

**Submission to**

*Have Your Say, Proposed New Laws for  
Personal Vaporisers (Electronic Cigarettes),  
Tobacco Licensing, and Smoking Bans.  
A Regulatory Impact Statement*

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## Summary

This RIS is bad.

It is *biased*, presenting only arguments against e-cigarettes and ignoring arguments in favour of e-cigarettes.

It is *selective*, presenting only evidence from three reports and it ignores other important research.

And it is based on *opinions* regarding future *unknown* possible problems with e-cigarettes.

This RIS *cannot* be used as a justification for the proposed law changes.

Unfortunately, e-cigarettes have generated many irrational and wrong opinions, exemplified by the absurd statement made by US Surgeon General, Dr Vivek Murthy that “[e-cigarettes] are the most commonly used form of tobacco among youth in the United States”<sup>1</sup> and his superficial claims regarding the problems that they might cause.<sup>2</sup>

A serious problem faced by people (including the authors of the RIS) is the inability to examine and understand all the research and reports available. Some reports (including the two main reports on which this submission is based) provide sensible summaries of evidence in research papers and enable the reader to assess the validity of what he or she is reading. Other reports provide no information and simply list a large number of often inaccessible research papers. In these circumstances the reader is forced to take at face value the conclusions presented and is unable to assess their validity. A good example is one of the primary sources used by the authors of the RIS, WHO.<sup>3</sup> However, this report has been extensively critiqued by the UK Centre for Tobacco and Alcohol Studies,<sup>4</sup> and its use by the RIS can be assessed.

Consequently, whether the proposed changes to Tasmanian laws are sensible or not can only be decided after an *impartial* review of the available evidence. And this has to be based on reviewed, intelligible research and reports.

I recommend that:

1. *Before the proposed laws are brought before parliament*, an independent review of the evidence should be undertaken.
2. The existing ban on the sale or possession of nicotine for use in e-cigarettes should be rescinded.

## Number of smokers in Tasmania

On page 4, the RIS states:

*While smoking levels by adults in Tasmania are at the lowest level recorded at 18.9% ...”*

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- 1 Alyssa Best, *The Great British vape off*, December 9, 2016, <http://scienceblog.cancerresearchuk.org/2016/12/09/the-great-british-vape-off/>
  - 2 Dr Vivek Murthy, *The facts on e-cigarette use among youth and young adults*, <https://e-cigarettes.surgeongeneral.gov/>
  - 3 WHO ENDS, *Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS)*, November 2016.
  - 4 UK Centre for Tobacco and Alcohol Studies, *Commentary on WHO report on electronic nicotine delivery systems and electronic non-nicotine delivery systems*, 26 October 2016, <http://ukctas.net/pdfs/UKCTAS-response-to-WHO-ENDS-report-26.10.2016.pdf>

To quantify this, in 2015 the population of Tasmania was 516,660 of which 94,200 were under 15.<sup>5</sup> So the approximate number of tobacco smokers is 79,834. Although this figure includes 15 to 17 year old people, there are numbers of children who smoke tobacco and approximately 80,000 is a reasonable figure.

On page 20, the RIS states that tobacco smoking costs Tasmania about \$1 billion a year in direct and intangible costs. That is, about \$12,500 per tobacco smoker. Consequently:

***Every possible means should be employed to reduce the number of tobacco smokers.***

Although I have not seen any relevant research, it is likely that getting the remaining tobacco smokers to quit will be extremely difficult. At this point in time most of the easy targets (casual and infrequent tobacco smokers) will have already quit, and most of potentially new tobacco smokers (especially young people) will not take up tobacco smoking. That is, most of the remaining tobacco smokers have significant dependency on tobacco that will be hard to overcome.

Other areas of society show the same trends. For example, driving under the influence of alcohol, using mobile phones whilst driving, and failing to use seat belts still occur. Although compliance with these laws is now excellent, it is apparent that there is small group of people who will continue to flout laws irrespective of punishment.

This view is supported in a 191-page report by the Royal College of Physicians:

*It is, however, these established smokers in middle and older age who will generate most of the population burden of morbidity and premature mortality caused by smoking over the next two decades.*<sup>6</sup>

Indeed, no matter what governments do, and despite changing social attitudes, some tobacco smokers will not quit.

But much more important is the group of tobacco smokers who want to quit but have not been able to do so. These people have usually made several attempts and have usually tried most or all of the available quitting aids without success. As was pointed by the Royal College of Physicians:

*When the RCP published its last report on harm reduction in 2007, options for alternative nicotine products for use in a population-level harm-reduction strategy were limited to smokeless tobacco ... and medicinal NRT products, which many smokers find unsatisfactory as a long-term substitute for smoking.*<sup>7</sup>

And regarding existing nicotine replacement therapies (NRTs) such as patches and gums:

*None, however, reproduces the rapid delivery of high doses of nicotine achieved by inhaling tobacco smoke, and few smokers find them enjoyable or satisfying.*<sup>8</sup>

And in reference to a plan adopted in the UK:

*The plan also proposed adopting a harm-reduction strategy based on helping tobacco users who cannot or are unwilling to quit smoking to substitute alternative safer sources of nicotine for tobacco, to be supported by guidance from the National Institute for Health and Care Excellence (NICE), and undertook to encourage the development of new, affordable and acceptable nicotine products.*<sup>9</sup>

5 <http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/3235.0Main%20Features402015?opendocument&tabname=Summary&prodno=3235.0&issue=2015&num=&view=>

6 Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*. London: RCP, April 2016, page 121. Available from <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-to-bacco-harm-reduction-0>

7 *Nicotine without smoke*, page 7.

8 *Nicotine without smoke*, page 69.

9 *Nicotine without smoke*, page 26.

It is this group of hardened tobacco smokers that may be harmed if the opinions expressed in the RIS become the basis for future lawmaking:

*Increasingly powerful incentives for existing smokers to try to quit smoking, and strong support to help them succeed, are therefore urgently required. Further application and extension of the conventional policy options ... might be expected, at best, to sustain the decline in smoking prevalence of close to 0.7 percentage point per year achieved over the past decade in the UK, **the consequence of which will be that most of the current smokers in the UK, and particularly the most heavily addicted smokers, will continue to smoke for several decades.** The public health imperative in relation to smoking is, however, to reduce prevalence as much and as quickly as possible, for example, to achieve the widely agreed objective of a 'tobacco-free' society (comprising smoking rates of 5% or less in all socioeconomic groups) by 2035, **and this requires the addition of new strategies.**<sup>10</sup> (my emphasis)*

The following examines the points made in the RIS with respect to e-cigarettes.

## E-cigarettes may cause harm

Citing a CEO statement from the NHMRC the RIS (page 5) states that there is

*insufficient evidence ... about the extent of their **potential** harms*

This CEO statement is naturally conservative, but it also includes:

*The potential risks and benefits of e-cigarettes are currently the subject of much debate among tobacco control and public health experts. Some argue that e-cigarettes have the potential to reduce the number of smoking-related diseases and deaths, by assisting smokers to quit, or by providing a safer alternative to tobacco cigarettes. This is based on the widely-held belief that e-cigarettes are likely to be less harmful than tobacco cigarettes, because they expose users to fewer toxic chemicals. There is some preliminary evidence that supports this view.<sup>11</sup>*

Referring to a 2014 WHO report, that correctly notes that *conclusive* evidence of possible harm will not be available for years, the RIS (page 7) states that e-cigarettes should be regulated:

*to protect non-smokers, ex-smokers and young people who are not smokers of tobacco from **these unknown health risks*** (my emphasis)

However, it is meaningless to talk about *harm* without at least trying to quantify it. Because seat belts and air bags can and do cause harm, should they be banned or restricted? Obviously not, because the harm done in accidents without these safety devices is far more serious, and the small harm they cause is acceptable when compared to the harm without them.

So, if we are to discuss *potential harms* and *unknown health risks* we must compare them with the *known harms* and *known health risks* of tobacco and decide which our society would prefer.

With regard to e-cigarettes:

*In normal conditions of use, toxin levels in inhaled e-cigarette vapour are probably well below prescribed threshold limit values for occupational exposure, in which case significant long-term harm is unlikely. Some harm from sustained exposure to low levels of toxins over many years may*

<sup>10</sup> Nicotine without smoke, page 121.

<sup>11</sup> NHMRC CEO Statement: *Electronic cigarettes (e-cigarettes)*, available from <https://www.nhmrc.gov.au/health-topics/electronic-cigarettes?>

*yet emerge, but the magnitude of these risks relative to those of sustained tobacco smoking is likely to be small.*<sup>12</sup>

*Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes.*<sup>13</sup>

*E-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. Although nicotine delivery from e-cigarettes depends on a number of factors, including level of user experience and device characteristics, they can in principle deliver a high dose of nicotine, in the absence of the vast majority of the harmful constituents of tobacco smoke (or at least at negligible levels), in a way that enables accurate self-titration.*<sup>14</sup>

As noted above, it is essential that any discussion of harm quantifies that harm. For example, the RIS, page 7, states

*E-cigarettes contain toxicants that have known health effects; metals at concentrations equal or greater than traditional cigarettes ...*

However,

*Carbonyl compounds (formaldehyde, acetaldehyde and acrolein), volatile organic carbons (toluene and trace levels of xylene), trace levels of tobacco-specific nitrosamines and very low levels of metals (cadmium, nickel and lead) were found in almost all examined electronic cigarette vapours. Compared with conventional cigarettes, formaldehyde, acetaldehyde and acrolein were 9–450 times lower; toluene levels 120 times lower; and NNN and NNK levels 380 and 40 times lower respectively. (NNN, N-Nitrosornnicotine; NNK, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.)*<sup>15</sup>

*Trace levels of several metals (including tin, copper, silver, iron, nickel, aluminium, chromium, lead) were found, some of them at higher level compared with conventional cigarettes. [The] number of microparticles from 10 electronic cigarette puffs were 880 times lower compared with one tobacco cigarette. [There is] no evidence of levels of contaminants that may be associated with risk to health. These include acrolein, formaldehyde, tobacco-specific nitrosamines, and metals.*<sup>16</sup>

*Only one sample [e-cigarette] was found to be marginally cytotoxic, whereas cigarette smoke was highly cytotoxic (approximately 795% more cytotoxic)*<sup>17</sup>

*Robertson and colleagues tested the effects on primates of inhaling propylene glycol vapor for several months and found no evidence of toxicity on any organ (including the lungs) after post-mortem examination of the animals. Similar observations were made in a recent study in rats and dogs.*<sup>18</sup>

In addition, *Safety evaluation and risk assessment*, page 73, provides a graph of toxic emissions scores. Four different cigarettes scored between 100 and 134. The e-cigarette tested scored zero.

*The above observations indicate that e-cigarettes deliver a much smaller range of toxins at much lower concentrations than cigarettes, and therefore indicate that harm from e-cigarette use is*

12 *Nicotine without smoke*, page 79.

13 Konstantinos E. Farsalinos and Riccardo Polosa, “Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review”, *Ther Adv Drug Saf* 2014, Vol. 5(2) 67–86.

14 *Nicotine without smoke*, page 63.

15 *Safety evaluation and risk assessment*, page 72.

16 *Safety evaluation and risk assessment*, page 73.

17 *Safety evaluation and risk assessment*, page 75.

18 *Safety evaluation and risk assessment*, page 75.

*likely to be far less than from smoking. They also demonstrate a possibility that some harm from long-term e-cigarette use cannot be dismissed. ... However, **the absolute magnitude of any risk** attributable to e-cigarette use is likely to be very small in absolute terms, and hence substantially smaller than that arising from tobacco smoking.<sup>19</sup> (my emphasis)*

*An analysis based on expert opinion quantified the likely harm to health and society of e-cigarettes at about 5% of the burden caused by tobacco smoking, and a recent report by Public Health England supported this conclusion. ... Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.<sup>20</sup>*

*Although the long-term hazards of e-cigarette use are not yet clearly defined, e-cigarettes are probably close to NRT in the harm that their use confers on the user and others. The long-term hazard associated with e-cigarette use is likely to fall, as a result of regulatory and technological developments.<sup>21</sup>*

To put it crudely, tobacco cigarettes do 95% more harm than e-cigarettes and if the use of e-cigarettes reduces tobacco smoking then there will be a substantial net good.

## E-cigarettes may increase smoking

Referring to a 2014 WHO document, the RIS (page 5) states: “e-cigarettes *may* ultimately contribute to the tobacco epidemic”. However, the evidence clearly points to the opposite happening:

*Among never-smokers, non-tobacco nicotine use is extremely uncommon. In 2015, 0.1% of never-smokers were using NRT and 0.3% an e-cigarette, and these figures have remained virtually unchanged since 2013.<sup>22</sup>*

*A recent US study assessed the impact of state bans on sales of e-cigarettes on smoking rates among 12- to 17-year-olds across the USA, and found that reducing access through age-of-sale laws increased smoking among 12- to 17-year-olds, suggesting that restrictive regulations on e-cigarettes may be counterproductive.<sup>23</sup>*

*Although ... the data have been used as arguments to support the fact that a new epidemic of nicotine addiction through the use of electronic cigarettes is appearing, in reality they are showing that any experimentation with electronic cigarettes is done by smokers. This is in fact a positive finding, and could lead to reduced smoking prevalence through adoption of electronic cigarette use. Therefore, electronic cigarettes could serve as gateway from smoking; on the contrary, there is no evidence indicating that they could be a gateway to smoking. It is promising to see that penetration of electronic cigarette use in youngsters is virtually nonexistent, especially when you take into consideration that there is currently no official regulation in most countries to prohibit the access to electronic cigarettes by youngsters.<sup>24</sup>*

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19 *Nicotine without smoke*, page 83.

20 *Nicotine without smoke*, page 84.

21 *Nicotine without smoke*, page 130.

22 *Nicotine without smoke*, page 112.

23 *Nicotine without smoke*, page 173.

24 *Safety evaluation and risk assessment*, page 81.



## E-cigarettes may not help quitting

Referring to a 2015 NHMRC document, the RIS (page 5) states there is “insufficient evidence ... whether e-cigarettes can benefit smokers in quitting”.

And again, on page 7, referring to a 2016 WHO document the RIS, (page 5) states that “it cannot yet be determined whether e-cigarettes may help most smokers to quit or prevent them from doing so”.

However, the small amount of evidence available flatly contradicts both of these assertions:

*As NHS Stop Smoking Services (SSSs) have only recently started to support quit attempts using e-cigarettes, the available data on success rates are limited, but early experience estimates quit rates to be at least as high as among those using other medication. In the year to March 2015 in England, only 2,221 SSS users made a quit attempt using an unlicensed nicotine product (ie an e-cigarette), from a total of 445,979 setting a quit date. The average quit rate in all smokers using SSSs was around 51%, and among e-cigarette users it was 66%; although factors other than the product itself are likely to be involved in this difference, the finding is certainly consistent with high efficacy as a cessation therapy.<sup>25</sup> ... The data available from NHS SSSs indicate that there is no reason to believe that the integration of e-cigarettes into treatment support would reduce quit rates.<sup>26</sup>*

*Smokers who use over-the-counter e-cigarettes or prescribed medications are more likely to succeed. ... Smokers who use nicotine products as a means of cutting down on smoking are more likely to make quit attempts. Promoting wider use of consumer nicotine products, such as e-cigarettes, could therefore substantially increase the number of smokers who quit.<sup>27</sup>*

## Preventing uptake of e-cigarettes

The RIS gives three reasons for introducing laws controlling e-cigarettes:

1. **prevent uptake** of e-cigarettes by young people, and discourage uptake by adult non-smokers and ex-smokers.
2. **prevent re-normalising** smoking behaviour.
3. **protect from possible harms** from exposure to second hand vapour from e-cigarettes.

This and the next two sections consider these objectives.

With regard to the uptake of e-cigarettes amongst young people:

*The 2014 Smoking, Drinking and Drug Use survey of children aged 11–15 in England found that 22% of participating children had ever used an e-cigarette, but only 1% reported regular use. Regular use of e-cigarettes among young people in the UK thus appears to be very rare.<sup>28</sup>*

*As in adults, it appears that [use of e-cigarettes] occurs predominantly among those who are using, or have used, tobacco cigarettes. In 2013 in the Scottish study, all of those who reported having used e-cigarettes more than a few times had been, or were still, smokers.<sup>29</sup>*

25 *Nicotine without smoke*, page 102.

26 *Nicotine without smoke*, page 103.

27 *Nicotine without smoke*, page 107.

28 *Nicotine without smoke*, page 117.

29 *Nicotine without smoke*, page 117.

... of the 13% of young people who reported in 2015 ever having tried an e-cigarette, most (80%) had done so only once or twice. Only 2.4% of all participants in the survey had used e-cigarettes once or more a month, and 0.5% once or more a week.<sup>30</sup>

... research has shown that **electronic cigarette use by youngsters is virtually nonexistent unless they are smokers**. Camenga and colleagues examined the use of electronic cigarettes and tobacco in a group of adolescents, in a survey conducted in three waves. In the first wave of the survey (February 2010), 1719 adolescents were surveyed from which only one nonsmoker was found to be using electronic cigarettes. In the second and third wave of the surveys, only five nonsmoking adolescents were using electronic cigarettes. In fact, these are adolescents who reported first ever use of electronic cigarettes in the past 30 days; therefore they were not necessarily regular or daily electronic cigarette consumers. The increased prevalence of electronic cigarette use from 0.9% in 2010 to 2.3% in 2011 concerned smoking adolescents, therefore it should be considered a positive finding that smokers are experimenting with the significantly less harmful electronic cigarettes. Similarly, the Medicines and Healthcare Products Regulatory Agency (MHRA) found that less than 1% of electronic cigarette users are never-smokers. Data from the Centers for Disease Control National Youth Tobacco Survey reported doubling in electronic cigarette experimentation by 13–18 year old students from 1.1% in 2011 to 2.1% in 2012; however, 90.6% of them were smokers. From the whole population, only 0.5% were nonsmokers experimenting with electronic cigarettes.<sup>31</sup> (my emphasis)

With regard to the uptake of e-cigarettes amongst adults:

*The ASH survey in 2015 found that the principal reasons given by ex-smokers who are currently vaping are 'to help me stop smoking entirely' (61%) and 'to help me keep off tobacco' (53%). The principal reasons given by current vapers who still smoke are 'to help me reduce the amount of tobacco I smoke, but not stop completely' (43%) and 'to help me stop smoking entirely' (41%). Whether some of these individuals would otherwise have relapsed back to cigarette smoking, had e-cigarettes not been available, is not clear. Exploration of the explanations for these trends is an important area for future research.<sup>32</sup>*

*In adults and young people in the UK, therefore, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.<sup>33</sup>*

*Fewer than 1% of never-smokers currently used e-cigarettes in every country surveyed.<sup>34</sup>*

On page 20, the RIS states that: “The benefit of the proposed legislation is to strengthen efforts to reduce uptake and social norms in relation to tobacco smoking, which is **difficult to quantify**.”

But it is clear that new uptake of tobacco smoking will be extremely rare and the legislation will have no significant effect on it.

Referring to the 2016 WHO document, the RIS (page 6) states that “minors using e-cigarettes who have never smoked at least double their chance of starting to smoke”.<sup>35</sup> However:

*Existing longitudinal studies ... do not provide evidence that ENDS use in young people leads to smoking. ... Trying an END once or twice, and then trying a tobacco cigarette (the measure was a puff in the last six months) does not demonstrate that young people will become regular users of*

30 *Nicotine without smoke*, page 116.

31 *Safety evaluation and risk assessment*, page 80.

32 *Nicotine without smoke*, page 112.

33 *Nicotine without smoke*, page 119.

34 *Nicotine without smoke*, page 171.

35 WHO ENDS, page 4.



*either product, and provides no evidence that the cause of the subsequent smoking was the prior ENDS use.*<sup>36</sup>

## Preventing re-normalising smoking behaviour

On page 20, the RIS states that the second reason for introducing laws controlling e-cigarettes is “Minimising the risk of future public health costs and harm arising from a renormalisation of tobacco use linked to e-cigarette use if not appropriately regulated.” In other words, e-cigarettes might act as a *gateway* into tobacco cigarette smoking.

However:

*There is no evidence that either NRT or e-cigarette use has resulted in renormalisation of smoking.*<sup>37</sup>

Indeed the reverse, further denormalisation of tobacco use, is more likely:

*The prevalence data on the use of e-cigarettes by both adults and children demonstrate that e-cigarette use in Britain is, to date, almost entirely restricted to current, past or experimental smokers. As with NRT, there is no evidence thus far that e-cigarette use has resulted, to any appreciable extent, in the initiation of smoking in either adults or children; the extremely low prevalence of use of e-cigarettes among never-smoking adults and children indicates that, even if such gateway progression does occur, it is likely to be inconsequential in population terms. Although it remains important to monitor the use of e-cigarettes in young people, to ensure the quick identification of evidence of any increase in uptake of smoking arising from e-cigarette use, it appears that, to date, concerns over gateway progression into smoking are unfounded. **The association between e-cigarette and tobacco cigarette use is therefore more likely to arise from common liability to use of these products, and to use e-cigarettes as a gateway from, rather than to, smoking.***<sup>38</sup> (my emphasis)

*Although children’s awareness of and experimentation with electronic cigarettes is increasing, regular use remains rare and is most common among those who currently smoke or have previously smoked. This indicates that it is unlikely that electronic cigarettes are currently acting as a gateway, something which leads causally to smoking.*<sup>39</sup>

## Protect people from second hand vapour

In support of this third reason for legislating, the RIS includes the following statements:

Page 8: “Evidence of the long term health effects of second hand exposure to emitted or exhaled vapour *is currently inconclusive.*”

Page 8: “While *the magnitude of the health risks are as yet unknown*, the WHO notes it is reasonable to assume the increased concentration of toxins ... poses an increased risk for the health of all bystanders.”

But by page 9 the *possible* risk has become *certain* harm: “The first objective is important to protect bystanders from the harms of exposure to e-cigarette vapours.”

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36 Commentary on WHO report, page 20.

37 *Nicotine without smoke*, page 130.

38 *Nicotine without smoke*, page 128.

39 Action on smoking and health, *Use of electronic cigarettes among children in Great Britain*, October 2016.

However the comments on page 20 are more reasonable: “Non-users are protected from *potential and unknown* health risks from second hand vapour.”

These vague claims are clearly contradicted in other research:

*Harm to others from vapour exposure is negligible.*<sup>40</sup>

*Given the lack of evidence on the harmfulness of e-cigarette vapour to others, it would be inappropriate for national legislation to prohibit their use in public places and workplaces.*<sup>41</sup>

*Some countries have regulated e-cigarettes in the same way as tobacco products, which we believe to be entirely inappropriate because e-cigarettes do not contain tobacco, and have a very different profile of risk.*<sup>42</sup>

*Passive smoking is an established risk factor for a variety of diseases. Therefore, it is important from a public health perspective to examine the impact of electronic cigarette use on bystanders. Indirect data can be derived from chemical studies in vapor mentioned above, which show that the potential of any significant adverse effects on bystanders is minimal. In fact, since sidestream exposure is nonexistent in electronic cigarettes (aerosol is produced only during activation of the device, while tobacco cigarettes emit smoke even when no puffs are taken), such studies are undoubtedly overestimating the risk of environmental exposure.*<sup>43</sup>

*Romagna and colleagues evaluated chemicals released in a realistic setting of a 60 m<sup>3</sup> room, by asking five smokers to smoke ad lib for 5 hours and five vapers to use electronic cigarettes ad lib for a similar period of time on two separate days. Nicotine, acrolein, toluene, xylene and polycyclic aromatic hydrocarbons were detected in room air after the smoking session, with the amount of total organic carbon (TOC) reaching to 6.66 mg/m<sup>3</sup>. In contrast, after the electronic cigarette session, only glycerol was detected in minimal levels (72 µg/m<sup>3</sup>), while TOC reached a maximum level of 0.73 mg/m<sup>3</sup>. Characteristically, the amount of TOC accumulated after 5 hours of electronic cigarette use was similar to the amount found after just 11 minutes of smoking.*

*The levels of heavy metals found in vapor were minimal, and considering the dispersion of these molecules in the whole room air, it is unlikely that any of these metals could be present in measurable quantities in the environment. ... An issue that needs further clarification relates to the findings of microparticles emitted from electronic cigarettes. ... Environmental microparticles are mainly carbon, metal, acid and organic microparticles, many of which result from combustion and are commonly called particulate matter. Particulate matter exposure is definitely associated with lung and cardiovascular disease. In the case of electronic cigarettes, microparticles are expected to consist mostly of propylene glycol, glycerol, water and nicotine droplets. Metal and silica nanoparticles may also be present, but, in general, emissions from electronic cigarettes are incomparable to environmental particulate matter or cigarette smoke microparticles. ... Although evaluating the effects of passive vaping requires further work, based on the existing evidence from environmental exposure and chemical analyses of vapor, it is safe to conclude that the effects of electronic cigarette use on bystanders are minimal compared with conventional cigarettes.*<sup>44</sup>

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40 *Nicotine without smoke*, page 127.

41 *Nicotine without smoke*, page 153.

42 *Nicotine without smoke*, page 161.

43 *Safety evaluation and risk assessment*, page 77.

44 *Safety evaluation and risk assessment*, page 78-79.

But to be fair:

*There is, so far, no direct evidence that such passive exposure is likely to cause significant harm, although one study has reported levels of polycyclic aromatic hydrocarbons that were outside defined safe-exposure limits.<sup>45</sup>*

The significance of this is unknown. Farsalinos and Polosa<sup>46</sup> point out that some research is unreliable for various reasons, and the above single result might be erroneous.

## Regulation

On page 15 of the RIS it is stated that:

*... the proposed laws will prohibit advertising ... The aim is to limit non-smokers, former smokers or young people's awareness of the product. Without restrictions on advertising, increases in e-cigarette and tobacco use **may** occur.*

This continues the bias in the RIS. It is *assumed* that e-cigarettes are harmful even though much of the available evidence contradicts that view. There is no evidence that increases in e-cigarette use lead to increases in tobacco use.

The WHO report provides regulatory options that are, presumably, the basis for the RIS.<sup>47</sup> However:

*The key objective of tobacco control, and the [Framework Convention on Tobacco Control], is prevent harm to health from tobacco use. The purpose of regulation should be to achieve this aim. Since ENDS offer smokers a means to escape from dependence on smoking tobacco it is essential that new regulation encourages, rather than discourages, use of ENDS and innovation to make products more effective and affordable. The WHO report does not appear to consider the extent to which the proposed regulatory options might reduce the appeal and effectiveness of ENDS and other novel nicotine devices, **and thereby perpetuate, rather than reduce, smoking.** (my emphasis)*

The RIS (page 23) considers the effects of no change to the law.

First, "None of the objectives noted in this RIS would be met." This is not surprising, because it seems that the objectives were set and then the RIS was written to support those objectives. Unfortunately the objectives are not substantiated by research.

Second, it would "undermine efforts to denormalise tobacco smoking." However, it is clear that e-cigarettes do not normalise tobacco.

"Impede the goal of preventing uptake of e-cigarettes by young people, non-smokers and ex-smokers." But as shown above, uptake of e-cigarettes by young people and non-smokers is extremely small, and uptake by ex-smokers is desirable if it leads to fewer relapses.

"No protection from possible harms to bystanders from exposure to second hand vapour". But possible harms are minimal.

*It is therefore important that the approach to regulating non-tobacco nicotine products recognises the need not only to meet the general requirements of safety and fitness for purpose, but also to encourage the development and uptake of competitive alternatives to the fatally toxic product currently chosen by most habitual nicotine users. Therefore, although regulation of all products should be proportionate to their potential hazard, proportionality in nicotine regulation must also incorporate the consideration that **regulation that discourages or delays the development***

45 Nicotine without smoke, page 84.

46 Safety evaluation and risk assessment.

47 WHO ENDS, page 6.

*and use of non-tobacco nicotine is likely, in effect, to sustain tobacco smoking and hence perpetuate harm to smokers and wider society.*<sup>48</sup> (my emphasis)

## Greatest net benefit/least net cost

*“Laws to regulate e-cigarettes and strengthen the tobacco licensing framework will deliver the greatest net benefit to the health of the Tasmanians.”*

This is absurd.

The RIS comprehensively fails to show that e-cigarettes cause significant harm.

The RIS fails to show that e-cigarettes may increase tobacco smoking, and the evidence contradicts that claim.

The RIS claims e-cigarettes may not help quitting, but the evidence shows that it does.

One aim of the RIS is to prevent the uptake of e-cigarettes, when evidence shows that uptake by people other than tobacco smokers or ex-smokers is very small, and that the uptake by tobacco smokers and ex-smokers is beneficial to society.

The RIS wants to prevent re-normalising of tobacco smoking behaviour, but the evidence suggests that e-cigarettes do not increase tobacco smoking, they actually reduce tobacco smoking.

The RIS wants to protect people from second hand e-cigarette vapour, when the evidence shows that second hand e-cigarette vapour is a tiny problem, and the benefits of e-cigarettes far outweighs it.

The RIS states that tobacco smoking costs Tasmania about \$1 billion a year, and yet the current evidence shows that e-cigarettes *with nicotine* are an effective and useful tool to help reduce this scourge.

That is, strengthening the laws will, at best, make a miniscule difference to the health of Tasmanians. But more likely it will seriously lower the health of Tasmanians by making it harder for tobacco smokers to quit, and harder for ex-smokers to avoid relapsing.

## The present nicotine ban

On page 5 of the RIS it is stated that “The existing ban will remain on the sale or possession of nicotine for use in e-cigarettes without authority.

This is bizarre.

First, nicotine is available over the counter in supermarkets and chemists. This includes nicotine for use in inhalers (where it is used cold), but

*Trace amounts of formaldehyde, acetaldehyde, cadmium, nickel and lead were also detected from the Nicorette inhalator.*<sup>49</sup>

So, to use the words in the RIS, at least one NRT available in Tasmania has *potential harm* and *unknown health risks*.

Second, the much more dangerous drug, alcohol, is freely available to adults.

<sup>48</sup> *Nicotine without smoke*, page 151.

<sup>49</sup> *Safety evaluation and risk assessment*, page 72.

Third, paracetamol is available over the counter in supermarkets and chemists, but:

*Paracetamol is a common pain reliever and fever reducer that is usually bought over the counter without a prescription. It is one of the most common medicines taken by young children in an accidental overdose. Paracetamol is also commonly taken by people who intend to harm themselves (suicide attempts).*

*There is only a small difference between the maximum daily dose of paracetamol and an overdose, which can cause liver damage. Large amounts of paracetamol are very dangerous, but the effects often don't show until about two to three days after taking the tablets. However, treatment must be started early to be effective, before the effects begin.<sup>50</sup> (my emphasis)*

In contrast:

*Nicotine is not, however, in itself, a highly hazardous drug. It increases heart rate and blood pressure, and has a range of local irritant effects, but is not a carcinogen. Of the three main causes of mortality from smoking, lung cancer arises primarily from direct exposure of the lungs to carcinogens in tobacco smoke, COPD from the irritant and proinflammatory effects of smoke, and cardiovascular disease from the effects of smoke on vascular coagulation and blood vessel walls. None is caused primarily by nicotine. For practical purposes, as argued by Mike Russell in the 1970s, 'smokers smoke for nicotine but are killed by tar'. Although the nature and extent of any long-term health hazard from inhaling nicotine remain uncertain, because there is no experience of such use other than from cigarettes, it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, **if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided.**<sup>51</sup> (my emphasis)*

However, the legal use of nicotine nasal sprays and inhalers in Australia, that can be bought over the counter, and the use of which will result in some nicotine being inhaled, presumably means that the NHMRC has approved them and it considers that inhaled nicotine is not a serious health risk.

In addition:

*Although nicotine is a toxic compound, overdosing on nicotine products used as directed is almost impossible, given the individual ability to titrate dose and the short half-life of nicotine.<sup>52</sup>*

And:

*[the] hazards of nicotine are likely to be of minimal consequence in relation to those associated with continued tobacco use. Notably, and in recognition of this fact, the UK Medicines and Healthcare products Regulatory Agency (MHRA) recently approved an extension to the indication of NRT to include 'harm reduction', defined as 'for use as a substitute or partial substitute for smoking tobacco, both for those making an attempt to quit and those not currently intending to make a quit attempt, without any restriction on its duration of use'. Guidelines on harm-reduction approaches to smoking from the National Institute for Health and Care Excellence (NICE) further state that 'it is safer to use licensed nicotine-containing products than to smoke' and 'there is reason to believe that lifetime use of licensed nicotine-containing products will be considerably less harmful than smoking'.<sup>53</sup>*

The RIS (page 8) recognises this: "An increase in smoking rates would mean an increase in the health, social, and economic costs for all Tasmanians."

50 BetterHealth, *Drug overdose*, <https://www.betterhealth.vic.gov.au/health/healthyliving/drug-overdose>

51 *Nicotine without smoke*, page 5.

52 *Nicotine without smoke*, page 57.

53 *Nicotine without smoke*, page 58.



But the obvious conclusion is not stated:

***A decrease in smoking rates would mean a decrease in the health, social, and economic costs for all Tasmanians.***

E-cigarettes without nicotine are next to useless lollies. Their sale and use will probably have no effect whatever on tobacco smoking rates and hence have no effect on the cost of tobacco to Tasmania. Indeed, if inhaling e-cigarette vapour is harmful then the cost to Tasmania may increase slightly.

In contrast e-cigarettes with nicotine are a valuable addition to the tools available to control and decrease tobacco use. And e-cigarettes appear to have *very low potential* side-effects compared with the *very high known* side-effects of tobacco smoking. The evidence is all but conclusive.

***If the government was seriously concerned about the cost of tobacco smoking to the community, then it would rescind the ban on nicotine for use with e-cigarettes.***

***By doing so, Tasmania would become a leader in the fight against tobacco smoking.***