A Look Back and Ahead: The State of Tobacco Control in Maryland

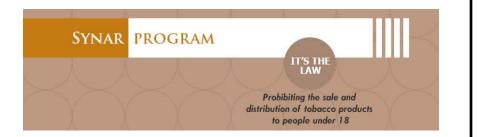
UNIVERSITY of MARYLAND FRANCIS KING CAREY SCHOOL OF LAW LEGAL RESOURCE CENTER FOR PUBLIC HEALTH POLICY

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Tobacco Sales to Minors

Electronic Cigarettes













SYNAR AMENDMENT

- Synar Amendment to the Alcohol, Drug Abuse and Mental Health Admin.
 Reorganization Act (Public Law 102-321)
 - Passed by Congress in 1992
 - Administered by SAMHSA (Substance Abuse and Mental Health Services Administration)
 - Named for Congressman Mike Synar of Oklahoma
 - Championed:
 - Warnings on smokeless
 - FDA regulation of tobacco
 - Restrictions on tobacco advertising



SYNAR AMENDMENT

- Requires all 50 states (and DC + all territories) to enact and enforce *laws prohibiting the sale of tobacco products to minors*
- Mandates annual, unannounced *inspections of at least 10% of tobacco retailers* in each state by the designated agency (sets protocols)
- Imposes sanctions if the noncompliance (youth sales) rate exceeds 20%

What is the sanction for failing to meet the Synar Amendment 20% rate?

SYNAR AMENDMENT

A state that fails to meet the 20% benchmark may suffer loss of a portion of the state's

Substance Abuse Prevention and Treatment Block Grant (SABG) :

- The SABG program's objective is to help plan, implement, and evaluate activities that prevent and treat substance abuse.
- These funds trickle down to local governments to address substance abuse.
- Funds may be used for substance abuse prevention, treatment and recovery resources.

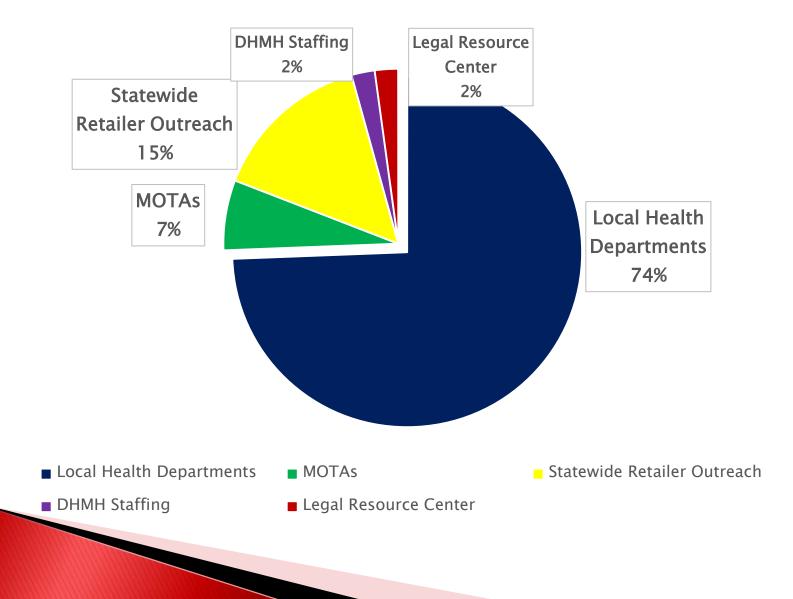
SYNAR IN MARYLAND

- FFY 2014 \rightarrow 24.1% Noncompliance rate
- ▶ FFY 2015 \rightarrow 31.9% Noncompliance rate
- MD agreed to "*alternative penalty*" in 2014 and 2015 in lieu of losing 40% of SABG
 Could have lost approximately \$35 million
- Alternative penalty required the state to spend *"new"* dollars on education and enforcement

PENALTY DOLLARS

- State invested
 - *\$1.3 million in FFY2015*
 - \$3.8 million in FFY2016
 - Funds were used by:
 - Local Health Departments
 - DHMH's Minority Outreach and Technical Assistance
 - Legal Resource Center
 - DHMH's Center for Tobacco Prevention and Control

SFY15 SYNAR PENALTY FUNDS



LOCAL HEALTH DEPARTMENTS

• Local Health Departments

- attend regional trainings
- host Youth Access Tobacco Sales Compliance meetings
- conduct minimum # of compliance checks
- and vendor education visits
- dedicate staff to new efforts

conduct youth education programs for cited youth

DHMH'S MINORITY OUTREACH AND TECHNICAL ASSISTANCE

- Minority Outreach and Technical Assistance conduct vendor education visits and outreach.
 - For SFY15:
 - Educational sessions at tobacco sales outlets = 591
 - Community education meetings on youth access to tobacco and nicotine products = 83
 - For SFY15:

Quarter 1: 360 face-to-face education sessions

LEGAL RESOURCE CENTER FOR PUBLIC HEALTH POLICY

- Provides guidance, training, and technical assistance, including:
 - Regional trainings to over 100 LHD staff/partners, covering all jurisdictions in state
 - Technical assistance to retailers, LHDs, community-based organizations, legislators, and other policymakers
 - Presentations at local coalition and other meetings across the state

DHMH'S CENTER FOR TOBACCO CONTROL AND PREVENTION

- Statewide Outreach to Retailers
 - Toolkit development and distribution
 - Direct mailings
 - Press releases

 Radio, billboard, and transit media development and placement

SFY 2016 IMPLEMENTATION: STATEWIDE MEDIA

- New creative developed as result of focus groups.
- Responsible Tobacco Retailer ads will run on billboards, transit, and will be sent to tobacco retailers throughout the State.
- Radio advertisements will air starting in January 2016, along with opportunities for new interviews to reintroduce the campaign.



UNDER 18? NO TOBACCO.

FFY16 RESULTS?

Violation Rate: 13.8%

WHAT IS AHEAD?

- Keeping the momentum going using state funds for LHDs, MOTA, LRC, and CTCP efforts!
- Follow up on Lessons Learned Roundtable from December 2015 LRC Workshop
- Database for tracking violators

And we take ideas!!!!

Electronic Cigarettes

Frequently Asked Questions

- What products are being sold and where?
- Who uses e-cigarettes?
- How does the sales and marketing of e-cigarettes compare to cigarettes?
- What are the known health effects associated with e-cigarette use?
- Are they a viable cessation device?

• How are electronic cigarettes currently regulated?

...Given all this information, what should be done about e-cigarettes?

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

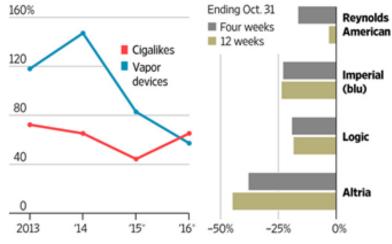
- Growth rate cut in half (114% to 57%)
- Sales of "cigalikes" rapidly declining

Out of Juice

Sales of e-cigarette devices like cigalikes and vaporizers are slowing down considerably this year.

Change from a year earlier in sales

Top companies, change from a year earlier in e-cigarette sales



*Forecast Sources: Euromonitor (overall sales); Nielsen, Wells Fargo (top companies) THE WALL STREET JOURNAL.

Blip or Trend?

"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

- Revenues 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 lack of 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

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 ecigarettes; 3.5% for 25-44; 1.2% for 45-64; .2% for 65+

E-Cigarettes vs. Cigarettes

	E-Cigarettes	Cigarettes
Total Revenue	\$3.3 billion	\$110 billion+
% of Population	3.7%	16.8%
Cost (per year)	\$9-10 (disposable) to \$25 to \$145 (rechargeable kits) (\$600-\$1,300 per year)	\$6.28 (\$2,500)
Marketing	\$115 million (2014)	\$9.17 billion (2013)
% Change YOY (2014/2015)	+57% (slowest year since 2007)	+2% (TTB)

Marketing Restrictions

	Cigarettes	E-Cigarettes
TV/Radio	Public Health Cigarette Smoking Act (1970) Bans cigarette ads on radio and TV	No restriction
Billboards/Outdoor Advertising	Tobacco Master Settlement Agreement (1997)	No restriction
Sporting/Entertainment Events	Tobacco Control Act (2009)	No restriction
Free Samples	Tobacco Control Act (2009)	No restriction

Sales Restrictions

	Cigarettes	E-Cigarettes
Sales to Minors	Prohibited	Prohibited in 46 States (no federal law)
Face-to-Face Transaction	Required	No
Vending Machines	18+ establishment only	Permitted
Flavor Ban	Yes	No
Minimum Pack Size	Twenty	None

Health Effects

- "Despite being on the market for several years, there still is a lot we do not know about e-cigarettes...the American Lung Association is concerned about the potential health consequences of e-cigarettes" - American Lung Association
- * "Many questions remain about the long-term health effects of these products for individual users and about the population-wide effects of these products. It is not clear whether these products will help people quit, discourage smokers from quitting completely, or lead to nicotine addiction and tobacco use for new users, including kids" - Campaign for Tobacco Free Kids
- "E-cigarettes have not been fully studied, so consumers currently don't know: (1) the potential risks of e-cigarettes when used as intended, (2) how much nicotine or other potentially harmful chemicals are being inhaled during use, or (3) whether there are any benefits associated with using these products. Additionally, it is not known whether e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death." – U.S. Food and Drug Administration, July 7, 2015

Chemical, Clinical and Toxicological Studies

- Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes." 2014 review of 41 safety/risk e-cig studies
- While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. It has been previously estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate. – Public Health England
- Harvard study shows that a majority of e-cigarette flavors contain diacetyl, a chemical known to cause inflammation, scarring and constriction of the tiny airways in the lung known as bronchioles (December 2015)

 "Our findings suggest that e-cigarettes are not neutral in terms of the effects on the lungs, we have observed that they increase the susceptibility to respiratory infections in mouse models." 2015 Johns Hopkins Study

Effectiveness as Cessation Device

- "Use of e-cigarettes is associated with smoking cessation and reduction. More randomised controlled trials are needed to assess effectiveness against other cessation methods." - 2015 review of 6 cessation studies using 7,000+ participants
- "The results of the only randomized control trial that compared use of ENDS, with or without nicotine, to use of nicotine patches without medical assistance in the general population, showed similar, although low, efficacy for quitting smoking...A recent study also shows some, although limited, effectiveness in real-world conditions." – 2014 WHO Report
- As currently being used, e-cigarettes are associated with significantly less quitting among smokers...E-cigarettes should not be recommended as effective smoking cessation aids until there is evidence that, as promoted and used, they assist smoking cessation. While there is no question that a puff on an e-cigarette is less dangerous than a puff on a conventional cigarette, the most dangerous thing about e-cigarettes is that they keep people smoking conventional cigarettes." – 2016 UCSF review of 38 scientific studies

In light of conflicting evidence and uncertainty, how do we proceed?

Existing Regulation

No Federal Regulation

Sottera v. FDA (2010)

- Congress
 - Child-resistant packaging (likely effective July 2016)
- FDA
 - Proposed "deeming" rule (April 24, 2014)
 - TCORS 14 academic centers awarded 5-year grants to study the marketing, health effects, toxicity, addictiveness etc. of various tobacco products, including e-cigarettes
- ► FTC
 - October 2015 proposed a study of e-cigarette sales and marketing (likely precursor to rulemaking)
- CDC
 - Surveys on sales, marketing and use
 - 2014 survey 68.9% of youth exposed to e-cigarette advertising
 - Youth use quadrupled between 2011 and 2014

State and Local Laws

Hodgepodge of sales/distribution, marketing, and use restrictions

Sales to minors – 46 states

- Packaging restrictions at least 20 states require child-resistant packaging
- Licensing at least 15 states require retailer license (either tobacco or e-cigarette)
- Clean Indoor Air at least 8 states prohibit indoor use in workplaces, including restaurants and bars
- Taxation at least 4 states levy (non-sales) taxes on the sale of e-cigarettes or e-liquid

So what should the focus be in the absence of data?

- Strengthen enforcement (youth access)
- License retailers
- Consumer Protection Act
 Unfair or deceptive trade practices
- Internet/mail order sales
- Educate public on safety/risks

- Marketing/advertising restrictions
- Continue and expand clinical, chemical and toxicological research

Questions?

Presenter Information

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