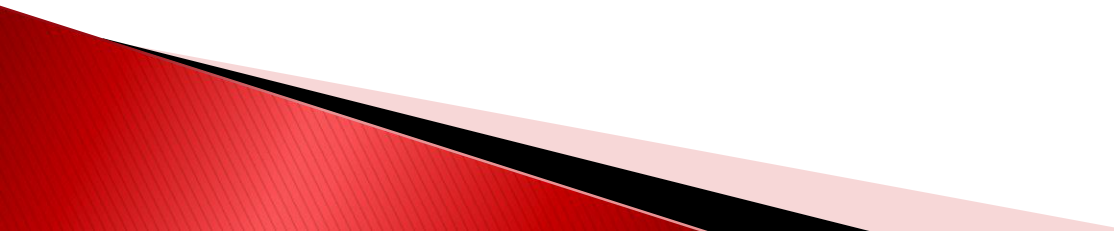


# Electronic Cigarettes: Past, Present and Future

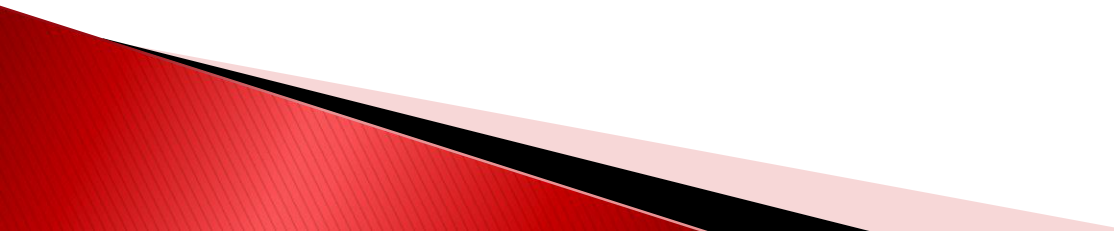


Healthy St. Mary's Partnership  
Inaugural Meeting  
June 4, 2015

# Presentation Overview

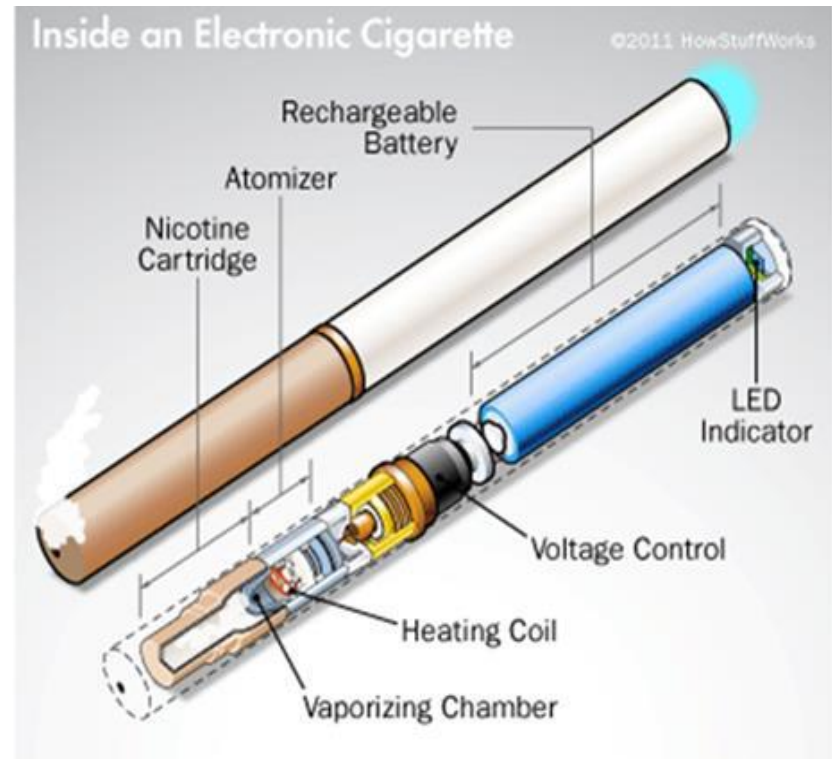
- ▶ **Overview of Electronic Cigarettes**
  - ▶ **Existing Regulation**
  - ▶ **FDA Proposed Rule**
  - ▶ **General Assembly 2015**
  - ▶ **What's Possible for Harford County?**
- 

# Electronic Cigarettes

- ▶ **What is an electronic cigarette?**
  - ▶ **Where are electronic cigarettes sold?**
  - ▶ **Who uses electronic cigarettes?**
  - ▶ **How do electronic cigarettes affect health?**
  - ▶ **How are electronic cigarettes currently regulated?**
- 

# What is an E-Cigarette?

- ▶ Battery-operated device containing liquid nicotine that is vaporized and inhaled by the user
- ▶ Many popular brands such as Blu and NJOY are disposable and resemble cigarettes or little cigars, but personal vaporizers or PVs make up the fastest growing part of the market



# Personal Vaporizers (PVs)





**OPTIMAL  
VAPOR**



**VAPOR99**

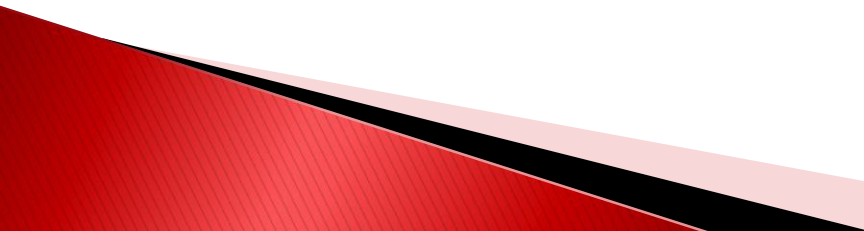
Grand Opening!



# Liquid Nicotine/E-Juice

- ▶ Usually comprised of propylene glycol or glycerol, nicotine, flavoring, and water.
- ▶ Available in flavors that entice adolescents/teens, including cotton candy, bubblegum, and cherry cola.
- ▶ Also attract young children, who risk poisoning even from exposure to skin.
- ▶ Typically contains a nicotine concentration of 2.4%, or 24mg/ml, though solutions with concentrations as high as 10% are available for purchase online.

# Where are e-cigarettes sold?

- ▶ May be sold at any retailer – **no tobacco license is required to sell**
  - ▶ Most convenience stores, gas stations, grocery stores offer the most popular brands like NJOY, Blu, etc. (disposable and refillable)
  - ▶ No restrictions on **internet sales** – youth may purchase online relatively easily
  - ▶ **Vape shops** – retailer stores specifically catering to electronic cigarettes and their accessories
- 



# Who Uses Electronic Cigarettes?

CDC Morbidity and Mortality Weekly, April 16, 2015

National Youth Tobacco Survey Results:

- ▶ From 2011 to 2014, statistically significant increases were observed among *high school students* for current e-cigarette use (1.5% to 13.4%):
  - The largest increase in e-cig use occurred from 2013 to 2014:
    - Current e-cigarette use **tripled** from 2013 (660,000 [4.5%]) to 2014 (2 million [13.4%]) among high school students
    - Among middle school students, prevalence increased by a similar magnitude, from 1.1% (120,000) to 3.9% (450,000)

*This means 2.4 million youth reported using electronic cigarettes.*

# Who Uses Electronic Cigarettes?

- ▶ Among *non-smoking youth* who had ever used e-cigarettes, 43.9% percent said they have intentions to smoke conventional cigarettes within the year.
- ▶ There is evidence that nicotine's adverse effects on adolescent brain development could result in lasting deficits in cognitive function.
- ▶ Adult e-cigarette use rose from 3.3% in 2010 to 8.5% in 2013.
  - Current cigarette smokers who have ever used an e-cigarette increased from 9.8% in 2010 to 36.5% in 2013.
  - Former cigarette smokers who have ever used an e-cigarette increased from 2.5% in 2010 to 9.6% in 2013.

# Sales and Marketing of E-cigs

- ▶ Market exceeded \$2.5 billion in 2014
- ▶ Revenues doubled *every year between 2008 and 2013* – growth slowed significantly in 2014
- ▶ Spending on all media increased from **\$5.6 million** in 2010 to **\$82.1 million** in 2013
- ▶ Altria (Philip Morris) subsidiary NuMark acquired ESD business Green Smoke, Inc. for \$110 million in February 2014; Lorillard purchased *Blu* in 2013 and R.J. Reynolds recently developed Vuse which entered the market in 2014
- ▶ Vaporizers growing twice as fast as “cigalikes” → total sales expected to increased 25% per year through 2018

# Individual health effects

- ▶ “We do not currently have sufficient data about e–cigarettes and similar products to determine what effects they have on public health.” *FDA report, April 2014*
- ▶ The FDA detected small levels of toxins and carcinogens in a small sample of ESDs in 2009
- ▶ ESD vapors have also been found to contain toxins (although at significantly lower levels than in cigarette smoke)
- ▶ 2<sup>nd</sup> generation e–cigarettes (i.e. PVs) heat liquid nicotine at significantly higher temperatures (approaching burning temps), which results in greater toxicity
- ▶ Number of calls to poison control increased from 1 per month in 2010 to 215 per month by early 2014

# Population level health effects

## The Good...

- ▶ Several studies show e-cigarettes to be “modestly effective” and “comparable to the patch” in terms of helping smokers quit
- ▶ Users generally use e-cigarettes because they perceive them to be less toxic than traditional cigarettes (83%), and to aid in tobacco craving (79%) and to quit (46%)
- ▶ Combustible tobacco (cigarettes and cigars) is far and away the greatest cause of premature death and analysts project e-cigarettes sales may overtake combustible sales within a decade

BUT.....





# Population level health effects



## The Bad...

- ▶ May cause confusion in enforcement of existing Clean Indoor Air laws
- ▶ May renormalize, glamorize and make tobacco products more attractive to youth
- ▶ *May promote continued, dual use of combustible tobacco products*

# Existing Regulation

# Existing Regulation of E-cigs

## ▶ *Sottera Inc., v. FDA* (2010)

- In 2008, FDA attempted to block the import of electronic cigarettes (most of which made overseas)
- Sottera, the maker of NJOY challenged the ban in federal court
- Holding: e-cigarettes are not drug delivery devices because the manufacturers have made no cessation claims. Therefore, the products may only be regulated under the Tobacco Control Act as a tobacco product

## ▶ **Maryland**

- **Health-General 24-305** – “a person may not sell, distribute, or offer for sale to a minor an electronic device that can be used to deliver nicotine to the individual inhaling from the device, including an electronic cigarette, cigar, cigarillo, or pipe.”
- *Amended in 2015 session*

# FDA Proposed Rule

# FDA and Tobacco Control

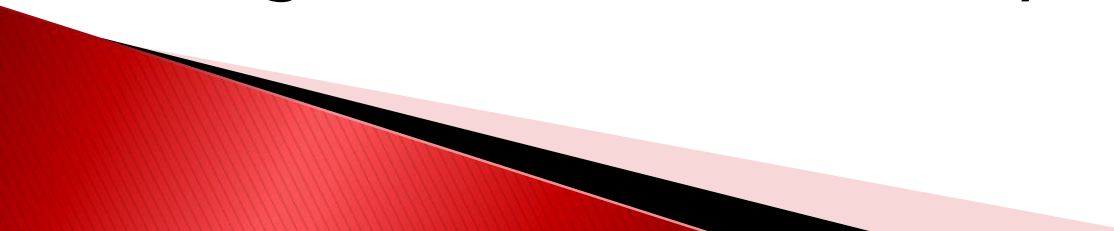
- ▶ Tobacco Control Act (2009) gave FDA authority over tobacco products, meaning *“any product made or derived from tobacco that is intended for human use.”*
- ▶ Congress also gave specific directions as to which tobacco products the FDA had to regulate immediately:
  - Cigarettes,
  - Cigarette tobacco,
  - Roll-your-own tobacco and
  - Smokeless tobacco
- ▶ Finally, the FDA may “deem,” by regulation, anything meeting the statutory definition of tobacco products as subject to the law or any of its parts.



# Proposed Rule

- ▶ After nearly 5 years, on April 24, 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
- ▶ Products to now be regulated include:
  - **electronic cigarettes,**
  - cigars,
  - little cigars,
  - pipe tobacco,
  - nicotine gels,
  - waterpipe (or hookah) tobacco, and
  - dissolvables
- ▶ So what does it mean that these products will now be regulated?

# FDA Deeming Regulation

- ▶ The Tobacco Control Act requires the FDA to adopt certain requirements for ALL tobacco products under its authority, but MOST authority is discretionary
  - ▶ Essentially, short of banning these newly deemed tobacco products, FDA may regulate as they see fit
  - ▶ In the proposed rule, FDA extends the same regulations to ALL newly deemed products
- 

# Automatic Requirements

- ▶ Any deemed tobacco product **MUST**:
  - Register with the FDA and report product and ingredient listings;
  - **Only market new products after FDA review**
  - 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)

# Non-Automatic Requirements

- ▶ 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)

# So what does it all mean?

- ▶ Rule exempts e-cigarette manufacturers from pre-market approval requirements, which could mean they don't have to comply with regulations for an additional 2 years following the final rule
- ▶ Many important regulations, such as flavored ban, were not 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

# Introduced Bills 2015

## PASSED

### Senate Bill 7 – Electronic Cigarettes – Sales to Minors

- ▶ Ban sale of e-cigs and component parts; grant enforcement authority to police and health officer (or designee); change from criminal to civil penalties
- ▶ Effective October 1, 2015
- ▶ Inadequacy of Existing Law:
  - No enforcement provision
  - Did not cover sale of liquid nicotine
  - Criminal penalties only

# Introduced Bills 2015

**FAILED**

## House Bill 26 – Use of Electronic Smoking Devices – Prohibition

- ▶ Expand definition of “smoking” to include electronic cigarettes
- ▶ Prohibit smoking in all indoor areas open to the public, including, bars, restaurants and workplaces

# Potential Bills 2016 and Beyond

## Child-Resistant Packaging

- ▶ Dramatic increase in e-cigarette related poison control calls in Maryland and nationwide
- ▶ More than half of poison control calls are for children under the age of 5
- ▶ MN, NY, VT, HI and WY have already adopted legislation; many other states considering bills

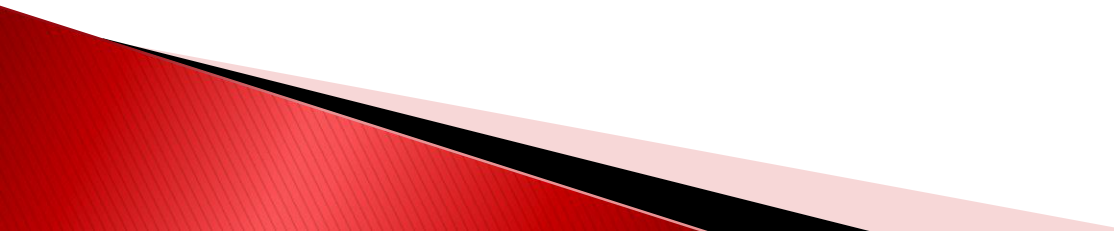
## Licensing

- ▶ Require manufacturers and retailers to acquire e-cigarette business licenses in order to do business in Maryland (similar to tobacco licenses)
- ▶ Assist state in identifying and monitoring these businesses; punish those violating sales to minors laws

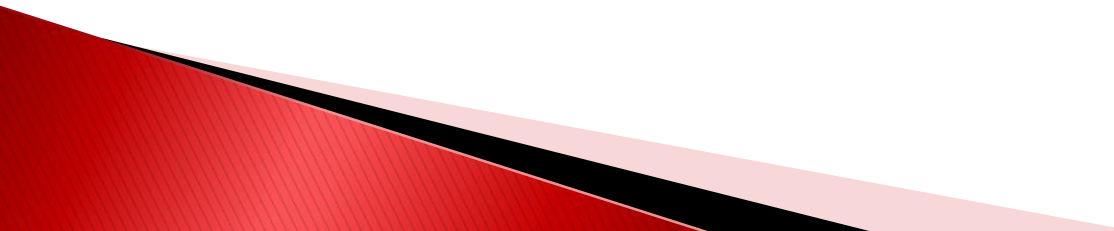
**!!!NOTE: NO STATE PREEMPTION!!!**

# What's next for St. Mary's County?

As a NON-HOME RULE County, St. Mary's County has limited authority to regulate for the public health but could:

- Seek legislative change at the General Assembly;
  - Pass a Board of Health regulation.
- 

# Options

- ❑ Enforcement of Youth Sales Prohibition
  - ❑ Vape Shops
    - Zoning
    - Age restrictions
    - Licensing
  - ❑ Packaging
    - Child Resistant
    - *Baltimore City; Montgomery County*
  - ❑ Indoor Use
  - ❑ Flavors
- 

Questions?



# Presenter Information

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