



# WHO study and position on Electronic cigarettes

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# Presentation Roadmap

- What are ENDS
- Scientific Evidence
- Global Availability
- WHO's Position



# What are ENDS?



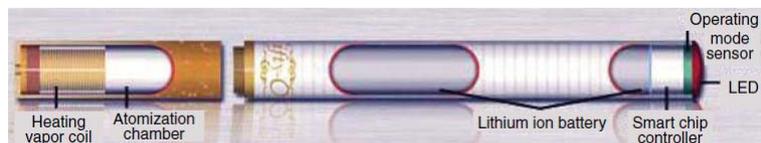
## Electronic Nicotine Delivery Systems

- Designed to deliver nicotine to the lungs
- First marketed in 2004
- Battery powered
- Deliver a vaporized propylene glycol /nicotine mixture into respiratory system
- Contain tobacco-derived substances, but tobacco is not necessary for operation
- Often offered in flavors that are attractive to adolescents



# E-Cigarettes

- Prototype of ENDS
- Three main components:
  - Smart chip + lithium ion battery (rechargeable)
  - Nicotine cartridge
  - Atomization chamber
- Liquid vaporized and then inhaled by user
- Do not generate smoke associated with conventional tobacco cigarettes



## Scientific Evidence

# Recent Findings on Toxicity

- ∅ At least 10 toxicants can be identified and quantified in electronic cigarettes<sup>1</sup>, including **known carcinogens** and **diethylene glycol**, an ingredient used in antifreeze.
- ∅ In Turkey, **propylene glycol** (which is potentially toxic) was found in all ENDS samples, **tobacco specific N-nitrosamines** (powerful carcinogens) in a majority of samples<sup>2</sup>
- ∅ E-cigarettes release **toxins** into the air, including acetic acid, acetone, isoprene, formaldehyde and acetaldehyde, averaging around **20%** of what the conventional cigarette produces<sup>3</sup>
- ∅ All e-cigarettes that the FDA has detained and examined meet the definition of a **combination drug-device** product under the Federal Food, Drug, and Cosmetic Act<sup>1</sup>.

1. U.S. FDA <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm173222.html>, Republic of Korea  
 2. FAME Laboratory, Institute of Human Performance and Rehabilitation, Center for Research and Technology, Thessaly, Trikala, Greece  
 3. Indoor Air, Germany

# Nicotine content and toxicity

- ∅ Similarly labeled ENDS cartridges were found to emit very **different amounts of nicotine**<sup>1</sup>
- ∅ This is dangerous because nicotine overdose can have **serious side effects**<sup>2</sup>

Table 2. Summary of features following acute exposure to nicotinic and nicotinic-like alkaloids

	Gastrointestinal	Respiratory	Cardiovascular	Neurological
Early phase	Nausea Vomiting Abdominal pain Salivation	Bronchorrhea Tachypnea	Hypertension Tachycardia Pallor	Miosis Dizziness Headache Ataxia Confusion Tremors Muscle fasciculations Seizures
Delayed phase	Diarrhea	Respiratory depression Dyspnea Apnea	Bradycardia Hypotension Dysrhythmia Shock	Mydriasis Weakness Hypotonia Lethargy Coma Muscle paralysis

1. FAME Laboratory, Institute of Human Performance and Rehabilitation, Center for Research and Technology, Trikala, Greece  
 2. SCHEP L, SLAUGHTER R, BEASLEY D. Nicotinic plant poisoning. *Clinical Toxicology* (15563650) [serial online]. September 2009;47(8):771-781. Available from: Academic Search Premier, Ipswich, MA. Accessed April 24, 2013.

## Additional Concerns

# NJOY

ALL THE PLEASURES OF SMOKING.  
WITHOUT ALL THE PROBLEMS.



- There are **no published studies** demonstrating the efficacy and safety of ENDS
- There is **no data** to confirm ENDS have cigarette mimicking sensory characteristics when heated and delivered to the lung
- The precise nature and the quantity of constituents in the emissions of ENDS are **unknown**
- There is a potential for **nicotine poisoning** from sale of nicotine refill vials

## Even More Additional Concerns

•Without regulation, electronic cigarette smoking will be **normalized** and **glamorized** like cigarette smoking



•People who consider quitting cigarette smoking will develop a new habit and **possibly relapse** to conventional cigarettes

•E-cigarettes are promoted for the occasions when one cannot smoke; this would **defy smoke-free ordinances**

•There is no knowledge about the levels of **carcinogens** in the second-hand smoke which would increase exposure of non-smokers

# Global Availability

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## Current use and experience

- European Union- the use of electronic cigarettes has grown markedly in recent years: 7% of citizens have at least tried electronic cigarettes
- Australia- ENDS avoid plain packaging laws and glamorize electronic cigarette use
- United Kingdom- Loophole in regulation only covers ENDS if they contain nicotine. Electronic cigarettes without nicotine are commonly sold
- Trends and limited regulation suggest that e-cigarette use will continue to grow despite limited understanding of the product's characteristics



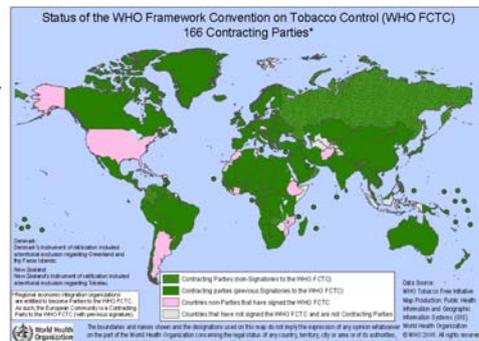
# Tobacco Industry Involvement

- Philip Morris International has **three prototypes** that more resemble a traditional cigarette that heats and does not burn.
- Lorillard Inc. acquired a maker of electronic cigarettes for \$135 million
- R.J. Reynolds has begun production on a new electronic cigarette
- By the acquisition of e-cigarettes, **major cigarette manufacturers** are signaling that they believe this is the next frontier for their companies
- **Without regulation, tobacco companies will be use their unparalleled knowledge and resources to produce and market e-cigarettes**



# WHO Findings: Questionnaire to Parties of the FCTC

- ENDS were available in about **half of respondent Parties**
- E-cigarettes were the most common form of ENDS available (followed by e-cigars)
- All countries reporting electronic cigarettes were **high-income or middle-income countries**
- Of the Parties that stated that ENDS are not available for sale in their jurisdictions, **only 4 had laws banning the manufacturing, importation, distribution, and sale of ENDS<sup>1</sup>**



1. Brazil, the Seychelles, Singapore and Uruguay

AVAILABILITY AND REGULATION OF ENDS IN PARTIES<sup>1</sup>

	Regulated (including banned)			Unregulated		
	<i>As a tobacco product</i>	<i>As a product with health/therapeutic claims</i>		<i>Regardless of whether or not contain nicotine or make health/therapeutic claims</i>	<i>Only if do <u>not</u> contain nicotine and/or <u>no</u> health/therapeutic claims are made</i>	
		<i>Contains nicotine</i>	<i>Does not contain nicotine</i>	<i>Regardless of whether or not contain nicotine</i>		
<b>Available</b>	Belgium, Republic of Korea	Hungary		United Kingdom of Great Britain and Northern Ireland <sup>2</sup>	Bulgaria, Ireland, Lithuania, Malaysia, Portugal, Romania, Serbia, South Africa, Trinidad and Tobago	Australia, <sup>3</sup> Belgium, Canada, Germany, <sup>4</sup> Hungary, New Zealand, United Kingdom of Great Britain and Northern Ireland
<b>Not available</b>	Bhutan, Brazil, <sup>5</sup> Norway, Seychelles, <sup>5</sup> Singapore, <sup>5</sup> Uruguay <sup>3</sup>	Australia, <sup>2</sup> Belgium, Canada, Germany, <sup>6</sup> New Zealand, Norway, Turkey		Japan, Uruguay	Ghana, Kuwait, Lesotho, Mauritania, Rwanda	Australia, <sup>2</sup> Germany <sup>4</sup>



Inconsistent and incomplete regulation in many countries

# WHO's Position

# WHO FCTC



- ENDS are currently not regulated under the Framework Convention of Tobacco Control
- However, ENDS undermine Articles 6 (taxation), 8 (second-hand smoke) and are exempted from Article 11 (plain packaging laws) of the FCTC
- Regardless of whether they are covered by the treaty, ENDS may normalize smoking, encourage dual use and by pass smoking ban in public places
- ENDS should be subject to regulation as tobacco products and as medicinal products



## Conclusions and Recommendations



- ENDS contain toxic chemicals. Their safety and impact on smoking cessation and on health has not been assessed.
- Increasing use without full assessment of consequences signals that regulations are necessary
- WHO suggests ENDS should be regulated through a two-pronged approach as both tobacco products and as medicinal products to prevent a situation in which loopholes are exploited and ENDS escape control
- Claims implying health benefits, less harm than cigarettes, or smoking cessation efficacy should not be allowed unless proven
- Burden of research demonstrating safety, efficacy, and efficiency should be on manufacturers and producers of ENDS (similar to pharmaceutical products)