

E-Cigarettes and Tobacco: Legislation, Health Effects & Prevention Strategies

*St. Mary's County Tobacco Free Living Town Hall Series
April 21, 2016*



Overview

Legislative Update

- ▶ Federal
- ▶ Maryland General Assembly
- ▶ Local e-cigarette policies

E-Cigarette Effects on Health

- ▶ Teen usage data
- ▶ Latest scientific studies

Underage Use Prevention & Reduction Strategies

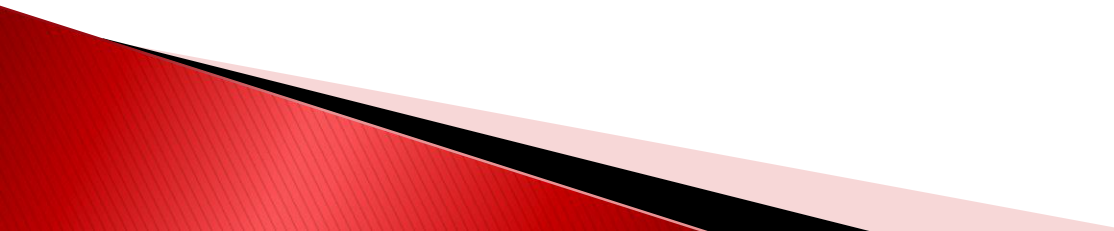
- ▶ Anti-vaping campaign mimics anti-tobacco methods

Related Issues

- ▶ Shatter
 - ▶ Hookah
- 

Federal Enacted & Proposed Legislation


Child Resistant Packaging Act of 2015

- ▶ E-liquid added to the list of hazardous substances that require child resistant packaging under the Federal Poison Prevention Packaging Act
 - ▶ FDA still has authority over e-cigarettes and e-liquid whenever they deem these to be tobacco products; as part of that power, they may regulate the packaging as they see fit
 - ▶ Sealed, pre-filled and disposable containers (i.e. Blu, Njoy) not subject to the Act – FDA can still choose to regulate
 - ▶ Effective July 2016
- 

Background on E-Cig Regulation: Device or Tobacco Product?

- ▶ *Sottera, Inc. v. FDA* (2010)
 - April 2009: FDA denies entry of NJOY and Smoking Everywhere e-cigarettes into the US 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)
- ▶ Therefore, if FDA is going to regulate e-cigarettes, they **MUST** do so within their **tobacco products authority**

E-Cig Regulation: FDA Proposed Rule

- ▶ Tobacco Control Act (TCA) gave FDA authority over tobacco products in 2009
 - ▶ April 2014: FDA issued the Notice of Proposed Rulemaking (NPRM) that “deems” anything meeting the statutory definition of a tobacco product as subject to the Tobacco Control Act
 - ▶ Under the NPRM, e-cigarettes would also be regulated
 - ▶ TCA requires the FDA to adopt certain requirements for ALL tobacco products under its authority
- 

FDA Proposed Rule Requirements

- ▶ Any deemed tobacco product **MUST**:
 - Register with the FDA & 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)
 - *Only market new products after FDA review*

- ▶ Non-Automatic Requirements extended to newly deemed tobacco products:
 - Minimum age (18) and ID requirements
 - Most states (including MD) already do this
 - Packaging must contain health warnings
 - FDA requested public comment on acceptable warnings
 - Vending machine sales prohibited (unless in 18+ facility)

Expected Outcomes

- ▶ Rule reviewed and finalized; currently before the Office of Management and Budget; expected any day
- ▶ Rule will almost certainly exempt e-cigarette manufacturers from pre-market approval requirements; whether it's a total exemption or 2 year delay is the question
- ▶ Many important regulations, such as flavored ban, will not be extended to any of the newly deemed tobacco products
- ▶ Rule is a step in the right direction, but many in the public health community believe the FDA should have done more

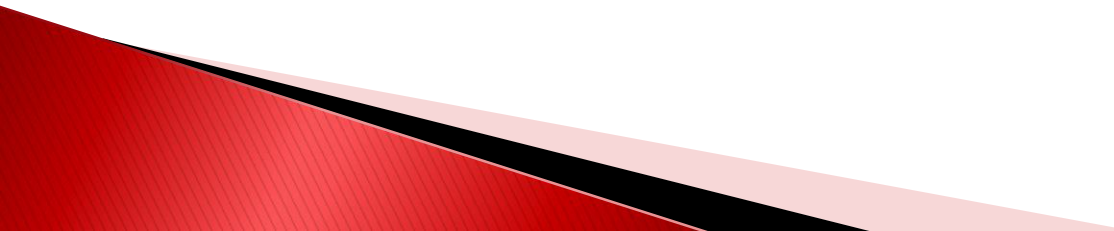
!!!NOTE: NO FEDERAL PREEMPTION!!!



Maryland General Assembly: 2015 Enacted & 2016 Proposed Legislation

2015 Enacted Legislation

MD Code, Health-General Article 24-305

- ▶ Effective October 1, 2015
 - ▶ Prohibits sale, distribution, offer for sale of all e-cigarette electronic devices, components, and liquid nicotine refills to minors
 - ▶ Law enforcement, health officer or designee authorized to enforce
 - ▶ Civil penalty fine, 1st – \$300; 2nd (and subsequent) – \$500
- 

2016 Bills: Tax Restrictions

Montgomery County License Fee, HB 1115

- ▶ Increases county license for retail cigarette sale from \$25 to \$125; percentage of each fee to Comptroller, rest to county for tobacco regulation enforcement efforts

Cigarette Restitution Fund, HB 1618 (Passed Senate)

- ▶ Establishes separate behavioral health treatment account in the CRF to be used for substance abuse treatment & specified community-based programs funded by Behavioral Health Administration or Medicaid; up to \$10m may be appropriated from the account any fiscal year

Healthy Maryland Initiative, HB 71

- ▶ Requires additional \$11 million in annual appropriations for tobacco use prevention and cessation programs starting in 2018 and in each fiscal year thereafter; alters tobacco tax rate on cigarettes and other tobacco products.

Premium Cigars Rate, HB 139

- ▶ Alters tobacco tax rate on premium cigars from 15% to 7.5% for 5 years

E-Cigarette Taxation, HB 861 (Withdrawn)

- ▶ *Adds electronic smoking devices to the definition of “cigarette” in laws related to collection of tobacco taxes*

2016 Bills: Use Restrictions

Prince George's Smoking Lounge Exception, HB 1069

- ▶ Included provisions allowing an exception to Clean Indoor Air Act prohibiting smoking at casinos by allowing smoking in specific smoking lounge area; amendment removed these provisions

Cars With Kids, HB 1431 (Withdrawn)

- ▶ *Prohibits smoking in a car carrying a child under 8; \$50 penalty; not a moving violation; primary offense; mobile homes serving as dwellings excluded*

Electronic Smoking Devices at Public Schools, HB 750 (Withdrawn)

- ▶ *Requires State Department of Education to work with local school systems to develop a policy prohibiting e-cigarette possession on school property, in school buses, and at school-sponsored events*

2016 Bills: Sales Restrictions

Civil Penalties for Sales to Minors, HB 1504 (Passed House)

- ▶ Enforces civil penalties not exceeding \$300/1st violation, \$1k/2nd violation within 24 months, \$3k/subsequent
- ▶ County health officer or designee may issue civil citation

Tobacco 21, HB 775 (Unfavorable report)

- ▶ *Increases minimum age to purchase tobacco products to 21; prohibits distribution of tobacco products and accessories to those under 21; includes vending machines (unless in a 21+ establishment)*

2016 Bills: Local Authority

Altadis Decision Reversal, HB 1485

- ▶ Court of Appeals struck down Prince George's County law requiring cigars be sold in packages of at least 5
- ▶ Decision can be interpreted narrowly to only preempt local cigar packaging laws **OR** more broadly to prevent local laws regulating sale or packaging of tobacco products
- ▶ Industry reps have threatened to sue, notifying multiple jurisdictions that their laws may be preempted
- ▶ Bill seeks to reverse courts decision and clarify that local regulation of tobacco products is permitted in MD
- ▶ **St. Mary's County is a County Commissioner and not a Code Home Rule government; not affected by this legislation yet**

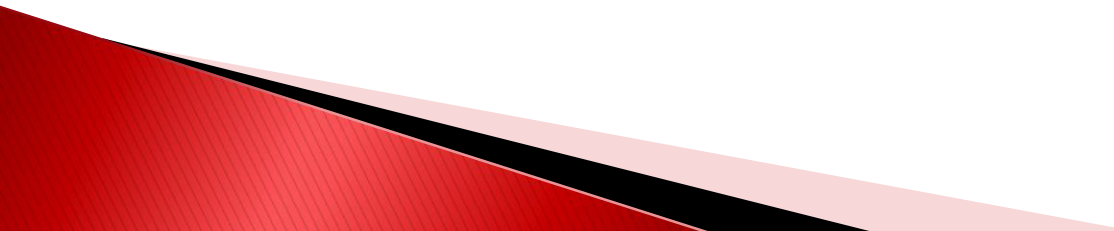
Local Legislation

County Specific E-Cigarette Regulation

County	Taxation	Sales to Minors	Clean Indoor Air	Child Resistant Packaging
Baltimore City	X	Sales to minors prohibited (Balt. City Code § 12-502)	Prohibited; exempts restaurants/taverns that allow e-cigarettes and provide such notice to patrons (Balt. City Code § 12-101)	X
Howard	X	X	Prohibited, with narrow exemptions (Howa. Co. Code § 12.601)	X
Montgomery	30% tax on wholesale e-cigarette price (Mont. Co. Code § 52-96)	Use by minors prohibited (Mont. Co. Code § 24-13)	Prohibited, with narrow exemptions (Mont. Co. Code § 24-9)	Currently effective (Mont. Co. Code § 24-14)
Prince George's	X	Effective 1/11/16 (CB-34)	Effective 1/11/16; exempts casino (CB-34)	Effective 1/11/16 (CB-34)
State Law	X	Prohibits e-cigarette and all component sale; police and health officers have enforcement authority; civil penalties enforced (Md. Code Ann., Health-Gen 24-305; SB 7, HB 489)	X	X

E-Cigarette Health Effects

What's Inside E-Cigs?

- ▶ E-liquid cartridge made up of nicotine extracted from tobacco, mixed with a base (usually propylene glycol); may contain flavorings, colorings, and other chemicals
 - ▶ Ingredients not yet known; studies found detectable levels of antifreeze, formaldehyde, benzene and other carcinogens
 - ▶ Flavors target kids, safety unknown
- 

Scientific Studies

- ▶ **E-cigarette vapor linked to decreased immunity against pneumonia and other viral infection; mice exposed to e-cig vapor showed significantly impaired pulmonary bacterial clearance**
 - *Electronic Cigarette Vapor Exposure Decreases Staphylococcus Aureus Susceptibility to Macrophage And Neutrophil Killing*, Crotty Alexander et al 2014;
 - *Exposure to Electronic Cigarettes Impairs Pulmonary Anti-Bacterial and Anti-Viral Defenses in a Mouse Model*, Sussan et al 2015

- ▶ **Harmful cardiac, pulmonary, and reproductive effects detected from exposure to e-cigarettes and other alternative tobacco products in human and animal studies; mice exposed in utero had increased cardiovascular risk factors, liver fibrosis and inflammation**
 - *Alternative Tobacco Products May Be Just as Dangerous As Cigarettes*, February 2016

Scientific Studies

- ▶ Flavors also showed effects in studies: cinnamon-flavored liquids repeatedly showed the most significant immune suppressive effects

▶ *Alternative Tobacco Products May Be Just as Dangerous As Cigarettes, February 2016*

- ▶ While FDA may classify flavoring agents “generally recognized as safe” for oral consumption, inhalation may show different results

▶ *Alternative Tobacco Products May Be Just as Dangerous As Cigarettes, February 2016*

- ▶ More research & time needed, especially when vaping ingredients are finally disclosed

Other Health Dangers

- ▶ Very toxic by ingestion
 - Through March 31, 2016, American Association of Poison Control Centers (AAPCC) has received 493 e-cigarette related calls; 2015 had 3073 reports
 - *AAPCC E-Cigarettes and Liquid Nicotine*
 - Fatal human dose estimated to be 50 to 60 mg; some e-cigs and refills go up to 54 mg
 - CDC, National Institute for Occupational Safety and Health, Nicotine Chemical Listing
 - Especially dangerous for kids
- ▶ Explosion incidents, most from battery failure

Underage Use Prevention & Reduction Strategies



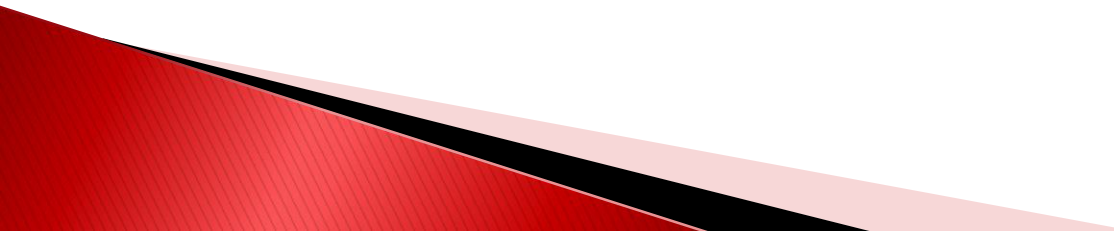
Teen Usage Data

- ▶ Latest data from CDC Morbidity and Mortality Weekly Report (MMWR), *Tobacco Use Among Middle and High School Students, United States 2011–2015*
 - 1 in 4 HS students and 1 in 13 MS students reported current use of any tobacco product
 - E-cigarette use at all-time high: jumped from 1.5% in 2011 to 16% in 2015 among HS, 0.6% to 5.3% among MS
 - Traditional tobacco product usage dropped

What Can We Do?

- ▶ On the state & county level:
 - Retailer education & training, incentives for retailers in compliance
 - Partner with local law enforcement to conduct compliance checks for underage e-cig sales
 - Vaping education and cessation programs for youth
 - Legislation targeting e-cigarettes, such as taxing electronic nicotine devices
 - TV, radio, and other media messages targeted to counter vaping among youth

What Can We Do?

- ▶ On the community level:
 - Community programs, school and college policies encouraging tobacco-free environments and lifestyles
 - Community programs that reduce vaping advertising, promotions, and availability of vaping products
 - Health coalitions partnering with schools and/or religious entities to lead anti-vaping youth activities
 - Health coalition town hall meetings to raise awareness
- 

Related Issues: Shatter and Hookah

Shatter

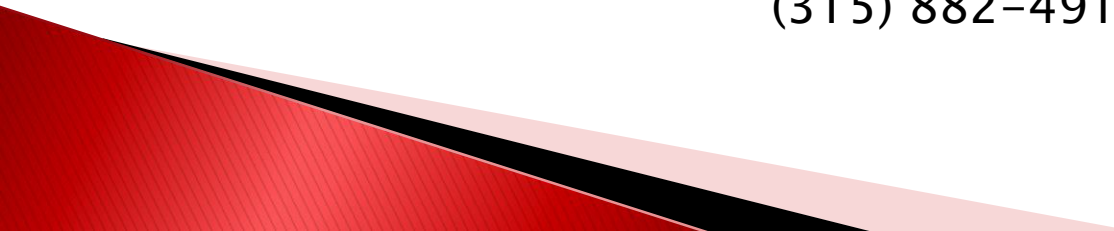
- ▶ New very high-potency marijuana, about 80% THC content (average THC of regular weed around 15%)
- ▶ A form of marijuana wax, derived from butane hash oil
- ▶ Smoked or inhaled with a vaporizer, often called “dabbing”: inhaling vapors from “dabs” of waxy or solid marijuana concentrate
- ▶ Powerful enough to make users pass out after one inhalation; some hospitalizations reported
- ▶ Legal for recreational use in Colorado and Washington; illegal in MD
- ▶ Popularity rising across the country; problematic as youth generally do not view marijuana as harmful
- ▶ High retail value in legal states (\$60/gram in CO); black market value even higher

Hookah

- ▶ Water pipes or shisha, used to smoke specially made tobacco, usually flavored; seen as a less harmful alternative to smoking
- ▶ Rising popularity among high schoolers and middle schoolers
 - From 2011 to 2015, use among HS increased from 4.1% to 7.2%; among MS, 1% to 2%
- ▶ One sitting (45–60 minute session) is equivalent to the same amount of tar and nicotine as a pack of cigarettes
- ▶ Charcoal used to heat tobacco produces smoke containing high levels of carbon monoxide, metals, and cancer-causing chemicals
- ▶ Hookah smokers may be at risk of the same diseases as cigarettes smokers (oral, lung, stomach, esophagus cancers; reduced lung function; decreased fertility)
- ▶ Infections may be passed by sharing a hookah
- ▶ Issue of herbal “no tobacco” hookah, proven untrue

Questions?

Lessa Vernyi-Kellogg, JD
Legal Resource Center for Public Health Policy
ovkellogg@law.umaryland.edu
(315) 882-4916

A decorative graphic in the bottom-left corner consisting of overlapping red and black diagonal stripes.