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:
Corey MMWR 2013
Douptcheva *J Epidemiol Comm H* 2013
King. *Nicotine Tob Res*. 2013
Sutfin *Drug Alc Depend*. 2013

2) Etter (2010), BMC Public Health, 10, 231.
Goniewicz (2013), Drug and Alcohol Review, 32, 133-140.
Kralikova (2013), Chest.


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 <18yr)

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 rethought, 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

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
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