bmj.com

Poll: Should electronic cigarettes be as freely available as tobacco?

- Cast your vote at bmj.com
- ▶ News: E-cigarettes are to be regulated as medicines from 2016 (*BMJ* 2013;346:f3859)
- Observations: Big Tobacco lights up e-cigarettes (*BMJ* 2013;346:f3418)

Should electronic cigarettes be as freely available as tobacco?

The Medicines and Healthcare Products Regulatory Agency has decided to license electronic cigarettes as medicines from 2016.

Jean-François Etter thinks they should be as freely available as tobacco to reduce harm to smokers, but **Simon Chapman** sees them as another way for big tobacco to try to make nicotine addiction socially acceptable again



Jean-François Etter professor, Institute of Social and Preventive Medicine, Faculty of Medicine, University of Geneva. Switzerland

Jean-Francois.Etter@unige.ch

At last smokers have a safer alternative to tobacco. The law in most countries allows the presence of nicotine only in tobacco and in drugs (for example, nicotine replacement therapy patches and gum), effectively prohibiting competitors to tobacco and drug companies from entering the drug market. Because drugs that contain nicotine are unattractive and not very effective, people addicted to nicotine tend to use tobacco. Arguably, the laws regulating nicotine cause millions of deaths and unjustifiably protect existing nicotine suppliers at the expense of more innovative competitors, who could devise safer products.

However, electronic cigarettes are about to change this. These products are very successful: sales of e-cigarettes in the United States have doubled every year since they were introduced in 2007.²

Harms of regulation

Until recently, e-cigarettes were able to fly under the legislative radar, and the sale of nicotine containing e-cigarettes, although not in compliance with legislation, was tolerated in many countries. But this tolerance is about to end. Unfortunately, governments, legislators, and regulation agencies want to over-regulate these products. Regulators are inherently risk averse, and presented with a new product with an incompletely documented risk profile they will zealously apply a precautionary principle. Examples of this approach include bans on e-cigarettes in several countries; the proposed European Union directive to limit the nicotine concentration in e-cigarettes to 2 mg/mL (which is much too low); the regulation of e-cigarettes as drugs; and the prohibition of use in public.³⁴

This approach is excessively cautious and harmful to public health. It makes no sense to cripple a safer product by excessive regulation, allowing a dangerous one to maintain its monopoly.

The spectacular success of e-cigarettes must and will trigger a public debate on the place of nicotine in society and in the law. The tremendous toll of disease and death caused by tobacco must remain a central element in this debate, and the risks of e-cigarettes must be compared with the risks of smoking. Because they are currently used by current and former smokers, either for enjoyment or to reduce or quit smoking, and rarely, if at all, by people

Simon Chapman professor of public health, University of Sydney, Australia simon.chapman@sydney.edu.au

Amid the feverish embrace of electronic cigarettes come several statements by the tobacco industry that should cause public health proponents of such products to get a grip. For example, the chief executive of Reynolds America told shareholders in November 2012, just six months before entering the e-cigarette market, "We have a little mantra inside of the company . . . which we call the 80-90-90... We spend about 80% of our resources in the combustible space. The combustible space is still 80%, 80+% of our operating income ... [and] 90% of the organizational focus . . . And despite a lot of these new innovations that you see coming out, 90% of our R&D [research and development] budgets are actually directed at the combustible category . . . That is the category that's still going to deliver a lot of growth into the future."1

Misconceptions

Big tobacco is not investing in e-cigarettes to wean itself off cigarette sales. Its recent oleaginous rhetoric about them saving lives is utter duplicity. None of the big companies now in the e-cigarettes market have desisted from virulent opposition to policies that are known to reduce smoking. None has declared accelerated targets for reducing cigarette sales. As with other forms of smokeless tobacco, big tobacco wants smokers to use e-cigarettes as well as cigarettes, not instead of them. Its five goals are widespread dual use; retarding smoking cessation; resocialising public smoking back into fashion from its forlorn exile outside buildings; conveying to young, apprehensive would-be smokers that nicotine is a benign drug; and welcoming back lapsed smokers.

If big tobacco succeeds with any of these ambitions, e-cigarettes may cause a net increase in population harm. Urged on by myopic health professionals who seem to have lost any population health focus they might have had, this may become one of the biggest blunders of modern public health.

Public health enthusiasts for e-cigarettes see their promise as a way to get smokers to quit or reduce toxic exposure, but they seem blasé about the other possible effects described above. There are many impassioned, vocal testimonies that e-cigarettes have helped many thousands to quit or cut down smoking. But

It makes no sense to cripple a safer product by excessive regulation, allowing a dangerous one to maintain its monopoly

who have never used tobacco, ⁵ e-cigarettes do not need to be absolutely safe, they need only to be safer than tobacco. Even if some risks are identified in the future, e-cigarettes will remain orders of magnitude safer than tobacco cigarettes. ⁶

To ensure that as many smokers as possible switch from smoking to "vaping," e-cigarettes must not be regulated more tightly than tobacco cigarettes. They should not be regulated as drugs either, because they are not drugs as long as vendors make no health claims.

The regulation of e-cigarettes should cover only quality control (to ensure that they do not deliver unexpected substances) and the marketing and sales to minors, to ensure that e-cigarettes are not advertised or sold to those who do not use tobacco. Any tighter regulation will act as a barrier to e-cigarette use and ensure that the death toll caused by smoked tobacco continues.

No evidence that e-cigarettes promote smoking

Prohibitionists claim that e-cigarettes are a gateway to smoking for young non-smokers.

Currently, no evidence supports this hypothesis. On the contrary, if e-cigarettes protect adult smokers from smoking, they probably also protect adolescents. However, tobacco companies, adept at targeting young consumers, are entering the e-cigarette market, and there is reason to fear that if smokers switch massively to e-cigarettes the pool of nicotine users will eventually need to be refilled with new, young consumers. This is why the marketing and sale of e-cigarettes to young non-smokers should be controlled but teenage smokers should be allowed to switch to e-cigarettes.

In a society where nicotine is widely available, some young people will inevitably try nicotine, and it is preferable for them to use e-cigarettes rather than tobacco cigarettes. Prohibition of e-cigarette sales to minors would not only be difficult to enforce but force new nicotine users to use tobacco.

Paradoxically, the most vocal opponents to e-cigarettes are found among tobacco control activists. They dislike a product that resembles tobacco cigarettes or disapprove of a smoking cessation tool that, being used without their participation or approval, threatens their status. Also, many experts refer to wariness among the public health community after it was fooled by "light" cigarettes—when the

tobacco industry deceptively manipulated cigarettes to decrease the amounts of toxic compounds measured by smoking machines. It took many years to show that light cigarettes were in fact as dangerous as regular cigarettes.

However, e-cigarettes are not a marketing ploy, and their success is explained primarily by their intrinsic qualities. If e-cigarettes are allowed to reach their full potential and become as satisfactory as smoking, there will be little incentive for smokers to continue to smoke. Even if some former smokers remain addicted to the nicotine delivered by e-cigarettes, this is not a public health problem, because e-cigarettes have not been proved to be toxic. Thousands of former smokers are addicted to nicotine gum, ⁸ 9 and this is not a public health problem either.

If governments, parliaments, regulation agencies, and experts are able to restrain their yearning to restrict access to e-cigarettes, these products are likely to represent a revolution in public health.

Competing interests: JFE was reimbursed by a manufacturer of e-cigarettes and e-liquids for travelling to London and to China to visit e-cigarette factories but received no honorariums for these meetings. He has written a book about e-cigarettes.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: BMJ 2013;346:f3845

the first prospective study found that although smoking cessation and harm reduction motivated many e-cigarette users, there were no differences in smoking quit rates between e-cigarette users and non-users.² And importantly, cutting down cigarettes rather than quitting confers little if any health benefit,³ so dual use may be as bad as continued smoking in terms of health outcomes.

Regulation is required

So how should we respond to e-cigarettes? The first step must be to move beyond anecdotal testimony and naive optimism and study large populations to build the evidence about whether e-cigarettes do accelerate quitting and to quantify behaviours indicative of the important industry goals above.

Tobacco use may kill a billion people this century, ⁴ largely because of tobacco's historical treatment as an unexceptional item of commerce and, later, decades of glacial action by governments failing to regulate this dangerous consumer product. But in the past 50 years we have learnt much about how to reduce tobacco use. For example, only 16% of Australians aged 15 or over now smoke daily, ⁵ and youth smoking has never been lower. ⁶ We are finally pull-

ing access to tobacco products back to where it should have started: expensive, highly regulated, non-advertised, plain packaged, and out of retail sight.

We should make none of the many disastrous mistakes made with cigarettes in the name of allowing e-cigarettes to compete better with cigarettes. We should start by not assuming they are benign items of commerce. Drug companies have long been able to sell nicotine in small doses as a quitting aid but have never tried to register high dose products. Their awareness of the role of nicotine in apoptosis, angiogenesis, inflammation, and cell proliferation⁷⁻⁹ has always put the brakes on any temptation to have regulatory agencies allow them to sell products with doses that genuinely compete with cigarettes. So why should e-cigarettes, for which users can create their own e-juice, escape such regulation?

Many smokers want to access e-cigarettes to quit or reduce risk, and they should not be denied this opportunity. But the needs of often desperate smokers must not become the tail that wags the dog of tobacco control policy, putting at risk the massive gains we have achieved. The advent of e-cigarettes provides a perfect pretext to introduce a form of user

Urged on by myopic health professionals who seem to have lost any population health focus they might have had, e-cigarettes may become one of the biggest blunders of modern public health

licence for nicotine products in the same way that access to potent drugs has long required a temporary licence (a prescription) for those who need them. ¹⁰ This would balance the right to use e-cigarettes with all the constraints and disincentives that are now, and should be further, applied to cigarettes.

In countries where e-cigarettes are virtually "off the leash" this will probably be impossible. But for most nations that have acted cautiously e-cigarettes may in fact turn out to be a Trojan horse, stimulating regulators to take more seriously the regulation of all tobacco and nicotine products—not just pharmaceutical nicotine—regardless of the motive of the individual user or the stated and unstated motives of the manufacturer.

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: BMJ 2013;346:f3840