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 tickets + hotel (London + China)

Outline

- How should e-cigarettes be regulated

  - regulation today (USA, UK, EU)

  - future regulation

  … as tobacco products ?

  … as medications ?

  … as consumer products ?

  … as a specific category ?

Summary of evidence

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

Sources:

1)

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3) Douptcheva et al. *J Epidemiol Comm Health.* 2013; Zhu et al. *PLOS One*. Oct 2013; ASH-UK. 2013

4) On addictiveness of e-cigs: Foulds *Int J Clin Pract* 2011, Goniewicz *Drug Alc Rev* 2013, Dawkins *Addiction* 2013, Farsalinos *IJERPH* 2013

Regulation: aims

- **Aims:**

  - decrease the number of cases of disease and death

  (which are mainly caused by smoked tobacco)

  - protect the freedom of citizens

- Should cover not just e-cigs but also ‘next generation’ products

Regulation

- E-cigs are mostly regulated as consumer products or tobacco, seldom regulated as medicines

- EU + FDA regulation will be extraordinarily influential + important
  Once written, these laws will be very hard to change

- In each country, regulation will differ because it will depend on specific :

  - stage of the tobacco epidemic
  - history of tobacco regulation
  - political process, weight of lobbies
  - stage of development of the e-cig market

Regulation: USA

- Currently :
  - FDA cannot regulate e-cigs as drugs : court decision Sottera 2010
  - FDA regulates all non-medicinal nicotine as tobacco : FSPTCA 2009
  - E-cigs are currently largely unregulated at federal level
  - State and local regulations (bans in public places, sales to <18 yr)

- FDA «deeming regulation» proposal due November 2013, *forecast* :
  - ban sales + advertising to minors
  - limit advertising
  - ban most flavors ?
  - ban Internet sales ?
  - require approbation for new products ?

Regulation: UK

- Medicines and Healthcare products Regulatory Agency (MHRA)
- MHRA public consultation, published in 2011
- MHRA announced (2013) that the UK Government will regulate e-cigs as medicines
- Rationale: to improve product safety, quality and efficacy
- There is no such thing as “light touch” regulation
- By asking MHRA (rather than any other agency) to propose e-cig regulation, one could expect this outcome
- Impact of EU directive on UK decision ?

Regulation: European Union (EU)

- Tobacco Products Directive: article 18
- EU Parliament (October 8)
  - prohibits sales to minors
  - restrictions on advertising and sponsorship
  - rejects proposal to regulate e-cigs as medicines
- Vote on medicines regulation was close (article 18, amendment 170):
  - for: 386
  - against: 283
  - *required to pass: 335*
- Trialogue
  - the Council and Commission are in favor of the medicines regulation
  - many member States want tighter regulation than EU Parliament

Regulation

- Intensive lobbying of FDA + EU Parliament + national governments
- Unprecedented lobbying by vapers, e-cig industry
- 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) and detrimental to those less present (Chinese inventors + manufacturers)
- Even before they have been drafted, financial analysts have said that future regulations may be favorable to Big Tobacco
  - best expertise in regulatory environment
  - treasure trove
  - lists of customers, mandatory shelf space in shops

Nicotine : only in smoked tobacco or in medications

- Currently, nicotine is available either in :
  - smoked tobacco (smokeless banned in many countries)
  - medications (patch, gum, etc.)
- For public health, this approach is largely a failure
- The most deadly product is cheap + available everywhere
- Nicotine replacement therapy
  - not very appealing
  - not very effective in the long term (increases smoking cessation rates by a few percentage points only)
- The success of e-cigs challenges this approach
- The regulation of nicotine needs to be rethinked, but how ?

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)
- Current measures used to control tobacco are excessive, disproportionate if applied to e-cigarettes
- Bans in public places
  - would require stronger evidence that passive vaping is toxic and
  - that vaping in public encourages smoking
- Advertising bans
  - would require stronger evidence that e-cigs are toxic
  - no evidence that non-smokers become regular users
  - consumers have a right to be informed by advertisements
- 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, «gateway» (advertising, age limits)

Problems with medicines regulation (in most, but perhaps not all countries)

- 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)

- Costs associated with obtaining drug approval
- Prices will increase
- Administrative barriers (application = 10,000 pages)

- Only large companies will survive (Big Tobacco + Big Pharma if they step in)
- Many products, manufacturers and retailers will disappear, in particular Chinese ones

Potential 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 + 1980s
- If flavors are banned, e-cigs will attract fewer smokers
- Maximum levels of nicotine in liquids: arbitrary, not evidence-based
- Excessive restrictions on marketing, advertisement
- Bans of unlicensed products
  - incompatible with quality control
  - banned products cannot be taxed
  - enforcement will be costly and ineffective
- Internet sales will continue
- Black market

Potential problems with medicines regulation (3)

- Contrary to constitutional free market principles : unnecessarily excludes a competitor
- Lack of popular support: not viable in democracy
- Unduly protects Big Pharma, which has not been innovative in NRT
- Fewer e-cig users = more smokers, more healthcare costs

2 main consequences of tobacco or medicines regulations :

- **Fewer users, fewer smokers will quit, more will die**
- **Gives the entire e-cig market to Big Tobacco ?**

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 (i.e. e-cigs + 'next generation' 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 cigarettes, not absolute risk,
  e-cigs don't need to be 100% safe, only 99% or 99.9% safer than cigarettes
- 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 when smoked) and in medications (gum, patch)

- Laws need to change, to accommodate this very popular product and also ‘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