Aerosolizing Nicotine Delivery Device
(A.K.A. the Electronic Cigarette)

A look at what we know and what we need to know

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**E-Cigarette**

- Battery-operated nicotine delivery device
  - White segment contains a rechargeable battery
  - Dark colored body contains a vaporizing chamber
  - Near the mouthpiece a replaceable cartridge with nicotine-containing solvent (propylene glycol)
Anatomy of E-Cigarette

- LED lights up when the smoker draws on the cigarette
- Sensor detects when smoker takes a drag
- Heater vaporises nicotine
- Battery controls heater and light
- Microprocessor
- Cartridge holds nicotine dissolved in propylene glycol

Source: Sam蛤, VERISPAN
E-Cigarette Legal Status

☐ Tobacco Product or Drug Delivery Device?
  ■ FDA tried banning them as drug delivery device
  ■ Successfully appealed by e-cigarette co.
  (Scottera, Inc. vs. FDA et al., 12/7/2010)

☐ The Family Smoking Prevention and Tobacco Control Act

☐ E-cigs can be sold in Maine
  ■ They are considered a tobacco product under Maine law
    ☐ Cannot be sold via the internet unless they are delivered to a licensed tobacco retailer
    ☐ Cannot be sold in mall kiosks
    ☐ Cannot be sold to minors

Opinion of Maine AG Paul Gauvreau
11/8/11
Starter Kits and Cartridges

- Starter kits (around $70)
- 32 flavors: Menthol, Moroccan, Columbian, Classic, Original.....
- Each cartridge lasts about 250 to 300 drags (advertised as roughly = to pack of cigarettes) (no evidence)

Flavor Chart

- Sweet
- Spicy
- Earthy
- Woody
Price Reduction:

ey easy access for youth

New to E-cigarettes? Overwhelmed by choices?
Get off to a good start with a top rated

Nebula starter kit!

Express kits just 7.95!

Deluxe kits only 29.95!
Just the beginning of design...
Product Expansion

E-cigars

E-pipes
“Good Vibrations”

☐ Blu is selling special packs of cigarettes that vibrate when they're within 50 feet of another pack

☐ The goal is to make smoking even more social

☐ The packs can also be configured to exchange information and will vibrate when they're near a store that sells Blu products

http://www.businessinsider.com/idea-of-the-day-vibrating-cigarette-packs-tell-you-when-other-smokers-are-nearby-2011-5#ixzz1dQ3gB4jo
### Advertised Level of Nicotine

<table>
<thead>
<tr>
<th>Nicotine Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 mg</td>
<td>Comparable to “non filters”</td>
</tr>
<tr>
<td></td>
<td>(Designed for the very heavy smoker.)</td>
</tr>
<tr>
<td>18 mg</td>
<td>Comparable to “full flavored”</td>
</tr>
<tr>
<td>14 mg</td>
<td>Comparable to “mediums”</td>
</tr>
<tr>
<td>11 mg</td>
<td>Comparable to “lights”</td>
</tr>
<tr>
<td>6 mg</td>
<td>Comparable to “ultra-lights”</td>
</tr>
<tr>
<td>0 mg</td>
<td>Cartridges with flavor but contain no nicotine</td>
</tr>
</tbody>
</table>

http://www.thesafecig.com/faq
Poll Question

- Ultra-light and light cigarettes have been shown...
  - to deliver less nicotine than a regular cigarette
  - to deliver less CO and particulates and are less harmful
  - to offer no benefits regarding harm nor nicotine delivery

L T Kozlowski & R J O’Connor, 2002
An EFFECTIVE MARKETING STRATEGY: “LIGHT” CIGARETTES

an extra row of ventilation holes

Image courtesy of Mayo Clinic Nicotine Dependence Center - Research Program / Dr. Richard D. Hurt

The Marlboro and Marlboro Lights logos are registered trademarks of Philip Morris USA.
The E-cigarette in Context

- PREPS – Potentially Reduced Exposure Products
  - Reduced exposure does not necessarily translate to reduced harm

- Vaping – breathing in the nicotine vapors vs. burned tobacco
Eclipse

- They primarily heat tobacco, giving off a vapor, instead of burning it
  - Carbon tip is lit
- Less tar and less secondhand smoke
- High levels of carbon monoxide and carcinogens

Fagerstrom et al., 2000
Slade et al., 2002
Eclipse Schematic

FILTER

PROCESSED TOBACCO

PROCESSED TOBACCO

GLASS MAT INSULATOR

HEAT SOURCE

DUAL SEGMENT TOBACCO ROLL

Carbon tip is lit

Fagerstrom et al., 2000
Vapor Pipes

- Heats the tobacco (not burned)
  - Does this mean it is safer?

Retails for $500-$600

Retails for $50
NRT Inhaler

- Advanced Tobacco Products (1994)
- Originally marketed as alternative to cigarette (the “Favor Inhaler”)
- Pulled from market by FDA as drug delivery device
- Tested, licensed and re-marketed as tobacco treatment medication (FDA approved 1996)

Leischow, Scott, 1994
Poll Question
Safety of E-cigarette “smoke”

- No tobacco is burned: the vapor is harmless
- We don’t know. There have been no definitive studies.
- Smoke is smoke. From a match or battery, the smoke is the same
Safety Concerns

- FDA warning letter to five manufacturing companies (9/9/10)
  - Unsubstantiated claims
  - Poor manufacturing practices
  - Inclusion of unapproved drugs in some samples
    - Tadalafil (an erectile dysfunction drug)
    - Rimonabant (a weight loss drug)
    - Deficiencies in the “smoke juice” refill solution
- In one sample, the FDA detected diethylene glycol, a chemical used in antifreeze
- Nitrosamines also found in some samples

FDA Press Release, 9/9/10
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225224.htm
Propylene glycol

- Used in theatrical smoke machines
- Used in many health and beauty products such as deodorant, hand sanitizers and massage oils
- Not tested: effect on humans of heating it to a vapor and inhaling it
  - Propylene glycol heated to 40-65 degrees centigrade (104-140 F)
- Some concern that users draw more heavily (stronger suction) on e-cigarette than typical cigarette
  - Effects of this unknown

Trtchounian et al., 2010
Refill Solution - Nicotine

- Multiple suppliers
- Single bottle may contain as much as 1000 mg of nicotine
  - Toxic dose for children = 10 mg
  - Toxic dose for adults = 30 - 60 mg

(American Legacy Foundation Fact Sheet, 7/09)

- Potential for non-nicotine use such as filling blank cartridge with cannabis oil
Poll Question: Nicotine delivery

- The vapor is inhaled into the lungs, similar to a cigarette
- The nicotine is delivered through the mucosa of the mouth
- It is not yet clear how the e-cigarette delivers nicotine
Nicotine Delivery?

- “Status of a neat theatre prop” (Foulds, 2010)
  - Propylene glycol heated to 40-65 degrees centigrade
  - Question how much nicotine is transferred via the vapor to the human body
    - Ineffective nicotine delivery device?
    - Variability device-to-device and even puff-to-puff
  - Vaporized nicotine molecule speculated to be too large to be absorbed efficiently

- Potentially powerful placebo effect

Vansickel et al., 2010
Cobb, N and Abrams, D, 2011
Maine Tobacco HelpLine: Guidance

- The Maine Tobacco HelpLine cannot endorse the use of the E-cigarette due to lack of information regarding its safety as a substitute for traditional tobacco products and its efficacy as a means to quit tobacco products. Specifically:
  - The composition of chemicals and the effect of the chemicals in the e-cigarette is unknown
  - There is concern expressed by the FDA regarding the uniformity and safety of manufacturing practices
  - There is no clear standard as to how much nicotine is actually being delivered by the e-cigarette
  - There is no clear evidence as to whether the e-cigarette helps a person quit other tobacco or can potentiate increased dependence on tobacco products
Medication Voucher Program

- Use of the e-cigarette is a use-exclusion for provision of NRT through HelpLine
  - Can not assess the amount of nicotine being delivered by the e-cigarette to be able to safely and/or effectively dose the amount of NRT
Needed Research

- **Non-clinical studies** < Composition of refill liquids. < Composition of vapour. < Product quality, description of the diversity of products and product change over time.

- **Animal studies** < Pharmacodynamics (PD), pharmacokinetics (PK), toxicokinetics. < Toxicology, carcinogenicity. < Effects of long-term exposure.

- **Clinical studies** < Deposition of droplets, exposure to nicotine, propylene glycol, flavours, etc. < PD, PK, toxicity, carcinogenicity, infectivity. < Addictive potential, abuse liability, risks of nicotine refill bottles. < Puff topography, dosage, duration, reasons for use, brand switching. < Optimal dosage, dosing regimen, effect of user experience with the device. < Effect on tobacco withdrawal symptoms, adverse effects. < Efficacy for smoking behaviour (cessation and reduction), comparison with nicotine replacement therapy (NRT). < Efficacy for administering other medications.


Etter et al., 2011
Questions
References


Fagerstrom, K. et al., “Randomized Trial Investigating Effect of a Novel Nicotine Delivery Device (Eclipse) and a Nicotine Oral Inhaler on Smoking Behavior, Nicotine and Carbon Monoxide Exposure, and Motivation to Quit”. Tobacco Control, 2000; vol. 9: 327-333.


Kozlowski, LT & O’Connor, RJ, “Cigarette Filter Ventilation is a defective design because of misleading taste, bigger puffs and blocked vents”. Tobacco Control, 2002; 11 (Suppl 1): 140-150


Slade, J. et al., “Eclipse: Does it live up to its health claims?” Tobacco Control, 2002; 11(Suppl II):ii64-ii70

Trtchounian, A. et al., Conventional and Electronic Cigarettes (e-cigarettes) Have Different Smoking Characteristics”. Nicotine Tob Res. 2010 Sep; 12(9): 905-12
