Response to Hansard proofs of Senate Committee hearing 13 November 2020

Patrick Hodder
Committee Secretary
Senate Select Committee on Tobacco Harm Reduction

20 November 2020

Dear Mr Hodder

I write to provide my answers to some of the questions that were asked at the Hearings on 13 November, 2020. I was not able to make myself heard by the Chair on the day and so could not have my answers recorded in Hansard.

The attached document provides answers to those questions where I had something to add to what my colleagues (Professors Borland, Gartner and McRobbie) said. I did not disagree with my colleagues' answers to the other questions. In what follows, I quote each Senator's question in bold font before providing my answer in normal text.

Yours sincerely

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Senator SHELDON: My first question is to everyone—and you might just quickly answer this. I sent you all a letter regarding article 5.3 of the World Health Organization Framework Convention on Tobacco Control and the need for this inquiry to be held to the highest levels of transparency and integrity. Can you all quickly state or submit a statement: have any of you been in receipt, directly or indirectly, in another organisation of financial support or other assistance in kind such as public relations, campaign support, travel expenses, IT support et cetera by any parties involved in the production, distribution or sale of tobacco, nicotine or vaping products; and could you disclose the nature of this support, the amount or value provided and the company or organisation providing that support

As Associate-Professor Gartner and I stated in our submission, we have never taken funds directly or indirectly from the tobacco or e-cigarette industries, or any entity funded by the tobacco industry (e.g. Foundation for a Smoke Free World).

We seem to have been asked this question primarily because we disagree with Australian policy on e-cigarettes. The implication seems to be that only researchers in receipt of tobacco industry funding would question Australia's policy. My mother and her sister both died of tobacco-related lung cancers so I have no interest in protecting the tobacco industry. My primary interest is in reducing tobacco-related harm. I accordingly support Australian tobacco control policies on taxation, age limits on cigarette purchase, smoke free policies, and plain packaging I do not, however, support Australia's prohibitionist policy towards e-cigarettes.

Senator SHELDON: I can. Can I ask each of you to give me your view in response to the declaration by the US surgeon general, Jerome Adams, that e-cigarette use among youth is an epidemic. It seems to me that Australia needs to find a way to encourage quitting amongst long-term smokers or, failing that, support methods of harm reduction while at the same time preventing a new generation of young people from taking up smoking

The USA has had a large increase in youth vaping primarily of the product JUUL which was heavily promoted by its manufacturer in the absence of restrictions on marketing. This increase has been interrupted by regulatory responses that have required changes in the products (e.g. flavourings), reduced youth access and restricted the ways that JUUL has been promoted, all regulations that I support. There has not been the same increase in vaping among youth in the UK or Canada (contrary to common misconceptions) because these countries have not allowed the promotional activities permitted in the USA.

I strongly support policies that will minimise youth vaping and cigarette smoking but I do not believe that the best or only way to achieve this goal is to ban the sales of e-cigarettes to adult smokers, except on prescription. Australia has reduced the prevalence of youth cigarette smoking without banning the sale of tobacco cigarettes to adult smokers. The same policies could be used to prevent youth vaping.

Senator GRIFF: You would agree that current and proposed regulatory approach nationally and at a state level is appropriate?

No. Australian e-cigarette policy has amounted to a de facto prohibition of e-cigarettes in the absence of any products approved by the TGA and in the face of the reluctance of medical practitioners to prescribe nicotine. Smokers who want to use e-cigarettes have had to resort to illicitly purchasing them.

Senator URQUHART: I'll throw this open to the group. You've all worked in tobacco control, as I understand it, for many years. All smoking cessation medications over the last, I think, 30 years have things like nicotine replacement therapies; IBAN and Champix et cetera all had to provide evidence of safety and efficacy to the TGA. We now have e-cigarettes with lots of claims being made about both their safety and their effectiveness. Do you think that the manufacturers of these products should also have to provide the same standard of information to regulators when the two claims are constantly being made about them?

The Senator's question assumes that the use of medicines regulation is the only acceptable approach to regulating e-cigarettes. I agree that this is the appropriate approach for products that make therapeutic claims but it is not the only way to regulate e-cigarettes. Given the widespread availability of cigarettes the exclusive use of the medicines regulations effectively bans smokers from using a less harmful product, while allowing them to continue to smoke cigarettes. As outlined below, there are better ways to regulate e-cigarettes that allow smokers to access them while minimising youth uptake.

Senator CANAVAN:…. Are there other international regulators using the precautionary principle in the same way as the Department of Health? If there is a difference in how it's being used, does that explain how groups like Public Health England seem to be completely at odds with the health advice we are getting here in Australia?

Australia's precautionary approach is out of step with other English-speaking countries, such as Canada, New Zealand and the United Kingdom. All of these countries allow the sale of e-cigarettes as consumer products under tighter regulations than apply in the USA. As has been argued in detail elsewhere (Morphett, Hall and Gartner, 2020), the precautionary principle has been inappropriately applied in Australia because regulators have: failed to consider the regulation of e-cigarettes in relation to tobacco cigarettes, have imposed regulations that are disproportionate to the level of risk, have failed to assess the costs of their own regulatory approach, and failed to undertake a cost/benefit analysis of a range of available regulatory options. Australian policy illustrates the risks of regulating nicotine products in isolation rather than considering them as part of a continuum of harmful nicotine products.

Senator HENDERSON: What's concerned me about your evidence today, as a group, I guess, is that the views and findings in your submissions run mostly contrary to the evidence provided by the Australian Department of Health, the TGA, the CSIRO, Professor Emily Banks from the ANU's school of population health, and most Australian health groups. So why do you believe that all of those groups and entities are wrong?

We are not alone in thinking that Australian regulatory authorities are mistaken. The Royal College of Physicians, Public Health England, the Action on Smoking and Health England and UK Cancer Research all disagree with Australian regulatory authorities' interpretations of the evidence and the policy approach.

The evidence on the public health risks and benefits of e-cigarettes is not clear cut, as was acknowledged by Professor Banks and the Commonwealth Department of Health. I believe that Department of Health and CSIRO have attempted to resolve the uncertainty by making a worse-case interpretation on the evidence on the harms of e-cigarettes by comparing the risks of e-cigarettes to those of not smoking rather than to those of conventional cigarettes. They have also uncritically accepted equivocal evidence that supports current policy (e.g. that on the gateway hypothesis) (Chan et al, 2020; Mendelsohn and Hall, 2020). They discount any evidence of benefits by adopting a hyper-sceptical attitude towards randomised controlled trials of e-cigarettes and observational studies which suggest that the uptake of e-cigarettes has reduced the smoking prevalence in the UK (Mendelsohn, Borland and Hall, 2020). They only cite sources that support Australian policy (e.g. a recent Irish report) and ignore reports from distinguished public health organisations that do not. These include the Royal College of Physicians, Public Health England, or Canada and New Zealand all of which are not cited in the submissions of the Commonwealth Department of Health or Professor Banks.

The Commonwealth and State Chief Health Officers used an outbreak of lung injuries in the USA to issue a public statement justifying their restrictive policy on e-cigarettes. They were very slow to correct their statement when the US CDC concluded in October 2019 that these injuries were caused by vaping cannabis oils and not vaping nicotine (Hall et al, 2020).

Senator SHELDON: I will just jump in there. Taking that into account, there are two things you may be able to make a comment about. One is the prescription pathway. If Australia were to adopt that, as is being considered by the TGA, how do you think it would be best crafted to assist the greatest number of smokers to quit?

In short, the TGA proposal aims to prevent youth uptake of e-cigarettes while providing legal access to smokers who want to use e-cigarettes to assist in smoking cessation. However the proposed regulations more likely to deny smokers access to e-cigarettes than creating a pathway for them to do so. They also include draconian penalties for smokers who access e-cigarettes without a prescription ($200,000 fines).

The rescheduling and the prohibition on the importation of nicotine is based on a misapplication of the precautionary principle (Morphett et al., 2020) that depends on an over-estimation of the strength of evidence that e-cigarettes are a gateway to smoking cigarettes (Chan et al., 2020; Mendelsohn & Hall, 2020). The proposed rescheduling fails to

assess the costs of this regulatory approach or to consider alternative ways of reducing adolescent access, such as imposing the same age limits on the purchase of e-cigarettes as apply to cigarettes and restricting where e-cigarettes can be purchased (Hall et al., 2015).

The proposed rescheduling may reduce adolescent access but at the cost of reducing smokers' access to these products and increasing the incentives for the illicit importation and sale of nicotine for use in vaporisers.

It is very unlikely to achieve the second goal of increasing smokers' access because medical practitioners are unwilling to prescribe nicotine or facilitate smokers' access to nicotine or vaporisers. Representatives of pharmacy organisations have expressed an unwillingness to dispense nicotine products on prescription. I am sceptical that the TGA will be able to ensure that vaping products are available and that it can persuade sufficient general practitioners to prescribe e-cigarettes to meet smokers' demand, given the hostility on the part of the AMA to their use. The proposed policy would also effectively criminalise vaping by adult smokers by imposing draconian fines (up to $200,000) on smokers who import nicotine without a prescription.

Senator SIEWERT: I want to go to the issue around vaping as a gateway. You all seem to reject the evidence we've heard around younger people taking up smoking as a result of vaping, or moving onto smoking as a result of vaping. Is that a correct understanding of your submissions and the evidence you've given today?

Yes, for two reasons. First, the observational evidence that vaping serves as a gateway to smoking is unconvincing in that smoking more often precedes vaping than vice versa and regular vaping by never-smokers is rare. The association between vaping and smoking is more plausibly explained by a common liability to engage in behaviour that is risky and socially disapproved of, such as cigarette smoking, illicit drug use and precious sexual behaviour (Mendelsohn and Hall, 2020). Second, even if the evidence were stronger, it would not justify a ban on the sale of e-cigarettes to adult smokers. There are other ways of preventing adolescent use that do not require a sales ban. This includes an alternative regulatory model that would address legitimate concerns by preventing adolescent uptake while allowing adult smokers to access these products for smoking cessation or as an alternative to smoking cigarettes (Hall et al, 2015, 2019).

Senator SIEWERT: So what approach would you take? I think it might have been you, Professor Gartner, who said that you wouldn't go down the advertising route. To everybody: can you outline the approach that you would suggest be taken, bearing in mind the precautionary principle and what you were saying about the precautionary approach?

It would be a better policy to remove e-cigarettes from the control of the TGA except when they were promoted as therapeutic goods. This would enable e-cigarettes to be regulated as consumer products in ways that can compete with cigarettes. The alternative policy would permit the importation of vaporisers and nicotine solutions that meet consumer safety standards and allow them to be sold in restricted retail outlets e.g. tobacconists, pharmacies, and vape shops. It would ban any advertising, other than at the point of sale,

set the same age of purchase as cigarettes and impose restrictions on where vaping can occur (Gartner et al., 2012; Hall & Gartner, 2014).

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