E-Cigarettes: Local Options in Light of Federal Action

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• Providing substantive public health policy knowledge, competencies & research in an interactive format

• Covering public health policy topics related to tobacco control

• Tuesdays from 12:00 p.m. to 1:30 p.m. Central Time

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The Tobacco Control Legal Consortium

A national legal network supporting tobacco control policy change.
E-Cigarettes: Local Options in Light of Federal Action

FDA’s Proposed Deeming Regulation
Maureen O’Brien
Tobacco Control Legal Consortium

Smoke-Free Policy Options and Opportunities
Cynthia Hallett
Americans for Non-Smokers’ Rights

Youth access and tax policy options
Thomas Carr
American Lung Association
The Tobacco Control Act
The Act: Sets Standards

- No sales of tobacco products (as currently defined) to minors
- No flavored cigarettes (except menthol)
- No use of terms “light,” “mild,” and “low tar” and generally no health claims by the industry
- Disclosures about the contents of tobacco products & FDA approval of products
- Larger, more informative warning labels for cigarettes and smokeless tobacco
- The FDA must require graphic warnings on cigarette packages
- Creation of the Tobacco Products Scientific Advisory Committee
- Tobacco manufacturer user fees
- Restrictions concerning cigarettes and smokeless tobacco through adoption of most of the 1996 regulations (no brand sponsorship of sporting/entertainment events, most free samples prohibited, cigarette packs must ≤ 20, most self-service sales prohibited)
The Act: FDA Authority

- Regulate sale and distribution of tobacco products (with some limitations)
- Regulate advertising and promotion to the extent permitted under the Federal Cigarette Labeling and Advertising Act and the First Amendment
- Change warning label requirements
The Act: FDA Authority

- Set product standards (rules regarding the design or safety of products)
- Require the disclosure of information about product contents and health effects of the products
- Extend existing requirements to other tobacco products
Public Health Standard

“Appropriate for the protection of the public health”

This is a new standard; the traditional FDA standard of “safe and effective” doesn’t translate well to tobacco
“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’s Proposed Deeming Regulation
The Deeming Regulation

1. Why does it matter?
2. What is it?
3. What does it do?
4. Missing pieces?
Why Should State and Local Public Health Advocates Care?

The FDA has proposed new rules.

But the rules fall short.

States and Local Governments can protect public health by filling those gaps.
The Deeming Regulation

1. Why does it matter?
2. What is it?
3. What does it do?
4. Missing Pieces
What's with the name?

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 \textit{deems} to be subject to this chapter.”
“Deeming” Regulation Mechanics
“Tobacco Products”

FDA Regulated
1. Cigarettes
2. Cigarette Tobacco
3. Roll-your-own Tobacco
4. Smokeless Tobacco

Not FDA Regulated
Dissolvables
Hookah/Shisha
Cigars
E-Cigarettes
“Deeming” Regulation Mechanics
FDA Regulated

1. Cigarettes
2. Cigarette Tobacco
3. Roll-your-own Tobacco
4. Smokeless Tobacco

Dissolvables
Cigars
Hookah/Shisha
E-Cigarettes
What is 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.”
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…
The Deeming Regulation

1. Why does it matter?
2. What is it?
3. What does it do?
4. Missing Pieces
So, what does this mean?

- E-cigarettes would be regulated along with other “tobacco products”
- The FDA will also have the authority to make new rules specifically covering e-cigarettes
What would the deeming reg do?

Require ingredient disclosure
What would the deeming reg do?

Require ingredient disclosure

Cooper

Aluminum

Nickel

Carcinogenic-compounds

Propylene-Glycol

Manganese

Toluene

Formaldehyde

Magnesium

Inaccurate-labels

Xylene

Volatile-Organic-Compounds

Ethylbenzene

Antifreeze

Potassium

Manganese Poison Control

Tobacco-based-carcinogens

Acrolein

Sodium

Lead

Chromium Benzene

Iron

Metals

Zinc

Tin
What would the deeming reg do?

Require disclosure of harmful and potentially harmful constituents.
What would the deeming reg do?

Raise the minimum purchase age to 18
What would the deeming reg do?

Require a warning label

“WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”
What would the deeming reg do?

Prohibit e-cigarette sales in vending machines...
in places where minors are allowed
What would the deeming reg do?

Require premarket review…eventually…probably
Procedural delays

- Comment Period
- FDA Review
- OIRA Review
- Litigation?
### Provision

<table>
<thead>
<tr>
<th>Provision</th>
<th>FDA Enforcement</th>
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<tbody>
<tr>
<td>Regulation of adulterated products</td>
<td>Immediate upon effective date of the Final Rule</td>
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<tr>
<td>Required disclosure of manufacturer identity and statement of weight, measure, or numerical count of contents</td>
<td>24 months after the issuance of the Final Rule</td>
</tr>
<tr>
<td>Prohibition on false or misleading advertising</td>
<td>Immediate upon effective date of Final Rule</td>
</tr>
<tr>
<td>Required disclosure of ingredients, substances, compounds and additives</td>
<td>6 months after the effective date of the Final Rule</td>
</tr>
<tr>
<td>Required disclosure of harmful and potentially harmful constituents</td>
<td>36 months after the effective date of the Final Rule</td>
</tr>
<tr>
<td>Required disclosure of health-related documents</td>
<td>6 months after the effective date of the Final Rule</td>
</tr>
<tr>
<td>Required registration of manufacturers</td>
<td>By the end of the calendar year in which the Final Rule is issued (if 2nd half of year, FDA picks date)</td>
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<tr>
<td>Required disclosure of product lists</td>
<td>Upon submission of new product applications</td>
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<tr>
<td>Prohibition of the use of “light,” “mild,” “low,” or similar descriptors</td>
<td>12 months after the effective date of the Final Rule</td>
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<tr>
<td>Premarket review of new tobacco products</td>
<td>24 months after the effective date of the Final Rule</td>
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The Deeming Regulation

1. Why does it matter?
2. What is it?
3. What does it do?
4. Missing Pieces
The Deeming Regulation
What can’t the deeming regulation do?

The FDA does not have the authority to include e-cigarettes in smoke-free laws or to tax them.
What didn't the deeming regulation do?

... it could have done more
# Product-Specific Rules

<table>
<thead>
<tr>
<th>Provision</th>
<th>Cigarettes</th>
<th>Smokeless Tobacco</th>
<th>Cigars</th>
<th>E-cigs and Other Newly-covered Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prohibition on self-service displays</td>
<td>Allowed in adults-only facilities</td>
<td>Allowed in adults-only facilities</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Minimum package size requirements</td>
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<tr>
<td>Prohibition on breaking packages by retailers (e.g., sales of loosies)</td>
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<tr>
<td>Prohibition on characterizing flavors</td>
<td>Menthol and tobacco allowed</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Prohibition on brand names on non-tobacco products and brand name sponsorship of sporting and cultural events</td>
<td>☑</td>
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<tr>
<td>Required notice of advertising in any non-traditional medium</td>
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</tbody>
</table>
Missed Opportunities

- Flavored Tobacco Products
- Television Advertising
- Internet Sales
- Brand Name Sponsorship
- Self-service Displays
- Minimum Package Size
- Child-resistant Packaging
Local Regulation: Filling the Gaps

- Add to smoke-free laws
- Add to youth access laws
- Add to retailer licensure laws
- Address non-nicotine e-cigarettes
- Require products to be behind the counter
Local Regulation: Filling the Gaps

- Prohibit the sale of flavored e-cigarettes
- Levy taxes
- Prohibit coupons, free samples, rebates
- Require point-of-sale warnings, marketing restrictions & broad sales prohibitions
Sample E-Cigarette Policy Provisions

• Understanding local authority – i.e., no preemption

• Clear definitions and concise language
  – All products – nicotine and non-nicotine
Definitions

Dreams cherry cigarettes became cherry "filtered cigars" right around the time the FDA’s ban on candy and fruit flavored cigarettes went into effect.
Sample E-Cigarette Policy Provisions

- Robust enforcement options
- Well-planned implementation process
Using Licensing and Zoning to Regulate Retailers

The Tobacco Control Legal Consortium has created this series of legal technical assistance guides to serve as a starting point for organizations interested in implementing certain tobacco control strategies. We encourage you to consult with local legal counsel before attempting to implement these strategies. For more details about these policy considerations, please contact the Consortium.

Licensing and Zoning

Several local governments are interested in enacting real-world compliance and enforcement strategies to increase the health and welfare of their residents. A few municipalities, such as Long Beach, Calif., have even hired enforcement officials who help to maintain and enforce legislation aimed at reducing tobacco sales to minors.

The general concept of tobacco licensing is that a concerned community would use policy powers to identify and prevent the delivery of tobacco products to minors. Enforcement of these policies varies quite a bit from city to city. The general idea is that city officials would have the power to investigate a series of events and determine whether a retailer should continue to be licensed.

Many municipalities already have in place a variety of tobacco control policies focused on managing the retail sale of tobacco products. Specific policy considerations for local jurisdictions include:

- **The Nature of Selling:**
- **Adolescents:**
- **Adult sales:**
- **CPA licenses:**
- **Accounting:**
- **벼랑에 서 있는 연소:**
- **Smoke-free zones:**

Knowledge of specific laws and regulations is critical to the implementation of these policies. We acknowledge that many local governments have not been trained in the implementation and enforcement of licensing and zoning laws. This brief policy overview is a first step to provide some general information about licensing and enforcement with local barriers.
Questions?

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Electronic Cigarettes: Policy Options and Opportunities

Cynthia Hallett, MPH
Executive Director

AMERICAN NONSMOKERS' RIGHTS FOUNDATION
Disclosure

• I have no conflicts of interest to disclose.
Current Policy Trends: Smokefree Laws

• Including e-cigarettes in smokefree laws:

188 municipalities and 3 states include e-cigarettes in 100% smokefree workplace, restaurant, and bar laws. Cities began to specifically add e-cigarettes to definitions of tobacco or smoking product to laws to prevent use of these products in smokefree spaces.
U.S. State and Local Laws Regulating Use of Electronic Cigarettes
American Nonsmokers’ Rights Foundation
As of July 3, 2014

Note: American Indian and Alaska Native sovereign tribal laws are not reflected on this map.
Policy Recommendations

• If your community or state has a strong 100% Workplace, Restaurant and Bar (WRB) law, amend the definitions of smoking and smoking devices to include e-cigarettes.

• If the law is only partial (not 100% WRB) or weak, then strengthen the law, and amend definition of smoking products.
  – See ANR’s Model Ordinance language
  – This presumes you have a strong coalition
Lessons Learned

• Exemptions in Smokefree laws are always problematic.
  – Chicago and Los Angeles exempted “vape lounges” because those exemptions exist in current ‘smokefree’ law.
  • Had to narrowly define lounges so bars couldn’t claim to be vape lounges and vape lounges could not start selling food or beverage.
  – These exemptions, and others, make implementation and enforcement more difficult too.
Additional Policy Options

• Think back to our other tobacco control policies:
  – Density/placement Conditional Use Permits for lounges & retail stores (e.g., specified distance from schools or other targeted neighborhoods)
  – Retailer licensing
  – Eliminate flavors (NYC and Chicago)
  – Ban on free product samples
  – Taxation

• Definitions are critical – please consult with TCLC, ANR, and others before you proceed!
Tobacco Industry Interference Tactics

- **Policy Diversion**
  - Weak policy language intended to give the appearance of “doing something” to address the problem
  - Diverting the policy debate away from health

- **“Third Party Endorsers”**
  - Formerly the National Restaurant Association and American Beverage Institute
  - Now CCF and ACSH
  - New groups like TVECA, CASAA, SFATA
  - State & local front groups

- **Propaganda machine**
  - Economic scare info—sales, jobs, tourism
  - Health scare tactics: “Quit or Die” argument
  - Attacks on science through 3rd party front groups and allies
  - Individual rights/anti-bureaucracy/anti-government

- **After-Enactment Tactics**
  - Litigation
  - Procedural maneuvers (efforts to repeal, rescind)
  - Electoral activity – council races, referenda, initiative
  - Preemption
In Their Own Words…

Big Tobacco’s Objective

• Create a body of opinion which makes government authorities very wary of smoking restrictions.

• Create a social climate where smoking is securely anchored within society despite the health concerns.

“Social Acceptability Program.” [Memo prepared by Burson-Marsteller for PM re: accommodation.]


Some things never change…
The Tobacco Industry is Transforming!

And so should you. As a retailer, wholesaler or consumer of tobacco products, you have long known about the impact of higher cigarette excise taxes. But as the industry changes, so do the risks to your individual rights!

In addition to fighting higher cigarette taxes, you should be concerned about:

- higher taxes on smokeless products
- illicit trade of cigarettes
- bans on vapor products
- youth tobacco sales and possession
- tobacco harm reduction

These are some of the issues that you will find on our Interactive Map. Click on your state and get involved TODAY!!!

Sign up for state e-mail alerts today!

Want a quick and easy way to stay informed about tobacco-related issues impacting your state? Sign up for state e-mail alerts today!
Overview of CASAA's Action Plan Regarding Proposed FDA Regulations

(NO: To keep up on CASAA Calls to Action and other posts regarding the FDA, please click and bookmark this link: FDA Alerts and Calls to Action)

In April 2014, FDA released its proposed regulation attempting to exert regulatory authority over e-cigarettes as tobacco products. To better understand the import of these regulations, please see our summary of the what and why of the deeming regulation and CASAA's preliminary analysis of proposed regulations.

Early on, we asked CASAA members to be patient and to refrain from making formal comments about the proposed regulations until CASAA leadership had sufficient time to review the regulations and offer guidance. The membership has been patient at a time when every instinct
Freedom Friday with Jason Healy

blu’s Founder and President on the Anti-Electronic Cigarette Agenda

Let’s set a few things straight, right from the start:

- Non-smokers dislike tobacco cigarettes, because who would want to go to a bar and come out smelling like other people’s cigarette smoke? I—a smoker—can understand that.
- Many smokers themselves don’t even want to smell like cigarette smoke. Smoke on the breath, in the hair, on the clothes—there are smokers out there who don’t want to deal with that, either.
- More smokers are tired of the other hassles associated with tobacco cigarettes: flicking messy ashes, being banished to the cold every half hour, fumbling around for a lighter and polluting with cigarette butts.

Ready for the best part? E-cigarettes solve every one of the aforementioned problems.

Your Freedom to Vape Is Under Attack
Entitled "Save Vape LA", the event is presented by the IMPROOF Movement (www.IMPROOFMovement.com and #IMPROOF) and sponsored by The Smoke Free Alternative Trade Association, CASAA, Emperor Brands, Vape Revolution and Craft Vapery as well as my law firm Daman & Associates.

**TIMELINE**

1:30pm - 2pm
- 200 free Save Vape LA T-shirts will be handed out at the VapeRev Bar (after 2pm, $10/shirt)

2pm Keynote Speakers
- Herbert Gilbert, Inventor of the first electronic cigarette in 1963
- John Cameron, CEO, Emperor Brands electronic cigarettes
- Phillip Daman, President of Smoke Free Alternatives Trade Association

3pm
- Opportunity to give your #IMPROOF testimonial at the media wall
Key peer-reviewed journal articles and research documents on the health effects of exposure to secondhand vapor from e-cigarettes, exposure to e-liquid and poisonings, impact of advertising and marketing, and more.

http://no-smoke.org/learnmore.php?id=645#ecig research
ANR/F Resources

http://www.no-smoke.org/ecigs.html
Electronic cigarettes page with fact sheets, links to research studies, news clips, model policy language, and more.

Electronic Cigarettes Laws List

Great article on local and state legislation and industry plea to “wait for FDA.”
"Despite the tobacco industry's superior financial resources, enactment of a specific local ordinance depends not on the tobacco industry but on how seriously the health advocates mobilize in support of the legislation. **When the health community makes a serious commitment of time and resources, it wins, but when the health community fails to make such a commitment, the tobacco industry prevails, more by default than because it has superior financial resources.**" - Samuels and Glantz (1991) ("The Politics of Local Tobacco Control," *Journal of the American Medical Association*, October 16, 1991)

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State and Local Options (Other than Smokefree) to Regulate E-Cigarettes

Thomas Carr
Director, National Policy
American Lung Association
State and Local Options to Regulate Electronic Cigarettes

- Policies that Reduce Youth Access to E-Cigarettes
- Licensing of E-Cigarette Retailers
- Taxation of E-Cigarettes
- Eliminating Flavors in E-Cigarettes
- Eliminating Coupons/Discounts for E-Cigarettes
- Zoning/Moratoriums on E-Cigarette Retailers
Policies that Can Reduce Youth Access to E-Cigarettes

Examples of Youth Access Policies:

• Requiring Only Store Employee-Assisted Sales of E-Cigarettes/No Self-Service Displays (not in proposed FDA deeming rule)

• Requiring E-Cigarette Vending Machines to be in locations that minors cannot enter
More Examples of Youth Access Policies

- Prohibiting Free/Low Cost Samples of E-Cigarettes
- Requiring the Checking of Photo ID before selling e-cigarettes to younger people
- Requiring e-cigarette retail shops/vape shops to be completely off limits to minors (proposed FDA rule doesn’t deal with this either)
Reducing Youth Access to E-Cigarettes

- Lots of activity on this issue at the state and local level especially over the past 2 years

- How E-Cigarettes are Defined in Local Policy is Important
  - Proposed FDA Deeming Rule Defines them as Tobacco Products
Map Categorizing State Laws Prohibiting E-Cigarette Sales to Minors

Last updated: July 15, 2014

- No law yet passed (10 + DC)
- Law uses tobacco industry definition for e-cigarettes (16)
- Law uses e-cigarette or separate non-industry term/definition for them but does not include in “tobacco product” definition (18)
- Law includes e-cigarettes as part of “tobacco products” definition (6)

DC (no law passed)
Tobacco/E-Cigarette Industry Heavily engaged on Youth Access Issue

• Have model language and definitions for e-cigarettes
  – Don’t want e-cigarettes defined as tobacco products
  – “Vapor products” or “Alternative Nicotine Products” are the definitions for e-cigarettes they typically suggest
More of the same from the Tobacco/E-Cigarette Industry

Tobacco/E-Cigarette Industry focusing on youth access to avoid more impactful strategies such as smokefree laws and taxes on e-cigarettes
Licensing of E-Cigarette Retailers

• Requires persons who sell e-cigarettes to obtain a license or permit before selling them

• Are often paired with youth access policies
  – Hard to enforce a law if you don’t know who is selling e-cigarettes

• Could be a way to limit number of e-cigarette retailers in a community
Licensing of E-Cigarette Retailers

• Seven states – IA, KS, LA, ME, MN, RI & VT require e-cigarette retailers to get licenses or permits

• E-Cigarette Industry has Generally Opposed Licensing
E-Cigarette Taxation

• FDA cannot act in this area, only states, communities* or U.S. Congress can
  – * If the state allows it, most states preempt taxes on other tobacco products
• Based on limited evidence available so far, it seems clear that price plays a big role in use of e-cigarettes
E-Cigarette Taxation

• Two states have taxes on e-cigarettes:
  – Minnesota – 95% of wholesale price (same as OTP)
  – North Carolina (2014) – 5 cents per milliliter of e-liquid

• Bills were introduced in a few additional states this year, but none other than NC have passed so far
Challenges with Taxing E-Cigarettes

• Do you tax the electronic cigarette, the separate cartridge/e-liquid or both?

• The distribution system for e-cigarettes is not fully understood yet.
E-Cigarette Industry Opposes Taxation

• Not surprisingly, the e-cigarette industry strongly opposes taxing e-cigarettes
  – especially at levels similar to other tobacco products

• Have started to see bills in some states from e-cigarette industry that sets very low tax rate for e-cigarettes
Eliminating Coupons/Discounts for E-Cigarettes

• Would involve eliminating ways that the e-cigarette industry may discount their products
  – i.e. buy one, get one free coupons

• Another way for states and communities to potentially affect the price of e-cigarettes
  – Will have less of an effect on price than taxation
Eliminating Coupons/Discounts for E-Cigarettes

• An untested policy option
  – No state has tried this yet
  – Discounting for e-cigarettes not yet well understood
  – E-cigarette industry would likely sue
E-Cigarette Flavors Galore

Candy flavors

Grape
Bubblegum
Gummy Bear
E-Cigarette Flavors Galore

• Recent study identified 7,764 unique flavors of e-cigarettes on market
  – 4,110 of them have come on to the market since 2012

Eliminating Flavors in E-Cigarettes

• States and communities could potentially prohibit the sale of flavors in e-cigarettes
  – No state has done this yet
  – Ordinance in Providence, RI includes e-cigarettes
  – States and communities likely to face lawsuit from the e-cigarette industry if they try
Zoning/Moratoriums on E-Cigarette Retailers and Vape Shops

• Communities especially have long recognized zoning powers to determine whether and where businesses can locate inside their boundaries
  – For example, communities could potentially prevent e-cigarette retailers or vape shops from locating within a certain distance of a school
  – Communities could also potentially place a moratorium on vape shops locating there
Contact Information

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• Q&A panel on your screen

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