E-cigarettes—
All that Vapes is not Nicotine...
Welcome
At the conclusion of this activity, participants should be able to:

• state what e-cigarettes are and how they are used.

• state the concerns about e-cigarettes and vaping devices from a public health standpoint

• articulate how to discuss e-cigarette use and exposure to vapor with patients and families in a clinical setting.

• summarize major provisions proposed by the recently-released FDA deeming regulations.

• understand how to submit a comment to FDA through the public commenting process.
Susanne Tanski, MD, MPH, FAAP
Associate Professor of Pediatrics
Geisel School of Medicine at Dartmouth
Mark Gottlieb, JD
Executive Director
Public Health Advocacy Institute
E-cigarettes –
all that vapes is not nicotine...

Susanne Tanski, MD, MPH, FAAP
American Academy of Pediatrics, Julius B. Richmond Center of Excellence
Norris Cotton Cancer Center, Department of Pediatrics
Predicting the Future, 20 years ago...

• “If people have difficulty overcoming both nicotine dependence and long-term habit change, then surely the solution is to help them avoid most of the health risks with only a minimal alteration in their nicotine seeking habit. This implies a nicotine replacement device that looks like a cigarette and delivers cigarette-like boli of nicotine but does not deliver the tar and carbon monoxide which causes the cast majority of smoking-related disease...the development and promotion of such a product (and the eventual replacement of tobacco) could have massive beneficial health implications.” Foulds, *Addiction*, 1994
What are e-cigarettes?

Inside the e-cigarette

1. A sensor detects when a smoker takes a drag, sending a signal to a processor that switches on a heater, known as an atomiser.
2. The atomiser heats up a nicotine solution to produce a vapour that can then be inhaled.
3. As someone draws on the e-cigarette, an LED light is also switched on by the processor, simulating a flame.
From Cigarette to Vapor Pen, an evolution in technology
A quickly changing product...

- First generation – poor battery life, very inconsistent
- Second generation – present one, with many manufactured in China, Lithium Ion battery but poor quality control
- Third generation – Vuse and MarkTen, processor controlled for temperature and puff typography
  - improved chemosensory effects
  - Improved deposition in the alveoli for arterial absorption
- It appears that e-Hookah and vapor pens have gone through similar evolutions
Constituents of e-juice: humectant, +/- nicotine and flavoring

• Propylene glycol: general recognized as safe
  – Acceptable for use in flavorings, drugs, cosmetics and as direct food additive
  – Few human studies for inhalation, however has been used as a tobacco humectant historically
    • Can cause eye and respiratory irritation
    • MSDS from Dow Chemical states “inhalation exposure to [propylene glycol] mists should be avoided”
  – (EPA cites a single rat study from 1947 for their inhalation effects).
  – Altria published a study in rats and dogs in 2011, stating a plan to conduct “first-time-in-man” human exposure studies

Werley et al, *Toxicology* 2011
Constituents of e-juice: humectant, +/- nicotine and flavoring

• Vegetable glycerin: generally recognized as safe
  – When heated and vaporized, can form acrolein, which can cause upper respiratory irritation

• For all: unknown long-term health impacts from repeated inhalation
For this patient, the suspected source of her exogenous lipoid pneumonia was recurrent exposure to glycerin-based oils found in e-cigarette nicotine vapor. Since the 1980s, there has been an ever-increasing development of electronic nicotine-delivery systems. The e-cigarette comprises a plastic tube and a battery-powered electronic heating device that vaporizes a liquid nicotine cartridge. E-cigarettes are advertised as an alternative to smoked tobacco and as a smoking cessation aide.
Constituents of e-juice: Nicotine

• Nicotine effects: low doses
  – Complex pharmacodynamics – neural stimulant at low doses and a depressant at high doses
    • Stimulates memory and alertness. People who use tobacco often depend on it to help them accomplish certain tasks and perform well.
    • Many people feel a sense of well-being.
    • Decreases the appetite (for this reason, the fear of weight gain affects some people's willingness to stop smoking); boosts mood and may relieve minor depression.
    • Increases intestinal activity, creates more saliva and phlegm, increases heart rate by 10 to 20 beats per minute; increases blood pressure by 5 to 10 mmHg.
Constituents of e-juice: Nicotine

• Nicotine overdose
  – Excess: nausea and vomiting, excessive salivation, abdominal pain, pallor, sweating, hypertension, tachycardia, ataxia, tremor, headache, dizziness, muscle fasciculations, and seizures
  – Death: several case reports of suicide by nicotine
    • One child death SO FAR from e-juice reported in the press
    • Surprisingly few deaths given toxicity
Nicotine Toxicity?

• The dose makes the poison
  – Oral nicotine ~20% bioavailable

• Lethal dose in rats = 50mg/kg; mice 3mg/kg

• Humans? Stated as 0.8mg/kg (60mg), which would make it more toxic than cyanide
  – Multiple literature reports of survival at much higher doses (6 mg/kg)
  – Recent review suggests 6.5-13mg/kg LD50 may be more reasonable

Archives of Toxicology, 2013
Math

- 36mg/ml, 10ml = 360 mg nicotine
  - Conventional idea of 60mg = death, this could kill 6 people!
  - New math = it would still kill an adult
  - My 3 year old = 13kg
    - 0.8mg/kg = 10mg = 0.28 ml!!
    - 6.5-13mg/kg = 2.3-5ml...

- 18mg/ml is more standard...

- But in perspective...
  - Infant Tylenol at 80mg/0.8ml, 3000mg in 1 oz bottle
  - 200mg/kg is hepatotoxic, so drinking a bottle could kill her...
FIGURE. Number of calls to poison centers for cigarette or e-cigarette exposures, by month — United States, September 2010–February 2014

- Cigarettes
- E-cigarettes
More Math...

• How much nicotine DO you get per puff?
  – Different bioavailability through puffing than drinking
  – Depends on many factors: temperature of the atomizer, how much juice is atomized, size of the atomized droplets, depth of the “puff”, concentration of the e-juice
    • Large droplets will deposit in the oropharynx and upper airway (venous absorption)
    • Small droplets can get deeper – into alveoli for arterial absorption
So how much do you get per puff?

• HIGHLY variable (remember the quality control issues?)

• 2013 study found 0-35 μg/puff, so minimum of 30 puffs to deliver the 1mg nicotine inhaled from a traditional cigarette
  – Only part of the nicotine is vaporized, and of that 50-60% of nicotine is inhaled
  – Wide variability in vaping behavior of ten volunteers:
    – Puff duration 1.8 +/- 0.9s, puff volume 70 +/- 68 ml, puffs/session 15 +/- 6.

Goniewicz, et al. *Nicotine and Tobacco Research* 2013
AGO Vaporizer

Quality & Stylish Charger

Small tools use to clean the vaporizer
WHEN YOU CAN’T HAVE JUST ONE

LIVE THE GOOD LIFE WITH STYLE

PLAYBOY PREMIUM ELECTRONIC CIGARETTES
BUY ONLINE AT PLAYBOYVAPOR.COM
Constituents of e-juice & beyond

- Flavorings and chemosensory agents
- Wax/hashish
- Wax/cannabis
- Oils
- Whole tobacco, Herbs, Marijuana
What are the health harms?

• Relative to smoked tobacco, markedly less
  – No tar
  – Variable levels of nicotine to allow “step down”

• Relative to NO tobacco or medical NRT
  – Unclear, but concern for decreased lung function
  – Quality control – adulterated products have been found

• May create new nicotine addiction
  – Among nicotine naïve, or former users

• Safety of other flavor and chemosensory agents when heated and inhaled is unknown
Ploom
What are the health harms?

- May maintain combusted tobacco use
  - Among users who might otherwise have quit completely

- At present (6/2013), completely unregulated
  - FDA has issued their Deeming Document for proposed rulemaking, currently accepting public comment
  - No Consumer Products Safety Commission oversight
  - ANYONE can manufacture and sell
  - Most of the market still comes from China
Cloud Vape Pen
What are the Public Health Harms?

• Second-hand vapor is NOT just water vapor
  – Emit variable levels of nicotine (1/10\textsuperscript{th} that of cigarettes), plus fine particles of similar size to that of cigarettes, and comparable concentration of fine particles
  – Emit low levels of other toxins: formaldehyde, acetaldehyde, metals

Czogala et al, *Nicotine and Tobacco Research* 2013
Fuoco et al, *Environmental Pollution* 2014
What are the public health harms?

• Re-normalizing the image of smoking
  – Allowed in places where smoking is not allowed
  – Advertising is completely unrestricted, with TV ads for the first time since 1971
  – Largely indistinguishable from cigarettes
blu e-cigarette ad
Why e-cigarettes/vape pen/e-hookah?

- Curiosity
- Reduction of other tobacco products
- Cessation
- Stealth
- Perception of a safer product
- Social acceptance
PREMIUM DISPOSABLE E-HOOKAH

Fluid™

FLAVORS
Berry Sexy
Vanilla Vixen
Double Green Apple
Grape Sensation
Son of a Peach
Mint Condition
Mel-On Wheels
Unorthodox Blue
Turkish Coffee

Taste your breath away....
What's in your mouth?

No Nicotine  No Tar  No Charcoal  No Mess

Fluid E-Hookah is not intended for anyone under the age of 18. Fluid E-Hookah does not contain nicotine. These products are not intended to diagnose, treat, cure or prevent any diseases. Fluid E-Hookah is a registered trademark and should not be used with the menthol content of the product. All Rights Reserved.
What is the prevalence of use?

• Not really clear... did we ask the right question??

• NYTS data: An estimated 1.78 million students reported having used e-cigarettes in 2012.
  
  – Electronic cigarette use 2011-2012 increased significantly among middle school (0.6% to 1.1%) and high school (1.5% to 2.8%) students, and hookah use increased among high school students (4.1% to 5.4%)
  
  – What about e-hookah???
  
  – Some 20.3% of middle-school students (aged 11—14 years) and 7.2% of high-school students (aged 14—18 years) who had ever tried e-cigarettes reported that they had never smoked conventional cigarettes

MMWR, 2013
The Utah Story, 2012

Current Tobacco or Nicotine Product Use
Figure 1. Percentage of students reporting use of tobacco or nicotine products by type of product, Grades 8, 10, 12, Utah, 2013

Current Electronic Cigarette Use
Figure 3. Percentage of students, Grades 8, 10, 12 in 2013 and Adults, 18+ in 2012, reporting current e-cigarette use, Utah

Source: Utah Prevention Needs Assessment, 2013
What is the prevalence of use?

• Among adults in 2011, 6.2% of all adults and 21.2% of current smokers had tried e-cigarettes

King et al, 2013
Is there evidence of efficacy for cessation?

Is there evidence for dual use?

• It’s close... and yes...

• Data continue to be published
## 2013 Lancet Paper

<table>
<thead>
<tr>
<th>Continuous abstinence</th>
<th>Nicotine e-cigarettes (n=289)</th>
<th>Patches (n=295)</th>
<th>Difference $\chi^2$ p value</th>
<th>Relative risk (95% CI)</th>
<th>Risk difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>67 (23.2%)</td>
<td>47 (15.9%)</td>
<td>0.03</td>
<td>1.46 (1.04 to 2.04)</td>
<td>7.25 (0.84 to 13.66)</td>
</tr>
<tr>
<td>3 months</td>
<td>38 (13.1%)</td>
<td>27 (9.2%)</td>
<td>0.12</td>
<td>1.44 (0.90 to 2.33)</td>
<td>4.00 (−1.10 to 9.10)</td>
</tr>
<tr>
<td>6 months (primary outcome)</td>
<td>21 (7.3%)</td>
<td>17 (5.8%)</td>
<td>0.46</td>
<td>1.26 (0.68 to 2.34)</td>
<td>1.51 (−2.49 to 5.51)</td>
</tr>
</tbody>
</table>

**Sensitivity analyses for 6 months continuous abstinence data**

| Complete case analysis* | 21/241 (8.7%) | 17/215 (7.9%) | 0.76 | 1.10 (0.60 to 2.03) | 0.80 (−4.27 to 5.87) |
| Per-protocol analysis 1† | 21/231 (9.1%) | 15/207 (7.2%) | 0.48 | 1.25 (0.66 to 2.37) | 1.84 (−3.28 to 6.96) |
| Per-protocol analysis 2‡ | 20/211 (9.5%) | 13/151 (8.6%) | 0.78 | 1.10 (0.57 to 2.14) | 0.87 (−5.10 to 6.84) |
| Per-protocol analysis 3§ | 12/147 (8.2%) | 12/138 (8.7%) | 0.87 | 0.94 (0.44 to 2.02) | −0.54 (−7.00 to 5.92) |
| Including not biochemically verified¶ | 30 (10.4%) | 21 (7.1%) | 0.16 | 1.46 (0.86 to 2.49) | 3.26 (−1.32 to 7.84) |

**Repeated measures analysis**

| Overall treatment effect | -- | -- | 0.05 | 1.61 (1.00 to 2.57) | -- |
| 1 month effect | -- | -- | 0.004 | 1.87 (1.23 to 2.85) | -- |
| 3 months effect | -- | -- | 0.12 | 1.52 (0.89 to 2.58) | -- |
| 6 months effect | -- | -- | 0.21 | 1.46 (0.81 to 2.62) | -- |

**7 day point prevalence abstinence**

| 1 month | 69 (23.9%) | 51 (17.3%) | 0.05 | 1.38 (1.00 to 1.91) | 6.59 (0.05 to 13.13) |
| 3 months | 62 (21.5%) | 50 (17.0%) | 0.17 | 1.27 (0.91 to 1.77) | 4.50 (−1.88 to 10.88) |
| 6 months | 61 (21.1%) | 46 (15.6%) | 0.09 | 1.35 (0.96 to 1.91) | 5.52 (−0.75 to 11.79) |
Figure 2: Kaplan-Meier analysis of time to relapse
EC = e-cigarettes.
### Table 4: Change from baseline in cigarettes consumed per day during follow-up period, nicotine e-cigarettes and patches

<table>
<thead>
<tr>
<th></th>
<th>Nicotine e-cigarettes</th>
<th>Patches</th>
<th>Difference (nicotine e-cigarettes–patches)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SE</td>
<td>Mean</td>
</tr>
<tr>
<td>Overall</td>
<td>11.1</td>
<td>0.4</td>
<td>9.1</td>
</tr>
<tr>
<td>1 month</td>
<td>12.9</td>
<td>0.4</td>
<td>10.5</td>
</tr>
<tr>
<td>3 months</td>
<td>10.8</td>
<td>0.4</td>
<td>9.1</td>
</tr>
<tr>
<td>6 months</td>
<td>9.7</td>
<td>0.4</td>
<td>7.7</td>
</tr>
</tbody>
</table>

*For those reporting smoking at least one cigarette in past 7 days.*
2013 Lancet Conclusions

• Not enough power to detect a difference between patch and e-cig and nicotine-free e-cig

• E-cig looks more promising, and was more favorable to the users
  – At 1m, 88% of e-cig users would recommend them to a friend, compared to 56% in patches group
Effects of Duration of E-Cigarette Use

- n=159. Longer e-cig use led to higher likelihood of being an ex-smoker than being dual user, & fewer combusted cigarettes among all.


![Graph showing traditional cigarettes smoked by duration of e-cigarette use.](image)
Best Evidence for Cessation (among those motivated to quit) yet...

Table 3: Associations between quitting method and abstinence

<table>
<thead>
<tr>
<th>Method</th>
<th>Full sample (n=5863)</th>
<th>Subsample: quit attempt started ≤ 26 weeks (n=3784)</th>
<th>Subsample: quit attempt started &gt; 26 weeks (n=2079)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1) E-cigarettes</td>
<td>(2) NRT over-the-counter</td>
<td>(3) No aid</td>
</tr>
<tr>
<td></td>
<td>% (N)</td>
<td>% (N)</td>
<td>% (N)</td>
</tr>
<tr>
<td>Self-reported non-smoking</td>
<td>20.0 (93/464)</td>
<td>10.1 (194/1922)</td>
<td>15.4 (535/3477)</td>
</tr>
<tr>
<td>Subsample: quit attempt started ≤ 26 weeks</td>
<td>20.3 (72/354)</td>
<td>11.0 (135/1222)</td>
<td>14.6 (323/2208)</td>
</tr>
<tr>
<td>Subsample: quit attempt started &gt; 26 weeks</td>
<td>19.1 (21/110)</td>
<td>8.4 (59/700)</td>
<td>16.7 (212/1269)</td>
</tr>
</tbody>
</table>

Model 1 = unadjusted. Model 2 = adjusted for age, sex, social grade, time since quit attempt started, quit attempts in the past year, abrupt vs. gradual quitting, and year of the survey. Model 3 = adjusted for the variables from model 2 and time spent with urges to smoke and strength of urges to smoke. Model 4 = adjusted for the variables from model 3 and the interaction terms time since last quit attempt started * time spent with urges and time since last quit attempt started * strength of urges to smoke. NB for the two subsample analyses, model 4 is redundant as there is no variation in the time since quit attempt. * p<0.05, ** p<0.01, *** p<0.001.
What happens now?

• Expected that FDA will assert jurisdiction
  – Improved quality control and production standards
  – More to come on this from the second half of webinar!

• Expected that the market will continue to explode
Market share projections
The Big 3 tobacco manufacturers — Altria Group Inc., Reynolds American Inc., and Lorillard Inc. — are projected to each hold about a 25 percent market share in the electronic cigarette sector by 2023. Only Lorillard, of the three, currently has national distribution with its blu eCigs product.

### Electronic cigarette market share in percent

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>2013</th>
<th>2015</th>
<th>2017</th>
<th>2019</th>
<th>2021</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altria Group Inc.</td>
<td>0</td>
<td>5</td>
<td>20</td>
<td>20</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Lorillard Inc.</td>
<td>30</td>
<td>28</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Reynolds American Inc.</td>
<td>2</td>
<td>15</td>
<td>20</td>
<td>20</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

### Electronic cigarette revenue (in billions)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>2013</th>
<th>2015</th>
<th>2017</th>
<th>2019</th>
<th>2021</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altria Group Inc.</td>
<td>$0</td>
<td>$0.1</td>
<td>$1.3</td>
<td>$2.1</td>
<td>$4.0</td>
<td>$5.2</td>
</tr>
<tr>
<td>Lorillard Inc.</td>
<td>$0.2</td>
<td>$0.5</td>
<td>$1.8</td>
<td>$2.9</td>
<td>$4.4</td>
<td>$5.8</td>
</tr>
<tr>
<td>Reynolds American Inc.</td>
<td>$0</td>
<td>$0.2</td>
<td>$1.3</td>
<td>$2.1</td>
<td>$4.0</td>
<td>$5.2</td>
</tr>
</tbody>
</table>

### Traditional cigarette revenue (in billions)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>2013</th>
<th>2015</th>
<th>2017</th>
<th>2019</th>
<th>2021</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altria Group Inc.</td>
<td>$14.9</td>
<td>$14.8</td>
<td>$13.1</td>
<td>$11.6</td>
<td>$9.5</td>
<td>$7.4</td>
</tr>
<tr>
<td>Lorillard Inc.</td>
<td>$4.7</td>
<td>$4.8</td>
<td>$4.3</td>
<td>$3.8</td>
<td>$3.1</td>
<td>$2.4</td>
</tr>
<tr>
<td>Reynolds American Inc.</td>
<td>$6.4</td>
<td>$6.1</td>
<td>$5.4</td>
<td>$4.8</td>
<td>$3.9</td>
<td>$3.1</td>
</tr>
</tbody>
</table>

Source: Wells Fargo Securities  
CASSANDRA SHERRILL/JOURNAL

So what to do?

• *Caveat emptor*
  – Must have a regulated product for an informed consumer, with fully disclosed labeling

• Research is imperative to assess second hand vapor effects (of all kinds), addiction potential and dual-use maintenance

• Until we know more about “eanything” and cessation, we can still recommend medicinal NRT, quit lines and support while people are becoming non-tobacco users
“Responsibly marketed and properly regulated, it is possible that e-cigarettes could benefit public health if they help significantly reduce the number of people who use conventional cigarettes and die of tobacco-related disease. But in the absence of FDA oversight, the easy availability of nicotine in uncontrolled quantities, packaging and flavors and marketing that appeals to youth raises serious concerns.” – Matt Meyer, Campaign for Tobacco Free Kids, 4/3/14
FDA’s Deeming Regulation

A foundational step toward comprehensive regulation of e-cigarettes and little cigars, premium cigars, hookah tobacco, and dissolvables

Mark Gottlieb, JD
FDA’s Deeming Regulation

- Family Smoking Prevention and Tobacco Control of 2009 conferred to FDA direct authority to regulate cigarettes, smokeless tobacco, and roll-your-own tobacco products.

- To regulate additional tobacco products, the FDA needs to deem them to be within their regulatory power under the 2009 law.

- On April 24, 2014, FDA’s Center for Tobacco Products issued a proposed deeming regulation to provide the agency with authority to directly regulate e-cigarettes, little cigars, premium cigars, hookah tobacco, and dissolvables.
But I Thought E-Cigarettes Do Not Contain Tobacco

- The FDA attempted to regulate e-cigarettes as drug delivery devices in 2008 and were taken to court by the industry.

- In December of 2010, the U.S. Court of Appeals for the DC Circuit ruled that because the nicotine in e-cigarettes is derived from tobacco, they should be regulated under by FDA’s Center for Tobacco Products. Unless they are marketed as cessation products, then normal drug approval requirements would apply.

- The deeming regulation seeks to give FDA authority to regulate any product that is “made or derived from tobacco that is intended for human consumption.”
E-Cigarette Proposal
(also applies to Hookah)

• National minimum sales age of 18 and age verification for age < 27.

• National prohibition on sampling.

• 1 static warning: WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

• Immediate prohibition on false/misleading advertising.

• Disclosure of ingredients, additives, compounds within 6 months.

• Disclosure of health-related documents within 6 months.
Components vs. Accessories

- The regulation covers components and parts of e-cigarettes and hookah, but not accessories.
  - E-cigarettes and their parts (or “vape pens” or “mods”) as well as the nicotine “e-juice” would be regulated.
  - Lighters, cases, hookah tongs, charcoal burners and items like cigar cutters or humidors would not be regulated by FDA.
Cigars: Regulatory Options

• The FDA is proposing 2 options:
  1. Would bring all cigars under the FDA’s authority;
  2. Would exempt premium cigars from FDA’s authority.

A premium cigar . . .
(1) Is wrapped in whole tobacco leaf;
(2) Contains a 100% leaf tobacco binder;
(3) Contains primarily long filler tobacco;
(4) Is made by combining manually the wrapper, filler, and binder;
(5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;
(6) Has a retail price (after any discounts) of no less than $10 per cigar;
(7) Does not have a characterizing flavor other than tobacco; and
(8) Weighs more than 6 pounds per 1000 units.
5 Proposed Rotating Warnings for Cigars

1. WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.

2. WARNING: Cigar smoking can cause lung cancer and heart disease.

3. WARNING: Cigars are not a safe alternative to cigarettes.

4. WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

5. WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.
Long Timeline for E-CIGARETTES

• Under proposal, e-cigarettes manufactures would be subject to *premarket review* in order to sell and market their products.
  – This normally means that FDA approval is required **before** product can be sold.

• FDA is proposing to give e-cigarette manufacturers 24 months after the deeming rule is finalized to submit a “premarket tobacco application.” During that time and until or unless the application is denied, sales and marketing can continue as it does now.
What the Deeming Regulation Does Not Do

- Ban flavors of cigars
- Restrictions on TV ads for e-cigarettes
- Marketing restrictions of any kind.
Better Late Than Never

• Deeming regulation is a foundational regulation.
• Needed for further action on e-cigarettes, cigars, etc.
• FDA is looking for a great deal of input to shape this and further regulatory actions.
• Public comment is a very important part of the regulatory process.
• Deeming regulation already has close to 11,000 comments.
• Your voice is critical.
Some Questions for Public Comment

• Should premium cigars be included?
  – How to approach fact that youth prefers flavored small or little cigars?
  – How should various categories of cigars be defined?

• What actions should the FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults?
  – What is the likelihood that individuals who engage in flavored tobacco product use will initiate cigarette use?
  – Should flavor ban on cigarettes be extended to cigars and/or e-cigarettes?

• How should e-cigarettes be regulated?
  – Should a continuum of risk among tobacco products be considered?
  – What component parts (vs. accessories) should be included in the product definition?

• Is the timeframe for premarket review applications (24 months) too long?

• Are proposed warnings sufficient?

• What restrictions on marketing of which products are appropriate?
How to Comment

• It is easy to comment.

• [http://shortlinks.phaionline.org/fda](http://shortlinks.phaionline.org/fda)

• Submit comments on the proposed rule by July 9, 2014.
Questions?

Submit questions into the box in the control panel. If we aren’t able to answer your question live, we will send a response to you after the webinar ends.

AAP Richmond Center

• Visit us: www.aap.org/richmondcenter
  – State-specific resources
  – Downloadable PowerPoint presentations
  – Funding opportunities
  – Tobacco control listserv

• Tobacco Prevention Policy Tool

• Contact us: richmondcenter@aap.org

www.facebook.com/aaprichmondcenter

• Next webinar: July 23rd
Link to post-webinar evaluation:

- https://www.surveymonkey.com/s/ECigWebinar