

# E-cigarettes

Nicotine Dependence Center Mayo Clinic

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# 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

# "Vaping"







# LBERTY

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

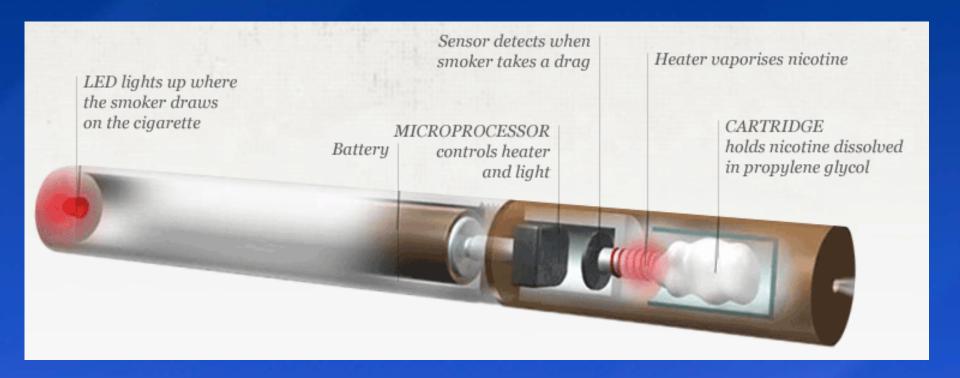
Same, Same, But Different

With Liberty Stix, You Have the Freedom To Smoke Anywhere, No Carbon Monoxide, No Tar, No Cancer causing agents!

# **ENDS**

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	85%	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.



# "E-Juice" or "Smoke Juice"

Total nicotine = 720 mg

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





Vegetable glycerine



SHOP

**LEARN** 

SWISS DARK - One of six amazing new flavors

**APPLAUSE** 

COMMITMENTS

SPRING IS ALMOST HERE

A PG-Free Smoke Juice From Johnson Creek

Vapor so intense, You can skip the chocolates.



**ABOUT** 

Winter Storm Causing Delays-2/9/10

MY ACCOUNT

Enter keywords

CONTACT

Announcing



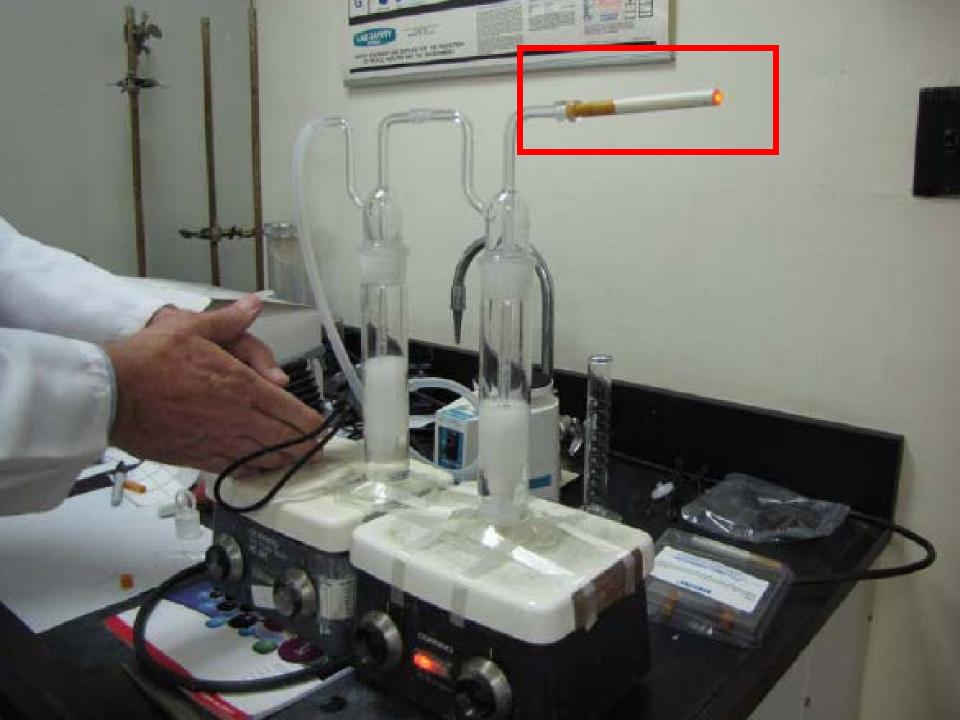
- In 2009, FDA's Center for Drug Evaluation, Division of Pharmaceutical Analysis (DPA) analyzed:
  - 2 samples of electronic cigarettes & components from two leading brands
    - 18 of the flavored, nicotine, and no-nicotine cartridges

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

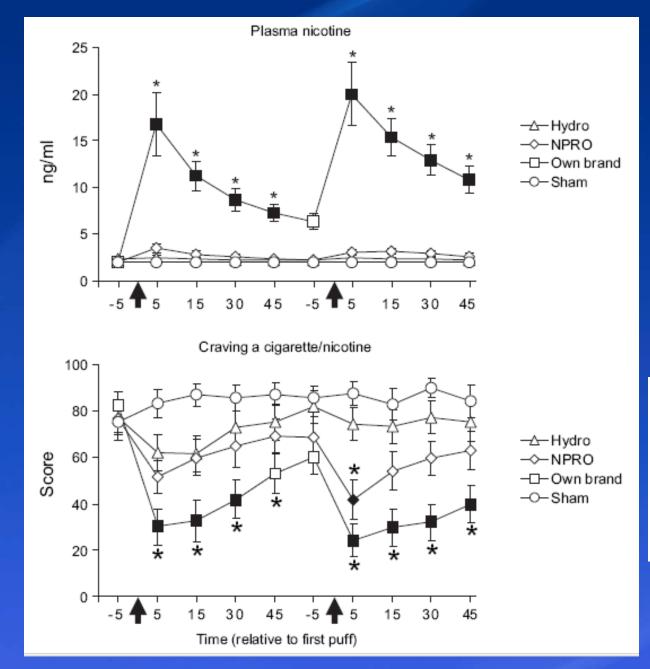
www.fda.gov







- 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



#### Crown 7 Hydro



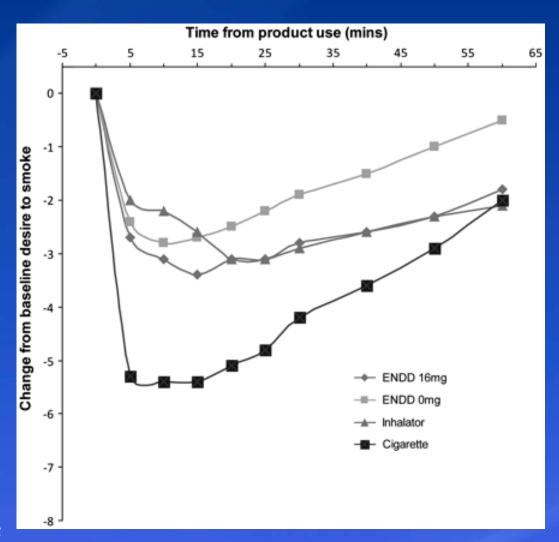
#### Njoy NPRO



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

## **ENDS:** Effect on desire to smoke

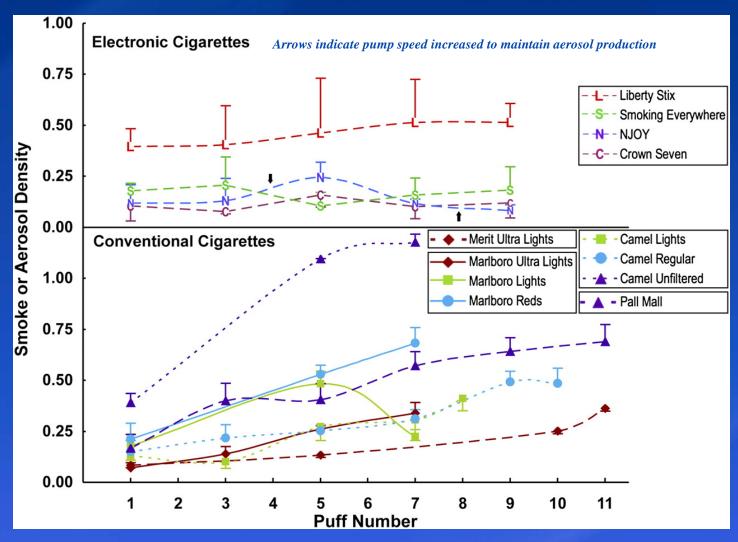
Bullen C, et al. **Tob Control** 2010;**19:**98-103 doi:10.1136/tc.2009.031567



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.



#### 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

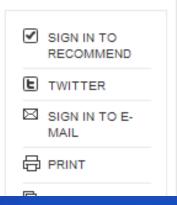
By DUFF WILSON

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

Stay tuned…



## **ENDS**

- 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

# <u>ENDS</u> 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



