

# The profile or 'vapers' and how e-cigarettes should be regulated

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# Disclosure

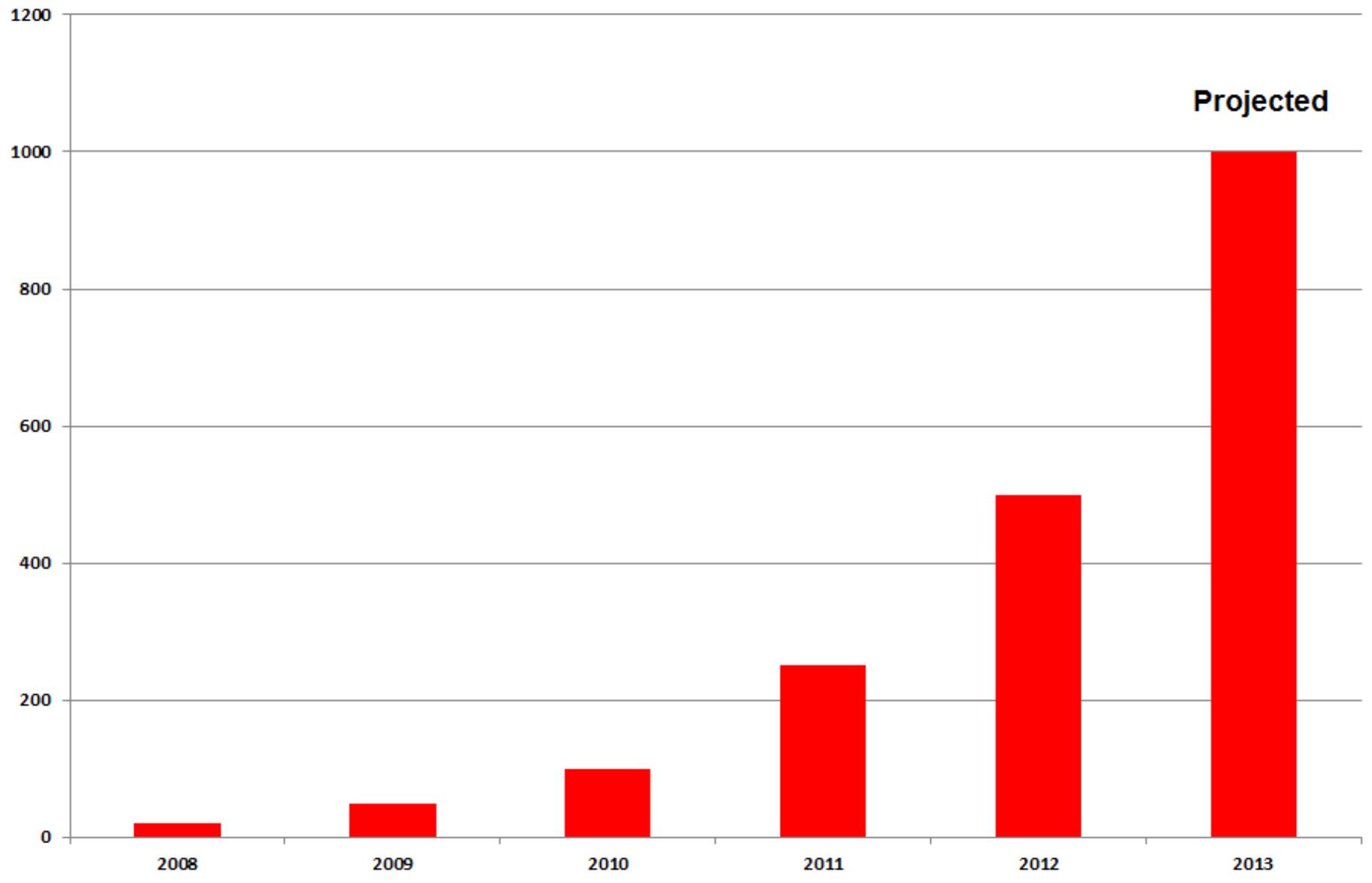
- Tobacco industry:
  - never received any funding
  - no conflict of interest
- Pharmaceutical industry
  - no funding in past 7 years
  - no conflict of interest
- E-cigarette industry
  - plane ticket + hotel (London + China)

# Outline

- Profile of vapers :
  - representative surveys, including use in non-smokers
  - surveys in convenience samples of vapers
  
- How should e-cigarettes be regulated
  - regulation today (USA, EU)
  - future regulation
    - ... as tobacco products ?
    - ... as medications ?
    - ... as consumer products ?
    - ... as a specific category ?

# Sales (Millions of Dollars) of E-cigarettes in the U.S., 2008-2013

(Source: UBS)



# Surveys in representative samples of the general population

1. ADKISON, S. E., O'CONNOR, R. J., BANSAL-TRIVERS, M. et al. (2013) Electronic nicotine delivery systems: international tobacco control four-country survey, *American Journal of Preventive Medicine*, 44, 207-15.
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13. PEPPER, J. K., REITER, P. L., MCREE, A. L. et al. (2013) Adolescent males' awareness of and willingness to try electronic cigarettes, *The Journal of Adolescent Health*, 52, 144-50.
14. POPOVA, L. & LING, P. M. (2013) Alternative tobacco product use and smoking cessation: a national study, *American Journal of Public Health*, 103, 923-30.
15. REGAN, A. K., PROMOFF, G., DUBE, S. R. & ARRAZOLA, R. (2011) Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA, *Tobacco Control*.
16. SUTFIN, E. L., MCCOY, T. P., MORRELL, H. E., HOEPPNER, B. B. & WOLFSON, M. (2013) Electronic cigarette use by college students, *Drug and Alcohol Dependence*.

# USA : use in the general population

- 0.6% in 2009
- 2.7% in 2010
- 6.2% in 2011

## Sources:

Regan.	<i>Tobacco Control</i>	2011
McMillen	<i>Journal Of Environmental &amp; Public Health.</i>	2012

## U.K.: current use in smokers

- In representative samples of the general population, only in smokers:
- 2.7% in 2010
- 6.7% in 2012
- 11% in 2013

# Age and gender, education and income

- From 6 surveys in representative samples of the general population
- Compared with non-users, vapers tend to be :
  - younger
  - better educated
  - higher income
  - no clear association with gender

## Sources:

Cho.	<i>J Adol Health.</i>	2011
Choi.	<i>Am J Public Health.</i>	2013
Li.	<i>New Zealand Med J.</i>	2013
Goniewicz.	<i>Pediatrics.</i>	2012
King.	<i>Nicotine Tob Res.</i>	2013
McMillen.	<i>J Environ Pub Health.</i>	2012

# Conversion from 'trying out' to 'use in past 30 days'

- This was documented in 10 surveys in representative samples of the general population
- UK, US, Australia, New Zealand, Canada, Poland, Switzerland
- 30-38%

## Sources:

Adkison	<i>Am J Prev Med</i>	2013
Corey	<i>MMWR</i>	2013
Dockrell	<i>Nic Tob Res</i>	2013
Douptcheva	<i>J Epidemio Comm H</i>	2013
Goniewicz.	<i>Pediatrics.</i>	2012
McMillen.	<i>J Environ Public H</i>	2012
Pearson	<i>Am J Public Health</i>	2012
Popova	<i>Am J Public Health</i>	2013
Regan	<i>Tob Control</i>	2011
Sutfin	<i>Drug Alc Depend</i>	2013

# Conversion from 'trying out' to 'daily use'

- This was documented in 2 surveys in representative samples of the general population
- Switzerland, Czech Republic.
- 12%, 14%

## Sources:

Douptcheva *J Epidemiol Comm H* 2013

Kralikova *Chest* 2013

# Experimentation and use by never smokers

- From 11 surveys in representative samples of the general population
- UK, USA, Australia, New Zealand, Canada, Poland, Switzerland, Czech
- Ever use in never smokers :
  - range : 0.1% to 3.8%
  - median : 0.5%
- Use in past 30 days, in never smokers :
  - range : 0% to 2.2%
  - median : 0.3%

## Sources:

Cho.	<i>J Adol Health.</i>	2011
Choi.	<i>Am J Public Health.</i>	2013
Corey	MMWR	2013
Dockrell	<i>Nic Tob Res</i>	2013
Douptcheva	<i>J Epidemio Comm H</i>	2013
Goniewicz.	<i>Pediatrics.</i>	2012
King.	<i>Nicotine Tob Res.</i>	2013
McMillen.	<i>J Environ Public H</i>	2012
Pearson	<i>Am J Public Health</i>	2012
Regan	<i>Tob Control</i>	2011
Sutfin	<i>Drug Alc Depend</i>	2013

# ‘Daily use’ by never smokers

- Was assessed in 2 surveys in representative samples of the general population
- UK, Switzerland
- To date, no ‘daily use’ in never smokers has been reported

## Sources:

Douptcheva. *J Epidemiol Comm Health*. 2013

ASH-UK. 2013

# MMWR report, CDC press release

- USA, 2011-2013, National Youth Tobacco Survey
- Representative sample, middle+high school, grades 6-12
- Reported on :
  - ever use (3.3% in 2011 and 6.8% in 2012)
  - use in past 30 days (1.1% in 2011 and 2.1% in 2012)
- No data were reported on daily use
- No data on addiction to e-cigs
- No data on progression to smoking
  
- CDC press release: main message not based on their published data:
- CDC Director Tom Frieden: “ Many teens who start with e-cigarettes may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes ”

Source: Corey *MMWR* 2013

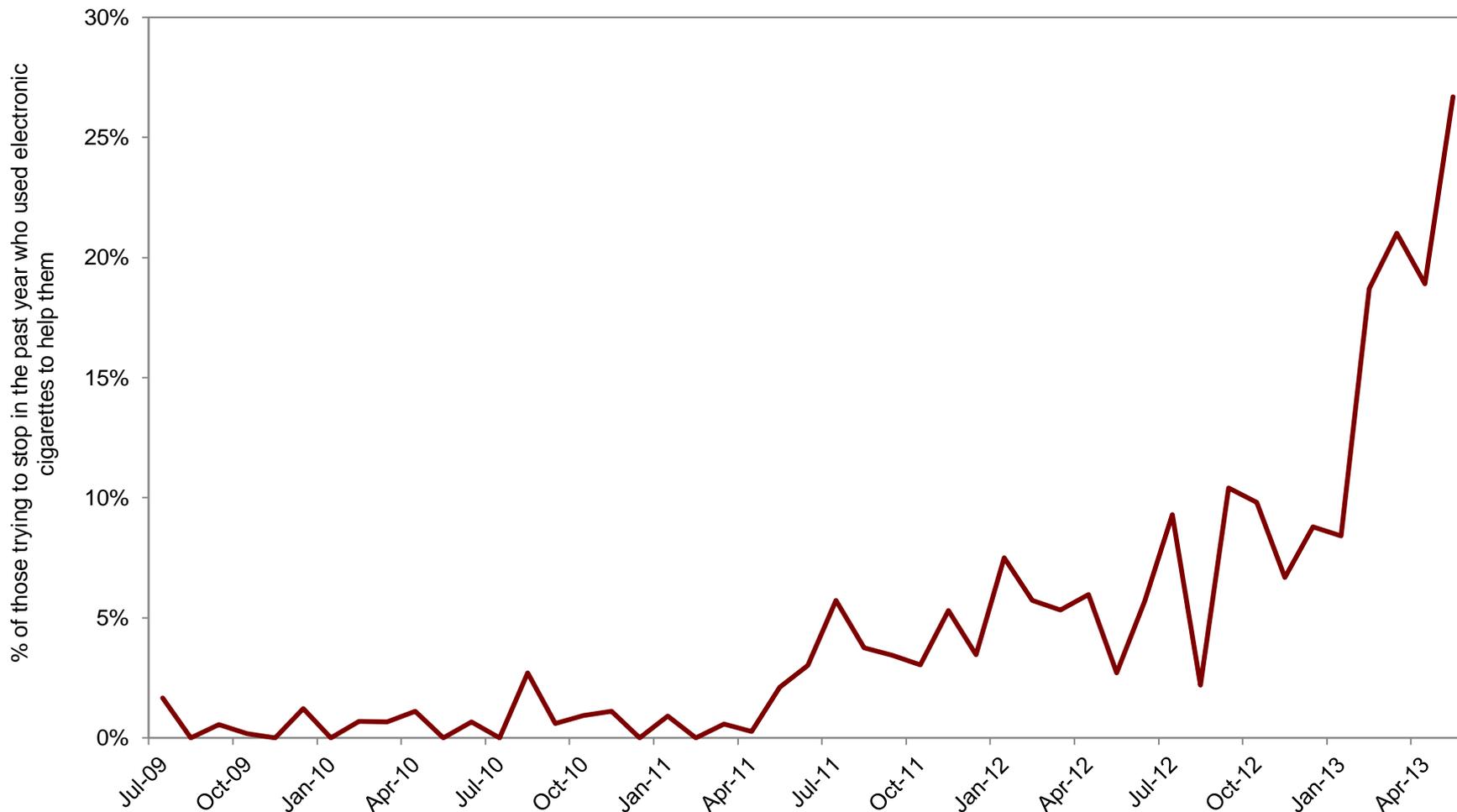
# Smoking status

- Across 8 surveys in representative samples, the proportion of EC users was 2 to 8 times higher in current smokers than in former smokers
- Most users = dual users (e-cig + cig)

## Sources:

Choi.	<i>Am J Public Health.</i>	2013
Dockrell	<i>Nic Tob Res</i>	2013
Douptcheva.	<i>J Epidemio Comm H</i>	2013
Goniewicz.	<i>Pediatrics.</i>	2012
King.	<i>Nicotine Tob Res.</i>	2013
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Pearson	<i>Am J Public Health</i>	2012
Regan	<i>Tob Control</i>	2011
Sutfin	<i>Drug Alc Depend</i>	2013

# % of those trying to quit who used e-cigs to help them quit - U.K. Smoking Toolkit Study



# Surveys in convenience samples of users

1. ETTER, J.-F. (2010) Electronic cigarettes: a survey of users, *BMC public health*, 10, 231.
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4. MCQUEEN, A., TOWER, S. & SUMNER, W. (2011) Interviews with "vapers": implications for future research with electronic cigarettes, *Nicotine & Tobacco Research*, 13, 860-7.
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13. KRALIKOVA, E., NOVAK, J., WEST, O., KMETOVA, A. & HAJEK, P. (2013) Do e-cigarettes have the potential to compete with conventional cigarettes? A survey of conventional cigarette smokers' experiences with e-cigarettes, *Chest*.
14. FARSALINOS, K. E., ROMAGNA, G., TSIAPRAS, D., KYRZOPOULOS, S. & VOUDRIS, V. (2013) Evaluation of electronic cigarette use (vaping) topography and estimation of liquid consumption: implications for research protocol standards definition and for public health authorities' regulation, *International journal of environmental research and public health*, 10, 2500-14.
15. VICKERMAN, K. A., CARPENTER, K. M., ALTMAN, T., NASH, C. M. & ZBIKOWSKI, S. M. (2013) Use of Electronic Cigarettes Among State Tobacco Cessation

# Surveys in convenience samples of users

- Not representative samples: interpret with caution
- In daily users :
  - 120 to 235 puffs per day on average
  - spend \$33 to \$52 per month on ecigs
  - 97-100% of daily users use e-cigs containing nicotine
  - 18 mg / ml : most popular nicotine concentration in e-liquid
  - Most popular flavors (in order of popularity) :
    - Tobacco
    - Mint
    - Fruit

# Cigarettes per day in dual users

- In dual users, cig./day when vaping = less than cig./day before they started to vape

<u>Cig./day before</u>	<u>Cig./day when vaping</u>	<u>Sources</u>
25	15	(1)
50% >20 cig	2% >20 cig	(2)

- Sources:
  - 1) Etter. *Addiction*, 2011
  - 2) Goniewicz. *Drug Alc Rev*, 2013

# Perceived effects on smoking reduction, cessation

- In 8 studies in convenience samples of vapers
- 42-99% of ex-smokers said e-cigs helped them quit smoking
- 60-86% of smokers said e-cigs helped them reduce cig./day

## Sources:

ETTER (2010), BMC Public Health, 10, 231.

SIEGEL (2011), American Journal of Preventive Medicine, 40, 472-5.

ETTER (2011), Addiction, 106, 2017-28.

FOULDS (2011) International Journal of Clinical Practice, 65, 1037-42.

GONIEWICZ (2013), Drug and Alcohol Review, 32, 133-140.

DAWKINS. (2013) Addiction.

KRALIKOVA (2013), Chest.

FARSALINOS (2013), International Journal of Environmental Research and Public Health, 10, 2500-14.

# Addictiveness of e-cigs

- In 4 studies in convenience samples of vapers:
- E-cigarettes were perceived as less addictive than cigarettes
- Time (minutes) between waking up and time to first use was longer for e-cigs than for cigarettes
- Only 18% craved e-cigs as much as tobacco
- Sources: Foulds 2011, Goniewicz 2013, Dawkins 2013, Farsalinos 2013
- Definition of addiction = 2 elements:  
Compulsive use in spite of adverse consequences for the user's health, family and social life
- The *adverse consequences* element is not proven so far

# Addictiveness of e-cigs

- Definition of addiction = 2 elements:  
Compulsive use in spite of adverse consequences for the user's health, family and social life
- The *adverse consequences* element is not proven so far
- E-cigs are not very addictive, even if e-cigs were addictive, this would not be a significant public health problem
- Legislation cannot be based on moral disapproval of recreational nicotine use

# Summary

- E-cigs are used by current and former smokers, as a cheaper and safer alternative to tobacco
- Most users report that e-cigs help them quit or reduce smoking
- Regular use in non-smokers has not been documented so far
- E-cigs are less addictive than cigarettes

# Regulation

- **Alms:**
  - **to decrease the number of cases of disease and death**
  - **freedom of citizens**
- Should cover not just e-cigs but also 'next generation' products

# Regulation

- E-cigs are regulated as consumer products or tobacco, not regulated as medicines in any country
- USA:
  - FDA cannot regulate e-cigs as drugs : court decision (Sottera 2010)
  - FDA regulates all non-medicinal nicotine as tobacco : FSPTCA 2009
  - State and local regulations (e.g. bans in public places)
  - FDA: «deeming regulation», due October 2013
- European Union (EU): Tobacco Products Directive: article 18
  - EU Parliament votes on October 8
  - Will they regulate e-cigs as medicines ?
  - There is no such thing as “light touch” regulation
- In October: EU TPD, FDA regulation will be extraordinarily important, because once written, laws are very hard to change

# Regulation

- Currently there is intensive lobbying of FDA, EU Parliament
- In general, governments + parliaments are excessively responsive to special interests, rather than to the general interest
- As a result almost *any* regulation will favor those who are best at lobbying (Big Tobacco, Big Pharma)
- Even before seeing them, financial analysts already say that future regulations will be favorable to Big Tobacco
- In each country, regulation will differ because it depends on specific :
  - history of tobacco regulation
  - political process, weight of lobbies
  - stage of development of e-cig market

# Regulation as a tobacco product

- Aim:  
to offer consumers the same level of protection as for tobacco products
- Bans in public places
- Restrictions on advertisements, marketing
- Sale restrictions to minors
- Content, additives

# Problems with tobacco regulation

- E-cigs do not contain tobacco  
(even though nicotine is extracted from tobacco)
- Measures used to control tobacco are excessive, disproportionate
- Bans in public places
  - no evidence that passive vaping is toxic
  - no evidence that vaping in public encourages smoking
- Advertising bans
  - no evidence that the product is toxic
  - no evidence that non-smokers become regular users
- Sale restrictions to minors who smoke
  - minors can buy nicotine gums, patches
  - e-cigs may protect both minors and adults against smoking

# Regulation as a medicine

- Aim:
  - to give consumers the same level of protection as for medicines
  - efficacy
  - safety, toxicity
  - quality requirements
  - stability of the product
  - protect young non-smokers (advertising, age limits)

# Problems with medicines regulation (1)

- No therapeutic claim: e-cigs are not medicines
- Medicines regulation has been and will be challenged in court
- Inequality with tobacco (makes e-cigs less competitive)
  
- Inadequate impact assessment by proponents of medicines regulation
  
- Costs associated with obtaining drug approval
- Administrative barriers
- Many products, manufacturers and retailers will disappear
- Only Big Tobacco will survive (+ Big Pharma if they step in)
- Prices will increase

## Problems with medicines regulation (2)

- Will kill innovation  
e.g. nicotine gum + patch 'frozen' in same stage as when they were first approved, in the 1970s
- Almost all flavors will be banned (e-cigs will attract fewer smokers)
- Excessive restrictions on marketing
- Ban of unlicensed product = incompatible with quality control
- No tax on banned products
- Sends the wrong message about nicotine
- More smokers, more healthcare costs
- Internet + high street shops will close:  
negative impact on employment

# Problems with medicines regulation (3)

- Contrary to constitutional free market principles
- Lack of popular support: not viable in democracy
- Bans of unlicensed products cannot be enforced
- Enforcement would be costly and ineffective
- Internet sales will continue
- Development of home made brews + e-cigs: unsafe
- Black market

## **2 main consequences of tobacco or medicines regulations :**

- **Fewer users, fewer smokers will quit, more will die**
- **Only Big Tobacco will survive**

# Regulation as a consumer product

- Aims:  
offer consumer the same protection as for many other consumer products, including food, cosmetics, chemicals, electrical devices, etc.
- Several EU Directives + national laws already apply to e-cigs :
  - safety
  - RAPEX system (alerts)
  - chemical safety (hazardous substances: RoHS Directive)
  - electrical safety
  - packaging, labeling
  - weights and measures
  - commercial practice (advertising, Internet)
  - data protection
- Source: C. Bates, G. Stimson. *Costs and burdens of medicines regulation for e-cigarettes*. September 2013

# Is regulation as a consumer product sufficient?

- First, apply and enforce existing laws and EU Directives
- If necessary, create a specific category or specific norms for recreational nicotine products :
  - manufacturing process, components, e-liquid content
  - advertisement
  - sales to minors
- This does not require regulation of e-cigs as medicines or tobacco
- Create a tax on e-cigs, earmarked for
  - research
  - education of the public, Drs, journalists, policy makers, legislators

# Conclusions (1)

- E-cigs = major innovation that has the potential to save many lives
- Regulation : balance public health impact vs risks
- Relative risk is relevant, compared with tobacco, not absolute risk
- Regulation as medicines or tobacco : disproportionate
- Prohibition of unlicensed products: not feasible, nor desirable
  
- Main danger for public health = excessive regulation, not e-cigs

## Conclusions (2)

- Current laws cannot survive, which allow nicotine only in tobacco (deadly) and in medications (gum, patch), which are not appealing, not very effective
- Laws need to change, to accommodate this very popular product and 'next generation' products
- One of the most important public health debates in recent decades:

**To redefine the place of nicotine in society and in the law, and make room for recreational nicotine products**