Science-Based Regulation of ENDS

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Big Tobacco involvement

Cliff Watson, CDC
Rapidly Evolving Marketplace for ENDS

“fixed-dose” / “closed” E-cigarettes

“open” / “tank” vaping systems

“mods” - high power adjustable vaping systems

E-hookahs & waterpipe inserts
Anatomy of E-cig

Indicator light
Lights up during inhalation; simulates glow of burning tobacco.

Battery

Cartridge
Holds the nicotine solution

Vaporization chamber

Battery

Sensor

Connector

Battery contacts

Heating coil
Current Situation with ENDS

“It’s a Wild West”

• No product standards
• No minimum/maximum for nicotine or other constituents
• Thousands of flavors
• Limited indoor air regulations
• No warning labels
• No advertising restrictions
• No across the board restrictions for sales to minors
Toxicity

Variability of toxicants within and across brands

- E-cigarettes primarily contain nicotine, propylene glycol, glycerin, water, and flavorants but also may contain some **unknown contaminants** (e.g., formaldehyde, acetaldehyde, acrolein, ethylene glycol, metals and traces of TSNA; Cheng 2014; Kosmider et al., 2015) or other **constituents with unknown effects** (e.g., rimonabant and amino-tadalafil; Hadiger et al., 2010).

- **No CO** exposures.

- Levels are **9 to 450 times lower** than conventional cigarettes and comparable to amounts generated by nicotine inhaler (Goniewicz et al., 2013, 2015; Laugesen, 2015).

- **BUT** unknown acute or long-term effects.
Toxicity: Flavors and Additives in Liquids

• DIACETYL (2,3-BUTANEDIONE) and ACETYL PROPIONYL (2,3-PENTANEDIONE) related to decline in lung function: found in 74.2% of the samples, mostly in sweet-flavored liquids.

  Farsalinos et al. Nicotine Tob Res 2014

• BENZALDEHYDE causes eye problems, burning of nose and throat and difficulty breathing: detected in 88 products (70%) with higher concentrations in cherry flavored products.

  Sobczak et al. SRNT, 2015

• CINNAMALDEHYDE & 2-METOXYCINNAMALDEHYDE is cytotoxic and found in cinnamon flavored e-liquids,

Nicotine

Variability of nicotine delivery within and across brands

- **Nicotine content of e-fluid**
- **Efficacy of nicotine vaporization** (varied from 21% to 83% across brands; Goniewicz et al., 2013).
- **Performance characteristics** (e.g., airflow rate, pressure drop, aerosol production, temperature; Trtchounian et al., 2010; Williams & Talbot, 2011; Brown & Cheng, 2014).
- **Experience and use patterns of user** (Behar et al., 2015; Eissnenberg, 2010; Etter & Bullen, 2011; Hajek et al., 2015; Vansickel et al., 2012; )
Toxicity/Nicotine

Concerns
• Variability of harmful constituents (but 9 to 450 times lower than cigarettes)
• Toxicity with some flavorants
• Variability in nicotine levels
• Reliability and safety of devices
• Long-term use consequences unknown

Potential Regulations
• Require a list of all ingredients, constituents, additives provided to regulators
• Require quality control (GMP)
• Establish product standards
  – Design, constituents, nicotine levels and other chemicals in vapor
• Provide accurate labeling information
Vaping in Public Places

Concerns

• Nicotine exposure
• Other constituents
• Normalization
• Cues for smoking

Potential regulations

• Comprehensive vaping ban
• Ban government buildings, schools, hospitals, restaurants
• Recommend no vaping in homes or in cars
Appeal: Flavorants

Concerns

• Multiple flavors and names
• Appeal to youth (USDHHS 2012; Kong et al., 2014)

Potential Regulation

• Ban candy-like and other flavors (brand names for cookies, soda, ice cream) that appeal to youth
Packaging

Concerns
• Easy to open and spill bottles
• No childproofing
• High youth appeal

Potential Regulations
• Childproof containers
• Not appealing to youth

Upstate New York boy, 1, dies after ingesting liquid

LEE MORAN NEW YORK DAILY NEWS Monday, December 15, 2014, 8:17 AM
Warning Labels

Concerns
• No warning labels on the majority of products
• Extensive warning labels on product manufacture by tobacco industry

Potential regulations
• Add health warning on packaging and marketing
  – This product contains nicotine. Nicotine is an addictive substance.
  – Nicotine can be toxic
  – Long-term effects are unknown
Marketing/Advertising

Youth and young adult exposure to ENDS ads on TV increased by over 250% from 2011 to 2013
Distribution
Minors successfully received deliveries of e-cigarettes from 76.5% of purchase attempts, with no attempts by delivery companies to verify their ages at delivery.

Williams et al., JAMA Pediatr, 2015)
Marketing/Advertisement/Distribution

Concerns

Potential regulations

- No implied or direct claims of reduced risk without evidence of benefit to public health
- Prohibit marketing that promotes dual use or dissuades smokers from complete cessation
- Restrict sales, distribution, marketing and advertising of ENDS to youth
- Apply same regulations for marketing and promotion of ENDS as applied to cigarettes
Uptake in Adults

- Overall ENDS use is low (2% some days or everyday; MMWR, 2014)
- Rate of e-cigarette use has been increasing annually
- Vast majority of users are smokers
  (Chapman and Wu, 2014; Grana et al., 2014)
Uptake among Adults: Who is Using

Youth Uptake: High School Students
National Youth Tobacco Survey

- 80.5% of those who used e-cigarettes within the past 30 days also smoked conventional cigarettes in the same period.
- 7.2% reported never smoking conventional cigarettes.
- In youths, concerns include the potential negative impact of nicotine on adolescent brain development, as well as the risk for nicotine addiction and initiation of the use of conventional cigarettes or other tobacco products.

<table>
<thead>
<tr>
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<th>2011</th>
<th>2012</th>
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<tbody>
<tr>
<td>Ever used</td>
<td>4.7%</td>
<td>10.0%</td>
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<tr>
<td>Used in past 30 days</td>
<td>1.5%</td>
<td>2.8%</td>
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MMWR, CDC, 2013
Youth Uptake: North Carolina YTS

% Who Used in Last 30 days

Survey Year

1999 | 2001 | 2003 | 2005 | 2007 | 2009 | 2011 | 2013
--- | --- | --- | --- | --- | --- | --- | ---
38.3 | 35.8 | 33.7 | 28.5 | 26.6 | 25.8 | 25.8 | 29.7

Legend:
- Conventional Cigarette
- E-Cigarette
- Any Tobacco Product
Cessation: ENDS

- Few studies have examined use of these products for cessation and how they compare with existing medicinal approaches.
- ENDS were more likely to result in at least six months abstinence than placebo ENDS.
- ENDS led to similar six month abstinence rates as nicotine patch.
- ENDS appear to help smokers unable to stop smoking altogether to reduce their cigarette consumption when compared with placebo ENDS and nicotine patches.
  
  (McRobbie et al., Cochrane Database Sust Rev. 2014)

- Second generation tank systems are believed to do better than first generation systems (Lechner et al., Addiction, 2015; Polosa et al., BMC Pub Health, 2014; ).
Uptake, Patterns of Use and Cessation

Concerns

• ENDS use has doubled in past several years (adults and youth)
• Most are current smokers.
  – Used to quit or reduce smoking
• Most engage in dual use
• Gateway to cigarettes?

Potential Regulations/Interventions

• Promotion as a cessation tool might await evidence based finding
• Anti-vaping campaigns targeted to youth
• Educational campaigns for adults
Research Needs

• Analyzing ENDS products
  – Design features and constituents associated with potential abuse liability, appeal and toxicity
• Assessing health impact of ENDS
  – Acute and chronic effects
• Understanding perception and patterns of use
• Understanding potential role of ENDS for smoking cessation
American Association for Cancer Research and the American Society of Clinical Oncology

Rapid elimination of combustible tobacco products would dramatically reduce the burden of tobacco-related death and disease. *The AACR and ASCO support every effort to reduce the use of combustible tobacco, and we support careful consideration of ENDS as a potentially harmful, and a potentially beneficial, product in this regard.*