



HD E-Cigarettes: Should we inhale?

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Electronic cigarettes. Are they saving the lives of countless smokers across the world? Or are they simply big tobacco's latest con-job?

Damien Carrick: Hello, welcome to the Law Report, Damien Carrick here. Electronic cigarettes, are they saving the lives of countless smokers across the world? Or are they simply big tobacco's latest con job? Here in Australia it's illegal to sell e-cigarettes containing nicotine, and a recent case in WA confirms that in some states even those without nicotine fall foul of the law. E-cigarettes, should we inhale? Well, **millions** of Europeans and Americans say yes.

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[E-cigarette ads]

Taking back your freedom and avoiding all that carcinogenic smoke. Surely that's a good thing. Or is it? What exactly are e-cigarettes? Marilyn Krawitz is a lecturer at the University of Notre Dame in Fremantle, and she is also a solicitor with Perth **firm** CMS Legal.

Marilyn Krawitz: E-cigarettes are devices that are made up of a tube and a battery and a cartridge. What happens is a person who uses the e-cigarette, they will press a button and then the solution in the cartridge will be heated, it will then become a vapour and the person who is using the electronic cigarette will then inhale the vapour. There are many different kinds of solutions that can be vaporised in the e-cigarette. One can put in a solution which has nicotine, but they can also put in a strawberry flavour, a mint flavour, a chocolate flavour, all sorts of kinds of alcoholic flavours as well.

Damien Carrick: And do they all look like cigarettes?

Marilyn Krawitz: Well, some of them do, but other ones look like USBs. They can look like lipsticks.

Damien Carrick: I believe that some of the ones which are meant to look like cigarettes even have a small LED light at the end which lights up so you could get a real sense of a fire at the end of the stick.

Marilyn Krawitz: That's true, and it's interesting that you say the word 'fire' in that e-cigarettes actually don't emit any smoke, they emit vapour.

Damien Carrick: How common are they? They are now a huge business, aren't they.

Marilyn Krawitz: They are a huge business and they are growing all the time. The first e-cigarette was created in 2003 by a **Chinese** pharmacist, and since then they are being used all over the world. There are at the moment thousands of Australians who use e-cigarettes, as well in the UK there is about 700,000 people who use e-cigarettes, and the industry is expected to be about a \$23 **billion** industry by about 2023.

Damien Carrick: Marilyn Krawitz, different countries around the world regulate these products very differently. What's the situation here in Australia?

Marilyn Krawitz: From a federal perspective, nicotine is listed in schedule 7 of the poison standards, and so what that means is that you can't sell nicotine unless it's for therapeutic use or it's in a device that's similar to traditional cigarettes, so like a cigar or a traditional cigarette. In terms of using e-cigarettes as a therapeutic device, the Australian Therapeutic Goods Administration has not registered it on the therapeutic goods register. So what this means is that e-cigarettes with nicotine cannot be sold.

From a perspective of customs, a lot of Aussies are importing e-cigarettes with nicotine from other countries. If you look on the customs website that mentions e-cigarettes, it says that the importation of e-cigarettes is not prohibited, and actually Australians can import about a three-month supply of e-cigarettes with nicotine. So we have a situation where federally you can't sell e-cigarettes with nicotine, but Australians can legally import a three-month supply, provided the supply doesn't state that it has therapeutic benefits.

From a state perspective, all the states and the ACT in their legislation, they do not permit the sale of e-cigarettes with nicotine. However, in the states of Western Australia, Queensland and South Australia, the sale of e-cigarettes without nicotine also appears to be prohibited.

Damien Carrick: Marilyn Krawitz from Notre Dame University, who is researching and writing about e-cigarettes.

In an Australian first, Perth businessman Vince Van Heerden was recently the subject of a prosecution under the WA state laws.

Vince Van Heerden: We were selling a small range of electronic cigarettes or personal vaporisers. Specifically there were only two models that we were selling, the 510-T and the eGo-T, two of the more common models available in the global marketplace at the time.

Damien Carrick: The ones you were selling, did they contain nicotine?

Vince Van Heerden: No. We did sell the liquids for them, the nicotine-free liquids.

Damien Carrick: I believe back in November 2011 officials from the WA Department of Health came knocking, they found on your premises a number of these e-cigarettes and a number of this e-juice, non-nicotine e-juice. You were charged with offences relating to the breach of the WA Product Control Act. What offences were you charged with?

Vince Van Heerden: They alleged that I breached section 106a of the Tobacco Products Control Act, 2006. The legislation was written to say that it is illegal to sell product that is not a tobacco product but is designed to resemble a tobacco product, and the legislation uses the words specifically 'food, toy or other' to define product, it was always our interpretation and I think the industry at large's interpretation that the words 'food' and 'toy' were the operative words, and the word 'other' was to expand upon the definition of 'food' and 'toy'. And the device that we sold didn't bear any resemblance to cigarettes.

Damien Carrick: As I understand it the device physically resembles at least, physically resembles a fountain pen. Is that right?

Vince Van Heerden: Most people will say, yes, a ballpoint pen or a fountain pen, or maybe a laser pointer.

Damien Carrick: Michael Perrella, Vince Van Heerden's lawyer, I might bring you in at this point. So your client was charged with offences under this WA Tobacco Products Control Act. The case was originally heard by a magistrate I think sitting in the Joondalup Magistrates Court in Perth. What did she find?

Michael Perrella: She found that the products that Mr Van Heerden was selling were not designed to resemble a tobacco product. The argument was run that by looking not just at the physical resemblance for the product but the intention behind it was not designed to resemble a cigarette or a cigar.

Damien Carrick: And the magistrate agreed and she actually threw the case out at that point, didn't she.

Michael Perrella: That's correct.

Damien Carrick: It went on appeal, the WA Department of Health appealed her decision and the matter was then heard by the WA Supreme Court who I think just recently handed down a decision going the other way. Justice Prichard actually found against your client. She said essentially the items were designed to resemble a tobacco product because they were used to inhale vapour in a way very similar to inhaling smoke from a cigarette. So rather than just concentrating on physical appearance she took a much broader view. Is that what happened?

Michael Perrella: Yes, that's right. Justice Prichard essentially arrived upon the argument from the appellant that the hand to mouth action combined with inhaling and exhaling a vapour that resembles tobacco smoke was sufficient essentially to be categorised as designed to resemble a tobacco product, namely a cigarette or a cigar.

Damien Carrick: So you look at how the product is used and broader similarities rather than just concentrate on physical resemblance.

Michael Perrella: That's right, yes.

Damien Carrick: Vince Van Heerden, have you actually been sentenced yet as a result of that Supreme Court ruling?

Vince Van Heerden: No, not as of yet. Sentencing was deferred until 24 June.

Damien Carrick: What could be the penalty?

Vince Van Heerden: I believe the maximum penalty for a first offence is \$10,000.

Damien Carrick: Are you considering an appeal?

Vince Van Heerden: Yes, absolutely. To me this is a situation where **millions** of people stand to get sick or die if I don't appeal it. As I'm the test case and I'm the one who has been found guilty, I'm the only one in a legal position to actually appeal this, and if I don't, as I say, people are going to die, and I can't have that on my conscience to not even try. So I've been doing everything I can to raise the funds required to mount an appeal, because the required funds are really considerable, and at this point I've spent so much money on the existing legal costs that I've got nothing left.

Damien Carrick: So you're saying this isn't just about your right to sell products and make a buck, you say that there is a health imperative here.

Vince Van Heerden: Absolutely, this is a situation where you've got a product where there are now dozens and dozens of studies, peer reviewed studies from all around the world that have shown there is a clear positive outcome as a result of using these devices. And if you simply go with the precautionary health principle and say 'until we know definitively that no possible harm can come from these, we are going to ban them', then you're endorsing people to continue to smoke.

There are so many people who have been trying for years to quit smoking, they've gone through every single legal nicotine cessation device available on the market, they've tried hypnotherapy, they've had antidepressants, they've done all sorts of things, but nothing has worked for them. They've resigned themselves to the fact that they are going to die and then they've discovered these personal vaporising devices and it has changed their lives, their health has improved incredibly and now they have this new lease on life.

There was a letter written recently to the World Health Organisation signed by I think it was 53 experts from all around the world, these are professors, doctors, that have said putting up any barrier to this technology would be catastrophic to the World Health Organisation's stated desire to reduce the number of tobacco related deaths. There's over a **million** tobacco related deaths every year, and this could be dramatically reduced if these products were allowed to be sold and people had the right to buy a more healthy, less harmful alternative.

Damien Carrick: Michael Perrella, is this case one out of the box? Is it the first of its kind, as far as you know?

Michael Perrella: As far as I know it is. And the way that the case was conducted in the Magistrates Court at first instance was on the basis that this is a test case.

Damien Carrick: And Vince Van Heerden, tell me, were you a smoker?

Vince Van Heerden: Yes.

Damien Carrick: And are you still a smoker?

Vince Van Heerden: No. The moment I got an electronic cigarette, the first time I got it, bam, that was it, never had a cigarette again.

Damien Carrick: Vince Van Heerden, and his lawyer Michael Perrella from Perth law **firm** Perrella Legal. Vince is now crowdsourcing the funds for his appeal. He wants all Australians to have legal access to e-cigarettes, with or without nicotine, and to allow advertising, as they have in the USA.

[E-cigarette ads]

Legalising and promoting e-cigarettes would be a huge mistake says Michael Daube who is the president of the Australian Council on Smoking and Health and also a professor of health policy at Curtin University. He describes e-cigarettes as 'a weapon of mass distraction', and he welcomes the recent WA Supreme Court ruling.

Michael Daube: So far as I can see, that was a sound legal decision. Here we have a small-time entrepreneur, clearly would have known he was selling a borderline dodgy product, he has been convicted of a criminal offence, and now he's going around making all kinds of wild statements and trying to present himself as a crusader for the public health. That's just baloney. And what we need to recognise is that there is a raft of legislation around tobacco and related products; the Therapeutic Goods Administration legislation federally, legislation on nicotine as a poison, legislation on cigarette lookalike products, and that's all for good reason. Cigarettes are the major preventable cause of death and disease in the community. Nicotine is not a harmless product, it has all kinds of potentials for harm, that's why it's used if you want to spray bugs off your roses, that's why you may be using a nicotine spray.

Damien Carrick: I understand though that amongst the scientific community there are differences of opinion about how best to deal with the e-cigarettes. I believe that something like 53 top scientists recently wrote to WHO urging them not to classify e-cigarettes in the same category as other tobacco products. What do we know about that letter and what's your view of it?

Michael Daube: Look, of course there are different opinions, as there should be, it's great in the scientific community that there is open debate. There are some people, some decent scientists whom I respect who have a strong view that is different from mine around e-cigarettes. Anybody can put together a letter with quite a lot of names on it. You know, 53 out of global scientists in my view isn't a whole heap, but they are entitled to write a letter and I see that one of the prominent e-cigarette bloggers is claiming credit for having helped to put that together. So I'm not sure what that letter was intended to achieve other than some publicity, but it certainly got some publicity.

As far as we are concerned here in Australia, let's put this in perspective. First, they are not electronic and they are not cigarettes, so e-cigarette is a misnomer. Second, they are in a long, long tradition of all kinds of different products and approaches that have been promoted as being miracle cures for smoking, and some of them heavily promoted by the tobacco industry—just think to the low tar fraud and filters and things like that—and they have all gone into the background one after the other because they weren't miracle cures.

We don't know, we have very little information about the short or the longer term harms. There is no quality control. The evidence on e-cigarettes as cessation aids is still in its very early times, and there is conflicting evidence, and in my view and that of other experts, there is not compelling evidence that they are significantly better than other quitting aids, but there is compelling evidence that quitting cold turkey is way the best way to quit.

There are major concerns about the way that e-cigarettes are being promoted elsewhere, in the UK and the US, normalising promotion, kids starting to take up e-cigarettes. And in Australia we are actually not doing badly at reducing smoking, the trends are going away in adults, they're going away in kids. We don't need this distraction, we need to get on with doing what we know is necessary to reduce smoking in the community, and particularly in some of those vulnerable groups, like people with mental health problems. 40% of our smokers are people with mental health problems. There may be scope to consider e-cigarettes, but let's take a stock standard public health approach to them.

Let me just add one other observation too. If any manufacturer producer wants to sell e-cigarettes as a cessation aid, all they need to do is take the product to the Therapeutic Goods Administration with good evidence, and then see if they can get it approved. Whether it's a small businessman, this fellow Van Heerden in Perth, or whether it's the big tobacco companies that are buying into e-cigarettes big time, they haven't yet got approval from the Therapeutic Goods Administration. That's the way to go.

Coral Gartner: I think there are a lot of drawbacks to our current approach. Currently the laws are very difficult to understand, to start with, and there are state to state differences. Many of the provisions also seem open to differences in interpretation, such as we saw with the case in WA.

Damien Carrick: Coral Gartner is a senior research fellow at the University of Queensland Centre for Clinical Research. She studies e-smokers. Unlike Professor Mike Daube, she doesn't think Australia's existing mechanisms are optimal.

Coral Gartner: These laws are actually quite Draconian because they criminalise Australians who are using e-cigarettes as a harm reduction approach. So some people argue that if they are used for quitting smoking that they should be regulated the same as all cessation aids. And there is some merit to this argument. In some ways it's unfair that pharmaceutical companies need to invest heavily in their nicotine products to get them through the regulatory hurdles before selling them in Australia. However practically this is simply a form of prohibition because there is no approved e-cigarette listed on the Australian register of therapeutic goods that is available to Australians.

Damien Carrick: But the process is open to those people who produce those products. They could put them forward to the TGA process.

Coral Gartner: Sure, but it's a very expensive and time consuming process to get your products through medicines regulation. Not all of the companies that are producing these products would have the resources to do that. Some people have also suggested that it actually favours tobacco companies who are buying up the e-cigarette companies, and so they have the resources to do this. So it may also be a way for them to corner the market. That is one argument that is made.

Also many users don't see e-cigarettes as a medicine, but they see them as an alternative, less harmful product to combustible cigarettes, this is likely part of their appeal for some smokers. So the fact that many Australians are using them despite current law suggests that there is a demand for this type of product that hasn't necessarily gone through full medicines regulation. So I think it's better if we have people using them, like we do now, to try and strike a regulatory balance that tries to achieve protection for the public health while still respecting smokers' autonomy to make decisions about these types of products.

Damien Carrick: What might that balance look like, in your view?

Coral Gartner: One particular option that I'm interested in is a nicotine licensing option. So this would be maybe delivered by government health departments, state health departments, where people could apply for a licence as a nicotine user, and if they could demonstrate that they had sufficient knowledge of safe handling practices, that they were going to be a responsible person, so you might limit...have other exclusion criteria to limit who could use it, age restrictions and so on. These people could apply to be able to **purchase** in a restricted way from licence sellers.

And this would be quite a cautious approach because we could still very strictly control things like how it was marketed, who it was sold to, monitor who was buying the nicotine, and even put restrictions on how much they could **purchase**. And we could also monitor what effect it had on smoking prevalence and so on. It would also allow us to kind of roll it back. If it was found not to be in the public interest, it would be much easier to **wind** that down. So I think a trial of something like that would be very useful to be able to explore whether these products are useful as a harm reduction option for smokers.

Damien Carrick: Coral Gartner, senior research fellow at the University of Queensland.

What do you think about regulating and monitoring e-cigarette use? You can leave a comment on the Law Report website at abc.net.au/rn. Damien Carrick with you.

Lawyer Marilyn Krawitz also takes the view that it may be better to regulate rather than ban e-cigarettes. Over the weekend Fairfax newspapers reported that the Victorian Poisons Information Centre had nine calls last year relating to the swallowing of nicotine in e-cigarettes, five of those calls involved kids under five.

Given these sorts of concerns, some suggest it's better for local regulators to enforce Australian product safety standards, like those around packaging, even if the product falls short of the TGA standard. Legal academic Marilyn Krawitz:

Marilyn Krawitz: Subject to being satisfied in respect to their safety and their impacts upon Australians' health then certainly I do think that the better way would just be to regulate them and ensure that they are safely made in Australia. If they are not as bad for people then they are not going to have the same sort of devastating impacts that using traditional smoking can have, then there should be some thought to allowing them to be sold because there are several products that are legally sold to Australians and Australians are allowed to use them responsibly, such as alcohol for example. So maybe the same sort of attitude should be applied to electronic cigarettes.

Damien Carrick: Marilyn Krawitz from Notre Dame University law school.

Mike Daube maintains that it would be extremely dangerous to bypass Australia's Therapeutic Goods Administration process.

While debates in this country centre around identifying the best form of regulation, in some countries there is virtually none at all.

[E-cigarette ad]

In the USA where annual sales top \$2 **billion**, there are few restrictions on the **sale** or promotion of e-cigarettes. Stan Glantz is a professor of medicine at the University of California, San Francisco. He is also director of its Centre for Tobacco Control, Research and Education. He says it's the new Wild West.

Stan Glantz: There have been several studies of the e-cigarette ads here in the United States, and they basically look like cigarette ads from the heyday of cigarette advertising in the '50s and '60s. They are making health claims, they're using sex, they're promoting freedom. It's just like going back to the 1960s before cigarette advertising was prohibited on television here. With the addition of high-tech kid friendly things like flavours, which greatly increase the appeal of e-cigarettes to kids.

Damien Carrick: Now, the big argument in favour of e-cigarettes is that, well, some of them don't contain nicotine, but those that do contain nicotine, they are much less harmful to users than traditional cigarettes because while they contain nicotine, which is bad, absolutely bad, they don't contain the carcinogens in the smoke.

Stan Glantz: It's true that a puff on an e-cigarette exposes you to less toxic chemicals than a puff on a cigarette, and the reason for that is a cigarette generates an aerosol of ultrafine particles that carry some nicotine into your lungs by burning the tobacco. So in addition to getting the ultrafine particles and the nicotine, you get a lot of combustion products, which include a lot of cancer-causing chemicals, industrial solvents and other irritants and other bad things. So you don't have nearly the exposure to the carcinogens and industrial solvents, but you are getting a big blast of nicotine, and nicotine itself is toxic. And also you're getting a blast of ultrafine particles, and those ultrafine particles have adverse health effects; they trigger inflammatory processes, and they've been related to triggering heart attacks and lung disease. And in fact the one short term health effect that has already been measured of e-cigarettes is pulmonary irritation and reductions in the ability of the lungs to move air in and out.

Damien Carrick: We don't live in a perfect world. What do you say to the argument that, okay, there are problems with nicotine, and you're telling me there are also problems with these very fine particles, but they do pale into insignificance or at least are dramatically, substantially less than the problems associated with cigarette smoking in traditional cigarettes. Given that huge discrepancy, shouldn't we be less hostile towards e-cigarettes?

Stan Glantz: They are going to be less dangerous, but I think the question of how much the difference is is still very much up in the air. But the real adverse health effects that e-cigarette have don't have anything to do with the relative toxicity of a puff on an e-cigarette compared to a puff on a cigarette. There is now five studies looking at the effect of e-cigarette use amongst smokers in the population, and all of them show that smokers who use e-cigarettes are about a third less likely to quit smoking than smokers who don't use e-cigarettes. If you are even smoking a few cigarettes a day, you're getting essentially the whole cardiovascular risk. And there is also a growing case that for cancer, how long you smoke is as important as how much you smoke. And so if e-cigarettes net effect is to keep most people smoking regular cigarettes, then the real negative health effects of e-cigarette are going to be the ill effects of cigarettes.


If someone switched from cigarettes to e-cigarettes entirely, then probably they would be better off. And there's no doubt a group of people who have successfully used e-cigarettes to stop smoking, but what the population level data shows is that for everybody like that there's more than one other person where the existence of e-cigarettes actually kept them smoking regular cigarettes.

Damien Carrick: Finally, what you think about the Australian approach which is to throw up lots of impediments at both the federal and the state level, and when it comes to e-cigarettes containing nicotine, all you can do is import them online for private use.

Stan Glantz: I think Australia is doing exactly the right thing in prohibiting the widespread commercial introduction of e-cigarettes into Australia. There are several countries, like the United States where we have essentially an unregulated environment, England where most of the health authorities have embraced e-cigarettes as a cessation device and are actively promoting their use. Then you have the evidence that is emerging that these e-cigarettes are, while again, a puff on an e-cigarette is less toxic than a puff on a cigarette, if the net effect is to keep people smoking cigarettes, there's going to be a net population negative effect.

And I think what I'm telling Australia and other countries that do not yet permit e-cigarettes is to just keep not permitting them to come in for a few years, let things play out in places like the United States and England, and within a few years we'll have a very clear view of whether or not the concerns that people like me have, namely that e-cigarettes are going to make the tobacco epidemic worse, whether we are right or whether the optimists who think it's the new technology that's going to wipe out conventional cigarettes are right. And then after Australia sees what happens, then you can take appropriate regulatory action.

Damien Carrick: Stan Glantz, professor of medicine at the University of California, San Francisco, and director of its Centre for Tobacco Control, Research and Education.

That's the Law Report for this week. A big thanks to producer Anita Barraud, and to technical producer this week John Jacobs. Do visit us online at abc.net.au/rn. I'm  Damien Carrick, talk to you next week with more law.

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IPD e-cigarettes

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