

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 Ecigarettes
- List current trends and possible consequences of Ecigarette use













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











ENDS – Liquid Solution Composition

Substance	Recipe 1	Recipe 2	Recipe 3	Recipe 4	Recipe 5
Propylene glycol	<mark>85%</mark>	80%	90%	80%	<65%
Nicotine	6%	4%	2%	0.1%	<3%
Glycerol	2%	5%	-	5%	<20%
Tobacco essence	-	4%	4.5%	1%	<5%
Essence	2%	-	1%	1%	<5%
Organic acid	1%	-	-	2%	<1%

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

en.wikipedia.org



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"E-Juice" or "Smoke Juice"

<u>Total nicotine</u> = 720 mg

<u>Lethal nicotine dose</u> =
40–60 mg (0.5-1.0 mg/kg)







- 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)







www.fda.gov





• DPA's analysis:

- Diethylene glycol in one cartridge @ 1%
 - Ingredient used in antifreeze & toxic to humans

U.S. Food and Drug Administration Protecting and Promoting *Your* Health

- Tobacco-specific nitrosamines (TSNA's) in 1/2 of samples
 - Human carcinogen
- Tobacco-specific impurities detected in a majority of the samples tested

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- May be harmful to humans
 - Anabasine
 - Myosmine
 - β-nicotyrine







- 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



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Crown 7 Hydro



Njoy NPRO



Eissenberg T. Tob Control. 2010 Feb;19(1):87-8..

ENDS: Effect on desire to smoke

Bullen C, et al. Tob Control 2010;19:98-103 doi:10.1136/tc.2009.031567



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.



-8

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



January, 2010

Judge Orders F.D.A. to Stop Blocking Imports of E-Cigarettes From China

By DUFF WILSON Published: January 14, 2010

A federal judge on Thursday ordered the <u>Food and Drug</u> <u>Administration</u> to stop blocking the importation of electronic <u>cigarettes</u> from China and indicated that the devices should be regulated as tobacco products rather than drug or medical devices.



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*









• 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- "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





















