</td>
<td>August 8, 2017 + 30 day sell-off period</td>
</tr>
<tr>
<td>Premarket review</td>
<td>August 8, 2017 – August 8, 2019</td>
</tr>
<tr>
<td>Disclosure of harmful and potentially harmful constituents</td>
<td>August 8, 2019</td>
</tr>
</tbody>
</table>
Tobacco Product Manufacturers

The term ‘tobacco product manufacturer’ means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product.
Tobacco Product Manufacturers

“If an establishment mixes or prepares e-liquids or creates or modifies aerosolizing apparatus for direct sale to consumers for use in ENDS, the establishment fits within the definition of ‘tobacco product manufacturer’”
Tobacco Product Manufacturers

- Premarket Review of all product combinations
- Registration
- Product Listing
- Ingredient Disclosure
- Health Document Disclosure
- Harmful and Potentially Harmful Constituent Disclosure
“Retailers who currently meet the definition of manufacturer may continue to operate but cease to engage in manufacturing activities and convert to a pure retail model.”

“. . . we expect that most vape shops will continue to operate but those that have not already switched pure retailing will likely do so.”
## Regulatory Framework

<table>
<thead>
<tr>
<th>Policy</th>
<th>Cigarettes</th>
<th>Smokeless Tobacco</th>
<th>Cigars</th>
<th>E-cigarettes and other products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum sales age of 18 and age verification under 27</td>
<td>✓</td>
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</tr>
<tr>
<td>Prohibition on vending sales</td>
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</tr>
<tr>
<td>Mandatory warning labels on packages and advertisements</td>
<td>9 Rotating warnings*</td>
<td>4 Rotating warnings</td>
<td>6 Rotating warnings*</td>
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</tbody>
</table>
Free Samples

21 C.F.R. § 1140.16(d)(1): 
. . . no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products . . .
Free Samples

“...allowing prospective adult buyers to smell or handle one of the newly deemed products is not considered distribution of a "free sample" as long as the free product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product.”
Free Samples

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“Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.”
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Free Samples

21 C.F.R. § 1140.16(d)(1): 
... no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food Drug and Cosmetic Act).
“Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.”

“The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .”
“nicotine-free e-liquid that is intended or reasonably expected to be used with or for the human consumption of tobacco products in most cases would be a component or part of a tobacco product and, therefore, within the scope of this rule. These products will be evaluated on a case-by-case basis.”
State & Local Regulation - Licensing

Who? Retailer type (pharmacies, adult-only facilities)

What? Product type (combustibles, flavored products)

Where? Proximity (near schools & other tobacco retailers)

When? School hours/recess

How? Minimum price, price discounts, minimum package size
Q & A … Contact us

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