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Submission in response to the:

Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

"We need to redouble efforts to help more smokers become tobacco-free. And, we need to have the science base to explore the potential to move current smokers – unable or unwilling to quit – to less harmful products, if they can't quit altogether. At all times, we must protect kids from the dangers of tobacco use."
-- Scott Gottlieb, M.D | 23rd Commissioner of United States FDA - May 15, 2017.

Response prepared by:

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Terms of reference

The Standing Committee on Health, Aged Care and Sport will inquire into and report on the use and marketing of electronic cigarettes (E-cigarettes) and personal vaporisers in Australia, in particular:

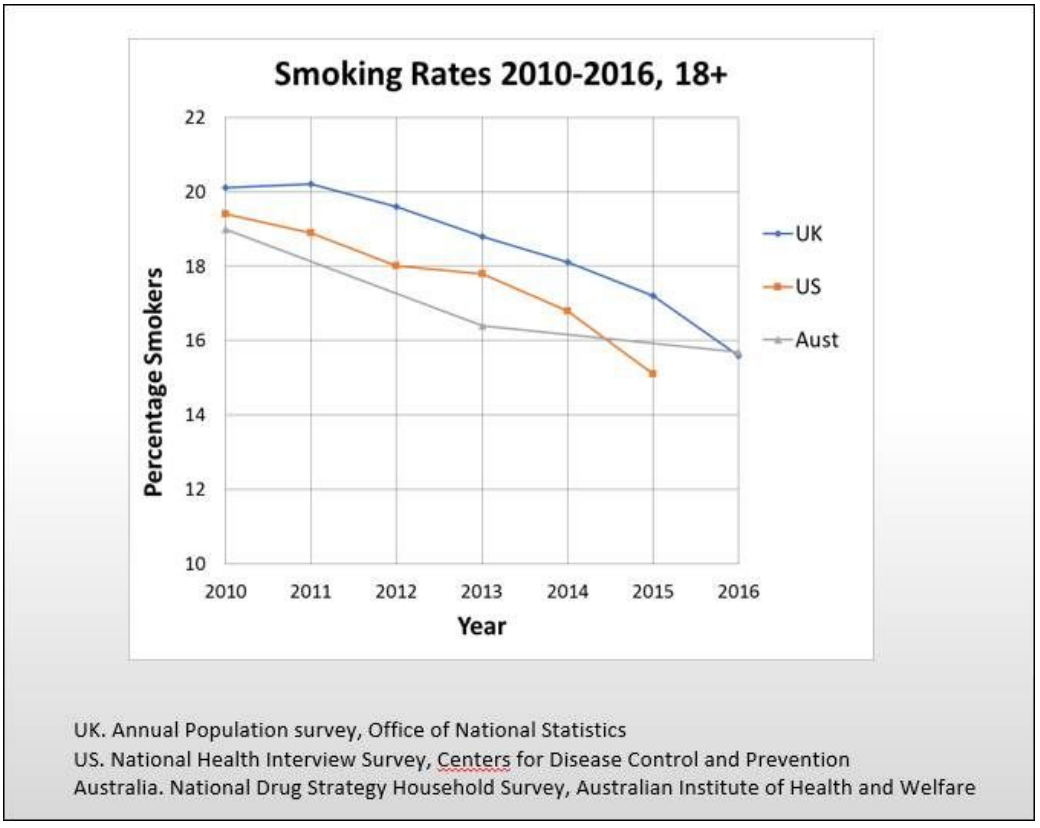
1. The use and marketing of E-cigarettes and personal vaporisers to assist people to quit smoking;

(i) The extent to which E-cigarettes and personal vaporisers assist smokers to quit is clearly important. But complete abstinence from smoking tobacco and nicotine should be regarded as a bonus with reduction of harm in the vast majority of smokers unable or unwilling to abstain from nicotine completely regarded as the major aim of policy (see response to Terms of Reference point 2);

(ii) There is impressive ecological evidence that E-cigarettes and other forms of tobacco harm reduction accelerate the decline in smoking rates;

(iii) Smoking rates have been declining faster since 2010 in the UK and USA (see following point for comparative data) where the policy and regulatory environment is far more accepting of E-cigarettes than in Australia where the regulatory environment is quite hostile. All nine Australian health departments, NHMRC, TGA, RACP, AMA, Cancer Council, National Heart Foundation and the Public Health Association of Australia oppose tobacco harm reduction. However, we should remember that the doyen of Australian tobacco control, Dr Nigel Gray, was cosignatory to a letter advocating in favour of Electronic cigarettes and tobacco harm reduction sent to Dr Margaret Chan, Director General WHO[20].

(iv) Comparative smoking rate with countries where Electronic cigarettes have been more widely embraced:

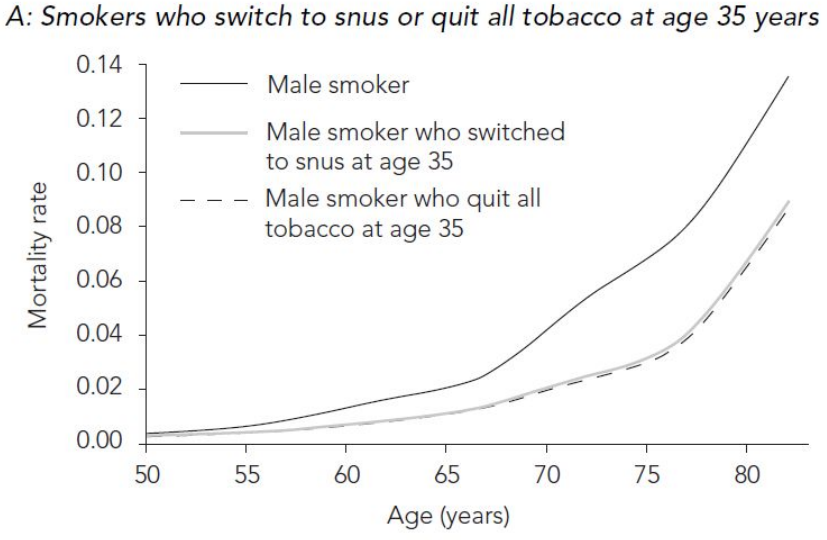


Graph prepared by Associate Professor Colin Mendelsohn

(v) Tobacco control efforts in Australia have focused primarily on a number of policies including steep cigarette price increases, plain packaging, advertising bans and subsidised treatments for people who are tobacco dependent. However, according to the AIHW for the first time in over two decades, "the daily smoking rate did not significantly decline" in persons aged 14 years and over from 12.8% in 2013 to 12.2% in 2016[1];

(vi) In Sweden the consumption of a smokeless tobacco product called 'snus' has largely replaced the most dangerous method of consuming nicotine - smoking cigarettes. It is estimated that at least half and probably up to two thirds of smokers will die from a tobacco related disease. The number of people in the world currently smoking is estimated at 1 billion with 1 billion estimated to die from a tobacco related cause in the next 100 years. Snus remains banned across all other European Union member states however in 2016 total smoking (i.e. daily plus non daily) fell to 7% prevalence while daily smoking fell to 5% prevalence [18]. Sweden has had the lowest smoking rates in the EU for many years. Sweden also has the lowest rate of tobacco related deaths and disease in the EU probably in part because of widespread adoption of less harmful smokeless tobacco products. The situation was well summarised by Professor Simon Chapman in the Medical Journal of Australia: "The emergence of low nitrosamine smokeless tobacco (LNST) products such as Swedish snus, which pose far less risk than smoking, and the emerging, compelling epidemiological evidence of an association between LNST use in Swedish men and their low rates of tobacco-related disease has led to widespread debate on whether this form of tobacco should be made more accessible."[19] Snus has been used in Sweden, mainly by men, for more than 200 years. The sale of snus is banned in other EU countries. Researchers have compared deaths and disease in Swedish men vs women and Swedish men vs EU men. It has been well studied. The benefits are clear while the adverse effects are minor. Snus is a very powerful argument for taking tobacco harm reduction seriously;

(vii) Mortality rates in smokers who continue smoking, switch to 'snus', or quit all tobacco[2]:



(viii) It is difficult to study the effectiveness of e-cigarettes by the usual clinical research methods for a number of reasons. First, in the 14 years since their commercial availability, E-cigarettes have rapidly evolved making studies completed even recently likely to be out of date by the time of publication. Second, E-cigarettes are primarily a customisable consumer product designed to consume nicotine without the need for tobacco. They have not been developed as a standardised medical device designed to treat tobacco dependence. Third, the phenomenon of E-cigarettes and a constellation of technological developments such as the widespread availability of

rechargeable batteries, online shopping, advice provided by enthusiasts in vaping shops and use of internet forums and online video to review and share product information appears to be forcing the tobacco industry to respond in an area where they have traditionally faced no competition. One of the largest tobacco companies in the world, PMI, with a market capitalisation of USD$181.842 billion has recently invested $US 3 billion in reduced risk product research. The PMI website in January 2017 declared a commitment to a 'smoke free future'[3]. PMI claims that margins on reduced risk products will be greater than their margins on cigarettes. The share price for PMI has increased from USD$92 in January 2017 to USD$122 in June 2017. While E-cigarette opponents express skepticism of tobacco harm reduction, institutional and other investors obviously have a different view. In contrast to conventional tobacco control, which is funded by taxpayers, tobacco harm reduction is paid for by smokers themselves. Smokers switching to E-cigarettes save thousands of dollars a year. This is particularly important as economically disadvantaged people are over-represented among smokers.;

In summary: hostility to Electronic cigarettes and tobacco harm reduction in Australia may have slowed the decline in smoking rates now seen in countries which make it easy for smokers to switch from cigarettes to vaping or other reduced risk products such as low nitrosamine Swedish 'snus'. Australia should adopt a policy which reflects the following reality 1) Conventional tobacco control has succeeded over recent decades in considerably reducing smoking rates In Australia and a number of other countries 2) Smoking prevalence is now dropping faster in E-cigarette friendly countries (such as the USA and UK) than Australia and has fallen much further in Sweden where snus is very popular among men. Faced with this reality, the Government should be prepared to embrace the idea of continuing to promote complete smoking cessation whilst simultaneously promoting tobacco harm reduction - and E-cigarettes - for people who continue to smoke despite intensification of tobacco control because they are unwilling or unable to quit smoking.

2. The health impacts of the use of E-cigarettes and personal vaporisers;

(i) It is widely accepted that the most dangerous method for self administering nicotine is when it is inhaled within tobacco smoke - the combustion of tobacco creates a matrix of thousands of chemicals which are toxic to living tissue.

(ii) In 1976 the late Dr Michael Russell, a pioneer in tobacco control and public health, explained that: 'People smoke for nicotine but they die from the tar'[4];

(iii) The UK Royal College of Physicians[5] and Public Health England[6] have both estimated, after reviewing the evidence, that E-cigarettes are at least 95% less harmful than cigarettes. Emeritus Professor Simon Chapman and his US colleague Professor Stan Glantz, both outspoken E-cigarette skeptics, accept that E-cigarettes are less harmful than smoking tobacco[7][8];

(iv) Numerous studies have shown far lower concentrations of toxicants in E-cigarette vapor than cigarette smoke[5][15-17];

(v) Many studies have shown partial improvement in physiological measures (such as improvement in blood pressure[9], asthma outcomes[10], weight gain[11] , lung function[12][14] and COPD exacerbations[13]) when smokers have switched to 'vaping' Electronic Cigarettes. It is hard to understand the extremely hostile attacks on E-cigarettes and their advocates until the history of other harm reduction interventions is returned into focus. Mandatory car seat belts, the distribution of condoms to reduce teenage pregnancy and Sexually Transmitted Infections, needle syringe programs to reduce the spread of HIV among and from people who inject drugs, and methadone for treating heroin dependence are some of the other harm reduction interventions

which were met with skepticism and hostility at the time of their introduction and for many years later. E-cigarettes (and snus) are examples of harm reduction;

(vi) 'Harm reduction' has been part of Australia's National Drug Strategy since 1985. It is also included in Australia's National Tobacco Strategy (2012-2018) and in the WHO Framework Convention on Tobacco Control (2003) which Australia is a signatory to;

In summary: While there may be some debate about the precise quantification of risk reduction provided by E-cigarettes, there can be little doubt that E-cigarettes are much less harmful than smoking cigarettes and other tobacco products already on the market in Australia. Based on current evidence people who are able to switch from smoking tobacco to the exclusive use of E-cigarettes are likely to enjoy benefits ranging from small improvements to their quality of life to/and hopefully major benefits such as reduced risk from smoking related diseases and increased life expectancy. A fundamental difference in attitudes to E-cigarettes is that opponents emphasise risks and virtually ignore benefits while supporters compare potential benefits and potential risks: supporters argue that it is certain that one half to two thirds of smokers will die from a tobacco related cause while it is highly probable that the risks of e-cigarettes are substantially less than the risks of combustible cigarettes;

3. International approaches to legislating and regulating the use of E-cigarettes and personal vaporisers;

(i) The UK and the USA have provided a positive policy and regulatory environment for some years;

(ii) On 29 March 2017 the New Zealand Government announced that they would legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products;

(iii) Canada is in the process of regulating E-cigarettes as a separate class of products rather than a tobacco product;

(iv) On August 8, 2016 the Obama Administration introduced, but has not yet enforced compliance with, 'deeming' provisions which expanded FDA authority over vaporizers and electronic cigarettes. Compliance with these new provisions has been labelled "burdensome and opaque, and far more onerous than for cigarettes" (refer to Appendix A). However, under the leadership of new FDA Director Dr Scott Gottlieb enforcement of compliance for Electronic cigarettes has been deferred for 3 months as it reviews numerous lawsuits challenging the new 'deeming' rules. This may indicate that a more positive regulatory environment for Electronic cigarettes will prevail in the USA.

(v) The World Health Organisation [WHO] considers Electronic Cigarettes an: "evolving frontier filled with promise and threat for tobacco control". It should be noted that the WHO was opposed to harm reduction and needle syringe programs for many years

In summary: Australia's failure to embrace tobacco harm reduction is now out of step with the policy direction of 4 countries we usually compare ourselves with as well as inconsistent with our National Drug Strategy, our National Tobacco Strategy and the WHO Framework Convention on Tobacco Control which Australia has signed.

4. The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia;

(i) E-cigarettes cannot presently be marketed to help people quit smoking or as an alternative to smoking even though they are less harmful than smoking tobacco. ***Australia should review this restriction on marketing.*** It is likely to reduce the uptake of E-cigarettes and lead to a perverse situation where adults and children are more likely to smoke or experiment with tobacco. A perverse effect of current Australian policy hostile to E-cigarettes is to protect the tobacco industry.

(ii) The current regulatory environment (inappropriately) treats E-cigarettes like tobacco products and even more harshly in some cases. This may mislead smokers into thinking there are few benefits from switching from smoking tobacco to the exclusive use of an E-cigarette when, in-fact, the opposite is true.

(iii) Widespread adoption of E-cigarettes will only occur if the reduced harmfulness of E-cigarettes can be clearly communicated to people currently dependent on nicotine from smoking tobacco. ***Anti-smoking policy should be strengthened to nudge people towards choosing E-cigarettes instead of continuing to smoke tobacco.***

(iv) The inappropriate scheduling of nicotine (as a controlled poison) stands in the way of more widespread use of E-cigarettes. ***Nicotine should be exempt from the Poisons Standard (the SUSMP) in concentrations packaged for use in an Electronic cigarette.*** This exemption would ensure that Electronic cigarettes users are never put in the position where they become the target of law enforcement or have their nicotine confiscated by authorities as they may return to smoking tobacco. Furthermore, electronic cigarettes that do not contain nicotine are unlikely to help people completely abstain from smoking tobacco. E-cigarettes should be regarded as a consumer device and regulated accordingly rather than as a therapeutic intervention regulated by the Therapeutic Goods Administration.

(v) The Electronic cigarette user and tobacco smoker are treated differently under the law. Commonwealth and state laws currently treat the possession and use of nicotine in Electronic cigarettes by adults as a punishable offence subjecting it to prohibition, not mere regulation. Far from posing as much risk to genuine state interests as those who smoke tobacco, adult 'vapers' pose less risk and yet they are treated more harshly under the law. The law's imbalance in this respect—its disproportionality— should be noted by the Committee with a view to correcting it.

(vi) ***E-cigarettes should be regulated primarily as a consumer good, not a therapeutic good.*** However, there is nothing preventing companies submitting products for regulation as a therapeutic good.

(vii) ***The regulations that have been applied to smoking tobacco should not automatically be carried across and applied to Electronic cigarettes.*** For example, forcing Electronic cigarette users to stand outside buildings alongside people who smoke tobacco exposes them to dangerous tobacco smoke and may increase their risk of relapse.

In summary: Regulation should be proportionate to the relative risk of tobacco free technologies like Electronic cigarettes. It should not preserve the status quo where the most dangerous nicotine product (cigarettes) are easier to obtain than less dangerous products such as Electronic cigarettes. Communication about tobacco free technology should be truthful, plain-speaking, and focused on helping consumers make informed choices about relative risks of competing products. Any Electronic cigarette that is marketed without making therapeutic claims ought to be regulated as a consumer good.

5. Any other related matter.

Refer to Appendix B

Appendix A

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IOWA DEPARTMENT OF JUSTICE
OFFICE OF THE ATTORNEY GENERAL

June 14, 2017

Dr. Scott Gottlieb, MD
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20857

Re: Reform of tobacco and nicotine regulation at FDA

Dear Dr. Gottlieb:

May we offer our sincere congratulations on your confirmation.

As specialists in the field of tobacco and nicotine science and policy, we were pleased to see your commitment to tobacco control reflected in your opening remarks to FDA staff: *"there's probably no single intervention, or product we're likely to create in the near future that can have as profound an impact on reducing illness and death from disease as our ability to increase the rate of decline in smoking."* We fully agree.

We also warmly welcome your openness to the concept of tobacco harm reduction: "*we need to have the science base to explore the potential to move current smokers – unable or unwilling to quit – to less harmful products, if they can't quit altogether.*"

There is already a considerable body of science and experience suggesting that a harm reduction approach, working together with the established evidence-based prevention and cessation tools of tobacco control, could yield substantial and highly cost-effective public health benefits. However, this will only be achieved if the right regulatory framework for less harmful products is adopted. We support FDA jurisdiction for these products, but at this time we do not believe that the current regulatory framework for the low-risk nicotine products such as e-cigarettes and smokeless tobacco is appropriate or will deliver the substantial public health benefits we hope and expect FDA's oversight will bring.

We hope that you and your colleagues will use the recently-announced three-month pause in enforcement deadlines to reconsider and improve the regulatory framework introduced in 2016 via the deeming rule and through the interpretation of the 2009 Tobacco Control Act. To that end, we would like to outline a potential change of approach and to draw your attention to two more detailed submissions.

Adopt sound regulatory principles

We believe that FDA's approach should be based on sound, principled foundations:

- **Regulation should be proportionate.** The burdens should be related to the relative risk of the products and regulation should not favor more harmful products over less harmful. The current regime for low-risk products is burdensome and opaque, and far more onerous than for cigarettes. The FDA's own estimates show application costs of between $286,000 and $2.6 million for electronic nicotine delivery devices and between $182,000 and $2.0 million for e-liquids. In addition, the criteria by which products will be assessed and approved as beneficial for public health are extremely broad and open to interpretation, so companies cannot judge if their applications will be successful before they spend the money. However, the more risky cigarette products have been 'grandfathered' and thousands of cigarette brands are on widespread sale without ever having faced an approval process.
- **Recognize potential benefits as well as risks and be wary of unintended consequences**. It is clear beyond reasonable doubt that vapor products present lower risks to nicotine users than smoking. FDA has rightly acknowledged a 'continuum of risk' in tobacco and nicotine products. It follows that regulators should recognize the potential unintended consequences of making uptake of lower-risk products more difficult or less attractive to smokers. Though we cannot be certain until the process is complete, we are concerned that the impact of the deeming rule will eliminate almost all of the vapor products that form the market. That may drive vapers back to smoking or reduce the rate of switching from smoking to vaping. Because the health and welfare costs of smoking are so high and the risks from vaping very much lower, this negative effect only needs to be small to exceed any conceivable benefits the deeming rule may bring.
- **Promote innovation.** Regulation should encourage pro-health innovation in low-risk alternatives to smoking. The current framework puts a hard brake on innovation by requiring a burdensome approval process for any changes, including safety and usability improvements.
- **Support informed choice through truthful communication of risk**. Risk communication should be truthful, plain-speaking, and focused on helping consumers make informed choices. The barriers to truthful communication are too high and leave consumers without important information that could be highly beneficial to their health.
- **Protection of young people**. Regulators should act to protect young people from use of any tobacco or nicotine product, while being mindful of positive and negative public health impacts arising from changes in cessation, uptake or use of other tobacco products that may arise as consequence of regulatory intervention.

Take action to avoid unnecessary damage to the market for innovative and disruptive technology

The costs and burdens of FDA's approach threaten to heavily contract and constrain the emerging market in vaping and other low-risk technologies, and some action is required in the short term to stabilize the market. Administrative options to do this include delaying enforcement dates for the Pre-

Market Tobacco Product (PMTA) authorization requirement for non-combustible products for at least an additional four years beyond the current dates. All the other protective measures that apply through the deeming rule, such as age restrictions, vending machine bans, and ingredients disclosures would remain. This will allow time to introduce a new standards-based regime, which addresses the problem more fundamentally (see below).

Move to a standards-based regime

The emergency interventions above, while necessary, do not provide an adequate long-term regulatory framework. This framework should be based on clear and transparent standards made through an open and consultative process. If vendors know what they are required to do, then the supply chain can adjust to be compliant. Consumers will know what they are buying. FDA can use its scientific resources efficiently. Standards can address, for example: chemical, electrical, battery, thermal and mechanical risks and related testing methods for devices, liquids and other consumables; manufacturing standards and quality control; and labelling and consumer information.

Useful standards have already been developed in the United States and are under development in other jurisdictions (e.g. France, UK). The approach taken in the European Union is to use standards and a notification regime for e-cigarettes.

Communicate useful information about risk to help consumers make informed choices

To improve communication of risk, federal entities such as FDA, CDC and the Surgeon General should embrace an objective to bring public perception closer to reality. FDA could, for example, approve standardized evidence-based and non-misleading statements that vendors of low-risk products could use in packaging and advertising, and exempt these from enforcement under the misbranding provisions of the Tobacco Control Act.

More detailed material

In addition to the general points made above, we invite you to consider two further documents.

1. *Liberating Nicotine from Smoke to Save Lives Now: Facing and Answering 7 Core Questions to Guide Regulation, Policy, and Communications*. The Director of the Center for Tobacco Products, Mitch Zeller, proposed seven questions about the place of nicotine in society. Several experts have responded to his challenge by writing the attached paper.
2. *Rethinking tobacco and nicotine policy*. This builds on the paper above and provides a more detailed discussion of the case for reforming FDA's approach to regulating tobacco and nicotine products, recognizing the constraints and flexibilities of the Tobacco Control Act.

Many issues have been raised about the FDA's regulatory approach to tobacco and nicotine in lawsuits and more generally. We hope that you find this letter and attachments to be a useful contribution to your consideration of these issues and how FDA might respond.

We would welcome your views on these points and the opportunity to meet you to discuss them.

Yours sincerely,

David B. Abrams, Ph.D.*

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* Drs. Abrams' and Niaura's signatures are solely in their personal capacity.

Appendix B:

The most frequently asked questions about electronic cigarettes

6 April 2017

Research shows that people are confused and misinformed about electronic cigarettes. (1, 2) Even public policy on e-cigarettes is being heavily influenced by fear and misinformation. (3) This evidence-based explainer article answers the most frequently asked questions.

Authors: Associate Professor Colin Mendelsohn and Dr Alex Wodak AM

1. Do e-cigarettes really help people to quit smoking?

Millions of people have now quit smoking using e-cigarettes. For example, in the European Union over 6 million smokers reported having quit using an e-cigarette (4) and a further 1.3 million have quit in the UK (5). Clinical trials of early e-cigarette models have found that they are at least as effective as nicotine replacement therapy, such as patches and gum (6, 7). However, these early models delivered low levels of nicotine and are now obsolete. More advanced devices which deliver higher nicotine levels are more effective. (8)

Comprehensive reviews including those by Public Health England, the UK Royal College of Physicians, the UK Centre for Tobacco and Alcohol Studies and the University of Victoria Centre for Addictions Research (Canada) which look at the full range of evidence on e-cigarettes have concluded that they are effective quitting aids. (9-12)

Randomised clinical trials are normally the gold standard for testing medicines but are not the best way to study complex, rapidly evolving consumer products. (9)

2. Don't most people who use e-cigarettes continue to smoke?

Some smokers quit very soon after using an e-cigarette for the first time. However, many others go through a transition stage of smoking and vaping together (dual use) before finally quitting smoking permanently. (10) This transition stage can take weeks or years. In one study, almost 60% of dual users went on to quit smoking completely within a 2 year period. (11) In another study, the quit rate of dual users was 26%. (12)

The evidence suggests that even long-term dual use is less harmful than smoking alone because most dual users significantly reduce the number of cigarettes they smoke (12, 13) thereby lowering their exposure to toxins (14-16). Consequently, health conditions such as emphysema (17), asthma (18) and high blood pressure improve (19) after switching to dual use. There is no evidence that dual use delays or prevents quitting. However, quitting smoking altogether should always be the preferred goal for smokers.

3. How safe are e-cigarettes?

The scientific consensus is that e-cigarettes are far safer than smoking. Public Health England and the UK Royal College of Physicians estimate the hazard to health from e-cigarettes is unlikely to exceed 5% of the harm from smoking tobacco. (20, 21) It is impossible to measure the precise risk reduction, but whether it is 1% or 10% less harmful than smoking, there is a clear health benefit for smokers who switch.

The harmful effects of smoking are almost entirely due to the tar, carbon monoxide and other toxic chemicals produced by burning tobacco. The vast majority of the 7,000 toxins in tobacco smoke are absent from e-cigarette vapour or are only present at trace levels. Studies of up to 12 months have demonstrated that e-cigarette users have substantially reduced levels of carcinogens and other

toxins in their bodies compared to smokers.(22)

There have been rare reported cases of e-cigarettes causing fires, but far fewer than the number caused by cigarettes, which are the most common cause of lethal house fires. (23) The risk of fire from e-cigarettes appears to be comparable to similar electrical goods (20) especially with lithium batteries (24). Electrical safety is improving and guidelines are available to reduce the risk. (25)

E-cigarettes are not completely safe. Nothing ever is. However, any risk needs to be compared to the risk from smoking which kills up to two in three long-term users. (26)

4. Isn't nicotine harmful?

Nicotine is relatively harmless in the low doses used in vaping (except in pregnancy). Although it is the main chemical that smokers are addicted to, there is no evidence that nicotine causes cancer or lung disease and it only plays a minor role in cardiovascular disease. (27, 28)

There is also no evidence in humans that nicotine is harmful to the adolescent brain (28) although there appears to be the case in some animal studies. However, it is unclear how this research translates to humans. It is important to note that nicotine replacement therapy (patches, gum, lozenges etc) are approved for use in adolescence from the age of 12 and appear to be well tolerated.(29)

Most cases of intentional or accidental nicotine poisoning involving nicotine e-liquid result in prompt vomiting and rarely cause serious harm. (30, 31) According to Public Health England, the risk from ingesting nicotine is comparable to similar potentially poisonous household substances. (20)

Fifty years of high dose nicotine use in snus (moist, oral tobacco) in Swedish men (32) and over 30 years of nicotine replacement therapies have not been associated with any significant adverse health effects (33).

5. What are the long-term risks of e-cigarettes?

Like all new products, the long-term health effects of e-cigarettes have yet to be established. However, based on current knowledge of the ingredients of e-cigarette vapour, e-cigarettes are likely to be much less harmful to vapers or bystanders. (34) Studies of up to two years have not detected any serious health harm from e-cigarette use. (35) Ten years of real-world experience have also not identified any significant harm to health.

6. Are e-cigarettes a gateway to smoking for children?

Overseas experience suggests that vaping is replacing—rather than encouraging—smoking of tobacco cigarettes among young people. (21, 36) Smoking rates in young people are falling faster in countries where e-cigarettes are readily available, and in some places faster than ever. (37)

Young people who experiment with vaping are more likely to become smokers, however there is no evidence that e-cigarette use leads to smoking. A more likely explanation is 'common liability' i.e. that young people who are more attracted to experimentation are more likely to try both products. (38) It is obviously better for young people not to use e-cigarettes, but vaping is still preferable to smoking. (39)

Regular vaping by non-smoking adolescents is rare. Most e-cigarette use by young people is experimental, occasional (not daily) and short-lived. (40-45) Many young smokers also use e-cigarettes to help them quit. (46, 47) Furthermore, the great majority of young people who experiment with vaping use flavoured solutions without nicotine. (37, 48)

7. Are adult non-smokers taking up e-cigarettes?

Regular e-cigarette use by adults who have never smoked is rare. The UK Royal College of Physicians concluded that 'e-cigarettes are being used almost exclusively as safer alternatives to smoked

tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely'.

In the 2014 US national survey, only 0.1% of never-smokers were daily e-cigarette users in 2014.(49) In Europe, only 0.04% of people who had never smoked were using nicotine e-cigarettes daily.(50) A German study found only 0.1% of never smokers were using e-cigarettes.(51)

8. Won't e-cigarettes just 'renormalise' smoking'?

There is no evidence that e-cigarettes are renormalising smoking. There is also no evidence that they are undermining the decline in cigarette smoking rates among adults and youth; on the contrary, present evidence suggests they are contributing to the decline. (20, 21, 40). Most e-cigarettes now look nothing like cigarettes and don't smell of smoke. Their visibility may encourage smokers to switch and quit smoking.

9. Is second-hand vapour harmful?

There is no evidence that second-hand e-cigarette vapour is dangerous to others. (20, 21, 34, 40, 52-54) Some studies have found traces of toxic chemicals in second-hand vapour, but at such low levels that they are not harmful. Also, vapour dissipates very quickly, unlike smoke which hangs around in the air for long periods. (55)

10. Aren't e-cigarettes just a tobacco company ploy to sell more cigarettes?

E-cigarettes were developed by consumers for consumers. More recently, the tobacco industry has started buying into the market fearing a loss of market share. However, not one e-cigarette sold in Australia is made by a tobacco company.

If the tobacco industry invests in 'reduced risk products' which replace combustible tobacco, that is a good thing. The more smokers who switch from combustible tobacco, the better, irrespective of who makes them.

The past behaviour of tobacco companies has been despicable, but the goal of public health is to reduce deaths, disease and costs from smoking, not to specifically destroy tobacco companies.

11. Is Australian policy on e-cigarettes consistent with other similar countries?

In Australia, it is illegal to possess or use nicotine in an e-cigarette without a prescription. (56) However, e-cigarettes with nicotine are now legal and freely available in the United Kingdom, the European Union and the United States. They are in the process of being legalised in Canada and New Zealand. (57) Australia is falling behind its peer countries in this important public health opportunity.

However, there are 2 options for Australian smokers who wish to use nicotine solutions in an e-cigarette to help them quit smoking. Firstly, they need to get a prescription for nicotine from a medical practitioner. (58) They can then have the nicotine solutions prepared by an Australian compounding pharmacist or can legally import supplies from overseas under the Therapeutic Goods Administration Personal Importation Scheme.

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