E-cigarettes

Nicotine Dependence Center
Mayo Clinic

Tom Gauvin, MA, CTTS
ENDS: Electronic Nicotine Delivery Systems

aka

“E-cigarettes”
Goals and objectives

• Describe the E-cigarette, and have an understanding of ingredients
• Discuss the Federal Court’s posture on E-cigarettes
• Identify the Authority of the FDA in regulating E-cigarettes
• List current trends and possible consequences of E-cigarette use
“Vaping”
Looks like a cigarette, feels like a cigarette, taste like a cigarette, but it isn't a cigarette. It's just a much better way to smoke! Better & healthier.

Smoking Everywhere™
Electronic Cigarette

www.SmokingEverywhere.com
1-800-613-0337
Liberty Stix Brand

It looks like a traditional cigarette,
It tastes like a traditional cigarette,
but it's not a traditional cigarette

Same, Same, But Different

With Liberty Stix, You Have the Freedom To
Smoke Anywhere, No Carbon Monoxide, No Tar,
No Cancer causing agents!
A battery-powered device that provides inhaled doses of vaporized nicotine solution. It is used as an alternative to smoked tobacco products, such as cigarettes, cigars, or pipes.
ENDS: Basic Structure

- LED lights up where the smoker draws on the cigarette
- Sensor detects when smoker takes a drag
- MICROPROCESSOR controls heater and light
- Battery
- Heater vaporises nicotine
- CARTRIDGE holds nicotine dissolved in propylene glycol
### ENDS – Liquid Solution Composition

<table>
<thead>
<tr>
<th>Substance</th>
<th>Recipe 1</th>
<th>Recipe 2</th>
<th>Recipe 3</th>
<th>Recipe 4</th>
<th>Recipe 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>85%</td>
<td>80%</td>
<td>90%</td>
<td>80%</td>
<td>&lt;65%</td>
</tr>
<tr>
<td>Nicotine</td>
<td>6%</td>
<td>4%</td>
<td>2%</td>
<td>0.1%</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>Glycerol</td>
<td>2%</td>
<td>5%</td>
<td>-</td>
<td>5%</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>Tobacco essence</td>
<td>-</td>
<td>4%</td>
<td>4.5%</td>
<td>1%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Essence</td>
<td>2%</td>
<td>-</td>
<td>1%</td>
<td>1%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Organic acid</td>
<td>1%</td>
<td>-</td>
<td>-</td>
<td>2%</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

**Propylene glycol**: pharmaceutical solvent, food additive, moisturizer (cosmetics & toothpaste), hand sanitizer, non-toxic antifreeze, deodorants, aircraft de-icer.

[en.wikipedia.org](http://en.wikipedia.org)
“E-Juice” or “Smoke Juice”

- **Total nicotine** = 720 mg
- **Lethal nicotine dose** = 40–60 mg (0.5-1.0 mg/kg)
Propylene glycol

Vegetable glycerine
In 2009, FDA's Center for Drug Evaluation, Division of Pharmaceutical Analysis (DPA) analyzed:

- 2 samples of electronic cigarettes & components from two leading brands
- 18 of the flavored, nicotine, and no-nicotine cartridges
- Nicotine inhaler (control)
• DPA's analysis:
  • Diethylene glycol in one cartridge @ 1%
    • Ingredient used in antifreeze & toxic to humans
  • Tobacco-specific nitrosamines (TSNA’s) in 1/2 of samples
    • Human carcinogen
  • Tobacco-specific impurities detected in a majority of the samples tested
    • May be harmful to humans
      • Anabasine
      • Myosmine
      • β-nicotyrine

www.fda.gov
• E-cigarette cartridges labeled as “no nicotine”
  • Low levels of nicotine present in all cartridges tested, except one.
• 3 different E-cigarette cartridges
  • Same label
  • Markedly different amount of nicotine with each puff.
  • Range: from 26.8 to 43.2 mcg nicotine/100 mL puff
• One high-nicotine cartridge delivered 2 x as much nicotine as the nicotine inhaler

www.fda.gov
ENDS: Effect on desire to smoke


40 participants were randomised to use ENDS containing 16 mg nicotine, 0 mg nicotine, nicotine inhaler or usual cigarette on each of four study days 3 days apart, with overnight smoking abstinence before use of each product.
ENDS: Aerosol density compared with cigarettes

Trtchounian A et al. Nicotine Tob Res 2010;12:905-912
Legal Status of ENDS (examples in 2009)

- **California**: Ban vetoed
- **Oregon**: AG reached a settlement in August with retailers and distributors not to sell them
- **New Hampshire**: Bill to ban sales to minors
- **New Jersey**: Bill to subject to the cigarette restrictions
- **New York**: Restricted in public places/banned sales to minors
Implications if the ruling stands...

- E-cigarettes can be imported and sold.
- E-cigarettes will not be regulated as a drug or device.
- On appeal a stay of the lower court order was issued February 2010 pending full appeal.
- Appeal denied April 2011… FDA will not pursue further
Phillip Morris Entering the ENDS Market?

- Philip Morris has been in negotiations with Ruyan Group
  - Manufacturer of the original e-cigarette

- Motivation?
  - Shut the industry down
  - Launching its own e-cigarette

- Stay tuned…
• Pros…
  • Low carcinogen exposure
  • No second-hand smoke production
  • May motivate smokers to quit smoking

• Cons…
  • No evidence for its safety with long-term use (compared with pharmaceutical NRT)
  • No evidence for efficacy as an aid to quitting smoking
  • Low and inconsistent levels of nicotine aerosol delivery and nicotine blood levels
  • Impurities in commercial solutions (including TSNA’s and other tobacco impurities)
ENDS: Where should the tobacco control community stand?

• Additional study to confirm safety
• Additional study of efficacy to treat tobacco dependence
• Until then…
  • restrict manufacturer claims regarding proven safety
  • usefulness as an aid to stop smoking
ENDS
Summary

- ENDS- “e-cigarettes”- electronic nicotine delivery systems
- Deliver nicotine solution by heating and vaporizing for inhalation
- Safety concerns have been raised
- Low level of nicotine delivery in limited tests
- No evidence to support use as a treatment to help smokers stop smoking
- Legal status in the US– regulated as tobacco
Tobacco

Medication

BOTH
Poly Tobacco Use

Combination Medication

BOTH
Poly Tobacco Use

E-Cig

Combination Medication
Poly Tobacco Use

Combination Medication (E-Cig)

BOTH