COALITIONS KICKING BUTTS: TOBACCO CONTROL POLICY APPROACHES

February 20, 2013
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ADVANCING TOBACCO POLICY CHANGE AT THE FEDERAL, STATE AND LOCAL LEVEL:

Peter Fisher
February 20, 2013
Tobacco’s Toll in U.S.

- Tobacco is the leading preventable cause of death, killing more than 400,000 each year
- Tobacco kills more than AIDS, alcohol, murders, car accidents, suicides, and fires combined
- Tobacco results in $96 billion in annual health care costs
- Nearly 90% of lung cancer cases, 1/3 of total cancer deaths, and 1 in 5 deaths from heart disease are tobacco related
Tobacco’s Toll in U.S.

- 4,000 kids try their first cigarette every day
- Another 1,000 kids become regular smokers every day; one-third will die from smoking-related diseases
- 18.1% of U.S. high school students smoke
- 12.8% of U.S. high school boys use smokeless tobacco
- 17.8% of U.S. high school boys smoke cigars (compared to 19.9% who smoke cigarettes)

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Expenditure</th>
<th>Price Discount</th>
<th>Source</th>
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<td>1998</td>
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<tr>
<td>2004</td>
<td>$14.15 Billion</td>
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<td>2005</td>
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<tr>
<td>2008</td>
<td>$9.94 Billion</td>
<td>$7.2b</td>
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* Before 1997, Coupons and Retail Value Added were combined into one category.
Now The Tobacco Industry Claims It Has Changed...
THE TRUTH

✓ Still Marketing to Kids & Targeting Young Adults
✓ Plethora of New & Novel Products
✓ Opposing Solutions
✓ Phony Image Campaigns
✓ Undermining Solutions When They Are Achieved
Making Tobacco Products Available, Attractive, & Affordable

Tobacco Companies Spend Billions Each Year To:

- Place products prominently

- Promote and advertise tobacco products heavily

- Price products cheaply to appeal to current and potential users, including kids
The Solutions
Why Policy Change?

• Program effects enhanced by policy
  – Tax, smoke-free encourage quitting

• Population based approaches more cost effective, especially in under-funded programs
The Tools of Tobacco Control

• Tobacco Taxes
• Smoke-free Laws
• Comprehensive Prevention & Cessation Programs
• Coverage for Smoking Cessation Services
• Limits on Industry Behavior (e.g., FDA)

TO BRING ABOUT

• Social & Environmental Change
Effects of Smoke-free Laws

- Protect everyone from secondhand smoke
- Improve health of workers & patrons
- Prompt more smokers to try to quit
- Increase the number of successful quit attempts
- Reduce the number of cigarettes that smokers consume
- Discourage kids from starting
- Do NOT hurt business
75% of New Yorkers Support The City’s Smoke-Free Law

The Law is Even More Popular Than a Variety of New York Institutions

Voter Support for the Smoke-Free Workplace Law

Favorable Rating

New York Yankees: 69%
New York Knicks: 63%
David Letterman: 62%
Coney Island Hot Dog: 61%
A deli corn beef sandwich: 60%
Krispy Kreme donuts: 49%
Donald Trump: 48%
George Steinbrenner: 39%

New York City
Survey of registered voters - March 2004
• A win for public health
• A win for state budgets
• A win among voters
Effects of a 10% Increase in Price

- Nearly 7% decline in youth prevalence
- A 2% decline in adult prevalence
- A 4% decline in overall consumption
Tobacco Taxes & State Revenues

• Despite inevitable declines in consumption of cigarettes ...

• Increasing tobacco taxes ALWAYS increases state revenues
The Kansas Tax Experience
From 24¢ to 70¢ on 7/1/02; from 70¢ to 79¢ on 1/1/03.

Packs Sold
- 21.6%

Revenue
+ 142.6%

Orzechowski & Walker, The Tax Burden on Tobacco, 2008
Support for a Significant Tobacco Tax Increase: Kansas Voters Favor a 75-Cent Increase in the Tobacco Tax

Would you favor or oppose a 75-cent per pack increase in the state tobacco tax, with part of the revenue dedicated to a program to reduce tobacco use, particularly among kids, and another part of the revenue used to address the state’s budget shortfall?

Total Favor: 72%

Total Oppose: 24%

Total numbers are rounded.
“To be effective, however, TC programs must be consistent, and budget cuts in TC programs are threatening that consistency …the committee recommends that all states maintain funding for their TC activities at the level suggested by the CDC – about $15-$20 per capita, depending on the state’s population, demography and smoking rate. ”
States with best funded and most sustained tobacco prevention programs during the 1990s – AZ, CA, MA and OR, reduced cigarette sales more than twice as much as the country as a whole.
FY2013 Funding for State Tobacco Prevention Programs

States that are spending 50% or more of CDC recommendation on tobacco prevention programs.
States that are spending 25% - 49% of CDC recommendation on tobacco prevention programs.
States that are spending 10% - 24% of CDC recommendation on tobacco prevention programs.
States that are spending less than 10% of CDC recommendation on tobacco prevention programs.

*As in FY2012, Alabama’s tobacco prevention program budget for FY2013 was not available when this report went to press. In FY2011, Alabama budgeted $860,000, which is just 1.5 percent of the CDC’s recommendation.
Only 3 states – AZ, CA and MA - spent any money on tobacco prevention prior to 1999. Settlement payments to states began in 1999. All states were receiving payments by 2001. Funding amounts only include state funds.
FY2013 Tobacco Money for Tobacco Prevention

- Total State Tobacco Revenues: $25.7 Billion
- Estimated Tobacco Tax Revenues: $7.3 Billion
- Estimated Tobacco Settlement Revenues: $18.4 Billion
- CDC Recommended Annual Funding For Tobacco Prevention: $3.7 Billion
- Actual Tobacco Prevention Spending: $459.5 Million
2012: 65%
30 states and hundreds of communities are smoke-free

1/1/1998: 12%
CA becomes 1st smoke-free state

1996: < 1%
Smoke-free laws in 13 communities nationwide

11/27/2002: 13%
DE becomes 2nd smoke-free state

Source: American Nonsmokers’ Rights Foundation
Includes state and local laws passed as of November 7, 2012
States that have recently passed or implemented a cigarette tax increase (since 1999)

- California
- North Dakota

States that have not passed tax increases since 1999

- Arizona
- Nevada
- Oregon
- Idaho
- Washington
- Montana
- Wyoming
- Colorado
- Nebraska
- Kansas
- South Dakota
- Iowa
- Minnesota
- Wisconsin
- Illinois
- Indiana
- Ohio
- Michigan
- Pennsylvania
- Virginia
- West Virginia
- Kentucky
- Arkansas
- Louisiana
- Texas
- Oklahoma
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- Virginia
- Washington, D.C.
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- New Jersey
- Delaware
- Maryland
- Virginia
- Washington, D.C.

State Average is $1.48 Per Pack

December 2012
Federal Cigarette Excise Tax + Average State Cigarette Tax

1980 federal rate (24¢) + state average (33¢): 57¢ per pack

1996 federal rate (24¢) + state average (33¢): 57¢ per pack

2001 federal rate (34¢) + state average (43¢): 77¢ per pack

Federal rate ($1.01) + current state average ($1.48): $2.49 per pack

December 2012
Impact of the Trifecta: Adult and Youth Smoking in NYC

Sources: Adult: Community Health Survey; Youth: CDC, YRBS.
National Youth Smoking Trends
1991 - 2009*

Youth Smoking Prevalence (%)

* Data are from the Youth Risk Behavior Surveillance Survey (1991-2009)
National Youth Smoking
1997 - 2009

Data are from the Youth Risk Behavior Surveillance Survey

Current cigarette use (smoked cigarettes on at least 1 day during the 30 days before the survey)
Current frequent cigarette use (smoked cigarettes on 20 or more days during the 30 days before the survey)
National Adult Smoking Trends
1994 - 2010*

* Data are from the National Health Interview Survey

22% decline 1997-2010
Due to these smoking declines:

- 2.9 million fewer current youth smokers
- 3.4 million youth kept from becoming addicted adult smokers
- 1.1 million fewer youth dying prematurely from smoking
- $60 billion in lifetime healthcare savings from smokers averted
- 9.6 million fewer adult smokers
- 2.5 million fewer adults dying prematurely from smoking
- $90 billion in lifetime healthcare savings from smokers averted
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Regulatory Science to Leverage the Food and Drug Administration (FDA) Center for Tobacco Products (CTP) Mandate

David B. Abrams, PhD

The Schroeder Institute For Tobacco Research And Policy Studies
The Johns Hopkins Bloomberg School of Public Health
Georgetown University Medical Center / Lombardi Comprehensive Cancer Center

dabrams@legacyforhealth.org
Family Smoking Prevention And Tobacco Control Act

Public Law 111–31
111th Congress

An Act

To protect the public health by providing the Food and Drug Administration certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees’ Retirement System, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

June 22, 2009
[H.R. 1256]
Public Health Standard

Calls for the review of the scientific evidence regarding

1. **Risks and benefits to the population as a whole**, including both users and non-users of tobacco products;

2. Whether there is an increased or decreased likelihood that existing users of tobacco products will **stop** using such products; and

3. Whether there is an increased or decreased likelihood that those who do not currently use tobacco products, most notably youth, will **start** to use tobacco products.
FDA ACT: Key Substantive Elements

1. Require the Industry to provide information to the Gov’t that allows Gov’t to better inform consumers

2. Restrict marketing that appeals to kids, misleads adults, deceptively encourages tobacco use

3. Strengthen restrictions on sales to youth
FDA ACT: Key Substantive Elements

4. More accurately inform consumers
   A. Improved warning Labels
   B. More accurate testing of tar, nicotine and other harmful substances
   C. Standards to prohibit unsubstantiated health claims

5. Regulation of the contents of the product to protect consumers

6. Articulate balance with state authority
Using Key Regulatory Tools in The Act
Reminders From Zeller .. FDA three years Later. Tobacco Control, 2012

- Mandatory “product standards” that would limit the allowable levels of ingredients in tobacco products (menthol, nicotine, etc)

- Determine whether an application for a new product will be subjected to a more robust premarket evaluation, or a shortened process because the product is “substantially equivalent” SE.

- What criteria will be employed to determine whether a manufacturer is able to make an exposure reduction or risk reduction claim under the provisions (section 911) governing “modified risk” tobacco products (MRTP)

- FDA’s current rules do not automatically apply to cigars (e.g. flavored LCCs), e-cigarettes or other products containing nicotine derived from tobacco, including certain dissolvable tobacco products (e.g., Verve). This has created a void. e-cigarettes and several other products reside in a regulatory “no man’s land” (i.e., sold without any regulatory oversight). ? Industry Playbook
Means to inform FDA CTP regulatory process

- **Citizens’ petitions, Dockets, Testimony, CTP website**
  - Menthol docket submission (Legacy & partners)

- **TPSAC presentations, Knowledge Synthesis,**
  - Analyses of national survey data (Giovino et al, under review)
  - Mathematical modeling (Levy et al, 2011)

- **Rapid Response, studies, peer publications**
  - Peer reviewed journal articles (Pearson et al, 2012; Villanti et al 2012)

- **FDA Tobacco Science Group: Convened by Schroeder-Legacy, CTFK…**
  - Identify priorities for regulatory science…Canary in coal mine…
  - Strengthen collaboration: scientists, lawyers, advocates, stakeholders
  - Anticipate Industry challenges and defend against them
  - SE / MRTP’s: New, Emerging products, pre- and post- market info..
Youth Access Restrictions

- Reinstates the 1996 Youth Access Requirement that all retailers ask for a photo ID of anyone who appears to be under 27 years of age.
- To the extent feasible requires FDA to contract with the states to carry out the inspections of retailers.
- Provides for both civil penalties and no-sale orders.
- States can still have their own penalty provisions.
- At request of communities seeking help, FDA to provide assistance on strategies to prevent underage use in communities with higher ratio of youth menthol cigarette use.
Sec. 907 – Tobacco Product Standards

- Authority to require product changes that FDA finds are “appropriate for the protection of the public health”
- Authority to reduce nicotine levels to below the point they cause addiction but not to zero
- Can ban menthol flavoring if the science supports it.. TPSAC says yes
- Focuses on both Individual and Population Effect
  - FDA can’t ban all cigarettes, all smokeless tobacco products, … or all roll your own tobacco products; or
  - Require the reduction of nicotine yields of a tobacco product to zero

THESE LIMITS DO NOT APPLY TO THE STATES
Sec 916 And Section 203—State/Federal Balance

- **916** - No State preemption of measures relating to the sale, distribution, possession, exposure to, access to, or advertising and promotion of tobacco products, information reporting or measures relating to fire safety or State, Tribal, or local taxation of tobacco products

- **203** - Permits States to restrict Time, Place and Manner of tobacco marketing
States may not establish any requirement that is different from or in addition to “any requirements under the provisions of this chapter” related to:

1. Tobacco product standards
2. Premarket approval
3. Adulteration
4. Misbranding
5. Labeling
6. Registration
7. Good manufacturing standards
8. Reduced risk product claims
Some Preemption Related Examples

For example, States are not preempted from:

- Raising the age of legal purchase
- Banning all free sampling of smokeless products
- Banning the sale of categories of tobacco products or ban all cigarettes, smokeless or roll-your-own products
- Requiring that cigarettes be sold by prescription
- Requiring that tobacco products be sold in only designated retail outlets
- Banning Internet sales
The Family Smoking Prevention and Tobacco Control Act (hereafter referred to as “the Act”) became law in 2009. One of its key provisions grants the Food and Drug Administration (FDA) authority to regulate tobacco products “for the protection of the public health.” Recognizing that the traditional “safe and effective” standard governing drugs and devices was inappropriate for tobacco products, which are inherently lethal, Congress designed the “public health standard . . . to be a flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products.”2 The language is intentionally broad, focusing on protecting the health of the population as a whole.
## Estimated number of lives saved after menthol ban, 2010-2050

<table>
<thead>
<tr>
<th></th>
<th>Lives saved</th>
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<tr>
<td><strong>TOTAL POPULATION</strong></td>
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<tr>
<td>10% change</td>
<td>323,107</td>
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<tr>
<td>20% change</td>
<td>478,154</td>
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<tr>
<td>30% change</td>
<td>633,252</td>
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<td><strong>AFRICAN AMERICANS ONLY</strong></td>
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<tr>
<td>10% change</td>
<td>91,744</td>
</tr>
<tr>
<td>20% change</td>
<td>164,465</td>
</tr>
<tr>
<td>30% change</td>
<td>237,317</td>
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Future Directions

- Skate to where the puck is going to be
- Implications of morphing of industry
  - Marketing MRTP’s and harm reduction messages, especially to youth and young adults
- Ending combusted tobacco use?
- Implications for research, intervention and policy
POINT-OF-SALE TOBACCO (POST)
SOCIO-DEMOGRAPHIC POST VARIATION

Average pack price: Newport
\[ M = $7.75 \] block-group white
\[ M = $7.29 \] block-group non-white
\[ p = 0.004 \]

Low pack price: All cigarette brands
\[ M = $6.73 \]

Average pack price: LCC
\[ M = $3.71 \ ($0.91 each) \]

LCCs more prevalent in non-white block-groups
\[ OR=1.26,\ 95\% CI=1.14-1.40 \]

Cantrell et al., (under review)
Modified Risk Tobacco Products (MRTPs)

“… the Secretary shall… issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as actually used by consumers, will

- benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.”
40.2% of Americans over the age of 18 had heard of an e-cigarette.

11.4% of smokers have ever tried an e-cigarette. Of these, about \( \frac{1}{3} \) (4.1%) had used an e-cigarette in the past 30 days.

Over 70% of smokers who have heard of e-cigarettes believe that e-cigarettes are less harmful than regular cigarettes.

Young smokers more likely to have tried e-cigarettes than older smokers.
On New Growth (MRTP) Tobacco Products

“I would like to share with you our progress on next Generation Products (NGPs) which represent a potential paradigm shift for our business. A PMI strategic priority is to commercialize products that can reduce the health risks of smoking on an individual and population basis. Some of you might know them as Modified Risk Tobacco Products or MRTPs.

These products have the potential to be the greatest innovation in the industry… We believe that risk reduction in combustible, conventional cigarettes through the selective elimination of harmful constituents would only produce marginal improvements that are unlikely to provide material health benefits.

Therefore, we believe the elimination of combustion via tobacco heating and other innovative systems for aerosol generation is the most promising path to secure risk reduction.”

We expect the first factory to be ready in 2016 with final data from clinical studies and a launch in the first markets between 2016 and 2017
Under the FSPTCA, Congress sought to protect and promote public health by empowering FDA to address the risk and harm associated with current tobacco use. In creating Section 911, Congress recognized the contribution that MRTPs could make in achieving this important public health goal and directed FDA to create an appropriate “new and flexible” regulatory framework. The Agency’s successful implementation of this regulatory framework has the potential to significantly advance FDA’s mission of protecting public health. In contrast, if the Agency does not take full advantage of the public health opportunity presented by consumer-acceptable, lower risk tobacco products, it may unintentionally preserve cigarette smoking as the dominant form of tobacco use in the U.S.
EMERGING TOBACCO PRODUCTS: “NEW PRODUCTS, SAME TARGETS”

Kristen Tertzakian

FEBRUARY 20, 2013
CAUSE FOR CONCERN

• The tobacco industry continues to create new, slick products to keep their customers addicted.

• Many of these products are not subject to smokefree air laws or FDA regulation.

• Little known about use and health consequences.
LITTLE CIGARS AND CIGARILLOS

• Cigars are defined by the US Federal government as “any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco” not intended to be sold as a cigarette.¹

Size Comparison:

- Cigarette < 3 lbs per 1000 units
- Little Cigar < 3 lbs per 1000 units
- Cigar > 3 lbs per 1000 units (includes cigarillo)

1. USC 5702. Available at: http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=browse_usc&docid=Cite:+26USC5702
SMALL/LITTLE CIGARS

A review of formerly-secret tobacco industry documents finds that little cigars were intended to replace cigarettes as advertising became restricted.

CIGARILLOS

CIGARILLO

CIGARILLO (TIPPED)
• Cigar use is associated with cancers of the oral cavity, larynx, esophagus, and lung.#

• Between 2000 to 2011, consumption of large cigars increased by 233% while consumption of cigarettes declined by 33%.*

• There are challenges to data collection, but several state surveys show that cigar use is on the rise.

• **Cigars are not currently regulated under the Family Smoking Prevention and Tobacco Control Act.**

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YOUTH CIGAR USE

• According to the 2011 YRBS, 13.1% of high school students are current cigar smokers, compared to 18.1% who currently smoke cigarettes.

  ◦ Cigar smoking surpassed cigarette smoking among high school students in five states: Georgia, Maryland, Massachusetts, Rhode Island and Wisconsin.

CDC. Youth Risk Behavior Surveillance – United States 2011. MMWR 2012;61(4); 1-162.
SMOKELESS TOBACCO

Over the past several years, several national surveys have documented an increase in the use of STPs among young males.

**Snus:** A spitless tobacco packaged in small teabag-like pouches. Modeled after a Swedish product.

**Moist Snuff:** Finely ground tobacco packaged in cans or pouches, sold moist (placed between the lower lip or cheek and gum).
SMOKELESS MARKETING

WARNING: This product can cause gum disease and tooth loss.

WARNING: This product is not a safe alternative to cigarettes.

$1 OFF ANY STYLE MARLBORO SNUS

WARNING: This product is not a safe alternative to cigarettes.

$1 OFF ANY STYLE MARLBORO SNUS

WARNING: This product is not a safe alternative to cigarettes.
DISSOLVABLE TOBACCO

Dissolvable Tobacco: Finely milled tobacco that dissolves in the mouth. Does not require spitting.
DISSOLVABLE MARKETING

CAMEL DISSOLVABLES, EMBRACE UNLIMITED POSSIBILITY

WARNING: This product can cause gum disease and tooth loss.

ENJOY THE EVOLUTION
Camel Dissolables are going to change the way you think about tobacco. Just put one in your mouth, let it dissolve and enjoy.

GET STICKS, STRIPS, OR ORBS AT YOUR LOCAL STORE TODAY.

WARNING: This product can cause gum disease and tooth loss.

DEMOGRAPHIC GRAPHIC GRAPHIC SECTIONS
FOR $1.00

WARNING: This product can cause gum disease and tooth loss.
TOBACCO-DERIVED DISCS

• Several companies have launched chewable nicotine discs or lozenges:
  ◦ Altria’s Verve is only available in Virginia. Test marketing started in June 2012.
  ◦ RJR’s Velo Rounds and Viceroy Flex are being test marketed in North Carolina.
HOOKAH

- Water pipe smoking that hails from Middle East.
- Water does not “filter” all the toxic compounds and chemicals.
- A single waterpipe use episode can yield slightly more nicotine than a single cigarette, and about 36 times the tar and 8 times the CO.

HOOKAH - PREVALENCE

• Few national and state surveys ask about hookah use.

• In 2011, 18.5% of 12th-grade students reported having smoked a hookah in the past year.*

• Hookah use among college students ranges from 9.5 percent to 20.4 percent for past month use and as high as 41 percent to 48 percent for lifetime use.**

E-CIGARETTES

• Battery-operated devices generally containing cartridges filled with nicotine, flavors and other chemicals. Vaporized, then inhaled.
• One small sample done by FDA found diethylene glycol (a chemical used in antifreeze, toxic to humans). Other samples FDA analyzed detected carcinogens, including nitrosamines.
• 70% of Americans believe that e-cigarettes are less harmful than regular cigarettes.*

YOUNG ADULT DUAL USE

• A Legacy study found that among young adults (18-34) who use tobacco, 30% are dual-users:
  ◦ 98% smoke cigarettes
  ◦ 26% smoke little cigars
  ◦ 23% smoke cigars
  ◦ 17% smoke hookah
  ◦ 12% use dip or snuff
  ◦ 12% use chewing tobacco
  ◦ 9% smoke e-cigarettes
  ◦ 3% use dissolvables

EXAMPLES OF STATE AND LOCAL POLICY

• **Maine** - Legislation to ban most flavors of cigars and cigarettes took effect July 1, 2009.

• **New York City and Providence** - banned sale of flavored tobacco products.

• **Baltimore City and Prince Georges County, MD** - banned single sales of cheap cigars, requiring that they be sold in packs of 5 (currently in litigation).

• **Boston** – Requires cigars to be sold in packs of at least 4.
EXAMPLES OF STATE AND LOCAL POLICY (CONT)

- **Boston** - bans e-cigarette use in public places (treated as cigarettes) and bans its sale to minors.

- **CA, CO, MN, NH, NJ, and UT** - prohibit the sale of e-cigarette to minors.

- **NJ** - extended its smokefree air law to include e-cigarettes (2010).

- **UT** – extended its smokefree air law to include e-cigarettes and hookah bars (Sunsets in 2017).

- **Guam** - Enacted legislation prohibiting the importation and sale of several emerging products.
STATE INITIATIVES

• Maryland’s The Cigar Trap public education campaign

• Massachusetts: Community research, public education, and youth activism

• Florida: Nearly 100 communities have adopted resolutions urging businesses to stop selling flavored tobacco products.

• Wisconsin’s Campaign:
GET INVOLVED

• Educate youth advocates and the community-at-large about these harmful products.

• Research gaps: Add product/brand-specific questions for little cigars and cigarillos, e-cigarettes, hookah, etc. to state and local surveys.

• Ensure that materials, campaigns and resources for tobacco prevention and control are culturally competent and linguistically appropriate.
THANK YOU

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QUESTIONS & ANSWERS

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