E-Cigs, Etc.: Policy Options for Regulating Nicotine Delivery Devices

Indiana Local Boards of Health Webinar
Feb. 12, 2015
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E-Cigs, Etc.: Policy Options for Regulating Nicotine Delivery Devices

Indiana Local Boards of Health Webinar
Feb. 12, 2015
Presenters

- Kerry Cork, J.D.
  Tobacco Control Legal Consortium

- Maureen O’Brien, J.D.
  Tobacco Control Legal Consortium
Tobacco Control Legal Consortium

Attorneys supporting tobacco control policy change.
What We Do

• Legal research, analysis & interpretation
• Policy development
• Litigation support
• Education and training
What We’ll Cover

1. Overview of national regulatory landscape regarding e-cigs

2. State and local regulatory trends and policy options
What’s In a Name?
Rechargeables

- Battery-operated heating elements & replaceable cartridges
- Heated atomizer converts contents of cartridge into vapor
Disposables
Subculture of Vapers
Banana Bread, Popcorn & Smores
Not Just Water Vapor

- Not Just Water Vapor
- Requiring ingredient disclosure
- Cooper
- Aluminum
- Nickel
- Chromium
- Benzene
- Lead
- Tin
- Sodium
- Acrolein
- Tobacco-based carcinogens
- Nicotine
- Toluene
- Formaldehyde
- Carcinogenic compounds
- Propylene-Glycol
- Magnesium
- Xylene
- Antifreeze
- Potassium
- Ethylbenzene
- Antifreeze
- Inaccurate labels
- Xylene
- Nickel
Electronic Delivery Devices: Concerns

- Unregulated manufacturing
- Insufficient data on health risks & use
- Misleading & unsubstantiated health claims
- Appealing to youth
The Family Smoking Prevention and Tobacco Control Act
FDA’s Authority

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.”
Is an E-cigarette a “Tobacco Product”?

21 U.S.C. § 321(a)

The term “tobacco product” means any product made or derived from tobacco that is intended for human consumption…
Proposed Deeming Regulation

- Require ingredient disclosure
- Require disclosure of harmful & potentially harmful constituents
- Raise the minimum purchase age to 18
- Require a warning label
- Prohibit e-cig sales in vending machines in places where minors are allowed
- Require premarket review eventually
# Missed Opportunities

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Cigarettes</th>
<th>Smokeless Tobacco</th>
<th>Cigars</th>
<th>E-Cigarettes and Other Newly-covered Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum purchase age of 18</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>No vending machine sales</td>
<td>✔</td>
<td>✗</td>
<td></td>
<td>Allowed in adults-only facilities</td>
</tr>
<tr>
<td>No self-service displays</td>
<td>Allowed in adults-only facilities</td>
<td>Allowed in adults-only facilities</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Minimum package size requirements</td>
<td>✔</td>
<td>✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No loosies</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No free samples</td>
<td>✔</td>
<td>Allowed in adults-only facilities</td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>No characterizing flavors</td>
<td>Menthol and tobacco allowed</td>
<td>✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warnings on packages and ads</td>
<td>9 Rotating warnings</td>
<td>4 Rotating warnings</td>
<td>4 Rotating warnings</td>
<td>1 Static warning re: containing nicotine, which is addictive</td>
</tr>
<tr>
<td>No brand-names sponsorship of sporting and cultural events, no brand names on non-tobacco items</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required notice of ads in any non-traditional medium</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Act: State and Local Authority

The FDA
- **YES**: Product standards
  - Nicotine yields
  - Ingredients, constituents
  - How constructed
- **NO**:
  - Smoke-free
  - Tax
  - Ban a class of products (e.g., all cigars)

States/Locals
- **NO**: Product standards
- **YES**:
  - Smoke-free
  - Youth access
  - Taxes and pricing
  - Sales & distribution
  - Advertising and promotion
Option: Restrict Use

• Rationale:
  – Health impact of second-hand aerosol
  – Social norm impact
  – Enforcement
Option: Restrict Youth Access

- No sales to minors / minimum purchase age
- No self-service displays
Option: Taxes and Pricing

Minnesota
- DOR interpretation of “tobacco product”
- Enforcement challenges
  - Claims of no nicotine; claims not derived from tobacco
  - Products that look like cigarettes; apportionment

North Carolina
- Passed law taxing volume of e-juice
- Industry-backed legislation

- St. Petersburg, Alaska (10/07/14)
  - 45% of wholesale price of parts or kits with e-juice
Option: Discounting Restrictions

FEATURED PRODUCT OF THE DAY
NICQUID

BUY ONE GET ONE
FREE
IN-STORE ONLY

SAVE 25%
STOREWIDE
During the V2 Memorial Day Weekend Sale

May 23-26
Shop Now

Not for Sale to Minors
Option: Retail Environment
Option: Sales Restrictions

NO TAR
NO ASH
NO SMELL
NO SMOKE

Tobacco  Menthol  Blueberry  Vanilla  Cherry  Grape  Coffee  Strawberry
Option: Packaging Restrictions
Option: Ads & Marketing
Indiana: Background

• Paul Stieler Enterprises, Inc. v. City of Evansville (2014)
• E-cigarettes in existing state law
• E-cigarettes in pending legislation:
  – HB 1169
  – SB 539
  – HB 1235
• State and local options
Paul Stieler Enterprises, Inc. v. City of Evansville

- City ordinance prohibiting smoking in bars and restaurants allowed exemption for riverboat casinos
- Claim: violation of Indiana Constitution, under the equal privileges and immunities clause
- No severability
Paul Stieler Enterprises, Inc. v. City of Evansville

Take away:

Exemptions can cause trouble, and severability clauses can help preserve
Paul Stieler Enterprises, Inc. v. City of Evansville

Important:
Court did not challenge the City’s authority to prohibit smoking, only the way it did so.
As used in this chapter, “electronic cigarette” means a device that is capable of providing an inhalable dose of nicotine by delivering a vaporized solution. The term includes the components and cartridges.

Ind. Code §35-46-1-1.5
Indiana: Existing Laws

A person who knowingly:

1. sells or distributes tobacco or an electronic cigarette to a person less than eighteen (18) years of age; or

2. purchases tobacco or an electronic cigarette for delivery to another person who is less than eighteen (18) years of age; commits a Class C infraction

Ind. Code §35-46-1-10
A retail establishment that sells or distributes tobacco or an electronic cigarette to a person less than eighteen (18) years of age commits a Class C infraction.

Ind. Code §35-46-1-10.2
**Indiana: Pending Legislation**

**HB 1169**: Prohibits the use of electronic cigarettes anywhere smoking is prohibited by state law

**SB 539**: Requires permit to manufacture e-liquid; prohibits e-liquid sales to minors

**HB 1235**: Imposes a tax on e-cigarettes and prohibits the use of electronic cigarettes anywhere smoking is prohibited
Indiana: Local Boards of Health

Ten Essential Services in Action at the Local Health Department

1. Monitor health status to identify community health problems
2. Diagnose and investigate health problems and health hazards in the community
3. Inform, educate and empower people about health issues
4. Mobilize community partnerships to identify and solve health problems
5. Develop policies and plans that support individual and community health efforts
6. Enforce laws and regulations that protect health and ensure safety
7. Link people to needed personal health services and assure the provision of healthcare when otherwise unavailable
8. Assure a competent public health and personal healthcare workforce
9. Evaluate the effectiveness, accessibility and quality of personal and population-based health services
10. Research new insights and innovative solutions to health problems

What can’t the FDA do?

The FDA does not have the authority to include products in smoke-free laws . . . .
What can’t the FDA do?

... or to tax products.
State and local government options
(a) This chapter does not prohibit a county, city, town, or other governmental unit from adopting an ordinance more restrictive than this chapter.

(b) This chapter does not supersede a smoking ordinance that is adopted by a county, city, town, or other governmental unit before the effective date of this chapter and that is more restrictive than this chapter.

Ind. Code Ann. § 7.1-5-12-13 (West)
State and local government: Indiana
An ordinance, a bylaw, or a rule of:

da county; a city; a township; [or]
da department, a board, or an agency . . .
concerning [regulation of the sale, 
distribution, or display of tobacco products]
is void, regardless of when enacted.

Ind. Code Ann. § 16-41-39-2 (West)
State and local government
State and local government
State and local government
State and local government

Placement of products **behind** the sales counter
State and local government
State and local government

- Clean indoor air
- Tax
- Flavored products
- Youth access laws
- Retailer licenses & store location
- Require products to be kept behind the counter, prohibit free samples
Resources

Electronic Smokers

What are e-cigarettes?

"E-cigarettes"—or electronic cigarette devices that allow users to mimic the act of smoking a cigarette while inhaling and exhaling a flavored and heated liquid—have been designed to allow for more flexibility in smoking, but they do not eliminate the risks associated with tobacco use.

Instead of smoke from burning tobacco, e-cigarettes release a mist, similar to a vaporizer. The device consists of an atomizer or cartridge that heats liquid nicotine and/or other chemicals to create a vapor that can be inhaled and then exhaled. The liquid is usually contained in a small container or reservoir, and the device provides a way to control the amount of nicotine and flavorings added to the liquid.

How dangerous are e-cigarettes?

The risks posed by e-cigarettes are not yet fully understood.

E-cigarettes are not as harmful as traditional cigarettes, but they are still considered a form of tobacco use. The nicotine content in e-cigarettes can vary, and some users may choose to smoke them without nicotine at all. In addition, some users may choose to smoke e-cigarettes for therapeutic reasons, such as to help with smoking cessation.

To help reduce the risks associated with e-cigarettes, it is recommended that users choose products that contain low levels of nicotine and that are designed to help with smoking cessation. It is also important to note that e-cigarettes are not regulated by the FDA, and the long-term effects of e-cigarette use are not yet fully understood.
Resources

Public Health Law Center

Improving health through the power of law

Tobacco Control
Policy tools and legal resources to restrict and prevent tobacco use

Healthy Eating | Active Living | Tobacco Control | FDA Tobacco Action Center | Other Public Health Law | Network for Public Health Law

Upcoming Webinars

Visit our FDA Tobacco Action Center page.

Student Research Assistant Openings at the Public Health Law Center

Are you interested in working at the Public Health Law Center? Our nonprofit group of attorneys and public health professionals work on many public health law topics in the headlines today, including issues related to tobacco control, obesity prevention, and workplace wellness. Our projects can involve intriguing constitutional issues, regulatory concerns, state and local policymaking, and social justice issues.

If you're a student in a J.D., M.P.H., or equivalent program, have excellent legal research and writing skills, are able to multi-task and think critically, and can work 10 to 20 hours per week during the school year (and perhaps more in the summer), please consider applying as a research assistant at our organization. To apply, send a cover letter, resume, and writing sample to Jon Lee at jon.lee@wmitcch.edu. Please indicate in your email and cover letter if you are work-study eligible. For more information, click here.

Use of Research in Shaping Formal Legislative Discourse about Childhood Obesity Policies

An exciting review of all formal written materials and oral testimony used by the Minnesota Legislature to consider 13 policy proposals to combat childhood obesity over a recent 5-year period revealed that less than half—41 percent—
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