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# THR and E-Cigarettes public health intro and overview

Joel L. Nitzkin, MD

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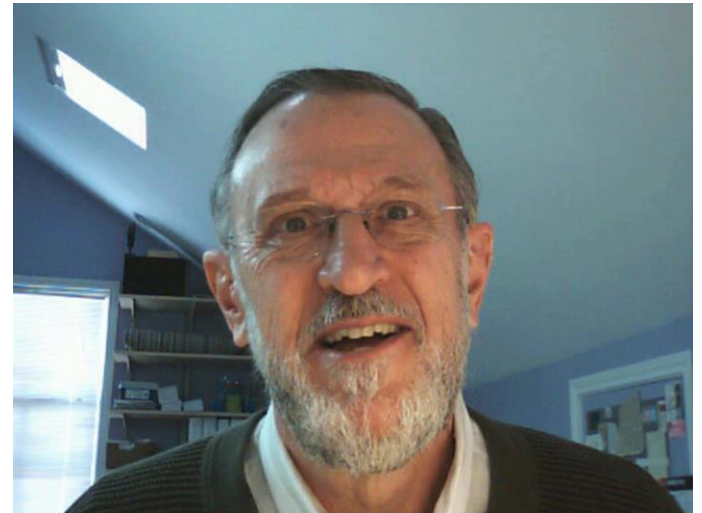
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# Today's Presentation

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- Tobacco as a public health issue
- Tobacco Harm Reduction (THR)
  - Definition
  - Issues
  - Public Health perspective
  - regulatory perspective
- E-cigarettes
  - What they are, and how they work
  - E-cigarettes as THR modality
  - Challenges to Industry

# Basic Principles, Slide 1

- Cigarettes dominate – 85% of nicotine use, >99% of illness and death (USA)
- Smoke-free products\* pose risk of death less than 1% risk posed by cigarettes
  - \* in USA and Scandinavia, but not in Asia



# Basic Principles, Slide 2

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- ❑ Smokers smoke for nicotine
- ❑ Products of combustion (not nicotine) cause the cancer, heart and lung disease



# Basic Principles, Slide 3

## Cigarette habituation/addiction

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- Nicotine
- handling ritual
- Image, emotion and fantasy
- ?other addictive substances?



# Basic Principles, Slide 4

## Comparative Risk

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- ❑ Tobacco cigarettes most hazardous and most addictive of nicotine delivery products
- ❑ Other combustible products intermediate in risk (with possible exception of hookahs – high risk)
- ❑ Smoke-free products (USA, Europe) low risk
- ❑ Nicotine-only are lowest risk and least addictive

# Basic Principles, Slide 5

Why these differences in risk?

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- Risk of addiction
  - Alveolar v. tracheal v. oral absorption
  - Strength and speed of nicotine “hit”
  - (other factors)
- Risk of potentially fatal tobacco-related illness
  - Alveolar v. tracheal v. oral absorption
  - Other ingredients
    - Gutkha/pan masala with tobacco
    - Hookah
    - E-cigarettes



# Smoking-Related Mortality

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- ❑ 480,000 Deaths Annually (US Smokers)
- ❑ 40,000 Deaths Annually (non-smokers)
- ❑ Responsible for one in five deaths in US
- ❑ **Of the 8.6 million deaths projected in smokers over the next 20 years, almost all are current adult smokers over 35 years of age**
- ❑ **40% of the risk of death dissapates within 2 years of quitting or switching**

# Smoking Cessation Therapy

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- ❑ Spontaneous – about 3% per year
- ❑ With NRT Therapy – about 7% at 1 year
- ❑ Chantix – about 9% at 1 year
- ❑ Evidence statistically significant
- ❑ Evidence – fails 93% or 91% of smokers
- ❑ Some non-pharmaceutical protocols show preliminary evidence of about 50% efficacy at 1 year (data very preliminary)

# THR Defined (for USA and Europe)

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- Informing smokers that they can cut their risk of potentially fatal tobacco-related illness by 99% or better by switching to a smoke-free product.
- Informing smokers that the lower risk product will be easier to quit.



# THR Issues, Slide 1:

## Public Health Science

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- Safety to user
- Safety to bystanders
- Efficacy for THR (long term substitute for cigarettes)
- Efficacy for smoking cessation
- Efficacy for nicotine abstinence
- Attractiveness to teens and other non-smokers
- Modeling use of an additive drug

# THR Issues, Slide 2:

## policy, politics

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- Distrust of “tobacco industry”
- Burden of proof
  - Who must bear burden of proof
  - Evidence vs. proof
- Failure of filters and lite cigarettes
- Goal of “tobacco-free society’

# THR Issues, Slide 3: regulatory perspective

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- Basis for comparison
  - Consumer products
  - ??Tobacco cigarettes??
- “Smoking” defined as “disease”
  - (nicotine addiction is a disease; smoking is a behavior; no clear demarcation between the two)
  - Can a non-drug product claim health benefit?
  - If licensed as drug, can only be used as drug (i.e. short term use)
- Issue of harm to non-users
  - Environmental smoke or vapor
  - Inducement of non-smokers to initiate use

# FDA Issues

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- Text of FDA Tobacco Law
  - Bias against any new product
  - Bias against THR
  - Pre-market studies required
    - Environmental vapor
    - Attractiveness to non-users
    - Impact on quit rates
  - Etc, etc.
- Four to ten more years before FDA regulates e-cigs (JLN estimate)

# Possible Harms and Threats of THR

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- ❑ Increase teen initiation of nicotine use
- ❑ Decrease adult quit rates
- ❑ Threats
  - to public health stakeholders
  - to pharmaceutical companies
  - to tobacco industry





# Smokeless Tobacco and Oral Cancer

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## Relative Risks

Smoking	~10
Alcohol Abuse	~4

## American Smokeless Tobacco\*

Chewing tobacco	1.2
Moist snuff	1.0

\* Over 20 epidemiologic studies, reviewed in: B Rodu, P Cole. Oral Surgery 93: 511-515, 2002.

\*\*New England Journal of Medicine 304: 745-749, 1981.

# Smokeless Tobacco and Other Cancer

Lee and Hamling, BMC Medicine 2009

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<u>Site (No. Studies)</u>	<u>RR (95% CI)- Smoking Adjusted</u>
Esophagus (7)	1.1 (0.95 – 1.4)
Stomach (8)	1.0 (0.9 – 1.2)
Pancreas (7)	1.1 (0.7 – 1.6)
Any Digestive (5)	0.9 (0.6 – 1.3)
Larynx (2)	1.3 (0.6 – 3.0)
Lung (6)	1.0 (0.7 – 1.4)
Prostate (4)	1.3 (1.1 – 1.6) <sup>***</sup>
Bladder (10)	1.0 (0.7 – 1.3)
Kidney (5)	1.1 (0.7 – 1.7)
Lymphoma (3)	1.4 (0.6 – 2.9)
All Cancer (7)	1.0 (0.8 – 1.2)

# Smokeless Tobacco and Cardiovascular Diseases

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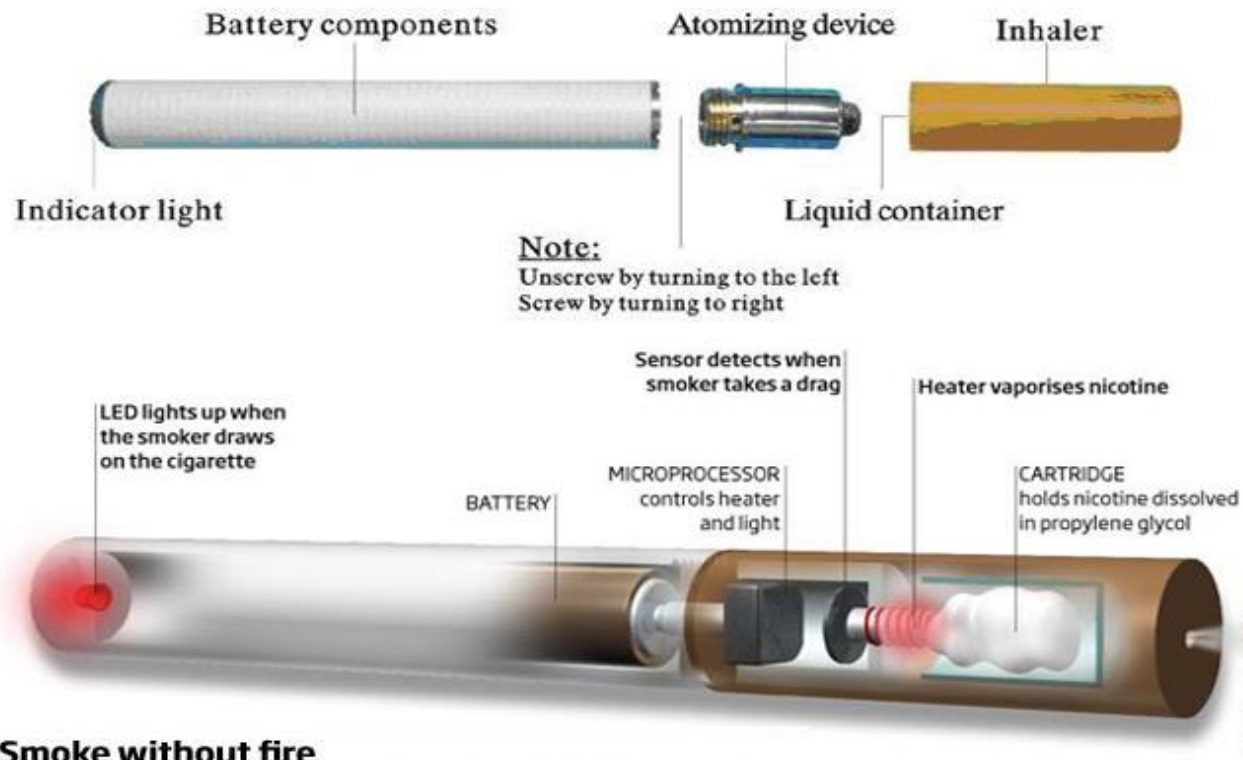
14 epidemiologic studies  
2 meta-analyses

	Relative Risk Among ST Users:	
	<u>Heart Attack</u>	<u>Stroke</u>
<sup>1</sup> Lee, 2007	1.12 (0.99 – 1.27)	1.42 (1.29 – 1.57)
<sup>2</sup> Boffetta-Straif, 2009	0.99 (0.89 – 1.10)	1.19 (0.97 – 1.47)

<sup>1</sup>International Journal of Epidemiology 36: 789-804, 2007

<sup>2</sup>BMJ Aug 18 (online), 2009

# E-cigarettes



## Smoke without fire

Suck on an e-cigarette and it produces a cloud of nicotine-carrying vapour with none of the toxic by-products of burning tobacco

# E-cigarette Market Trends 2013

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- ❑ Invented in China 2003
- ❑ Entered American Market 2006
- ❑ Sales now doubling to quadrupling each year in USA
- ❑ Latest forecast, USA: up from \$0.5b in 2012 to projected \$1.7b in 2013 Hertzog, B (Wells Fargo)  
<http://cnbc.com/id/100991511>
- ❑ (traditional cigarette market about \$80b)
- ❑ E-cigs could overtake traditional cigarettes within the decade (ibid)

# E-cigarette Market Trends 2014

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- ❑ “Cig-a-like” sales flat to slightly down
- ❑ All new market growth (USA) now going to “mods” and “tanks”
- ❑ Dose and flavor can be customized
- ❑ Cheaper than cigarettes for long-term use (more than a month)
- ❑ Industry quality-of-liquid standards
- ❑ Many small-scale manufacturers

# Notes on e-cigarettes

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- E-cigarettes only tobacco/nicotine product with huge, vocal, politically active users groups not initially affiliated or supported by manufacturers or vendors
- Health hazard presented by vapor devices probably less than smokeless tobacco, but far from “harmless water vapor”

# Toxicity of E-cigarettes

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- ❑ The concentrations of carcinogens and other trace toxins associated with e-cigarette nicotine are only marginally above the levels in the pharmaceutical gums, patches, inhalers, etc, already approved by FDA.
- ❑ Nicotine in these products is not harmless.
- ❑ Research now underway relative to
  - **Toxins in flavorings, if inhaled (lipids and other)**
  - **Hazards if PG or other ingredients overheated by malfunctioning unit.**
  - **No long term epidemiologic studies (none possible for publication for at least another ten years)**



# E-cigarettes and Dual Use

(Dawkins et al Addiction 108(6) 11115-25 2013)

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- ❑ Survey of 1,347 e-cigarette users from 33 countries recruited from two e-cigarette web sites
- ❑ 57% have not smoked “for months” after quitting, using e-cigarette to quit
- ❑ 88% either quit or cut down substantially on cigarettes smoked

# Smokers Uninterested in Quitting

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- Six month pilot study (Italy) smokers uninterested/unwilling to quit
  - 9/40 (22.5%) abstinent at 6 months;
  - 13/40 (32.5%) 50% or more reduction in smoking;
  - 35/40 (87.5%) reduced or discontinued cigarette use  
(Polosa et al BMC Public Health 11:786 2011)
  
- Twelve month pilot study (Italy) schizophrenic smokers uninterested in quitting
  - 2/14 (14.4%) abstinent at 12 months
  - 9/14 (64.3%) abstinent or 50% reduction at 12 months  
(Caponnetto et al Int J Environ Res Public Health 10(2) 446-61 2013)

# Attractiveness to Teens and other non-smokers

(re smoke-free alternatives compared to cigarettes)

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- ❑ No pandemic of tobacco use prior to predatory marketing of machine-made cigarettes
- ❑ 30% of smokers can satisfy their urge to smoke with zero-nicotine from e-cigarette (Eissenberg Tobc Control 19: 87-8 2010)
- ❑ Non-smokers know about e-cigarettes, but don't use them despite unrestricted marketing
  - National (US) study of 3,240 adults could only find 6 non-smokers who have ever tried e-cigarettes (McMillen et al J Env Pub H Article ID 98974, 2012)
  - ASH (Great Britain) commissioned survey of 12,171 adults and 2,178 children age 11-18 could not find a single non-smoker, youth or adult that regularly used e-cigarettes ([www.ash.org.uk](http://www.ash.org.uk) Fact Sheet May 2013)

# Myths

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- ❑ Pharmaceutical smoking cessation products are highly effective
- ❑ Smokeless tobacco (in USA) causes mouth cancer
- ❑ Nicotine is responsible for the cardiovascular mortality of cigarettes
- ❑ Candy and fruit flavors are not intended to attract adults
- ❑ Lack of FDA approval of e-cigarettes is because e-cigarettes fail to meet FDA standards
- ❑ E-cigarettes are harmless

# “p” Politics of E-cigarettes

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- CASAA
- Tobacco Control Programs
- Pharmaceutical Industry
- Tobacco Industry

# Regulatory Challenge to FDA

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- -- five years into Tobacco Control Act
- FDA CTP has not yet proposed quality and safety standards for any tobacco/nicotine product
- Proposed “Deeming” regulations for e-cigarettes require studies more expensive and more difficult than for most drugs
- (E-cigs to remain unregulated for another 4-10 years JLN best estimate)

# Regulatory Challenge ctd

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- ❑ CTP initially staffed by tobacco prohibitionists
- ❑ Initial Scientific Advisory Committee (TPSAC) included pharmaceutical researchers
- ❑ TPSAC has recommended that tobacco industry funded research not to be trusted (requires “third party” yet to be defined)
- ❑ Feds have no interest in funding research into non-pharmaceutical tobacco/nicotine products

# Regulatory Promise

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- New Director of CTP dedicated to implementing concept of “spectrum of risk”



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