



ENDDs

Electronic Nicotine Delivery Devices

The Pro(pylene)s and the Cons

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E-cigarette ad

Goals & Objectives

- Define what an ENDD is
- Understand what is known about nicotine delivery and safety of ENDDs
- Know the legal status of ENDDs
- Consider available evidence in the context of conversations with patients about the benefit/risk ratio of ENDDs



The Major Ingredient in E-Cigarettes is:

1. Isopropyl alcohol
2. Propylene glycol
3. Nicotine
4. Glycerol

People are using E-cigarettes:

1. To try something new
2. Reduce cigarette consumption
3. Quit smoking
4. Cheaper than cigarettes

E-cigarettes are regulated as a:

- 1) Tobacco product
- 2) Pharmaceutical product

ENDDs



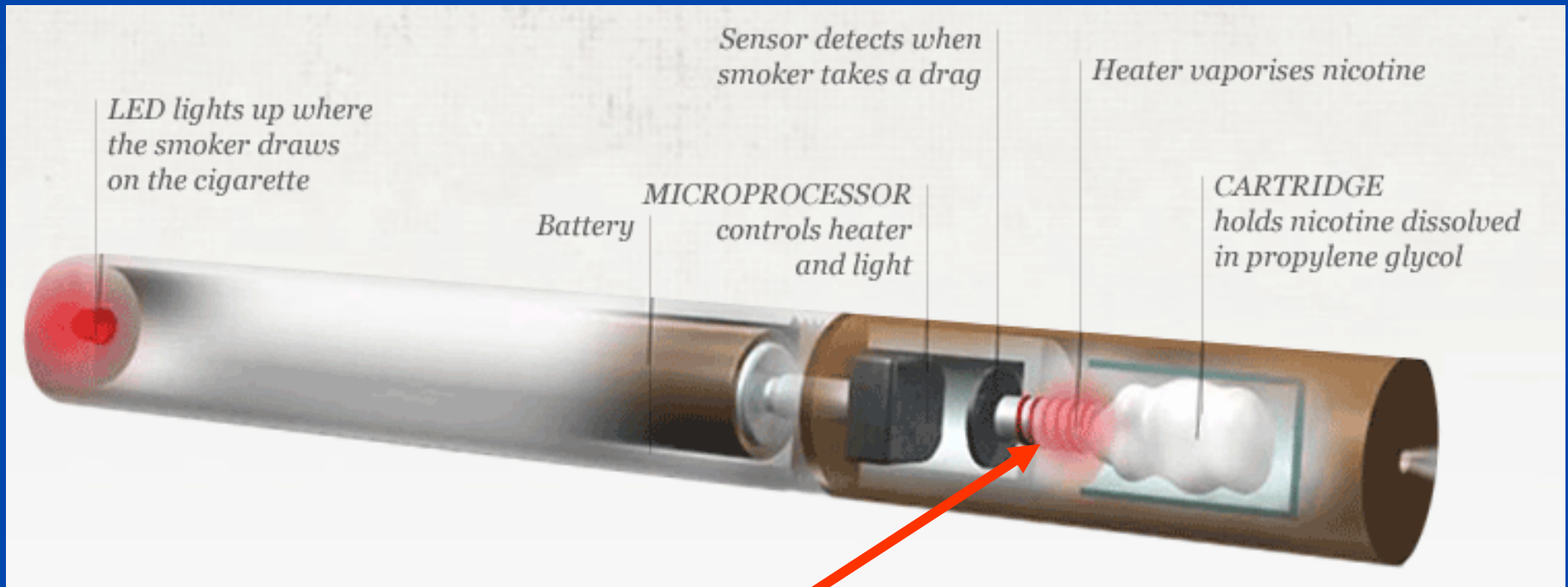
- Patented & launched in 2003 by Ruyan (Beijing, China)
 - Ruyan translation = “to resemble smoking”
 - Designed by Chinese pharmacist Hon Lik
 - Earliest known description in 1963
 - Patent by Herbert A. Gilbert
- Battery-powered device that provides inhaled doses of vaporized nicotine solution
 - Heat
 - Ultrasonics

ENDD: In the Beginning...



ENDD

Basic Structure



Atomizer – or “atty”

Atomizer – lose efficiency over time and need replacement. Recurring expense.

Cartomizer - single integrated cartridge & atomizer components. Disposable.

“Vaping”





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the world's largest
e-cigarette forum

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Forum

ELIQUID DEPOT
eliquiddepot.com

CHEAP REFILLS

FITS ANY BRAND

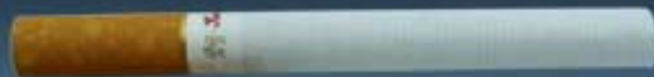
Hi! Welcome to ECF, the largest e-cigarette website in the world.

There are tens of thousands of visitors to this site every day, and over 100,000 posts a month on the forum.

Everything you need to know is here. We welcome your questions: just register, then you can post in the New Members Forum and someone will help you. Or, get in touch via our Contacts page, linked at the top and bottom of every page.

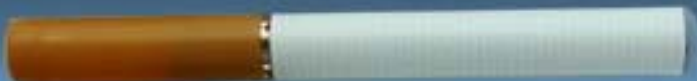
For many people, ECF is the start of a new phase of their life - a life without tobacco but every bit as enjoyable. More enjoyable in every way, in fact. Come on in and join us!





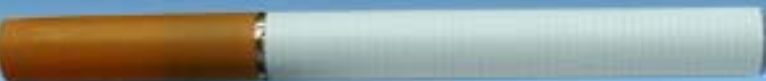
Cigarette

8.5(D)*89(L)mm



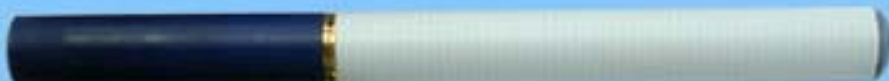
KR-808A

8.5(D)*98(L)mm



KR-808

9.2(D)*110(L)mm



KR-308

9.2(D)*110(L)mm



KR-308

9.2(D)*110(L)mm



KR-308

9.2(D)*119(L)mm



KR-208

9.2(D)*153(L)mm



KR-108





The ScrewDriver



“Mods” = Design Modifications



ENDDs – “Mods” and Safety

Man Suffers Severe Injuries After E-Cigarette Explodes in His Mouth



Man Burned by Exploding Electronic Cigarette

AUTO START: ON OFF



By MIKAELA CONLEY (@mikaelaconley)
Feb. 15, 2012

ENDD Specifications

- Most electronic cigarette components have standardized threaded fittings
 - Standards: 510 & 808D
- Rechargeable batteries
 - Portable charging cases (“PCCs”) frequently look like cigarette packs
 - USB





\$3.99



\$4.99



\$14.99





Disposable:

~\$7

ENDDs – 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, asthma inhalers & nebulizers.



en.wikipedia.org

“E-Juice” or “Smoke Juice”

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



E-Juice Manufacturing

- China
 - Nontoxic testing permit is only requirement
 - Compliant with ISO
 - International Organization for Standardization



- United States
 - Adhere to the Federal Food, Drug and Cosmetic Act

“E-Juice”: Pre-Mixed or Mix Your Own

Flavour Descriptions:

Aromatic	Carmel	Cherry Cheroot
A relaxing pipe-style vape, with no briar required.	Our take on Camel, with a light turkish twist.	A flavoursome combination of sweet cherries and smokey Tobacco.
Cuban Cigar	Gallois	Hylton
Rich and mellow with notes of leather, sandalwood and shadegrown leaf.	A french style blend of Turkish and oriental flavours.	Sweeter than the Real Tabs, with a touch of Caramel.

Marlbury	Oldport	Real Tabs
Smooth and tasty cowboy flavour.	Our take on Newport Menthols.	A light analog Tobacco Flavor well rounded woody and smol notes.

Rich Pine	Statex	Virginian Gold
A complex pipe T nice after dinner v		A sweet Virginian Flavour - q ght.



Amaretto	Angelica	Apple	Apricot
An Italian liqueur which is normally strong, with a subtle flavour of almonds, with which you may get along. <i>Amaretto is usually associated with the taste of almond paste (marzipan).</i> Recommended concentration: 20 - 25% (4 to 5 drops per ml)	As in the sweet succulent leaves of old, you will find this flavour sweet and bold. <i>Angelica is a candied leaf, often seen on cake decorations.</i> Recommended concentration: 10% (2 drops per ml)	Sweet and tangy as in the skin, savour the flavour of the apple within. Recommended concentration: 10% (2 drops per ml)	Sweeter than plum yet not like a peach, the rich golden flesh is a wonderful treat. Recommended concentration: 10% (2 drops per ml)
Banana	Beer	Betel Nut	Black Tea
If you want you can act the ape, but really this banana is a jolly good vape. Recommended concentration: 10% (2 drops per ml)	Hops and yeast you'll want cheer, pull up a seat and have a beer. Recommended concentration: 10% (2 drops per ml)	Pacific palms provide the fruit, a sweet syrup taste for you might suit. <i>Betel Nut is the nut from the palm trees grown in the South Pacific, with the taste of Palm Dates.</i> Recommended concentration: 10% (2 drops per ml)	If you enjoy the flavour of tea, then this is the one it has to be, fragrant and perfumed with the tang of the leaf, I'm sure it's winner, a great aperitif. Recommended concentration: 10% (2 drops per ml)
Black Walnut	Blackcurrant	Blueberry	Brandy
Dry and smoky with			

ENDDs: Direct “Dripping” Method

Atomizer with “exposed bridge”



“Drip Tip”

U.S. Food & Drug Administration

Protecting and Promoting Your Health

- 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)



U.S. Food & Drug Administration

Protecting and Promoting Your Health

- DPA's analysis
 - Diethylene glycol in one cartridge @ 1%
 - Ingredient used in antifreeze & toxic to humans
 - Tobacco-specific nitrosamines (TSNA's) in half of samples
 - Human carcinogen
 - Tobacco-specific impurities detected in a majority of the samples tested
 - May be harmful to humans
 - Anabasine
 - Myosmine
 - β -nicotyrine



U.S. Food & Drug Administration

Protecting and Promoting Your Health

- 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 26.8-43.2 mcg nicotine/100 mL puff
- One high-nicotine cartridge delivered 2 x as much nicotine as the nicotine inhaler



Do ENDDs Alleviate Craving?

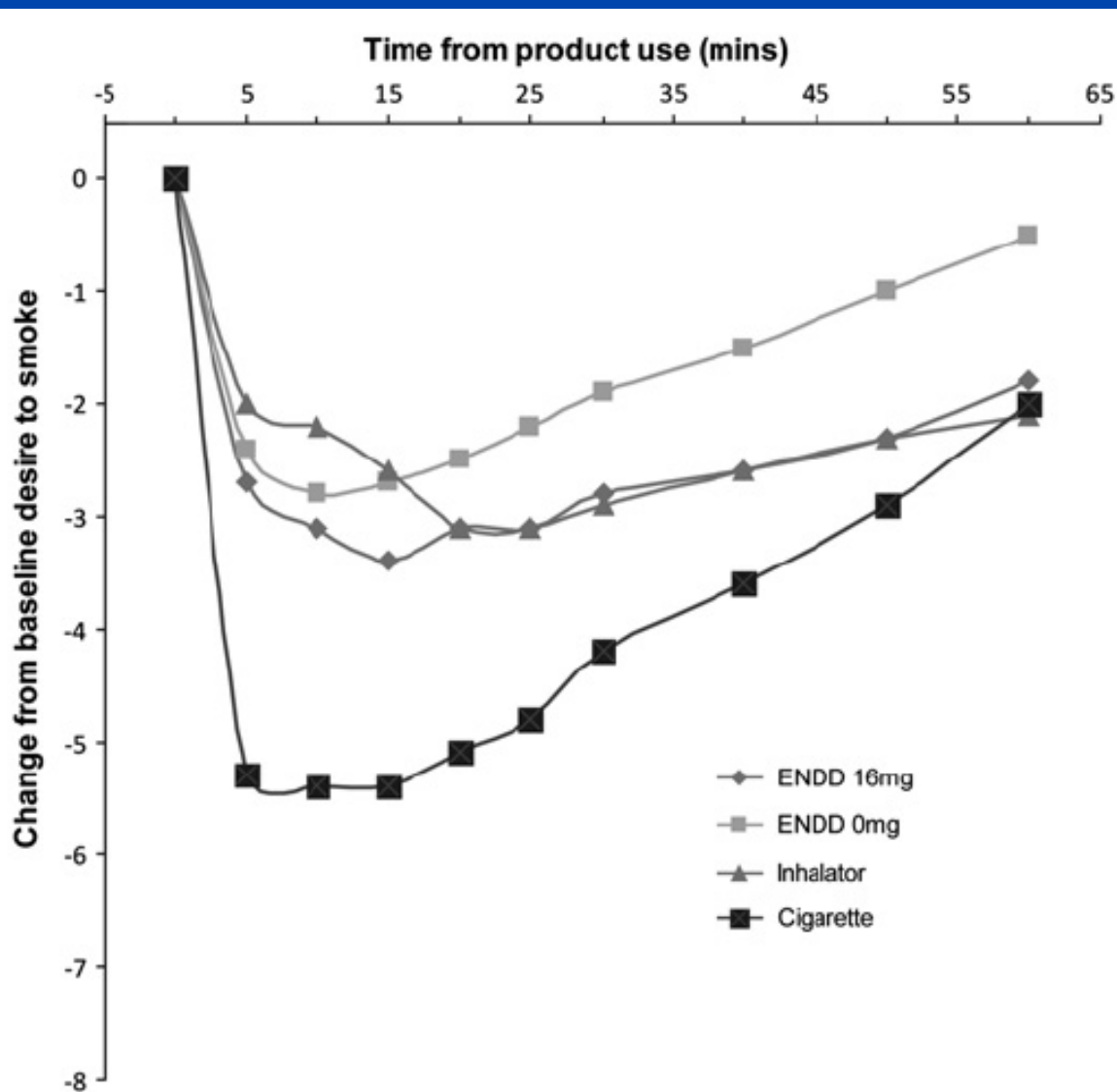


Figure 2 Change in desire to smoke from baseline over the first hour after each product use.

- Smokers
- Aged 18 and 70 years
- Smoked ≥ 10 cigarettes
- Overnight abstinence
- 16 mg ENDD less desire to smoke than placebo
- No difference in desire to smoke between 16 mg ENDD & inhaler
- ENDDs more pleasant than inhaler

Pharmacokinetics of Cigarette, ENDDs, and Inhaler

Product	Mean t _{max} (min) (95% CI)	Mean C _{max} (ng/mL) (95% CI)*
Usual cigarette (n=9)	14.3 (8.8 to 19.9)	13.4 (6.5 to 20.3)
16 mg ENDD (n=8)	19.6 (4.9 to 34.2)	1.3 (0.0 to 2.6)
Nicorette inhalator (n=10)	32.0 (18.7 to 45.3)	2.1 (1.0 to 3.1)

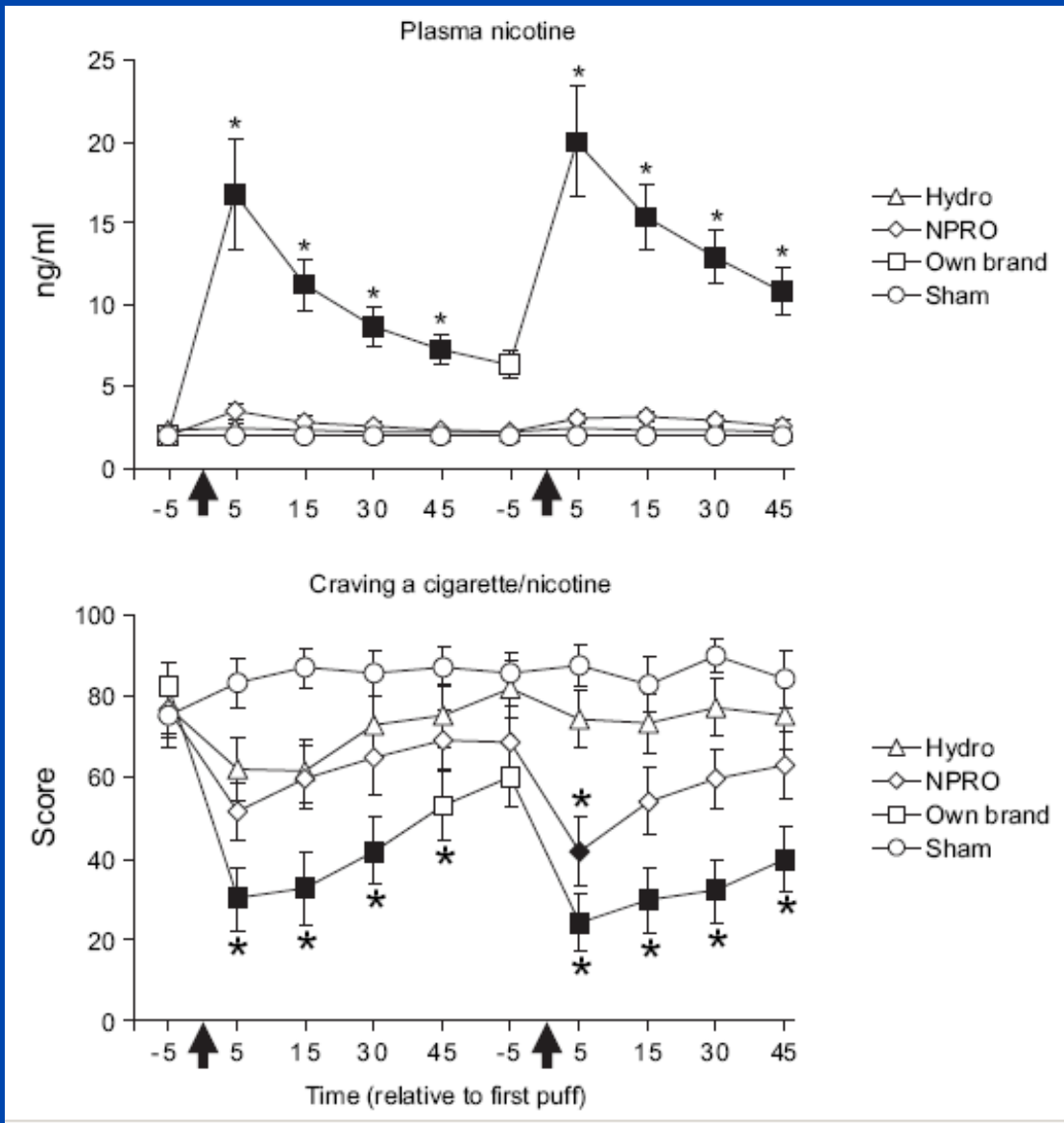
ENDD, electronic nicotine delivery device.
*Corrected for baseline nicotine levels.

Bullen C et al. Tob Control 2010 19: 98-103.

Crown 7 Hydro



Njoy NPRO



Eissenberg T. Tobacco Control 19(1):87, Feb 2010.

Comparing ENDDs to Conventional Cigarettes

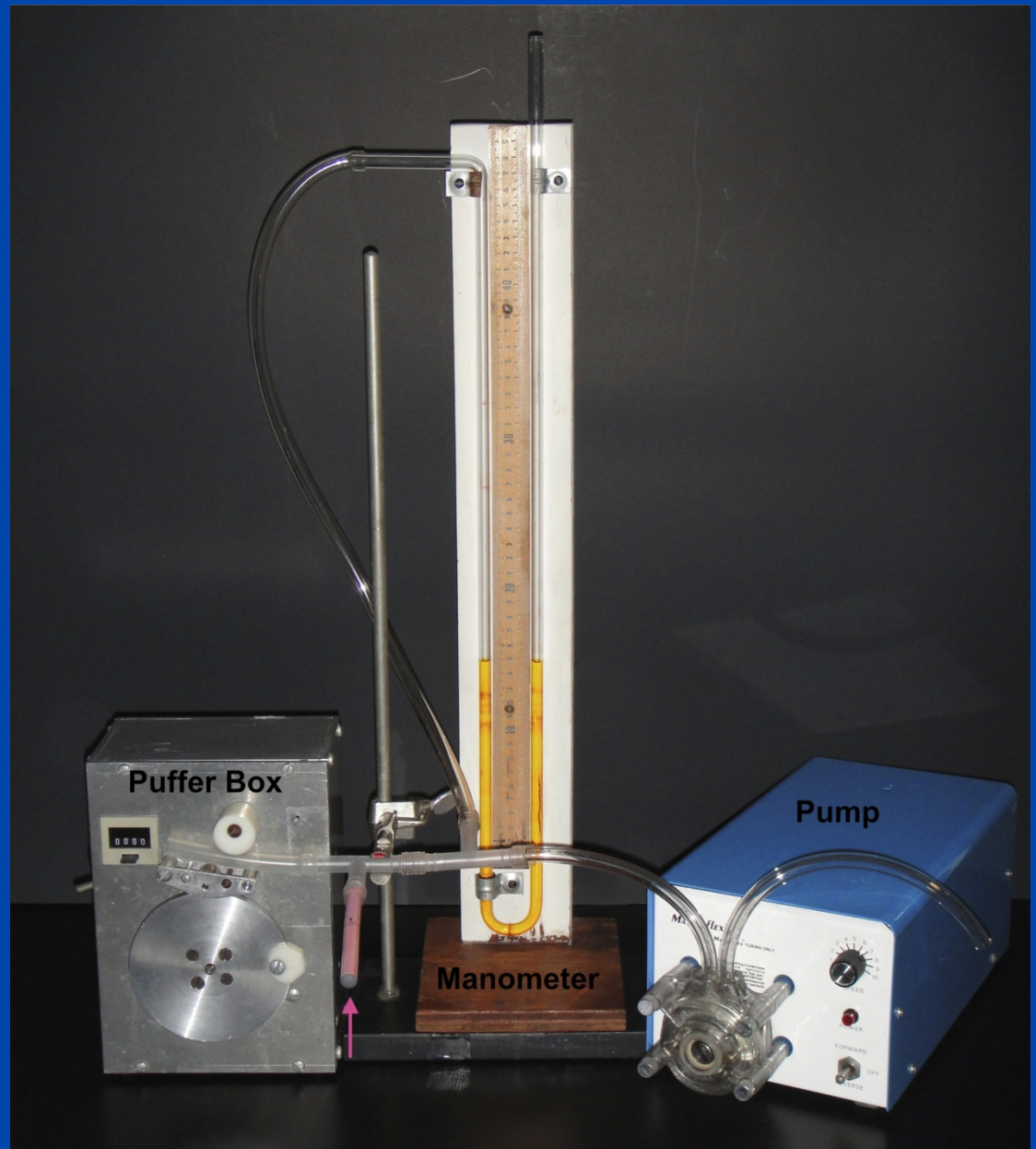
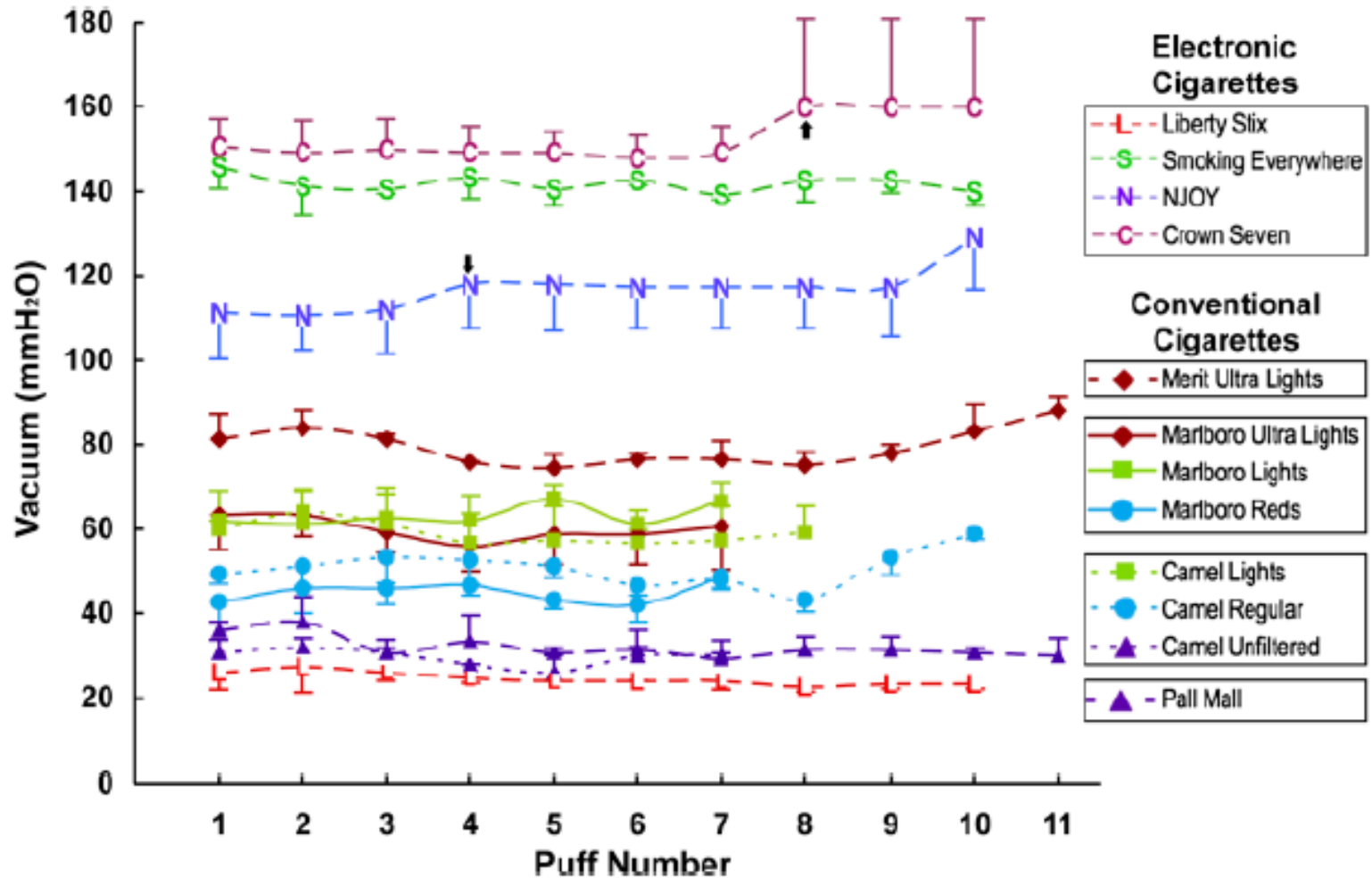


Photo courtesy of P. Talbot

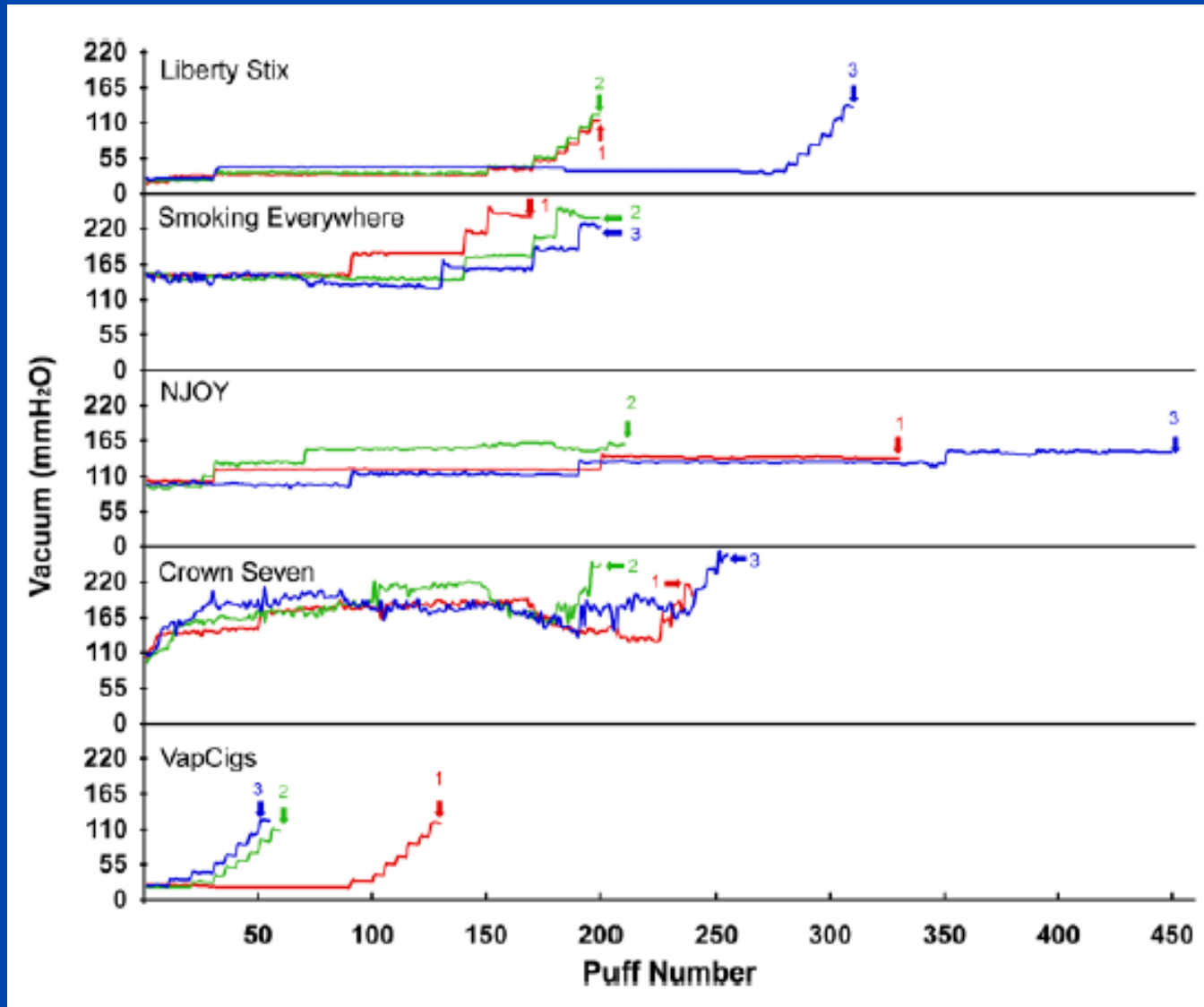
Trtchounian A. Nicotine Tob Res. 2010 Sep;12(9):905-12.

“Vacuum”: Conventional vs. ENDDs



Trtchounian A. Nicotine Tob Res. 2010 Sep;12(9):905-12.

Changes in Vacuum During ENDDs “Smoke Out”



Trtchounian A. Nicotine Tob Res. 2010 Sep;12(9):905-12.

ENDDs Properties

- E-cigarettes required stronger suction to smoke than conventional brands
- Amount of aerosol produced by e-cigarettes decreased during smoking
 - Necessitated increasing puff strength to produce aerosol.
- “Decreased efficiency of aerosol production during e-cigarette smoking makes dosing nonuniform over time and calls into question their usefulness as nicotine delivery devices.”



Trtchounian A. Nicotine Tob Res. 2010 Sep;12(9):905-12.

ENDDs: Health Effects

- 30 healthy smokers (Athens, Greece)
 - Minimum of 5 pack-years
 - Aged 19-56 years
 - 14 male
- E-cigarette for 5 minutes
- ENDDs associated with a significant increase in airway resistance



ENDDs – Are they “Addicting”?

- 20 participants
 - Smoked >15 cigarettes per day
 - Aged 18-55 years
- ENDDs were associated with:
 - Significant nicotine delivery
 - Tobacco abstinence symptom suppression
 - Increased product acceptability ratings



Vansickel AR, *et al.* *Addiction*. 2012 Jan 9. PubMed PMID: 22229871.

How are People Using ENDDs?

- Internet-administered survey
- Men 77%
- Smoking status
 - Former smokers 63%
 - Daily smokers 23%
 - Occasional (non-daily) smokers 13%
- Smokers: 12 cpd

How are People Using ENDDs?

	Number of comments
To quit smoking	53
For health, as e-cigarettes were perceived to be less toxic than tobacco	49
Less expensive than regular cigarettes	26
Can be smoked everywhere, including smoke-free places	21
To avoid disturbing other people, or producing environmental tobacco smoke or the smell of stale smoke	20
For the pleasure of smoking, including the pleasure of inhaling and smoking-related actions	19
To reduce cigarette consumption	14
Curious to test a new product	10
Ecigarettes taste and smell good	8
Previously failed to quit with either nicotine patch or bupropion	3
To get nicotine	2
<i>Total (from three open-ended fields)</i>	225



Etter JF. BMC Public Health. 2010 May 4;10:231.

Legal Status of ENDDs in the U.S.

- **California:** Ban vetoed
- **Maryland:** Bans sales to minors
- **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 [Food and Drug Administration](#) to stop blocking the importation of electronic [cigarettes](#) from China and indicated that the devices should be regulated as tobacco products rather than drug or medical devices.

SIGN IN TO RECOMMEND

 TWITTER

SIGN IN TO E-MAIL

 PRINT

- February, 2010 – appealed and a stay of the lower court order was issued pending full appeal

December 2010 Implications

- E-cigarettes can be imported and sold
- E-cigarettes will not be regulated as a drug or device

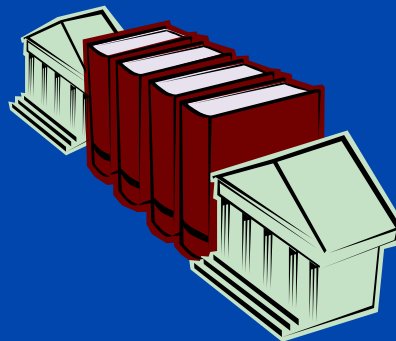
Electronic cigarettes should be treated like tobacco, court ruling says

Crown Seven is a type of electronic cigarette that is tobacco-free.



April 25, 2011

- FDA announced in a letter to stakeholders that it will not appeal the decision
- FDA is developing a strategy to regulate this emerging class of products as tobacco products under the Family Smoking Prevention and Tobacco Control Act



E-Cigarettes & Air Travel



- Oregon, February 2012
 - Continental Airlines flight diverted back to airport of origin when a passenger refused to stop using his e-cigarette
 - Passenger detained & charges are expected to be filed
- FAA has not ruled on ENDD use on airplanes, but airlines are permitted to establish their own policies

Legal Status of ENDDs Around World

- Cannot be sold in Australia, Brazil, Canada, Denmark, Switzerland, Singapore
 - Australia – can be purchased on internet for personal use
- Legal in India, China, South Korea
- New Zealand – ENDDs are a “registered medicine” and sold in pharmacies



World Health Organization (WHO)

“no rigorous, peer-reviewed studies have been conducted showing that the electronic cigarette is a safe and effective nicotine replacement therapy. WHO does not discount the possibility that the electronic cigarette could be useful as a smoking cessation aid.”



Phillip Morris Entering ENDD 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...



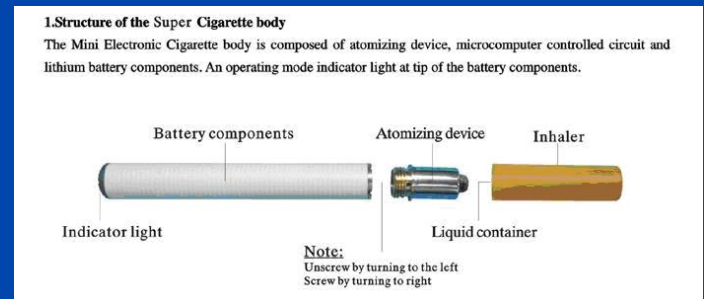
ENDDs

- Pros

- Lower carcinogen exposure than cigarettes
- No second-hand smoke production
- May motivate smokers to quit

- Cons

- More risk than NRT
- No evidence for its safety with long-term use
- No evidence for efficacy as an aid to quitting smoking
- Low and inconsistent levels of nicotine delivery
- Impurities & no regulatory framework to monitor GMP standards



ENDDs: Where Should the Tobacco Control Community Stand?

- Additional studies needed to confirm safety
- Additional studies to evaluate efficacy for tobacco dependence treatment
- Restrict manufacturer claims regarding safety & usefulness as an aid to stop smoking



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