

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

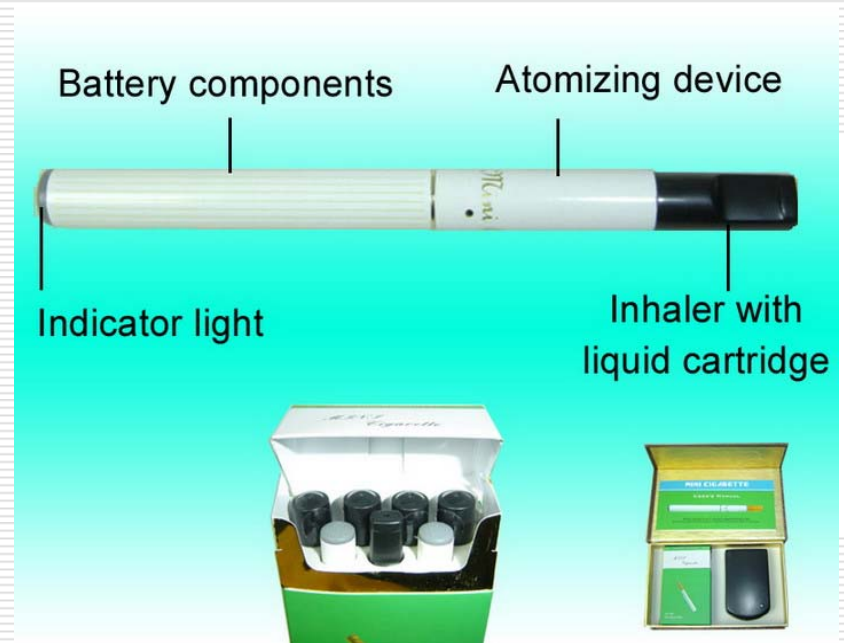
A look at what we know and what we need to know



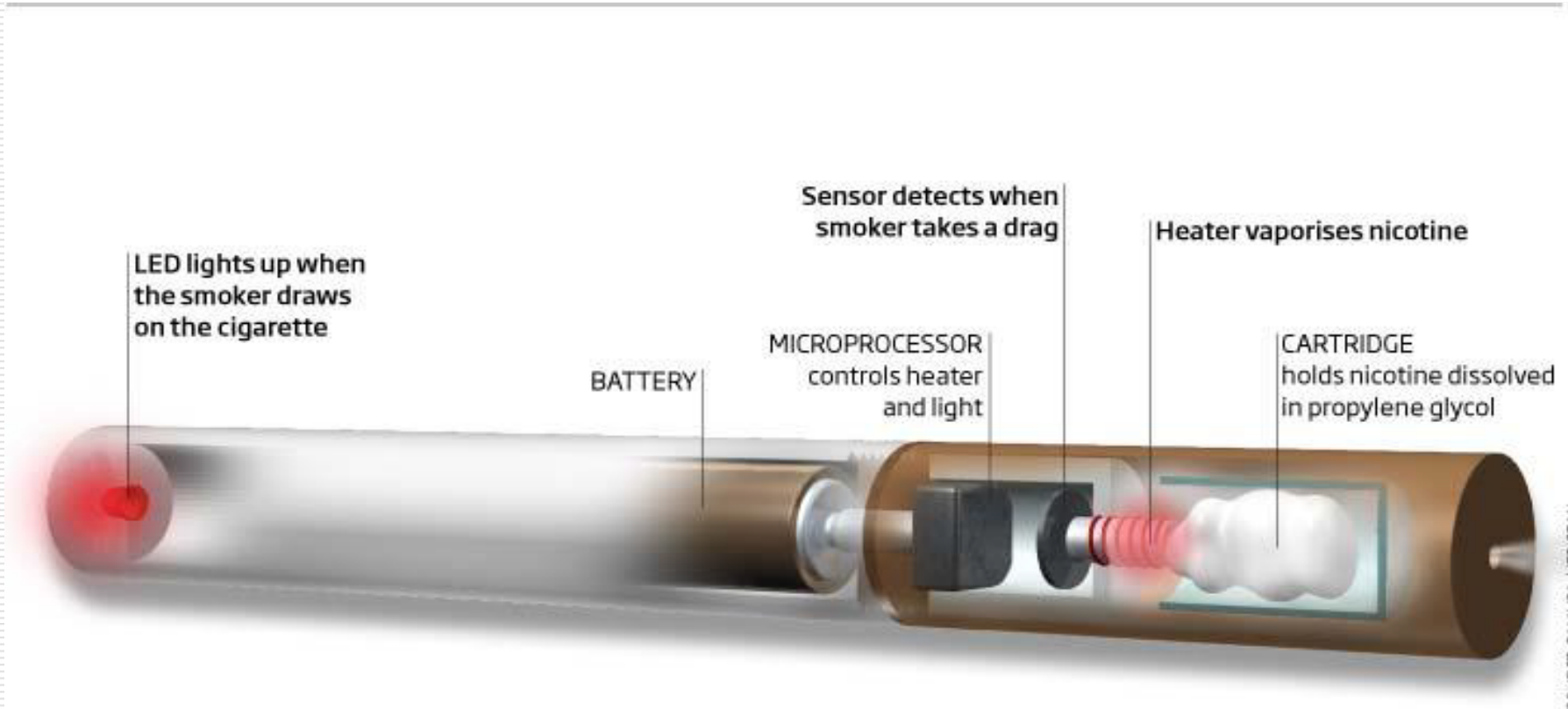
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E-Cigarette

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



Anatomy of E-Cigarette



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





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: easy access for youth

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

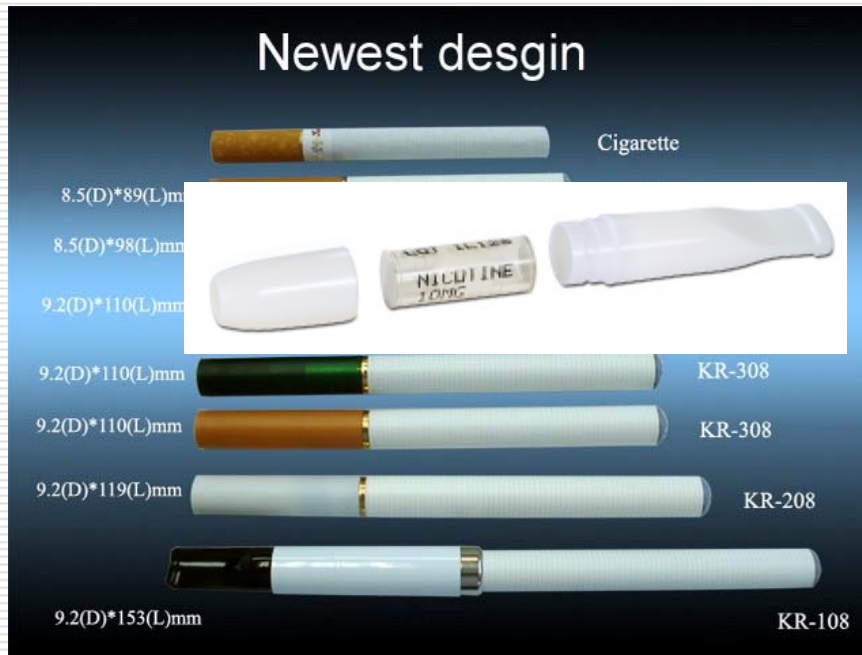


Express kits just 7.95!



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

Advertised Level of Nicotine

24 mg = Comparable to "non filters"
(Designed for the very heavy smoker.)

18 mg = Comparable to "full flavored"

14 mg = Comparable to "mediums"

11 mg = Comparable to "lights"

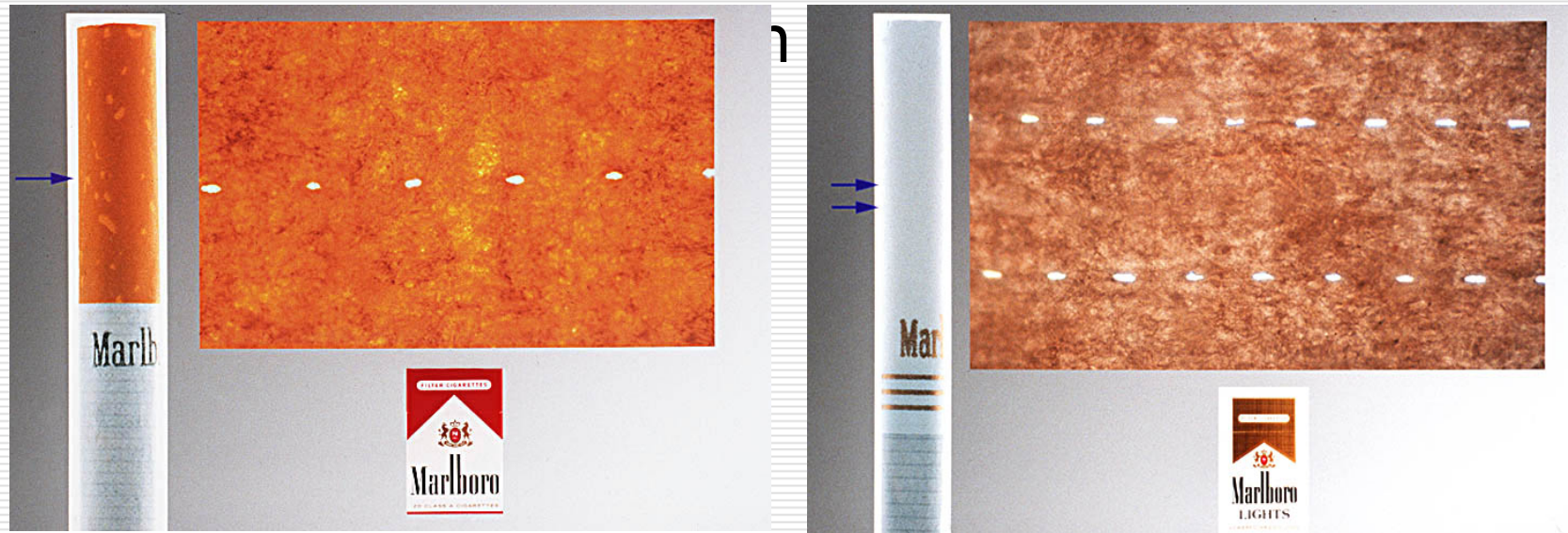
6 mg = Comparable to "ultra-lights"

0 mg = Cartridges with flavor but contain no nicotine

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

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

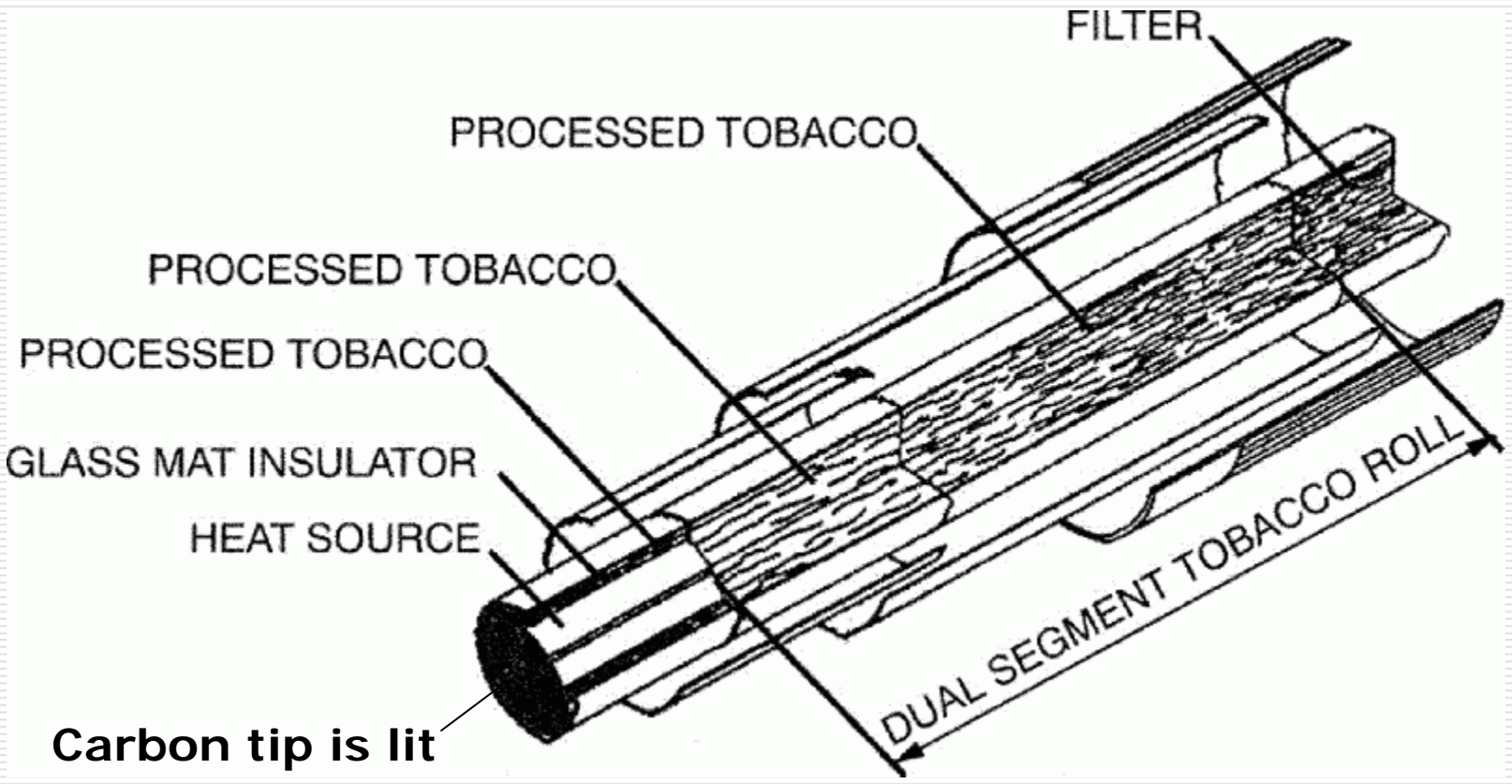
 - Vaping – breathing in the nicotine vapors vs. burned tobacco
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Eclipse

- 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



Eclipse Schematic



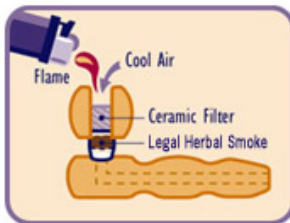
Fagerstom et al., 2000

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)



How does the NICOTROL Inhaler work?

A nicotine vapor cartridge is pierced when put into the inhaler.



One cartridge lasts about 20 minutes with continuous puffing.

- Each cartridge delivers 4 mg of nicotine but only 2 mg is actually absorbed (similar to the amount of nicotine from 2 cigarettes).¹

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
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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

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

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
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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

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
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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
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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.
- ❑ **Public health studies** < Prevalence of use in population subgroups. < Utilisation patterns (long-term use), preferred brands, satisfaction of users. < Use to administer illicit drugs or medications. < Surveillance, pharmacovigilance, sales data. < Effects of exhaled ('secondhand') vapour. Fewer fires and burns due to less smoking? < Effect of good manufacturing practice on the quality of products. < Economic studies, cost effectiveness, impact on healthcare costs. < Impact on prevalences of quit attempts, quit rates and smoking in the population.

Questions



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