

E-cigarettes: too important to be regulated?

Written by The Conversation USA

New research published today in the [Medical Journal of Australia](#) shows that 9% of New South Wales smokers and recent quitters, and 16% of those aged 18–29, are currently using e-cigarettes. Most of these use them less than weekly, suggesting widespread curiosity use.

As has been repeatedly found overseas, the vast majority of people who vape are [also smoking](#).

They are not vaping instead of smoking but as well as smoking, despite 42% – as found in today's MJA study – saying they are vaping in order to quit.

In an accompanying [editorial](#) in the MJA written with two colleagues, we argue for a twin-track regulatory oversight of the devices in Australia:

The first involves the application of existing provisions for the authorisation, marketing (eg. claims regarding effectiveness as quitting aids) and sales of therapeutic goods. The second involves applying existing controls on all promotions that may encourage smoking, including exposure of children and young people to advertising and other forms of promotion and to any other use of smoking or tobacco-related imagery.

If Australia takes this route it will follow the United States and the European Union in regulating the devices. E-cigarette advocates have recently suffered two blows to their ambition to have governments continue to allow these devices to escape stringent regulation.

The Food and Drug Administration (FDA) is an agency within the United States Department of Health and Human Services. Its [remit is to protect](#) public health “by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices”.

The agency is also responsible for the safety and security of the nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and regulating tobacco products.

E-cigarettes: too important to be regulated?

Written by The Conversation USA

Since June 2009, the [FDA has regulated cigarettes](#), roll-your-own tobacco and smokeless tobacco. But from August this year, it will also have power to regulate e-cigarettes, dissolvable tobacco products, hookahs, pipe tobacco, cigars and all “novel and future tobacco products”.

With e-cigarettes, the FDA will require all devices already on the market to be subject to FDA oversight. This will see all ingredients, and claims and promotions for existing devices and e-juice supplies, having to be examined by the FDA. The e-cigarette industry is appealing.

Similarly, this month the [Court of Justice of the European Union](#) upheld the EU’s planned rules on e-cigarettes. The court stated:

The Court points out that the identified and potential risks linked to the use of electronic cigarettes have led the EU legislature to act in a manner consistent with the requirements stemming from the precautionary principle [...] the Court rejects the argument that the obligation on manufacturers and importers of electronic cigarettes and refill containers to submit each year, to the competent authorities of the Member States, certain data enabling those authorities to monitor the development of the market infringes the principles of proportionality and legal certainty. Similarly, by fixing the maximum nicotine yield which may be contained in the liquid of electronic cigarettes at 20 mg/ml, the legislature has not acted arbitrarily or manifestly exceeded the limits of what was appropriate and necessary in order to achieve the objective pursued by the directive.

We’re too important to be regulated

Both announcements have not been welcome news among vaping activists. E-cigarette advocates and manufacturers have sought to argue that due to the potential health benefits of the devices, they should be considered above nearly all such regulation.

A new “documentary” called [A Billion Lives](#) sets out the case for this exceptionalism. With a billion lives predicted to be lost to tobacco smoking this century, the promise is that all of these will be saved if all smokers switched to vaping.

But such an outcome is wildly speculative. A recent [US study](#) concluded:

E-cigarettes: too important to be regulated?

Written by The Conversation USA

since most current smokers who have tried ENDS [Electronic Nicotine Delivery Systems] reject them as a satisfying alternative to regular cigarettes, the potential of ENDS becoming a disruptive technology replacing regular cigarettes remains uncertain.

And Professor Robert West, a prominent expert in English smoking cessation and director of the ongoing [Smoking in England](#) survey told the [BBC](#) in February:

If they were this game changer, if they were going to...have this massive effect on everyone switching to e-cigarettes and stopping smoking we might have expected to see a bigger effect than we have seen so far which has actually been relatively small.

In the frantic zeal to sell the case for open slather light-touch regulation and make many small manufacturers very rich, some truly bizarre arguments are being advanced.

Not therapeutic devices?

First, they argue – in all seriousness – that e-cigarettes are not therapeutic devices and that claims are never made about how effective they are as smoking cessation aids. They therefore have no business being regulated as such. In reality, any discussion about e-cigarettes cuts, within a nanosecond, to often wildly hyperbolic claims about how amazing they are for quitting.

Those who argue this way insist that e-cigarettes must only be seen as harm reduction products: that they are far less dangerous than cigarettes and that cutting down the number of cigarettes smoked is self-evidently a good thing.

But Robert West [also said](#)

We know that most who use e-cigarettes are continuing to smoke and when you ask them they tell you they are mostly doing that to cut down the amount they smoke. But we also know they are smoking, it's not really that much different from what they would have done since they

E-cigarettes: too important to be regulated?

Written by The Conversation USA

started using e-cigarettes.

And in bad news for harm reduction, cutting down rather than quitting has been shown in prospective studies like [this one](#) to confer little if any risk reduction.

E-cigarettes have only been used extensively for less than a decade so the data on their [safety remains speculative](#), with worrying evidence being published about concerns including [oxidative stress](#) and [acute pulmonary function impairment](#). There is a massive campaign to rehabilitate nicotine as a benign drug with [molecular and other evidence](#) being blithely dismissed as irrelevant.

Anyone cautious is corrupt

There are also continuing efforts to paint anyone who ever questions the effectiveness or near-to-harmless health risks of vaping (“just like coffee”) as corrupt and mendacious.

A Billion Lives director Aaron Biebert told a New Zealand [radio audience](#) in April:

It’s interesting. You find that a lot of the doctors that are the most vocal in thinking that vaping is bad are people who are actually related to the cancer business. And if you think about that they have a complete conflict of interest with this because their business depends on people getting cancer and smoking is one of the ... in fact I think it is the main reason why people are getting cancer. And so I find that to be a kind of a problem.

It is difficult to imagine a more whacko conspiratorial argument than this. Biebert would have us believe here that every cancer control researcher, agency or charity; every cancer prevention campaign and every anti-smoking campaign is purposefully doing its best to not prevent or cure cancer because ... wait for this ... they want to keep their jobs.

E-cigarettes: too important to be regulated?

Written by The Conversation USA

By the same logic, those working in any form of prevention (obesity, road safety, domestic violence etc.) don't want those problems to reduce either and the police purposefully avoid solving crime.

If this was true, then here is a [list of 31](#) of America's most experienced and evidence-driven health and medical agencies who are conflicted by Biebert's conspiratorial understanding of self-interest.

And what to make of the decades of successful tobacco control in this country which has seen smoking, lung cancer and heart disease fall dramatically? Why have cancer and heart charities been at the front of these efforts?

But Biebert went further, taking his scythe to health charities:

There are all these associations and charities which are taking money from really big business and they're coming out against it [vaping] and they're very powerful voices. So we can't let big business run our lives and cause us to do the things which are killing people. We can't do it. We've got to fight together.

He didn't specify which "big business" he meant but one might assume he was talking about the pharmaceutical industry which sells smoking cessation products, and who would plausibly see e-cigarettes as eroding their business.

In Australia, the Cancer Councils, the Heart Foundation and the Australian Medical Association have taken hasten-slowly positions on e-cigarettes. Awkwardly for Biebert's argument, my enquiries found that none of these groups take funding from any of the three manufacturers selling smoking cessation aids in Australia.

Local e-cigarette advocates like [Colin Mendelsohn](#) want to see "no advertising [of e-cigarettes] to people under 18 years". This was of course an argument paraded by the tobacco industry for decades when they argued that their cigarette advertising was magically seen only by adult

E-cigarettes: too important to be regulated?

Written by The Conversation USA

smokers and some mysterious barrier known only to them prevented kids from ever noticing it.

The promise of e-cigarettes is that they will do to smoking what the digital camera did to the film camera and bring massive health benefits in the process. But we have seen two monumental harm reduction disasters with smoking in the last 50 years: the false promises of filter tips and the now-banned “lights and milds” labelling fiasco that convinced 80% of Australian smokers to switch and keep smoking.

Sensible regulation, as exists across different categories of pharmaceuticals, would allow Australia to keep a short leash on e-cigarettes at first. If our own and the international experience shows their promise being fulfilled, regulatory control could be loosened. But if serious concerns arise and this is monitored through regulatory oversight, the leash could be tightened.

Disclosure

Before retiring from employment with the University of Sydney the author contributed to an options paper on the regulation of Electronic Nicotine Delivery Systems commissioned by the Department of Health, Canberra. He wrote a first draft of a section on their use in smoking cessation.

Read more <http://theconversation.com/e-cigarettes-too-important-to-be-regulated-50579>