E-Cigarettes: Past, Present and Future

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Disclaimer

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This document was developed by William C. Tilburg, Senior Staff Attorney at the Network for Public Health Law. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.
What is the Network?

» **Funded by Robert Wood Johnson Foundation**
   The mission of the Foundation is to improve the health and health care of all Americans. Our goal is clear: To help our society transform itself for the better.

» **One National Coordinating Center**
   Donna Levin, Executive Director

» **Five Regional Offices**
   Northern, Western, Mid-States, Southeastern, Eastern

» **Three Program Partners**
   1. Public Health Law Research Program
   2. Change Lab Solutions
   3. Public Health Law Center/Tobacco Control Legal Consortium
Overview

- **Sales and Use Trends**

- **Existing Laws**
  - Sales to Minors
  - *Sottera v. FDA (2010)*

- **Forthcoming Laws**
  - Deeming Regulation
  - Child Nicotine Poisoning Prevention Act

- **State and Local Policy Options**
E-Cigarettes in the News

The New York Times
Is Vaping Worse Than Smoking?

Not Only Do E-Cigs Make You Look Dorky as Hell, They Also Might Explode in Your Face

Eviden

the guardian
E-cigarettes may be 'no better' than regular cigarettes

Rolling Stone
E-Cigarettes One Million Times More Harmful Than Air In Hong Kong, Chinese Study Finds

International Business Times
Sales and Use Trends
E-Cigarette Market in 2016: Current Sales and Future Projections

Sales Growth 2010-2014
» Average annual growth rate: 114%
» Annual Sales:
  2010 - $82 million
  2011 - $195 million
  2012 - $500 million
  2013 - $1.7 billion
  2014 - $2.5 billion
  2015 - $3.3 billion

Market Slowdown 2015
» Growth rate cut in half (114% to 57%)
» Sales of “cigalikes” rapidly declining
Revenue declined for **4 straight months** to end 2015 (first time ever)

Total sales eclipsed 2014, but were **$200 million** below estimates

Conflicting health and safety data and regulatory uncertainty blamed for declining sales

Economic analysts “cautiously optimistic” on continued growth of industry:

- **Total Revenue 2023 (projected)** - $21.6 billion

**Changing landscape: “Cigalikes” vs. Personal Vaporizers**

- **Cigalikes**: $1.4 billion
- **Vaporizers**: $1.9 billion

**Independent Manufacturers vs. Tobacco Manufacturers**

- **Industry % of market**:
  - 2013 – 32%;
  - 2015 – 48%;
  - **2023 (projected)** – 75%

- **Industry Total Revenue**:
  - 2013 - $.2 billion;
  - 2015 - $.8 billion;
  - **2023 (projected)** - $16 billion

“Consumers are disenchanted right now with these products. It’s not that different from diet soda, e-cigs need to mimic cigarettes or users won’t switch.”
- Bonnie Herzog, Senior Analyst, Wells Fargo
Shifting Retail Market

2008 to 2013 - “Cigalike” sales made up majority of the U.S. market

2014 – “Open systems” or vaporizers surpass cigalikes; account for 60% of overall market

2015 - U.S. Market Sales:

Mass Retail Stores (convenience, grocery, etc.)
- Cigalikes – $600 million
- Vaporizers - $300 million

Online
- Cigalikes - $800 million
- Vaporizers - $400 million

Vape Shops
- Cigalikes - $400 million
- Vaporizers - $1.2 billion
Who Uses E-Cigarettes?

Youth

» From 2011 to 2014, e-cig use among high school students increased from 2% to 13.4%

» In 2014, e-cigarettes (13.4%) became the most commonly used tobacco product among middle and high school students, outpacing cigarettes (9.2%), cigars (8.2%) and smokeless (5.5%)

Adults

» 3.7% of adults use e-cigarettes, and 12.6% have ever used

» 22% of former smokers use and 55.4% of former smokers have ever used

» 15.9% of current smokers use and 47.6% have ever used

» Current/former smokers trying to quit were most likely group to use e-cigarettes

» 9.7% of 18-24 year old never smokers had tried e-cigarettes; 3.5% for 25-44; 1.2% for 45-64; .2% for 65+
# E-Cigarettes vs. Cigarettes

<table>
<thead>
<tr>
<th></th>
<th>E-Cigarettes</th>
<th>Cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Revenue</td>
<td>$3.3 billion</td>
<td>$110 billion+</td>
</tr>
<tr>
<td>% of Population</td>
<td>3.7%</td>
<td>16.8%</td>
</tr>
<tr>
<td>Cost (per year)</td>
<td>$9-10 (disposable) to $25 to $145 (rechargeable kits) ($600-$1,300 per year)</td>
<td>$6.28 ($2,500)</td>
</tr>
<tr>
<td>% Change YOY (2014/2015)</td>
<td>+57% (slowest year since 2007)</td>
<td>+2% (TTB)</td>
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Existing and Forthcoming Laws
# Current Marketing Restrictions

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<thead>
<tr>
<th></th>
<th>Cigarettes</th>
<th>E-Cigarettes</th>
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</thead>
<tbody>
<tr>
<td><strong>TV/Radio</strong></td>
<td>Public Health Cigarette Smoking Act (1970)</td>
<td>No restriction</td>
</tr>
<tr>
<td></td>
<td>Bans cigarette ads on radio and TV</td>
<td></td>
</tr>
<tr>
<td><strong>Sporting/Entertainment Events</strong></td>
<td>Tobacco Control Act (2009)</td>
<td>No restriction</td>
</tr>
<tr>
<td><strong>Free Samples</strong></td>
<td>Tobacco Control Act (2009)</td>
<td>No restriction</td>
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## Current Sales Restrictions

<table>
<thead>
<tr>
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<th>Cigarettes</th>
<th>E-Cigarettes</th>
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<tbody>
<tr>
<td><strong>Sales to Minors</strong></td>
<td>Prohibited</td>
<td>Prohibited in 46 States</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(no federal law)</td>
</tr>
<tr>
<td><strong>Face-to-Face Transaction</strong></td>
<td>Required</td>
<td>No</td>
</tr>
<tr>
<td><strong>Vending Machines</strong></td>
<td>18+ establishment only</td>
<td>Permitted</td>
</tr>
<tr>
<td><strong>Flavor Ban</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Minimum Pack Size</strong></td>
<td>Twenty</td>
<td>None</td>
</tr>
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Sales to Minors

- At least **46 states** have banned the sale of electronic cigarettes to individuals under the age of 18
  - **Note:** AL, AK, NJ and UT have increased the age of purchase to 19; Effective 1/1/16, Hawai‘i raised the age of purchase to 21

- Laws vary greatly between jurisdictions

- Common issues with existing laws include:
  - Ban only applies to the device, not the e-liquid
  - No designated enforcement agency
  - No mandatory compliance checks
  - No data on locations where the products are sold
  - Illegal to sell, not to possess
Device or Tobacco Product?

*Sottera, Inc. v. FDA* (2010)

- **April 2009** – FDA denies entry of NJOY and Smoking Everywhere e-cigarettes into the U.S. on the grounds that they were unapproved drug-device combinations under the federal Food, Drug and Cosmetic Act.

- Sottera (NJOY) and Smoking Everywhere bring suit arguing e-cigarettes are not drug-devices but tobacco products since the liquid nicotine is derived from tobacco

- **Result**: Court held that FDA lacked authority to regulate e-cigarettes as drug-devices absent therapeutic claims (i.e. helps people quit smoking)

So, if FDA is going to regulate e-cigarettes they **MUST** do so within their tobacco products authority…
Deeming Regulation

- The Tobacco Control Act (2009) granted FDA authority over the manufacture, marketing and sale of tobacco products

- The Act directly regulated cigarettes, cigarette tobacco, roll-your-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 April 24, 2014 FDA issued the Notice of Proposed Rulemaking (NPRM) that “deems” anything meeting the statutory definition of a tobacco product, including e-cigarettes as subject to the Tobacco Control Act; comment period closed August 8, 2014
What will “Deeming” Mean for E-Cigarettes?

- **Automatic Requirements** – any deemed tobacco product must:
  - Register with FDA and report product and ingredient listings;
  - Not make reduced risk claims without scientific data and FDA approval;
  - Not distribute free samples;
  - Pay user fees (CTP is user fee funded, not taxpayer funded);
  - Pre-market review of all products marketed after February 15, 2007*

- **Non-Automatic Requirements**
  - Minimum Age (18) and ID check requirements;
  - Health warnings on packaging;
  - Vending machine sales prohibited (unless in 18+ facility)
Child-Resistant Packaging

Child Nicotine Poisoning Prevention Act of 2015

- Any “liquid nicotine container” must meet federal “special packaging” standard
  - Significantly difficult for children under 5 to open, but not difficult for adults to use properly
  - 80 percent of children tested must not open the package within 10 minutes; 90 percent of adults tested are able to open properly in under 5 minutes, and within 1 minute in a second test
- Excludes “sealed, pre-filled, and disposable” e-liquid containers IF inaccessible through customary use
- FDA may still regulate child-resistant packaging
- Enforcement
  - CPSC may levy civil money penalties, seize products, enjoin import or sale
  - State Attorneys General may bring suit and enjoin for violation of the Act
- Effective 180 days after enactment (date signed by President), or July 26, 2016
Recap

On the books now, or in the coming months, are the following:

- Sales to minors (state and federal)
- Child-resistant packaging
- ID Check
- Vending Machine Sales
- Health Warnings

- So, what regulatory gaps are left for state and local governments?
State and Local Regulation

- Age Restrictions
  - Sales to Minors
  - 18+ Establishments
  - ID Check
- Child-Resistant Packaging
- Online Sales
- Product Placement
- Taxation
- Indoor Use
- Flavor Restrictions
- Licensing
- Labeling
- Free Samples
- Disposal
Age Restrictions

Sales to Minors
- Amend statutes to:
  - Include e-liquid
  - Mandate compliance checks
  - Authorize penalties and designate enforcement agency

18+ Establishments
- Mirror tobacconist designation
- Exempt from face-to-face transaction and sampling requirements

ID Check
- Federal law will soon require, but state/local authorities cannot enforce federal law
Product Placement

- **No** self-service displays

- All products must be stored behind the sales counter or otherwise not freely accessible to customers of any age

- Federal law (once enacted) not enforceable by state/local officials
Child-Resistant Packaging

- Consumer Product Safety Commission permits state/local governments to enact identical or more stringent packaging laws.

- At least 16 states have already enacted child-resistant packaging requirements for e-liquid containers.

- Why enact a state or local law?
  - State/local laws enable state/local authorities to enforce.
  - CPSC enforcement is largely complaint-based.
Licensing

- Retail establishments seeking to sell e-cigarettes must secure a specific license.
- If included in tobacco license, should separately designate vape shops.
- Licensing program assists health and law enforcement officials locate and inspect stores selling e-cigarettes.
- In many states, local governments are preempted from regulating tobacco, but not e-cigarettes (including licensing).
- Licensing authority may suspend or revoke license for repeated violations.
License Fees

- **General rule** – fee may cover estimated costs related to issuing the license, and supervising, inspecting and regulating the license holders.

- Costs may include:
  - Training staff
  - Establishing electronic database
  - Reviewing/Issuing applications
  - Processing payments
  - Conducting checks
  - Prosecuting violators
  - Developing Materials
  - Educating retailers
Collecting and Reporting Data

- In many states multiple violations result in:
  - Increased penalties (i.e. fines)
  - License suspension
  - License revocation

- Yet often no statutory requirement to collect or report data

- Benefits of collecting inspection data:
  - Track repeat violators
  - Focus education/inspection efforts
  - Policy change requires good data!
Enforcement Considerations

- Civil vs. Criminal Enforcement
- Active vs. Complaint Based Enforcement
  - Alternative: Require X number of inspections per year
- Enforcement Authority
- Nicotine vs. Non-Nicotine E-Liquid
Questions?

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